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Marc Doncieux

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Veronique Deltort

EuroIntervention.com
Ronnie Lassiaille
Gregori Despeaux
Sonia Morcuende

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Introduction to the PCR e-Course 2020 Abstracts Book

First of all, sincere thanks to the thousands of peers who have submitted their best work to PCR since the beginning of this year. The number of contributions to the various Calls for Submissions never fails to remind us how important it is to enable the interventional cardiovascular community to share their work with their peers around the world.

It is a great pleasure to be in a position to include a large number of the abstract submissions in this Abstract Book released to coincide with the PCR e-Course 2020. This three-day digital Course is serving to maintain the global dissemination of the latest scientific news and best practice in interventional cardiology, in a context where gathering together in person is unfortunately not an option.

As always, the submitted abstracts mainly addressed coronary interventions (69%), followed by interventions for valvular disease (21%). The remainder of the submissions is made up of peripheral interventions, heart failure and stroke interventions, and hypertension.

Concerning the geographical origins of the submissions, the top five countries all have an established track record in the matter. Top of the list comes Japan, then Italy, Germany, Spain and the United Kingdom. Close behind we find India, the Netherlands and the Republic of Korea.

With over 1,000 abstract submissions came once again the need for a large number of graders. Our warm thanks go out to the 200+ colleagues who kindly agreed to use their valuable time to review and assess the abstracts through a blinded online grading process. Their names will be found in these pages as a small token of recognition.

Please take advantage of the opportunity to browse this Abstract Book, which is also available on the EuroIntervention website. During the #PCReCourse, remember as well to access a dedicated channel which is broadcasting a selection of best graded abstracts and clinical cases presented online by their authors.

Last but not least, we wish you a very warm welcome to the PCR e-Course, be it a digital one, and we encourage you to network with all companions in the chatboxes while navigating the immersive Course platform.

Enjoy your PCR e-Course 2020!

Salvatore Brugaletta
Davide Capodanno
Jean Fajadet
William Wijns

2020 PCR e-Course Coronary interventions

Euro20A-OP041
Abstract | Oral presentation

CTO - Tools, devices and techniques

Independent predictors of coronary perforations in patients undergoing PCI for CTO lesions: a recent update – insights from a single experience European CTO operator

RIBEIRO Marcelo [1,2], RIBEIRO Marcelo [1,2], CAMPOS Carlos [1], ARAUJO Gustavo [3], BOUKHRIS Marouane [7], AZZALINI Lorenzo [6], DALLAN Luis Augusto [1], GIUNTA Rocco [4], SUCATO Vincenzo [4], NOVO Giuseppina [4], GALASSI Alfredo [4]

(1) Heart Institute, University of São Paulo, State of São Paulo, Brazil; (2) SOS Cardio, State of Santa Catarina, Brazil; (3) Hospital de Clínicas de Porto Alegre, RS, Brazil; (4) University of Palermo, Province of Palermo, Italy; (5) Cleveland State University, OH, USA; (6) Mount Sinai Medical Center, NY, USA; (7) Centre Hospitalier de l'Université de Montréal, QC, Canada; (8) Universidad de La Sabana, Cundinamarca, Colombia; (9) ICBA Instituto Cardiovascular, Buenos Aires, Argentina

Aims: Advances in techniques have improved the volume and procedural success rates of percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) lesions in recent years. Increased risk of coronary perforation is an important limitation of this technique. Our aim was to identify the frequency, predictors and clinical implications of coronary perforation in chronic total occlusion (CTO) percutaneous interventions (PCI).

Methods and results: We report the data of a prospective registry including patients who underwent CTO PCI from a single-experience European CTO operator. In-hospital events were analysed. Coronary perforation was defined as evidence of extravasation of dye or blood from the coronary artery during or following the interventional procedure. A stepwise logistic regression was performed to investigate the independent predictors of coronary perforations. From 2015 to 2017, 502 consecutive patients worldwide underwent CTO PCI in this registry. Mean age was 60 years (±10), 91% were male, 65% had hypertension and 31% had diabetes. Angina was present in 80% of patients, and 50% had a positive stress test. Median CTO duration was 12 months. The most commonly involved CTO vessel was RCA (53%). Median J-CTO score was 2 and a J-CTO score 2 or higher was present in 45% of patients. Procedural success was achieved in 91.6% of cases. Coronary perforation occurred in 3.4% of cases: Type 1.19%, Type 2 1.02% and Type 3 1.19%. In comparison to patients without perforation, cardiac tamponade was more common in patients with perforation (0% x 35%, $p<0.001$), with no need for blood transfusion. Death, stroke or myocardial infarction did not occur during hospitalisation. At multivariate analysis, the independent predictors of coronary perforation were first CTO attempt ($p=0.032$; HR 10.1 [1.86-194]), calcification ($p=0.008$, HR 7.33 [1.45-29.8]) and retrograde technique ($p=0.020$, HR 3.46 [1.18-9.48]).

Conclusions: Coronary perforation during PCI from a single experience European CTO operator registry (including patients worldwide) occurred in 3.4% of patients, being related to adverse events but not in-hospital all-cause mortality. Calcification, retrograde approach and first attempt were identified as independent predictors of this complication.

2020 PCR e-Course Coronary interventions

Euro20A-OP043
Abstract | Oral presentation

Other Coronary interventions - Calcified lesions

In-hospital and one-year results of rotational atherectomy in left main coronary artery disease – results from a multicentre registry

RAKOTOARISON Oscar [1,2], RAKOTOARISON Oscar [1,2], KÜBLER Piotr [1,2], TOMASIEWICZ Brunon [1,2], ZIMOCH Wojciech [1,2], FIGATOWSKI Tomasz [3], WAŃHA Wojciech [4], JAGUSZEWSKI Milosz [3], OCHAŁA Andrzej [4], WOJAKOWSKI Wojciech [4], RECZUCH Krzysztof [1,2]

(1) Wroclaw Medical University, Wroclaw, Poland; (2) Department of Cardiology, University Hospital, Wroclaw, Poland; (3) Gdański Uniwersytet Medyczny, Gdansk, Poland; (4) Medical University of Silesia, Katowice, Poland

Aims: Rotational atherectomy is a well-known method of percutaneous coronary intervention (PCI) facilitation in highly calcified and fibrotic coronary lesions. Despite encouraging results of rotational atherectomy in a wide range of clinical scenarios, contemporary literature on its results in treatment of left main coronary artery disease is limited. Our aim was to assess the results of rotational atherectomy performed in this challenging population.

Methods and results: We analysed data from 544 consecutive patients who underwent rotational atherectomy procedures in three high-volume tertiary centres. A total of 48 patients (9%) underwent the procedure in LM disease (27 unprotected, 21 protected). Most of the patients were male (63%), mean age of population was 75±13 years. We observed high prevalence of traditional risk factors, presented as follows: hypertension 98%, diabetes 56%, hyperlipidaemia 58%, prior stroke 13%, prior PCI 60%, prior coronary artery bypass grafting (CABG) 44%, renal insufficiency 25%. Mean ejection fraction was 48±13%. The population was burdened with high risk of both surgical and percutaneous procedures as assessed by EuroSCORE II (median 4.6 pts.; 2.5-7.6) and SYNTAX score (24±8 points) respectively. On this basis 73% of patients were disqualified from CABG by local Heart Team. Procedure was performed *ad hoc*, due to high calcium burden, in 48% of patients. Remaining patients underwent earlier unsuccessful PCI attempts resulting in incomplete balloon expansion (23%) or unsuccessful balloon delivery (33%). Procedures were performed in acute setting in 33% of patients, mainly via radial access (63%). Procedural success was achieved in 44 cases (92%) with very low incidence of periprocedural complications consisting of one case of coronary artery dissection. We did not observe other significant complications such as: no or slow flow, side branch occlusion, perforation or need for emergency CABG. At 1-year follow-up, we noted 5 (19%) new acute coronary syndromes and no deaths or strokes.

Conclusions: Rotational atherectomy performed in left main coronary artery disease is feasible and safe when performed in experienced centres. Moreover, for many patients it may be the last available revascularisation option as most of the presented population was disqualified from surgical procedures after undergoing unsuccessful PCI attempt without rotational atherecotmy.

Other Coronary interventions - Other

Transcoronary stem cell transfer and evolution of atherosclerosis in the infarct-related artery: insights from the myocardial regeneration by intracoronary infusion of selected population of stem cells in AMI (REGENT) trial

MUSIALEK Piotr [3], DABROWSKI Wladyslaw [1], TEKIELI Lukasz [1], MAZUREK Adam [3], LANOCHA Magdalena [5], BANYS R. Pawel [4], ZMUDKA Krzysztof [6], TRACZ Wieslawa [3], WOJAKOWSKI Wojciech [8], TENDERA Michal [9], MUSIALEK Piotr [3]

(1) John Paul II Hospital, Jagiellonian University Dept of Interventional Cardiology, Kraków, Poland; (2) John Paul II Hospital, Jagiellonian University Dept of Interventional Cardiology, Krakow, Poland; (3) Jagiellonian University Dept. of Cardiac & Vascular Diseases, John Paul II Hospital, Krakow, Poland; (4) Department of Radiology, John Paul II Hospital, Krakow, Poland; (5) Copper Health Center, Lubin, Poland; (6) Jagiellonian University Dept of Interventional Cardiology, John Paul II Hospital, Krakow, Poland; (7) Jagiellonian University Institute of Cardiology, John Paul II Hospital, Krakow, Poland; (8) Department of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland; (9) Medical University of Silesia, Katowice, Poland

Aims: It has been suggested that intracoronary stem cell transfer in AMI might stimulate atherosclerosis progression in the infarct-related artery as shown by a diffuse luminal loss and increased plaque burden. This, if confirmed, could negatively impact routine use of the transcoronary route for stem cell transfer to myocardium.

Methods and results: As a REGENT Trial (NCT00316381) substudy, angiographic analysis and intravascular ultrasound imaging (20 MHz, grey-scale and virtual histology imaging) was performed in 22 consecutive patients (4 women) aged 60 (52-66; median, Q1-Q3) years with a large anterior STEMI (peak CKMB 460 [345-767]U/L, cardiac magnetic resonance imaging infarct size 32 [22.2-40.6]%). On a median day 7 post primary PCI, transcoronary infusion of 4.52 (2.73-5.96)x106 CD34CXCR4-positive autologous bone marrow cells was performed. Angiography and IVUS interrogation were repeated at 12 months. Quantitative angiographic and grey-scale IVUS analysis was performed (matched angiograms and IVUS runs anonymised in a random order for baseline vs 12 months) along qualitative (plaque type) virtual histology (standard analysis as per routine corelab tools) and several novel quantitative parameters relevant to plaque biomechanics, shown recently to exhibit inter- and intra-observer reproducibility exceeding that of conventional parameters. One in every five study subjects (18.2%) showed no angiographic or IVUS atherosclerosis evidence distal to the stent at baseline, and no progression at 12 months. In the remaining cohort, there were 28 lesions by quantitative angiographic analysis and 32 by IVUS. Qualitative virtual histology plaque types were, at baseline, the following: fibro-fatty–3, fibrotic–0, fibrocalcific–20, fibroatheroma–6, calcified fibroatheroma–3, thin-cap fiboatheroma–0, calcified thin-cap fibroatheroma–0. At 12 months, transition of fibroatheroma to calcified fibroatheroma occurred in 2, fibroatheroma to fibrocalcific in 1 and fibro-fatty to fibroatheroma in 1. Other plaque types showed no transition, and no new lesions occurred. Quantitative angiographic analysis showed, for the minimal lumen diameter (mm^2) 1.43 (1.32-1.78) vs 1.7 (1.36-1.94) (p=0.349), and for the diameter stenosis (%) 29.5 (25.5-35.5) vs 26.5 (21.0-31.5)% (p=0.012). Consistent results were found on the grey-scale IVUS with minimal lumen area (mm^2) of 3.2 (2.46-3.92) vs 3.22 (2.59-3.94), (p=0.135); IVUS area stenosis (%) of 33.75(27.5-39.5) vs 31.0 (24.15-38.0), (p=0.004); and IVUS plaque burden (%) of 66.27 (60.22-69.36) vs 64.56 (59.93-67.85), (p=0.009); baseline vs 12-month data for all. Plaque peak fibrotic content (%) decreased from 75.0 (68.67-79.79) to 70.41 (65.2-75.41), (p=0.004) whereas peak fibro-fatty, necrotic core, and calcific content (%) remained stable (p=0.708). Peak confluent necrotic core area (mm^2) and minimal fibrous cap thickness (mm) showed no change 0.59 (0.31-0.73) vs 0.64 (0.2-0.74), (p=0.290) and 0.16 (0.13-0.2) vs 0.15 (0.13-0.19) (p=0.642), indicating no progression to unstable plaque characteristics by quantitative virtual histology.

Conclusions: This study, using a range of classic and novel imaging techniques, shows lack of any stimulatory effect on coronary atherosclerosis with transcoronary stem cell transfer. A moderate reduction in angiographic diameter stenosis and ultrasonographic area stenosis and plaque burden at 12 months may be related to maximised medical therapy and/or stem cell transfer; this requires further elucidation.

2020 PCR e-Course Coronary interventions

Euro20A-OP047
Abstract I Oral presentation

Stable CAD - Tools, devices and techniques

Safety and effectiveness of coronary intravascular lithotripsy in calcified eccentric coronary lesions: a patient-level pooled analysis from the Disrupt CAD I and CAD II studies

NEF Holger [1], NEF Holger [1], ALI Ziad [8], FAJADET Jean [3], ESCANED Javier [4], HILL Jonathan [5], WERNER Nikos [9], BANNING Adrian [6], LANSKY Alexandra [7], LEFEVRE Thierry [10], DI MARIO Carlo [2]

(1) University Hospital of Giessen, Giessen, Germany; (2) Careggi University Hospital, Metropolitan City of Florence, Italy; (3) Clinique Pasteur, Toulouse, France; (4) Hospital Clinico Universitario San Carlos, Madrid, Spain; (5) London Bridge Hospital, London, United Kingdom; (6) Oxford University Hospitals, Oxford, United Kingdom; (7) Yale New Haven Hospital, CT, USA; (8) Presbyterian Hospital, NY, USA; (9) Krankenhaus der Barmherzigen Brüder, Trier, Germany; (10) Cardiovascular Institute Paris Sud (ICPS), Massy, France

Aims: To assess the safety and effectiveness of intravascular lithotripsy in treating calcified eccentric coronary lesions.

Methods and results: Disrupt CAD I (N=60) was a pre-market, prospective, single arm, multicentre study designed to evaluate the safety and performance of the Shockwave Coronary Intravascular Lithotripsy (IVL) System in the treatment of calcified coronary lesions for the purpose of enhancing the placement of stents and reducing the ultimate residual stenosis. Disrupt CAD II (N=120) was a post-market surveillance study evaluating the safety and performance of the coronary IVL system following expansion to a broader patient population and additional physician users. Inclusion and exclusion criteria for both studies were similar and included subjects with significant native calcified coronary artery disease suitable for PCI. The same independent angiographic core lab (ACL) was utilised for both studies and analysed all procedural angiograms (Yale Cardiovascular Research Group, USA). The ACL defined an eccentric lesion as a stenotic lesion that had one of its luminal edges in the outer one-quarter of the apparent normal vessel lumen. Between December 2015 and March 2019, 180 subjects were enrolled in the Disrupt CAD I and CAD II studies across 19 sites in 10 countries. Patient-level data were pooled from these two studies with eccentric lesions identified in 47 subjects accounting for 26% (N=180) of all lesions. There were no significant differences in baseline patient or pre-treatment angiographic lesion characteristics between the eccentric and concentric cohorts with the exception of mean lesion length, which was significantly shorter in the eccentric group vs the concentric group (16.7±7.0 vs 20.9±10.7 mm, p=0.04). There were no differences in procedural parameters between the two groups including number of IVL pulses, IVL inflation pressure, and pre- and post-dilatation rates (p>0.05 for all procedural comparisons). Low vascular complication rates were observed, including flow-limiting dissections (Grade D-F: 0% eccentric, 1.7% concentric), with no perforations, abrupt closure, slow flow or no reflow events in either group. Clinical success, defined as residual stenosis <50% after stenting with no in-hospital MACE, was also similar between the eccentric and concentric cohorts (93.6% vs 93.2%, p=0.80). While final acute gain and percent residual stenosis were similar between the two groups, the final minimum stent diameter was significantly greater in eccentric vs concentric lesions (3.0±0.5 vs 2.7±0.5 mm, p=0.004).

Conclusions: In this first report from a pooled patient-level analysis of coronary IVL from the Disrupt CAD I and CAD II studies, IVL use was associated with good clinical outcomes in both eccentric and concentric calcified lesions. This analysis also demonstrates effectiveness of IVL in calcified eccentric lesions.

2020 PCR e-Course Coronary interventions

Euro20A-OP050
Abstract | Oral presentation

Stents and scaffolds - CT / MRI imaging, Bifurcation lesion - Tools, devices and techniques

The risk of stent size selection according to the distal main branch diameter in the single stent implantation for left main coronary bifurcation: analysis from the three-dimensional left main elastic bifurcated coronary artery models and micro CT

HIKICHI Yutaka [1], HIKICHI Yutaka [1], SUGIYAMA Kouta [2], ZHU Xiaodong [2], MATSUBARA Kaito [2], MATSUHASHI Yuki [2], KANEKO Tetsuya [1], INOUE Yohei [1], NATSUAKI Masahiro [1], NODE Koichi [1], IWASAKI Kiyotaka [3]

(1) Department of Cardiovascular Division, Saga University, Saga, Japan; (2) Major in Modern Mechanical Engineering, Graduate School of Science and Engineering, Waseda University, Tokyo, Japan; (3) Cooperative Major in Advanced Biomedical Sciences, Graduate School of Advanced Science and Engineering, Waseda University, Tokyo, Japan

Aims: The EBC recommends "main branch stenting using a stent diameter according to the distal main branch reference" as the method for determining the stent size selection. However, there are limited data available with regard to the clinical outcomes of this strategy. This study aimed to investigate the influence of stent size selection on the reduction of incomplete stent apposition volume (ISA-volume) and incomplete stent apposition area (ISA-area), between 3.5 mm diameter SYNERGY stent and 4.0mm diameter SYNERGY stent, using a three-dimensional elastic LM coronary artery bifurcated model.

Methods and results: The referenced LM bifurcation angle data of 209 patients were stratified by tertiles focusing on the angle between the LM trunk and left anterior descending artery. Then, a modified-angled bifurcation model with angles of 141°, 122°, and 71° for LM trunk–left anterior descending, LM trunk–left circumflex, and left anterior descending–left circumflex, respectively, was fabricated, with diameters of 4.3mm, 3.3mm, and 3.0 mm for LM trunk, left anterior descending, and left circumflex, respectively; these diameters fulfill Murray's law. 60% and 50% stenoses were included along the LM trunk–left anterior descending and LM trunk–left circumflex. All *in vitro* experiments were performed under fluoroscopy in the catheterisation laboratory. Six 3.5 mm SYNERGY stentings and six 4.0mm SYNERGY stentings were performed using one stent and the kissing balloon inflation technique. In the 3.5 mm SYNERGY group, the stent was implanted from left main trunk to left anterior descending with 8atm. In the 4.0 mm SYNERGY stent group, the stent was implanted from left main trunk to left anterior descending with 5atm. In both groups, optimal size balloon inflation was performed in the distal part of the bifurcation. POT was performed in both groups. The final kissing balloon inflation was performed using 3.5mm semi-compliant +3.0mm semi-compliant balloon with 8 atm+9 atm in both groups. Each case was successfully performed and completed. ISA-volume of left main trunk and ISA-area of left circumflex ostium were quantified using micro-CT. Micro-CT analysis showed a higher proportion of ISA-volume in the main left main trunk with 3.5mm SYNERGY group compared to 4.0mm SYNERGY group, (0.56 ± 1.56 mm^3 vs 0.16 ± 0.14 mm^3; p=0.071). Also this analysis showed a higher proportion of ISA-area in the left circumflex ostium with 3.5mm SYNERGY group compared to 4.0 mm SYNERGY group, (1.71 ± 0.64 mm^2 vs 0.56 ± 0.45 mm^2; p=0.02).

Conclusions: The incomplete stent apposition volume can be reduced, and the stent expansion rate can be greatly increased at the left main trunk after single stent+KBT performance by larger stent size selection. The incomplete stent apposition area can be reduced at the left circumflex ostium after single stent+KBT by larger stent size selection. When performing a crossover stenting to LMT-LAD, the stent size should be selected according to the vessel diameter on the proximal side of the bifurcation.

Euro20A-OP052
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

High-pressure cutting balloon performance for calcified coronary lesions

LARICCHIA Alessandra [(1)], LARICCHIA Alessandra [(1)], KHOKHAR Arif [(1)], MANGIERI Antonio [(1)], RUGGIERO Rossella [(1)], STICCHI Alessandro [(1)], GIANNINI Francesco [(1)], COLOMBO Antonio [(1,2)]

(1) Maria Cecilia Hospital, Province of Ravenna, Italy; (2) EMO GVM - Centro Cuore Columbus, Metropolitan City of Milan, Italy

Aims: Percutaneous treatment of calcified coronary lesions is challenging due to worse device deliverability and potentially suboptimal procedural results. However, adequate calcium fracture as achieved by cutting balloons (CB) is associated with better lumen gain and more favourable late outcomes. The aim of the present study is to analyse procedural and clinical results of unconventional high-pressure and very high-pressure CB inflations.

Methods and results: We retrospectively analysed data from 915 consecutive patients who underwent PCI with CB in a single centre in Milan between 1994 and 2019. The mean age of the total population was 65 years old and 88% were males. Among 2,298 lesions treated, CB was used in 1,262. 13 lesions were excluded from the analysis, as the pressure of inflation was not reported. CB were inflated at nominal pressure (NP, up to 6 atm) to rated burst pressure (RBP, up to 12 atm) in the majority of cases (29 and 908 cases respectively, 75% of the total); conversely 210 lesions (16.8%) were treated with high-pressure inflations (13 to 19 atm) and 102 lesions (8.2%) were treated with very high-pressure (≥20 atm) inflations. Less than a half of the procedures were IVUS guided (37.9%), with a comparable distribution among groups (p=0.255). Procedural complications (a composite of coronary perforation, pericardial tamponade, major coronary dissection, cardiac arrest and procedural death) were not more common with higher pressures of inflation (NP 0, RBP 4.1%, HP 2.4%, VHP 1%, p=0.195) and procedural success was reached in the large majority of cases (99.5%, p=0.872). Angiographic follow-up was available for 58.6% of total lesions at a median of 222 days (IQR 180-361). The incidence of documented restenosis was comparable among groups (NP 13.8%, RBP 23%, HP 21.9%, VHP 12.7%, p=0.08).

Conclusions: At low-pressure inflations (as recommended by manufacturer's instructions) three to four blades longitudinally mounted on CB surface provide discrete incisions in the atherosclerotic plaque whilst preventing uncontrolled dissections and other injuries to the vessel wall. We analysed the performance of an unconventional CB employment. Results of the present work show that both high pressure and very high-pressure CB inflation are feasible. Both safety and effectiveness are preserved and comparable to standard inflations (as demonstrated by the low incidence of procedural complications and the good procedural results). The main limitations of the study are its retrospective nature and the low use of intracoronary imaging. We suppose that a prospective randomised trial with imaging-guided balloon sizing could show the additive value of high-pressure CB inflations: the combination of calcium fracture with plaque redistribution and arterial stretching (which are usually prerogative of other devices) could result in improved lumen gain as well as being time saving.

Stents and scaffolds - Tools, devices and techniques

Nine-month angiographic results of the novel polymer-free biolimus A9-coated stent with a cobalt-chromium platform in an all-comer population

COSTA Ricardo [1], COSTA Ricardo [1], SABATE Manel [2], LASSEN Jens Flensted [3], OKKELS-JENSEN Lisette Okkels-Jensen [4], TILSTEDT Hans-Henrik Tilstedt [5], MORENO Raul [6], COPT Samuel [7], SCHUETTE Diana [7], STOLL Hans-Peter [7]

(1) Cardiovascular Research Center, State of São Paulo, Brazil; (2) Hospital Clínic de Barcelona, Barcelona, Spain; (3) Aarhus University Hospital, Aarhus Municipality, Denmark; (4) Odense University Hospital, Odense Municipality, Denmark; (5) Rigshospitalet, Copenhagen Municipality, Denmark; (6) University Hospital La Paz, Madrid, Spain; (7) Biosensors Europe SA, Morges, Switzerland

Aims: The BioFreedom polymer-free Biolimus-A9 coated stent with a stainless-steel platform has demonstrated safety and efficacy in preventing neointimal hyperplasia in patients with high risk for bleeding. However, low-profile cobalt-chromium alloys with enhanced deliverability have become the standard for new-generation drug-eluting stents. Our goal was to evaluate the efficacy of the new BioFreedom Ultra™ drug-coated stent with a cobalt-chromium platform (BF-CC) versus the standard BioFreedom drug-coated stent with a stainless steel platform (BF-SS) in the treatment of an all-comer population.

Methods and results: This was a prospective, multicentre, active comparator, non-inferiority trial comparing the BF-CC versus the BF-SS in patients undergoing percutaneous coronary intervention in daily practice. The primary (efficacy) endpoint was in-stent late lumen loss as determined by quantitative coronary angiographic assessment performed at an independent core laboratory blinded to the study results. A total of 200 patients (by intention-to-treat) were prospectively enrolled and randomised in a 1:1 ratio for treatment with the BF-CC (101 patients / 129 lesions) versus BF-SS (99 patients / 140 lesions) at 8 centres in Spain and Denmark. Baseline clinical and lesion characteristics were similar among the groups. Overall, the number of stents implanted per patient was 1.5±0.7 in the BF-CC versus 1.5±0.8 in the BF-SS. At 9-month angiographic follow-up (available in 163 patients from a pre-specified subset), mean in-stent late lumen loss was 0.34±0.49 mm in BF-CC versus 0.29±0.37 mm in the BF-SS, (median values: 0.16 mm [0.06-0.43] versus 0.17 mm [0.07-0.34], respectively), p=0.006 for non-inferiority.

Conclusions: The BF-CC was non-inferior to the BF-SS in terms of in-stent late lumen loss, a surrogate of neointimal hyperplasia, at 9-month angiographic follow-up.

2020 PCR e-Course Coronary interventions

Euro20A-OP054
Abstract I Oral presentation

Stents and scaffolds - Tools, devices and techniques

Outcomes of patients with MiStent ultrathin strut biodegradable polymer coated crystalline sirolimus-eluting stent in complex lesions: insights from patient-level pooled data of the DESSOLVE III and Japan trial

SERRUYS Patrick W. [1], TAKAHAHSI Kuniaki [2], ONO Masfumi [2], BUSZMAN Pawel [3], MILEWSKI Krzysztof P. [4], WYKRZYKOWSKA Joanna J. [2], ONUMA Yoshinobu [1], SAITO Shigeru [5], DE WINTER Robbert J. [2], WIJNS Wiliam [1]

(1) National University of Ireland Galway, Galway, Ireland; (2) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (3) Medical University of Silesia, Katowice, Poland; (4) American Heart of Poland, Katowice, Poland; (5) Shonan Kamakura General Hospital, Kanagawa, Japan

Aims: Impact of the use of ultrathin- versus thin-strut drug-eluting stents (DES) in complex lesions has not been investigated. The aim of the present analysis was to evaluate a relative treatment benefit of ultrathin strut sirolimus-eluting bioresorbable polymer coated MiStent versus thin-strut everolimus-eluting durable polymer coated XIENCE stent in patients with complex lesions.

Methods and results: The present investigation from a patient-level pooled data of the DESSOLVE III and Japan trial evaluated at one year the primary endpoint of device-oriented composite endpoint (DOCE), defined as the composite of cardiac death, target vessel myocardial infarction (TV-MI), or clinically-indicated target lesion revascularisation (CI-TLR), in patients with or without complex lesions. Complex lesions included at least one of the following lesion characteristics: ST-elevation myocardial infarction (STEMI), chronic total occlusions (CTO), bifurcated lesions, left main lesions, restenotic lesions, bypass grafts, more than three lesions treated, lesions treated in more than two major epicardial vessels, or more than two lesions treated in a single major epicardial vessel. Among 1,470 patients included in this analysis, 471 (32.0%) were treated for complex lesions. Those allocated to the MiStent had a significantly lower risk of the primary endpoint at one year, compared with the XIENCE stent (3.4% vs 8.3%; HR: 0.40; 95% CI: 0.18-0.91; p=0.028), an observation not made in those with non-complex lesions (Pinteraction= 0.024). This favourable effect of MiStent vs XIENCE was mainly driven by a significantly reduced risk of CI-TLR among patients with complex lesions (0.8% vs 4.3%; HR: 0.19; 95% CI: 0.04-0.86; p=0.032).

Conclusions: The present patient-level pooled analysis of the DESSOLVE III and Japan has demonstrated that ultrathin-strut MiStent was associated with a significantly lower risk of the primary endpoint of DOCE at one year compared with XIENCE, especially in patients with complex lesions.

2020 PCR e-Course Coronary interventions

Euro20A-OP055
Abstract | Oral presentation

Stable CAD - Diabetes, Left main and multivessel disease - Diabetes

Treatment of only de novo coronary artery lesions with paclitaxel DCB in diabetic and non-diabetic patients – a single-centre experience

KHIN MAUNG ZAN Mohd [(1)], TEY Yee Sin [(1)], MOHAMED NAZEEB Mohamed Nazrul [(1)], ROSLAN Aslannif [(1)], NURUDDIN Amin Ariff [(1)]

(1) Institut Jantung Negara, Federal Territory of Kuala Lumpur, Malaysia

Aims: Diabetes is recognised to increase morbidity and mortality after coronary revascularisation. Many recent trials reported that treating *de novo* lesions with drug-coated balloons (DCB) is non-inferior to treatment with drug-eluting stents (DES). However, trials of DCB in treating *de novo* lesions in diabetes are limited. This study is to compare the outcomes of paclitaxel drug-coated balloon treatment in diabetic and non-diabetic patients with *de novo* lesions.

Methods and results: A retrospective, single centre study was conducted from January 2016 till December 2018. All diabetic and non-diabetic patients who underwent angioplasty to only *de novo* coronary artery lesions were included in the study. Patients' baseline characteristics, angiographic data, post-procedural and 12-month follow-up outcomes including major adverse coronary artery events (MACE), target lesion revascularisation (TLR) and myocardial infarction (MI) are compared. A total of 1,257 patients (726 diabetic and 531 non-diabetic) with a total of 1,385 *de novo* lesions (791 lesions in the diabetic group and 594 lesions in the non-diabetic group) were included in this study. Mean age for the non-diabetic group was 57.6±10.6 years and the diabetic group was 59.6±9.6 years with male predominance (91.1% in the non-diabetic group, n=484 and 79.2% in the diabetic group, n=575). The majority of the diabetic group had hypertension (83.7%, n=608 vs 58.6%, n+311), chronic renal failure (10.3%, n=75 vs 1.9%, n=10), documented coronary artery disease (55.6%, n=404 vs 47.5%, n=252) and previous coronary angioplasty 39.5%, n=287 vs 28.8%, n=153). The percentage of dyslipidaemia in both groups was similar and the majority of the non-diabetic group were smokers (48.4%, n=257 vs 36.2%, n=263). 5.5% (n=29) of non-diabetic and 4.4% (n=32) of diabetic patients were admitted for STEMI and 7.9% (n=42) of the non-diabetic group and 9.0% of the diabetic group were admitted for NSTEMI. The majority of lesions were in the left anterior descending artery followed by left circumflex artery in both groups. Type of lesion, mean vessel diameter and length of stenosis were similar in both groups. The percentage of stenosis prior to angioplasty in the non-diabetic group was 90±10.47% and 90±10.79 % in the diabetic group (p=0.838). Adequate predilatation was done in both groups (98.5%, n=585 in the non-diabetic group and 99.4%, n=786 in the diabetic group; p=0.000). Mean DCB diameter and length were similar in both groups. Mean residual stenosis after DCB was 11.15±16.9 % in the non-diabetic group and 13.13±13.4% in the diabetic group (p=0.008). 74.6% of the non-diabetic group (n=396) and 77.1% of the diabetic group (n=560) were on dual antiplatelet therapy for 12 months. 86.8% (n=461) of non-diabetic and 88.4% (n=642) of diabetic patients were available for follow-up. MACE events were significantly higher (p=0.000) in the diabetic group (4.3%, n=31) as compared to the non-diabetic group (0.6%, n=3). Target lesion revascularisation and myocardial infarction were also significantly higher in the diabetic group (TLR 1.4%, N=10 vs 0.6%, n=3, p=0.049; MI 2.6%, n=19 vs 0.4%, n=2, p=0.002).

Conclusions: Our study shows that treating *de novo* coronary lesions in diabetic patients with DCB was associated with significantly higher MACE events, target lesion revascularisation and myocardial infarction. High restenosis rates, persistent haemostatic abnormalities and progression of atherosclerosis may contribute to the poor outcomes in diabetic patients. Aggressive control of risk factors which frequently accompany diabetes should be implemented in all diabetic patients.

Stents and scaffolds - Invasive imaging and functional assessment

Prognostic implication and determinant of residual ischaemia after DES implantation

ZHANG Jinlong [1], ZHANG Jinlong [1], HWANG Doyeon [1], YANG Seokhun [1], LEE Joo Myung [2], PARK Jiesuck [1], CHOI Ki Hong [2], KIM Chee Hae [8], NAM Chang-Wook [3], SHIN Eun-Seok [4], DOH Joon-Hyung [5], HOSHINO Masahiro [6], HAMAYA Rikuta [6], KANAJI Yoshihisa [6], MURAI Tadashi [6], ZHANG Jun-Jie [7], YE Fei [7], LI Xiaobo [7], GE Zhen [7], CHEN Shao-Liang [7], KAKUTA Tsunekazu [6], KOO Bon-Kwon [1]

(1) Seoul National University Hospital, Seoul, Republic of Korea; (2) Samsung Medical Center, Seoul, Republic of Korea; (3) Keimyung University Dongsan Hospital, Daegu, Republic of Korea; (4) Ulsan Hospital, Ulsan, Republic of Korea; (5) Inje University Ilsan Paik Hospital, Gyeonggi-do, Republic of Korea; (6) Tsuchiura Kyodo Hospital, Ibaraki, Japan; (7) Nanjing First Hospital, Nanjing, China; (8) VHS Medical Center, Seoul, Republic of Korea

Aims: We sought to investigate the prognostic implication and determinant of residual ischaemia after drug-eluting stent (DES) implantation.

Methods and results: A total of 1,132 patients who underwent physiology-guided percutaneous coronary intervention (PCI) (fractional flow reserve [FFR] ≤ 0.8) with second-generation DES from the international post-stent FFR registry were analysed. The primary outcome was target vessel failure which was defined as a composite of cardiac death, target vessel-related myocardial infarction and clinically driven target vessel revascularisation at 2 years and residual ischaemia was defined as a post-PCI FFR ≤ 0.8. Among the population, 12.9% of the patients had residual ischaemia after PCI and they showed a higher risk of target vessel failure at two years than those without residual ischaemia (adjusted hazard ratio: 2.04; 95% confidence interval: 1.10-3.76; p=0.023). All pre-PCI parameters, including lesion length, reference diameter, pre-PCI percent diameter stenosis and pre-PCI minimum lumen diameter, showed poor correlations with post-PCI FFR (lesion length: r = 0.064, p=0.030; reference diameter: r = 0.197, p<0.001; pre-PCI percent diameter stenosis: r = 0.045, p=0.133; pre-PCI minimum lumen diameter: r = 0.042, p=0.162; pre-PCI FFR: r = 0.164, p<0.001). An unsupervised machine learning - hierarchical cluster analysis was performed to cluster the similar relevant parameters with post-PCI FFR and showed that post-PCI FFR was isolated from any other interventional parameters. The independent predictors for residual ischaemia were reference diameter (adjusted odds ratio: 0.94; 95% confidence interval: 0.91-0.98; p=0.004) among pre-PCI angiographic parameters and post-PCI minimum lumen diameter (adjusted odds ratio: 0.93; 95% confidence interval: 0.90-0.97; p=0.001) and post-PCI percent diameter stenosis (adjusted odds ratio: 1.34; 95% confidence interval: 1.05-1.71; p=0.020) among post-PCI parameters. The prediction models for residual ischaemia showed low predictive values when the models used pre- or post-PCI angiographic parameters (using pre-PCI angiographic parameters C-statistic: 57.9, 95% confidence interval: 52.9-63.0; both pre- and post-PCI angiographic parameters C-statistic: 60.9, 95% confidence interval: 56.1-65.7). However, there was an incremental improvement of the prediction model when the pre-PCI FFR values were added, (C-statistic: 71.2; 95% confidence interval: 67.1-75.4).

Conclusions: Patients with residual ischaemia had a higher risk of clinical events during two-year follow-up. Our study results showed the importance of pre- and post-FFR measurement in optimisation of coronary stent implantation.

STEMI - Invasive imaging and functional assessment

Diagnostic performance of quantitative flow ratio in patients with AMI

TERENTES-PRINTZIOS Dimitrios [1], TERENTES-PRINTZIOS Dimitrios [1], SCARSINI Roberto [1], SHANMUGANATHAN Mayooran [1], KOTRONIAS Rafail A. [1], LANGRISH Jeremy P. [1], LUCKING Andrew J. [1], CHANNON Keith M. [1], GARCIA-GARCIA Hector M. [2], BANNING Adrian P. [1], DE MARIA Giovanni Luigi [1]

(1) Oxford University, Oxford, United Kingdom; (2) MedStar Washington Hospital Center, DC, USA

Aims: The accuracy of quantitative flow ratio (QFR) has not been assessed in the infarct-related artery (IRA) of patients with acute myocardial infarction (AMI). Moreover, the classification agreement between QFR and fractional flow reserve (FFR) is uncertain in the case of extreme coronary microvasculature dysfunction (CMD).

Methods and results: Overall 76 patients (55 patients with AMI and 21 controls with chronic coronary syndromes [CCS]) with 118 coronary lesions underwent intracoronary physiology and QFR assessment. Among AMI patients, 40 (73%) presented with ST-elevation myocardial infarction and 15 (27%) with non-ST-elevation myocardial infarction. The median age was 62 (56-71) years and 73% were male. The severity of CMD was evaluated using thermodilution-derived index of microcirculatory resistance (IMR). Coronary vasodilatory reserve was assessed using resistive reserve ratio (RRR). As expected IMR and RRR were significantly impaired in the IRA compared with non-culprit lesions (NCL) and controls. The correlation between QFR and FFR was good in the NCL ($r=0.75$, $p<0.001$) and in the controls ($r=0.78$, $p<0.001$) but moderate in the IRA ($r=0.55$, $p<0.001$). Nevertheless, the accuracy of QFR in identifying an abnormal FFR was comparable in the IRA (AUC=0.90) vs NCL and controls (AUC=0.95). Adenosine-QFR did not demonstrate incremental diagnostic performance compared with contrast-QFR. When the classification agreement between QFR and FFR was tested across the spectrum of IMR values, an inverse relationship was observed. The diagnostic accuracy of QFR was excellent (94.5%) in coronary vessels with IMR equal or less than 50U but it was moderate in cases with extreme (IMR>50U) CMD (76.9% vs 94.5%, $p=0.054$). Notably, no difference in QFR diagnostic accuracy was observed in patients with or without evidence microvascular obstruction at cardiovascular magnetic resonance imaging.

Conclusions: QFR demonstrated excellent diagnostic performance in patients with AMI maintaining a classification agreement >90% with FFR until extreme levels of CMD, when the validity of FFR itself may be questionable.

Euro20A-OP061
Abstract | Oral presentation

Left main and multivessel disease - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Intravascular lithotripsy for the treatment of calcific distal left main disease

COSGROVE Claudia [1], COSGROVE Claudia [1], WILSON Simon [2], BOGLE Richard [3], HANRATTY Colm [2], WILLIAMS Rupert [1], WALSH Simon [2], MCENTEGART Margaret [4], SPRATT James [1]

(1) St George's Hospital, London, United Kingdom; (2) Belfast City Hospital, Belfast, United Kingdom; (3) Epsom and St Helier University Hospitals, Epsom, United Kingdom; (4) Golden Jubilee National Hospital, Clydebank, United Kingdom

Aims: Coronary intravascular lithotripsy (IVL) is a novel technology for modification of calcific atheromatous plaque prior to stent placement, thereby facilitating optimal stent expansion. This is of particular importance in the left main (LM) coronary artery, where the consequence of stent under-expansion can be severe. We present the first description of procedural and in-hospital outcomes following intravascular lithotripsy for calcific distal left main disease.

Methods and results: We performed a retrospective analysis across 3 centres of all patients who underwent IVL for undilatable calcific distal LM (or equivalent) disease between May 2018 and April 2019. Analysis of angiographic and intracoronary imaging was performed on a segmental basis (distal LM, ostial left anterior descending (LAD) and ostial left circumflex (LCX)). Thirty-one consecutive patients were included in the final analysis. The mean age was 75.1 years (±8.1) and 87% were male. The indication for PCI was chronic stable angina in 58% and ACS in 42%. 13 patients (42%) had LVEF<50% and 5 patients (16%) had undergone previous coronary bypass surgery. In all patients, intracoronary imaging was performed prior to IVL therapy (74% with IVUS and 26% with OCT). All patients had at least one segment of obstructive disease with an arc of calcium >270°, and an arc of >180° was demonstrated in 91% of distal LM, 82% ostial LAD and 82% ostial LCX. In all patients, IVL was performed after the segment proved undilatable. The final balloon prior to switching to IVL was a semi-compliant, non-compliant and cutting balloon in 16, 15 and 1 patient, respectively. In 2 patients, rotational atherectomy also failed to modify the lesion adequately. In total, IVL was performed in 58 undilatable segments. The mean maximum IVL balloon diameter was 3.56mm, and the mean number of pulses delivered was 77. Twenty (65%) patients had repeat intracoronary imaging performed after IVL and prior to stenting. In all of these cases, multiple calcium fractures were demonstrated. A single-stent strategy was used in 19 patients (62%), a 2-stent strategy (all culotte technique) in 11 patients (35%) and drug-eluting balloon only in one case. The mean minimum stent area (MSA) by segment was 13.3mm^2 (±3.1), 9.7mm^2 (±1.6), and 8.2mm^2 (±1.2) for the distal LM, ostial LAD, and ostial LCX, respectively. Target MSAs (distal LM=8.2, ostial LAD=6.3, ostial LCX=5.0mm^2) were achieved in 96.6% (56/58) of all IVL treated segments and 97.3% (72/74) of all stented segments. IVL was not associated with any procedural complications or in-hospital adverse events. The 30-day rate of major adverse cardiac events (MACE) was 3.2%, with the single recorded event being a non-ST-elevation MI from plaque rupture in a non-target vessel (right coronary artery), confirmed on coronary angiography.

Conclusions: IVL appears to be a safe and effective treatment for undilatable calcific distal LM disease, with high rates of adequate luminal area achieved and a low frequency of periprocedural and in-hospital adverse events.

Euro20A-OP062
Abstract | Oral presentation

Stents and scaffolds - Invasive imaging and functional assessment

Impact of IVUS findings in patients with a post-PCI FFR ≤ 0.85 on two-year clinical outcome

DAEMEN Joost [1], DAEMEN Joost [1], VAN ZANDVOORT Laurens [1], MASDJEDI Kaneshka [1], NELEMAN Tara [1], TOVAR FORERO Maria Natalia [1], WILSCHUT Jeroen [1], DEN DEKKER Wijnand [1], DE JAEGERE Peter [1], DILETTI Roberto [1], ZIJLSTRA Felix [1], VAN MIEGHEM Nicolas [1]

(1) Erasmus MC, Rotterdam, the Netherlands

Aims: Patients with a low post percutaneous coronary intervention (PCI) fractional flow reserve (FFR) are at increased risk for future adverse cardiac events. The aim of the present FFR-SEARCH study was to assess the impact of specific intravascular ultrasound (IVUS) findings in patients with a low post-PCI FFR on long-term clinical outcome.

Methods and results: FFR-SEARCH is a prospective registry in which a consecutive series of 1,000 all-comer patients underwent FFR evaluation after angiographically successful PCI. In 95 patients (100 vessels) with a post-procedural FFR ≤0.85, IVUS was performed. The primary endpoint at 2-year follow-up was major adverse cardiac events (MACE), a composite of cardiac death, any myocardial infarction or any revascularisation. Mean post-PCI FFR was 0.79±0.05. Minimal lumen area was 2.19 (1.81–3.19) mm^2, mean lumen area was 5.95 (5.01–7.03) mm^2, and minimal stent area was 4.01 (3.09–5.21) mm^2. Significant focal lesions proximal or distal to the treated segment were found in 29% and 30% of the vessels respectively. Stent underexpansion was present in 74% (>10% underexpansion) of the vessels with a mean expansion rate of 78.7. (74% of the vessels). An underexpansion rate >20% was present in 50% of the vessels. Malapposition was found in 23% of the vessels. Spasm was present in 9% of the vessels analysed and in 8% of the vessels diffuse disease was present. In 87% of the vessels, either a focal lesion, underexpansion, a lumen compromising haematoma or malapposition were present. At two years, the cumulative survival free of MACE in patients with a post-PCI FFR ≤0.85 in the IVUS subcohort was 91.4%. MACE-free survival rates were 88.5% vs 92.5% for patients with versus without residual proximal lesions and 88.2% vs 92.5% for patients with versus without residual distal lesions, respectively. MACE-free survival was 89% vs 93.7% in patients with versus without stent underexpansion >20% and 89.3% vs 93.3% in patients with versus without any residual focal lesion (p=ns for all).

Conclusions: At two years, the cumulative survival free of MACE in patients with a post-PCI FFR ≤0.85 was 91.4%. Numerically higher MACE rates were observed in patients with a post-PCI FFR ≤0.85 and clear focal residual disease as assessed with IVUS.

Euro20A-OP063
Abstract | Oral presentation

Stable CAD - Invasive imaging and functional assessment

CABG or FFR-guided PCI in diabetic patients with multivessel disease

DI GIOIA Giuseppe [1,2], DI GIOIA Giuseppe [1,2], SOTO FLORES Nina [1], FRANCO Danilo [2], COLAIORI Iginio [1], SONCK Jeroen [1], GIGANTE Carlo [1], KODEBOINA Monika [1], BARTUNEK Jozef [1], VANDERHEYDEN Marc [1], VAN PRAET Frank [1], CASSELMAN Filip [1], DEGRIEK Ivan [1], STOCKMAN Bernard [1], BARBATO Emanuele [2], COLLET Carlos [1], DE BRUYNE Bernard [1]

(1) Cardiovascular Center Aalst, OLV Clinic, Aalst, Belgium; (2) Department of Advanced Biomedical Sciences, Federico II University, Naples, Italy

Aims: In diabetic patients with multivessel coronary disease (MVD), coronary artery bypass grafting (CABG) has shown long-term benefits over percutaneous coronary revascularisation (PCI). Nevertheless, the impact of fractional flow reserve (FFR)-guided PCI on clinical outcomes has never been investigated in these patients. We aimed to evaluate long-term clinical outcomes of diabetic patients with MVD treated with FFR-guided PCI compared to CABG.

Methods and results: From 2010 to 2018, 4,622 diabetic patients undergoing coronary angiography in our centre were screened for inclusion. The inclusion criterion was presence of at least two-vessel CAD defined as with DS ≥ 50%, in which at least one intermediate stenosis (DS 30-70%) was treated or deferred according to FFR. To account for confounders, we compared outcomes through inverse probability of treatment weighting (IPTW). The primary endpoint was major adverse cardiovascular and cerebrovascular events (MACCE), defined as all-cause death, spontaneous MI, revascularisation and stroke. A total of 418 patients were included in the analysis. Among them, 209 patients underwent CABG and 209 FFR-guided PCI. Clinical follow-up was obtained in 99% of the patients at a median follow-up of 5 years. The incidence of MACCE was higher in the FFR-guided PCI vs the CABG group (44.5% vs 31.9%. HR [95% CI] 1.60 [1.15-2.22]; p=0.005). No difference was found in the composite of all-cause death, MI or stroke (28.8% vs 27.5%. HR [95% CI] 1.05 [0.72-1.53]; p=0.81). Revascularisation was more frequent with FFR-guided PCI vs CABG (24.9% vs 8.2%. HR [95% CI] 3.51 [1.93-6.40]; p<0.001).

Conclusions: In diabetic patients with MVD, CABG was associated with a lower rate of revascularisation. No difference between CABG and FFR-guided PCI was observed in all-cause death, spontaneous MI, or stroke at 5-year follow-up.

2020 PCR e-Course Coronary interventions

Euro20A-OP064
Abstract | Oral presentation

Stable CAD - Invasive imaging and functional assessment

Role of the local haemodynamic forces estimated in 3D quantitative coronary angiography models in predicting non-flow limiting coronary lesions that cause cardiovascular events: a retrospective, observational multicentre study

TUFARO Vincenzo [1], TUFARO Vincenzo [1], SAFI Hannah [1,2], TORII Ryo [2], RAMASAMY Anantharaman [1,3], MATHUR Anthony [1,3], JONES Daniel [1,3], LANSKY Alexandra [3,4], KONSTANTINOU Klio [5], LITTLE Callum [6], RAKHIT Roby [6], KARAMASIS Grigoris [5], BAUMBACH Andreas [1,3,4], BOURANTAS Christos [1,2,3]

(1) St Bartholomew's Hospital, London, United Kingdom; (2) University College London, London, United Kingdom; (3) Queen Mary University of London, London, United Kingdom; (4) Yale University, CT, USA; (5) The Essex Cardiothoracic Centre, Basildon, United Kingdom; (6) Royal Free Hospital, London, United Kingdom

Aims: Recent studies have highlighted that local haemodynamic forces, calculated using models derived from intravascular imaging, may have a role in predicting the risk of future cardiovascular events in non-flow limiting coronary lesions. In this study, we evaluated for the first time the efficacy of using wall shear stress (WSS), estimated in models reconstructed by 3D-QCA, for identifying non-flow limiting lesions with a borderline fractional flow reserve (FFR: 0.81-0.85) that were associated with a risk of future adverse events.

Methods and results: Between January 2012 and June 2017, we identified 554 patients who were treated conservatively, had an FFR between 0.81-0.85, and complete clinical and follow-up data. From these patients, we selected all the lesions that had angiographic data suitable for 3D-QCA modelling (289 lesions, 282 patients) and reconstructed their anatomy using dedicated 3D-QCA software (QAngio XA 3D RE, Medis Specials bv, Leiden, the Netherlands); side branches with diameter >1 mm were included in the reconstruction. In the obtained geometric models, blood flow simulation was performed and the WSS was estimated. Each lesion was divided in 3-mm segments and for each segment the mean WSS was computed; these values were used to investigate the association between WSS and patients' outcome. Our primary composite endpoint was the incidence of major adverse cardiovascular events (MACE) defined as a composite of all-cause mortality, target lesion related myocardial infarction (MI) or clinically indicated target lesion revascularisation (TLR). The secondary endpoint was defined as the rate of target lesion related MI or TLR. During a median follow-up of 44.1 months, 46 MACE were reported (16 deaths, 9 target lesion related MI and 21 TLR). There were no differences in the baseline demographics between patients that had a MACE and those that did not have an event. Lesions associated with MACE had a greater area stenosis (AS) (63.5±9.9% vs 54.2±11.9%, p<0.001), smaller minimum lumen area (MLA, 1.88±0.71 mm^2 vs 2.33±1.23 mm^2, p=0.002) and higher WSS at the MLA (9.72±6.76Pa vs 6.10±4.21Pa, p<0.001) than those that remained quiescent. In the Cox regression analysis, AS, MLA and WSS at the MLA were the only predictors of MACE or target lesions events (MI or TLR). In the multivariable Cox regression analysis, AS (HR=1.05, CI: 1.02-1.09, p=0.001) and WSS at the MLA (HR=1.06, CI: 1.01-1.11, p=0.026) were independent predictors of MACE. Results were similar when analysing the secondary endpoint of target lesion related MI or clinically indicated TLR: AS (HR=1.09, CI: 1.05-1.13, p<0.001) and WSS at the MLA (HR=1.06, CI: 1-1.13, p=0.036) were the only independent predictors of these events. Lesions with an increased AS (>57%) that were exposed to high WSS at the MLA (6.53Pa) were at a higher risk of suffering MACE (35.7%) than those that had increased AS and low WSS (16.4%) or those that were exposed to high WSS and had a low AS (8.9%) or to the lesions that had low WSS and AS (5%, p<0.001).

Conclusions: This study highlights the potential value of 3D-QCA-derived WSS in detecting a risk for future adverse events among intermediate coronary lesions with borderline FFR. Further research is required to confirm the above findings and developments are needed to expedite the computation of 3D-QCA-derived WSS before advocating its use in the clinical setting as a tool to stratify cardiovascular risk.

Euro20A-OP066
Abstract | Oral presentation

Stents and scaffolds - Invasive imaging and functional assessment

Long-term outcomes in patients with non-physiologically significant in-stent restenosis

MCINERNEY Angela [1], MCINERNEY Angela [1], CASTRO MEJIA Alex [1], TRAVIESO GONZALEZ Alejandro [1], TIRADO-CONTE Gabriela [1], MEJÍA-RENTERÍA Hernan [1], ESCANED Javier [1], GONZALO Nieves [1]

(1) Hospital Clínico San Carlos, Madrid, Spain

Aims: In-stent restenosis (ISR) has decreased significantly since the introduction of drug-eluting stents. The optimal treatment continues to be debated, but regardless of treatment chosen, repeat stenosis occurs commonly. Physiological assessment of coronary artery disease has led to a significant reduction in revascularisation with non-physiologically significant stenosis being safely deferred. The use of invasive physiology to assess ISR, has not been rigorously assessed. The aim of this study was to assess the safety of deferring treatment of ISR based on physiological assessment of ischaemia.

Methods and results: This was a single-centre retrospective review of patients presenting with moderate restenosis of a previously deployed stent who had treatment deferred based on physiological assessment. Patients with ISR involving the left main stem were excluded. Baseline characteristics and angiographic data were collected. Outcomes were assessed by reviewing clinical follow-up. Comparison was made between patients with ISR deferred based on physiological assessment and a group of patients with moderate native coronary artery stenosis also deferred based on physiological assessment. Seventy patients with moderate ISR were included and compared to 512 patients with native coronary artery disease. The groups were well matched in terms of baseline characteristics with no significant differences in age, gender, history of diabetes, hypertension, hyperlipidaemia, baseline renal function, history of COPD and baseline left ventricular systolic function ($p>0.05$ for all). Previous MI and a background history of smoking were more common in the ISR group ($p<0.05$ for both parameters). There were no differences in coronary artery assessed between the groups ($p>0.05$) with the left anterior descending artery being most commonly undergoing physiological assessment. Within the ISR group, 62% of patients had Mehran class 1 ISR (15.7% 1B, 44.28% 1C, 2.85% 1D) with Mehran class 2 in 21.43% and class 3 in 10%. The average percent stenosis using quantitative coronary angiography (QCA) was 46.48% (SD 10.76). Kaplan-Meier survival analysis showed no difference in the composite end point of death, target vessel MI (TVMI) or target vessel revascularisation (TVR) at three years between the two groups (log rank $p=0.20$). Furthermore, individual end points of all-cause mortality, TVMI, TVR and target lesion revascularisation (TLR) were not significantly different between the groups (log rank $p=0.619$, 0.495, 0.188 and 0.158 respectively).

Conclusions: Deferral of revascularisation of moderate ISR based on physiological assessment of ischaemia is safe with no significant difference in all-cause mortality, TLR and TVR at three-year follow-up compared to a similar cohort of patients with native coronary artery disease.

Euro20A-OP067
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

PCI in small coronary vessels: a sirolimus-coated balloon or sirolimus-eluting stent?

CORTESE Bernardo [1], DANI Sameer [2]

(1) Clinica San Carlo, Milan, Italy; (2) Apollo Hospitals & Apollo CVHF Heart Institute, Ahmedabad, India

Aims: Percutaneous coronary intervention (PCI) of small coronary vessels remains challenging due to an impaired device delivery and a higher restenosis rate, even with the use of newer-generation drug-eluting stents. Drug-coated balloons (DCB) represent an attractive emerging PCI option in this scenario. We compared the clinical outcomes of sirolimus-coated balloons – (SCB) (MagicTouch SCB, Concept Medical) vs novel sirolimus-eluting stents (SES) which have unique coating technology (Abluminus DES+, Concept Medical) in patients with lesions located in small coronary vessels (≤2.75mm).

Methods and results: We analysed 1,450 total patients with *de novo* lesions in small coronary arteries. Among these, 197 were treated with MagicTouch SCB and 1,253 with Abluminus DES+. We assessed and compared major adverse cardiac events (MACE) at 1 year. MACE was defined as the composite of target lesion revascularisation (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. The baseline characteristics of the patients in both groups were similar. Diabetes mellitus accounted for 38.6% vs 43% (p=0.249) for SCB and SES groups. In both groups the majority of patients presented with acute coronary syndrome (52.3% vs 62.2%, p=0.009). Most patients treated with SCB were prescribed a minimum 3 months DAPT while patients treated with DES were prescribed 12-month DAPT. We have a complete follow-up for the entire population at 12 months. The incidence of MACE was 3.6% vs 3.8%, HR 0.969, 95% CI: 0.437-2.145; p=0.937, at 1 year in the SCB group vs the DES group, while TLR was 2.5% vs 2.1%, HR 1.276, 95% CI: 0.489-3.334, p=0.619. Cardiac death occurred in 1.0% vs 1.3%, HR 0.793, 95% CI: 0.182-3.448, p=0.757 for SCB and DES patients, respectively. No TV-MI was reported in the SCB group. Finally, 0.7% patients treated with DES experienced a stent thrombosis, and none in the SCB group.

Conclusions: In patients with lesions in small coronary vessels, treatment with SCB was associated with similar outcomes compared with the novel sirolimus-eluting stent Abluminus DES+. A randomised controlled trial is needed to support these results.

Stents and scaffolds - Tools, devices and techniques

A randomised comparison of healing response to the BuMA Supreme stent and the XIENCE stent at two-year follow-up: the PIONEER-II OCT randomised controlled trial

CHEN Yundai [(1)], CHEN Yundai [(1)]

(1) Chinese PLA General Hospital, Beijing, China; (2) Shanghai 9th People's Hospital, China, Shanghai, China; (3) Affiliated Hospital of ZunYi Medical College, China, Zunyi, China; (4) Wuhan Asia Heart Hospital, Hubei, China; (5) Sir Run Run Shaw Hospital, ZheJiang U. School of Medicine, China, Hangzhou, China; (6) 2nd Affiliated Hospital of NanChang University, China, Nanchang, China; (7) 1st Affiliated Hospital of DaLian Medical University, China, Dalian, China; (8) 1st Affiliated Hospital of Xi'An JiaoTong University, China, Xi'An, China

Aims: The aim of this study was to compare the strut coverage of the XIENCE stent with that of the BuMA Supreme sirolimus-eluting cobalt-chromium stent, which has a shorter drug elution profile and a biodegradable drug coating technology, on optical coherence tomography (OCT) at different time points. The one-month and two-month follow-up has been reported previously, and the long-term two-year follow-up was scheduled and compared to further investigate the healing response between the two different stents.

Methods and results: The PIONEER-II OCT trial was a multicentre, two-arm randomised trial, which comprised two cohorts: cohort-1 underwent an OCT imaging one month after coronary intervention (BuMA: 16 patients with 18 lesions, XIENCE: 15 patients with 17 lesions), whereas cohort-2 underwent OCT at two months (BuMA: 21 patients with 21 lesions, XIENCE: 23 patients with 28 lesions). In cohort-1, the BuMA stent was non-inferior to the XIENCE stent in terms of the strut coverage (83.8±10.4% for BuMA vs 73.0±17.5% for XIENCE, Pfor non-inferiority <0.001), and was also significantly higher than the XIENCE (Pfor superiority = 0.037). In cohort-2, the BuMA stent was non-inferior to the XIENCE stent in OCT strut coverage (80.3±18.3% vs 73.3±21.3%, Pfor non-inferiority = 0.006, Pfor superiority = 0.24). All the patients from the cohort-1 and cohort-2 were scheduled to a two-year follow-up on OCT to compare the long-term healing response between groups. A total of 27 patients treated with the BuMA stents and 22 patients treated with the XIENCE stents completed the OCT imaging follow-up at two-year. The OCT and quantitative coronary angiography (QCA) analysis is undertaken by the independent imaging Corelab. At two-year OCT follow-up, the BuMA stent (29 lesions) was similar to XIENCE stent (26 lesions) in terms of the percentage of strut coverage (99.46±0.95% vs 99.61±0.67%, p=0.4915). Also the mean thickness of membrane on strut (75.46±77.34 vs 48.58±54.83 μm, p=0.1472), the mean lumen area (6.93±2.20 vs 7.07±2.04 mm^2, p=0.8131), the minimum lumen area (5.02±2.06 vs 5.09±1.86 mm^2, p=0.8924), and the percentage of malaposition (0.15±0.35 vs 0.03±0.10%, p=0.0968) were similar in patients treated with BuMA and XIENCE stents, respectively. In two-year QCA analysis, there were no significant differences in the in-stent late lumen loss (0.19±0.49 vs 0.19±0.51 mm, p=0.9783) and the percentage of in-stent stenosis (15.37±14.95% vs 11.80±12.61%, p=0.3458) between BuMA and XIENCE groups.

Conclusions: The BuMA Supreme stent previously demonstrated a faster coverage than XIENCE stent at one month, presumably due to the faster and shorter sirolimus elution profile. The two-year follow-up on OCT is to compare the long-term healing response between the two different stents; whether the drug elution profile and the biodegradable/durable coating technologies would play a role at two years. Clinicaltrials.gov Identifier: NCT02747329.

Euro20A-OP070
Abstract | Oral presentation

Stable CAD - Invasive imaging and functional assessment

Absolute resting coronary flow, microvascular resistance and resistance reserve measured by coronary thermodilution

GALLINORO Emanuele [1,2], GALLINORO Emanuele [1,2], COLAIORI Iginio [1], DI GIOIA GIuseppe [1,3], FOURNIER Stephane [4], KOIDEBOINA Monika [1,3], CANDREVA Alessandro [1], SONCK Jeroen [1,3], PIJLS Nico H.J. [5], COLLET BORTONE Carlos [1], DE BRUYNE Bernard [1]

(1) Cardiovascular Center, Aalst, OLV-clinic, Aalst, Belgium; (2) Department of Translational Medical Sciences, University of Campania "Luigi Vanvitelli", Naples, Italy; (3) Department of Advanced Biomedical Sciences, Federico II University, Naples, Italy; (4) Department of Cardiology, Lausanne University Hospital, Lausanne, Switzerland; (5) Catharina Ziekenhuis, Eindhoven, the Netherlands

Aims: Hyperaemic absolute coronary blood flow (in mL/min) can be safely and reproducibly measured with intracoronary continuous thermodilution of saline at room temperature at an infusion rate of 20 mL/min. This study aims at assessing whether continuous thermodilution can also measure resting flow and microvascular resistance.

Methods and results: In 80 coronary arteries (49 patients) with angiographic non-significant stenoses, absolute flow was assessed by continuous thermodilution of saline at infusion rates of 10 mL/min and 20 mL/min using a pressure/temperature sensored guide wire, a dedicated infusion catheter (RayFlowTM, Hexacath, Paris, France) and a dedicated software (CoroFlow™ System, Uppsala, Sweden). In addition, in 24 arteries, average peak velocity (APV, FloWire, Volcano/Philips) was measured simultaneously. There was no significant difference between Pd/Pa at baseline and during saline infusion at 10 mL/min, (0.95±0.05 vs 0.95±0.04, respectively (p=0.58) and there was no significant difference in APV at baseline and during the infusion of saline at 10 mL/min (19.5±7.06 vs 21.5±7.77 cm/s, respectively, p=0.17), thus indicating presence of resting coronary blood flow during the infusion of 10 mL/min of saline. In contrast, at an infusion rate of 20 mL/min, a significant decrease in Pd/Pa was observed compared to baseline: (0.85±0.08 vs 0.95±0.05 vs, respectively, p<0.001) and a significant increase in APV was observed (19.3±6.99 cm/s to 48.8±16.7 cm/s, respectively, p<0.001). The coronary flow reserve calculated by thermodilution and by Doppler flow velocity were similar (2.70±0.64 vs 2.65±0.60, respectively and their individual values correlated closely (r=0.95, 95% CI: 0.89-0.98, p<0,001).

Conclusions: Absolute coronary blood flow (in mL/min) can be measured by continuous thermodilution both at rest and during hyperaemia. This allows accurate and reproducible direct volumetric calculation of CFR, and microvascular resistance reserve, which, in turn, allows the quantification of microvascular function.

Euro20A-OP072
Abstract | Oral presentation

CTO - Tools, devices and techniques

A patient's quality of life after successful coronary CTO antegrade recanalisation: single-centre study results

STELMASHOK Valeriy [1], STELMASHOK Valeriy [1], MROCHEK Alexander [1], POLONETSKY Oleg [1], STRYGO Nikolai [1]

(1) Republican Scientific and Practical Centre «Cardiology», Minsk, Belarus

Aims: In clinical trials, we usually control the patient's clinical status and visualisation results and do not pay much attention to the patient's quality of life. In our study we analysed the patient's psychological, emotional and mental status after endovascular correction of coronary CTO lesions in the mid-term period.

Methods and results: In our single centre study we included 158 patients after successful antegrade coronary artery CTO recanalisation. All patients completed the SF-36 survey the day before revascularisation (baseline data) and in the mid-term follow-up period (6.1±0.9 months and 12.7±1.6 months after successful CTO PCI). All data was analysed in Statistica 10.0 software (StatSoft Inc., USA). At 6.1±0.9 months after the successful CTO recanalization, significant increase of patients' physical and mental health was observed ($p<0.001$ compared with baseline data). The quality of life at 12.7±1.6 months after normal vessel patency restoration did not differ significantly from the 6.1±0.9 months level. At 12.7 months after CTO PCI we did not observe any differences in the quality of life between individual subgroups: diabetic/non-diabetic patients (0.03 [-0.13, 0.19], p=0.68), patients with and without of arterial hypertension (0.13 [-0.07, 0.33], p=0.20), as well as persons with high and normal body weight (0.13 [-0.07, 0.33], p=0.20). A higher quality of life at the end of the mid-term observation period was revealed in male patients (0.47 [0.23, 0.71], p=0.0001). It was established that the development of target lesion failure was not associated with any changes in the patient's quality of life (0.13 [-0.04, 0.30], p=0.12). Also, there was no difference in physical and mental health among patients with and without verified restenosis in the target lesion area at 12.7 months angio control (0.47 [-0.05, 0.29], p=0.17).

Conclusions: The obtained data shows the improvement of patients' psychological, emotional and mental status in the mid-term period after coronary CTO recanalisation and illustrate effectiveness of endovascular CTO correction in terms of life quality. The 12.7-month control did not differ from the 6.1-month results, which means there is a prolonged effect of CTO intervention on patients' quality of life.

Stable CAD - Bypass surgery

Graft patency and progression of coronary artery disease after CABG assessed by angiography-derived FFR

SONCK Jeroen [1], SONCK Jeroen [1], GIGANTE Carlo [4], MIZUKAMI Takuya [1], NAGUMO Sakura [1], GALLINORO Emanuele [1], CANDREVA Alessandro [1], TANZILLI Alessandra [2], DE BRUYNE Bernard [1], ANDREINI Daniele [3,4], COLLET Carlos [1]

(1) Cardiovascular Center Aalst, OLV Clinic, Aalst, Belgium; (2) Department of Cardiovascular Sciences, Sapienza University, Rome, Italy; (3) Centro Cardiologico Monzino, IRCCS, Milan, Italy; (4) Department of Clinical Sciences and Community Health, Cardiovascular Section, University of Milan, Milan, Italy

Aims: We aimed to characterise the functional progression of coronary artery disease (CAD) in native vessels after coronary artery bypass graft surgery (CABG), and to assess the relationship between preoperative angiography-derived fractional flow reserve (vFFR), derived flow reserve and graft occlusion.

Methods and results: This is a retrospective, multicentre study of consecutive patients treated with CABG who underwent clinically indicated coronary angiography after surgery. All patients had a preoperative angiogram performed within 2 months of CABG. Post-CABG angiograms had been performed at least 6 months after CABG. Angiography-derived FFR was performed with vFFR software (CAAS 8.2 Software, Pie Medical Imaging, Maastricht, The Netherlands). Serial vFFR analyses were obtained in each major native coronary vessel before and after CABG. Pre- and post-CABG analyses were matched based on anatomical landmarks using the same angiographic projections for the 3D reconstructions. Non-grafted vessels were reconstructed from the ostium up to the distal coronary segment. To allow for the evaluation of functional CAD progression in grafted vessels, vFFR analyses were performed in the coronary segment proximal to the anastomosis. Delta vFFR was calculated to determine the functional progression of CAD in bypassed and non-bypassed vessels. Receiver operating characteristic (ROC) curves were used to assess the best vFFR cutoff to predict graft occlusion. A total of 403 patients underwent CABG during the study period. In 73 patients (182 native vessels, 69 (37.9%) LAD, 62 (34.1%) LCX, 51 (28.0%) RCA) serial angiograms were suitable for vFFR analysis, including 118 grafted (86 arterial and 32 saphenous grafts) and 64 non-grafted vessels. The median time between CABG and follow-up angiography was 2.4 years [IQR 1.5, 3.3]. Overall, vFFR significantly decreased over time (0.76 [IQR 0.67, 0.88] to 0.68 [IQR 0.50, 0.85], p<0.001). Diameter stenosis significantly increased between preoperative and follow up angiography in grafted vessels (pre-CABG %DS 51.50 [IQR 45.00, 57.00] vs post-CABG %DS 59.00 [IQR 49.25, 71.75], p<0.001). The functional CAD progression was significantly higher in grafted compared to non-grafted vessels (delta vFFR in grafted vessels 0.10 [IQR 0.05, 0.18] vs delta vFFR in non-grafted vessels 0.01 [IQR -0.01, 0.03], p<0.001). Graft occlusion was observed in 19/118 (16.1%) of conduits. The median preoperative vFFR value in the native vessel was higher in occluded compared to patent grafts (0.75 [IQR 0.68, 0.80] vs 0.69 [IQR 0.60, 0.76], p=0.028). Preoperative vFFR predicted graft occlusion (AUC: 0.66, 95% CI: 0.52 to 0.80, p=0.031).

Conclusions: In patients undergoing CABG, preoperative vFFR derived from conventional angiograms without the use of pressure wire predicted graft failure. Graft occlusion was more frequent in vessels with high vFFR values. vFFR characterised the functional progression of CAD. Grafted native coronary vessels exhibited accelerated functional CAD progression whereas in non-grafted native coronaries the functional status remained unchanged.

Euro20A-OP075
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

Comparison between one-stent vs two-stent technique on long-term clinical outcomes with new-generation DES for unprotected left main disease

HIROMASA Takashi [(1)], HIROMASA Takashi [(1)], KURAMITSU Shoichi [(1)], DOMEI Takenori [(1)], YAMAJI Kyohei [(1)], HYODO Makoto [(1)], ANDO Kenji [(1)]

(1) Kokura Memorial Hospital, Fukuoka, Japan

Aims: Comparison between one-stent versus two-stent technique on long-term clinical outcomes after new-generation drug-eluting stents (DES) implantation for unprotected left main disease (ULMD) remains unclear.

Methods and results: Between February 2010 and July 2012, 2519 consecutive patients with 3,410 lesions were treated only with new-generation DES implantation. Of these, 159 ULMD patients with 159 lesions were analysed. We assessed the cumulative 5-year incidences of major adverse cardiac events (MACE), defined as a composite of cardiac death, myocardial infarction, definite stent thrombosis, and clinically driven target lesion revascularisation (CDTLR) between the one-stent and two-stent groups. Of the 159 ULMD patients with 159 lesions, 142 patients had 142 lesions treated with one-stent DES and were compared with 17 patients with 17 lesions treated with two-stent DES. Baseline characteristics were more adverse in patients in the two-stent DES group. Baseline SYNTAX score was lower in the one-stent DES group than in the two-stent DES group (19.8±9.4 vs 28.6±10.4, p<0.001). Cumulative 5-year incidence of MACE was not significantly different between the two groups (28.2% vs 23.5%, p=0.86). The cumulative incidence of cardiac death, myocardial infarction, stent thrombosis and CDTLR were similar between the two groups (11.9% vs 5.9%, p =0.53; 4.1% vs 5.9%, p=0.67; 1.5% vs 5.9%, p=0.21; 14.9% vs 23.5%, p=0.24, respectively).

Conclusions: For ULMD patients, the 5-year clinical outcome after new-generation DES implantation appears similar between the one-stent and two-stent strategy.

Stents and scaffolds - Invasive imaging and functional assessment, Other Coronary interventions - Other

Impact of IVUS imaging guidance on 12-month outcome of PCI with everolimus-BRS in heart transplanted patients affected by cardiac allograft vasculopathy

PIGHI Michele [1], PIGHI Michele [1], FEZZI Simone [1], GRATTA Andrea [1], TOMAI Fabrizio [2], PETROLINI Alessandro [2], TARANTINI Giuseppe [3], SPEDICATO Leonardo [4], LOI Bruno [5], PESARINI Gabriele [1], RIBICHINI Flavio [1]

(1) Azienda Ospedaliera Universitaria Integrata Verona, VR, Italy; (2) European Hospital, Metropolitan City of Rome, Italy; (3) University of Padua, Province of Padua, Italy; (4) Azienda Sanitaria Universitaria Integrata di Udine, Province of Udine, Italy; (5) azienda ospedaliera G. Brotzu, Metropolitan City of Cagliari, Italy

Aims: Cardiac allograft vasculopathy is a form of accelerated inflammatory fibroproliferative atherosclerotic disease affecting coronary vessels of heart transplanted patients. PCI in this setting is still considered a palliative measure because of the high incidence of in-stent restenosis and the poor prognosis associated with the disease itself. IVUS has proven to be more sensitive for detecting the disease at an early stage and to correlate better with the clinical outcome compared to coronary angiography. However, its role in guiding PCI in this context has not been evaluated.

Methods and results: We analysed the impact of IVUS assessment on the primary endpoint (angiographic in-segment restenosis rate at 1-year post-procedure) of the cardiac allograft regenerative therapy (CART) study, a prospective, multicentre, single-arm, open-label study assessing the performance of bioresorbable vascular scaffolds (BRS) in cardiac allograft vasculopathy. Of 35 heart transplant recipients affected by CAV, all underwent PCI with 51 second-generation everolimus-eluting BRS on 44 lesions. IVUS was used to guide the PCI of 30 lesions detected in 22 patients. We compared 12-month angiographic outcome of the IVUS-guided interventions versus the non-IVUS-guided ones. At the baseline quantitative coronary analysis (QCA), no significant differences were present between lesions undergoing IVUS-guided PCI compared to PCI without IVUS in terms of percentage of stenosis, lesion length and reference vessel diameter. Furthermore patients undergoing IVUS-guided PCI presented a higher severity of disease according to international society for heart and lung transplantation's CAV classification (ISHLT 2-3: 95% versus 69%, $p<0,05$), compared to patients undergoing non IVUS-guided PCI. The primary endpoint was significantly inferior in IVUS-guided PCI group (4,0% vs 33,3%, $p=0,01$), also after logistic regression, regardless of kidney function, smoking habit, diabetes mellitus and years since transplantation.

Conclusions: IVUS guidance in PCI with BRS in the context of cardiac allograft vasculopathy was associated with a significant decreased risk of 1-year in-segment restenosis.

Euro20A-OP080
Abstract | Oral presentation

STEMI - Invasive imaging and functional assessment

Comparison of thromboresistance between everolimus-eluting fluoropolymer stent and other standard DES in an ex vivo swine shunt model under clopidogrel-only antiplatelet therapy

JINNOUCHI Hiroyuki [(1)], JINNOUCHI Hiroyuki [(1)], SATO Yu [(1)], KOLODGIE Frank [(1)], CHENG Qi [(1)], JANIFER Christine [(1)], SAKAMOTO Atsushi [(1)], CORNELISSEN Anne [(1)], PERKINS Laura [(2)], VIRMANI Renu [(1)], FINN Aloke [(1)]

(1) Cvpath Institute Inc, MD, USA; (2) Abbott Vascular Inc, CA, USA

Aims: Recent clinical studies suggest that 1-month dual antiplatelet therapy is feasible for patients receiving XIENCE everolimus-eluting stents, but whether this applies to other current DES remains uncertain. Under low dose heparin treatment, *ex vivo* porcine arteriovenous shunt (AV) studies have supported superior thromboresistance for XIENCE. However, a comparative assessment of thromboresistance of between XIENCE and other DES under single antiplatelet therapy (i.e. clopidogrel, SAPT) has never been performed in this model.

Methods and results: Using SAPT (i.e. clopidogrel), the thrombogenicity of XIENCE relative to standard DESs (Synergy and Onyx) was assessed acutely using a porcine AV shunt model. The stents were bisected and each half was dual immunostained using antibodies against platelets (CD61/CD42b) and inflammatory markers (i.e. neutrophils (PM1) and monocytes (CD14)). Staining was visualised by confocal microscopy and quantified by histomorphometry. *Ex vivo* shunt study under clopidogrel only therapy is in progress.

Conclusions: We tested the thromboresistance of several competitive DES under single antiplatelet clopidogrel therapy in the porcine AV shunt model.

Stable CAD - Invasive imaging and functional assessment

Deep learning for prediction of FFR from resting coronary pressure curves (ARTIST study)

ZIMMERMANN Frederik [1], ZIMMERMANN Frederik [1], MAST Thomas [1], JOHNSON Nils [2], EVERTS Ivo [3], DE BRUYNE Bernard [5], FEARON William [4], OLDROYD Keith [6], PIJLS Nico [1], TONINO Pim [1], VAN 'T VEER Marcel [1]

(1) Catharina Ziekenhuis Eindhoven, Eindhoven, the Netherlands; (2) McGovern Medical School at UTHealth, TX, USA; (3) GoDataDriven, Amsterdam, the Netherlands; (4) Stanford University, CA, USA; (5) Olv Ziekenhuis, Aalst, Belgium; (6) Golden Jubilee National Hospital, glasgow, United Kingdom

Aims: It would be ideal for a non-hyperaemic index to predict fractional flow reserve (FFR) more accurately, given FFR's extensive validation in a multitude of clinical settings. The aim of this study was to derive a novel non-hyperaemic algorithm based on deep learning and to validate it in an internal validation cohort against FFR.

Methods and results: The ARTIST study is a *post hoc* analysis of 3 previously published studies. In a derivation cohort (random 80% sample of the total cohort) a deep neural network was trained (deep learning) with paired examples of resting coronary pressure curves and their FFR values. The resulting algorithm was validated against unseen resting pressure curves from a random 20% sample of the total cohort. To reduce the variance in the precision, we used a 5-fold cross-validation procedure. The primary endpoint was diagnostic accuracy of the deep learning-derived algorithms against binary FFR≤0.8. A total of 1,666 patients with 1,718 coronary lesions and 2,928 coronary pressure tracings were included. Diagnostic accuracy of our convolutional neural network (CNN) and recurrent neural networks (RNN) against binary FFR≤0.80 were 79.6±1.9%, and 77.6±2.3%, respectively. The accuracy of our neural networks to predict binary FFR was not statistically different from the most accurate non-hyperaemic pressure ratio.

Conclusions: In the first study using a deep learning-based algorithm to predict FFR from resting coronary pressure curves, we did not find a clinically relevant increase in diagnostic accuracy versus non-hyperaemic pressure ratios. Our findings eliminate a larger class of possible hidden information than has been examined before. Adding clinical information or (non-invasive) anatomical information might increase the diagnostic performance of future deep learning models.

Euro20A-OP082
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

In vitro mechanical behaviour and in vivo healing response of a new-generation biodegradable polymer-coated thin strut sirolimus-eluting stent

GASIOR Pawel [(1)], GASIOR Pawel [(1)], PYKA Lukasz [(2)], HAWRANEK Michal [(2)], GARBACZ Michal [(2)], GASIOR Mariusz [(2)], WOJAKOWSKI Wojciech [(1)], LEKSTON Andrzej [(2)]

(1) Division of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland; (2) Third Department of Cardiology, School of Medicine with the Division of Dentistry in Zabrze, Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland

Aims: Recent advancements in drug-eluting stents (DES) technologies reduced the rate of repeat revascularisation. However, treatment of complex lesions still remain challenging. In this study we aimed to evaluate the biomechanical behavior and vascular healing profile of a new-generation biodegradable polymer-coated thin strut sirolimus-eluting stent (Alex NG, Balton, Poland).

Methods and results: *In vitro* biomechanical testing was performed under static conditions. We compared Alex NG with the commercially available previous-generation platform (Alex Plus, Balton, Poland) and the leading DES (Orsiro, Biotronik, Germany). We investigated the difference in stent designs and the results obtained after post-expansion with larger balloon sizes. A total of 6 domestic swine were implanted with Alex NG (n=12) and Alex Plus (n=6) for healing evaluation at 30 days. Overexpansion 1mm above nominal diameter resulted in no fractures or significant deformations during examination by light microscopy in all studied groups. Furthermore, post-dilatation 1.5mm above the nominal diameter revealed no fractures in Alex NG and Orsiro. Also, the largest cell opening diameter was observed in the Alex NG both at the nominal and upsized diameters. Optical coherence tomography analysis demonstrated comparable neoinitimal thickness at 30 days in Alex NG when compared to Alex Plus (respectively: 0,14±0,03 vs 0,14±0,05, p=0,887). Histology confirmed high biocompatibility of Alex NG stent.

Conclusions: The new-generation Alex NG demonstrated improved biomechanical behavior to the previous-generation platform (Alex Plus) with the results similar to the Orsiro stent. Furthermore, Alex NG demonstrated a favourable healing profile in the *in vivo* setting.

2020 PCR e-Course Coronary interventions

Euro20A-OP083
Abstract | Oral presentation

Stable CAD - Invasive imaging and functional assessment

Long-term variations of FFR and iFR after TAVI

SCARSINI Roberto [1], SCARSINI Roberto [1], LUNARDI Mattia [1], VENTURI Gabriele [1], PESARINI Gabriele [1], RIBICHINI Flavio [1]

(1) Università degli Studi di Verona, VR, Italy

Aims: Fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) coronary lesion assessment is controversial in patients with severe aortic stenosis (AS). The acute variations of FFR and iFR immediately after transcatheter aortic valve implantation (TAVI) have been previously evaluated. We aimed to assess the long-term follow-up after TAVI to test the variation of physiologic indexes in response to ventricular structural remodelling as opposed to acute afterload removal.

Methods and results: A prospective cohort of patients with severe AS and intermediate coronary lesions (ICL) underwent pressure-wire assessment at baseline and immediately after TAVI. PCI was advised in case of FFR ≤0.80 but, ultimately, the decision was left to the operator's discretion. Patients with deferred ICL at the index procedure were readmitted more than 6 months after TAVI for physiological reassessment. The study was approved by our institutional ethical review board (ID CESC 2015-498) and all patients eligible for the protocol provided their written consent. FFR and iFR were measured in a standard fashion using a pressure-monitoring guidewire (VerrataPlus, Volcano Therapeutics, Rancho Cordova, CA, USA). Fourteen patients (23 lesions) with severe AS were included in this analysis. The median time between TAVI and the follow-up procedure was 14 (7-29) months. Median age was 85 (78-88) and 79% were female. At follow-up all the patients experienced significant symptom improvement after TAVI and 84% were in NYHA class I-II. No vessel-oriented cardiovascular events were observed during the study period. At transthoracic echocardiography, mean valve gradient decreased significantly as an effect of TAVI (39 [34-50] vs 10 [6-16], p=0.001). Conversely, the interventricular septum thickness was not significantly different compared with the baseline (14 mm [13-18] vs 14 mm [13-14], p=0.13). The angiographic severity of the analysed lesions did not change at follow-up (54% [45-64] vs 54% [49-63], p=0.53), and no case of significant lesion progression was recorded. Overall, FFR values did not change at follow up (FFRpre-TAVI 0.87 [0.85-0.92], FFRpost-TAVI 0.88 [0.83-0.92], FFRFU 0.88 [0.82-0.92]; p=0.46). The mean difference between FFRpre-TAVI and FFRFU was 0.024±0.080. FFR was £0.80 in 3/23 (13.0%) pre-TAVI and in 4/23 (17.4%) at follow-up (McNemar test p=1.00). Notably, 3 (13%) ICL deferred with abnormal FFR at the time of TAVI showed further decrease at follow up, whereas cases with normal FFR remained stable over time. Overall iFR value did not change significantly at follow-up (iFRpreTAVI 0.88 [0.85-0.96], iFRpost-TAVI 0.90 [0.83-0.93], iFRFU 0.91 [0.86-0.97]; p=0.31). The mean difference between iFRpre-TAVI and iFRFU was -0.012±0.082. iFR was <0.89 in 11/23 (47.8%) pre-TAVI and in 6/23 (26.1%) at follow-up (p=0.22). Inter-measurement variability was similar immediately after TAVI and at follow-up for FFR (4.6% [1.7-11.1] vs 3.7% [2.1-13.4], p=0.82) and iFR (5.5% [1.1-8.1] vs 6.7% [1.7-11.4], p=0.08). However, iFR crossed the clinical cut-off at follow-up more frequently than FFR (10/23 (43.5%) vs 3/23 (13.0%), p=0.02).

Conclusions: The long-term ventricular structural remodelling and the normalisation aortic valve gradient demonstrated only minor impact on coronary physiology assessment after TAVI. However, caution seems advisable in the interpretation of borderline FFR and iFR results. These preliminary data require confirmation in larger dedicated studies.

Euro20A-OP084
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

New-generation ultrathin strut (60 µm) everolimus-eluting stents for coronary artery disease: an all-comer study

DURGAPRASAD Rajasekhar [(1)], DURGAPRASAD Rajasekhar [(1)], VANAJAKSHAMMA VELAM [(1)], NAIK K Sreedhar [(1)], USHASREE DALAVAI [(1)]

(1) Sri Venkateswara Institute of Medical Sciences (SVIMS), Andhra Pradesh, India

Aims: An all-comer study incorporates a broader range of patients to imitate a real-world scenario. The aim of this study was to evaluate clinical outcomes of latest-generation ultrathin strut (60 µm) biodegradable polymer-coated Tetrilimus (Sahajanand Medical Technologies Pvt Ltd, Surat, India) everolimus-eluting stent (EES) in an all-comer patient population.

Methods and results: This was a single centre, observational, all-comer, investigator-initiated study conducted between January 2017 and June 2019. Patients treated with Tetrilimus EES, regardless of baseline characteristics and/or lesion complexity, were included in this study. The data were collected from a prospectively maintained database. The primary endpoint was target lesion failure, a composite of cardiac death, target-vessel myocardial infarction, and target lesion revascularisation at six months. The safety endpoint was stent thrombosis as per Academic Research Consortium. A total of 1,065 patients were included in this study. The mean age of the population was 51.2±7.5 years and 842 (79.1 %) were male. The most common risk factors were hypertension (543, 51.0 %), diabetes mellitus (400, 37.6 %), smoking (232, 21.8 %) and family history of coronary artery disease (230, 21.6 %). Five hundred eighty-nine (55.3 %) patients had STEMI. Radial arterial access was used in 604 (56.7 %) patients. A total of 1,419 lesions were treated in 1,065 patients with 1,422 Tetrilimus EES. Of the total 1,419 lesions, 664 (46.8 %) were in the left anterior descending artery, 406 (28.6 %) were in the right coronary artery, and 349 (24.6 %) were in the left circumflex artery. The number of stents deployed per patient was 1.3±0.5. Stents per lesions were 1.0±0.1. Average stent length and diameter were 23.1±8.4 mm and 2.8±0.3 mm, respectively. Follow-up of 99.8 % patients was available at six months. At six months, target lesion failure was reported in 35 (3.3 %) patients comprising ten (0.9 %) cardiac deaths, 16 (1.5 %) target vessel myocardial infarctions, and nine (0.8 %) target lesion revascularisations. Fifteen (1.4 %) patients had stent thrombosis at six-month follow-up including nine (0.8 %) definite and six (0.6 %) probable stent thromboses.

Conclusions: Low event rates at six months in patients treated with Tetrilimus EES showed better clinical outcomes of the device in a real-world, all-comer population.

Stents and scaffolds - Tools, devices and techniques

Primary efficacy and safety outcomes of a sirolimus-eluting thin-strut coronary stent system in all-comer patients undergoing PCI: the MILES-UK registry.

MENOWN Ian [1], MENOWN Ian [1], DE SILVA Ramesh [2], MITRA Rito [3], BALACHANDRAN Kanarath [4], MORE Ranjit [5], SPYROU Nicos [6], CLIFFORD Piers [7], ZAMAN Azfar [8], RAJA Yogesh [9], ORDOUBADI Farzin Fath [10]

(1) Craigavon Area Hospital, Craigavon, United Kingdom; (2) Bedford Hospital South Wing, Bedford, United Kingdom; (3) University Hospital of Wales, Cardiff, United Kingdom; (4) Royal Blackburn Hospital, Blackburn, United Kingdom; (5) Blackpool Victoria Hospital, Blackpool, United Kingdom; (6) Royal Berkshire Hospital, Reading, United Kingdom; (7) Wycombe Hospital, High Wycombe, United Kingdom; (8) Freeman Hospital, Newcastle upon Tyne, United Kingdom; (9) Sunderland Royal Hospital, Sunderland, United Kingdom; (10) Manchester Royal Infirmary, Manchester, United Kingdom

Aims: We aimed to evaluate the efficacy and safety of a new ultrathin (65 µm) strut cobalt chromium sirolimus-eluting stent with a hybrid design (closed cell at ends and open cells in middle to reduce edge injury and optimise conformability) in all-comer patients undergoing PCI.

Methods and results: We enrolled 752 patients undergoing PCI from 14 sites into a prospective, non-randomised, multicentre, open-label, observational registry. Inclusion of patients with complex anatomy (long stent lengths, bifurcations and chronic total occlusions) was encouraged. Clinical follow-up was scheduled at 1, 9, 12 and 24 months. The primary endpoint was cumulative rate of target vessel failure - cardiac death, myocardial infarction not clearly attributed to any other vessel and target vessel revascularisation - at 9 months. Mean patient age was 64.7±12.2 years; 20.7% had diabetes, 58.8% had dyslipidaemia; 40.4% had a multivessel disease; 22.2% had previous PCI, 4.7% had previous coronary-artery bypass graft, and 19.6% had a clinical history of previous myocardial infarction. Mean length of lesions treated with the study stent was 25.7±17.3 mm. The primary efficacy endpoint of cumulative target vessel failure up to 9 months (from 661 patients reaching 9-month follow-up) occurred in 12 (1.81%) patients, including 6 (0.91%) cardiac deaths, 5 (0.75%) myocardial infarctions and 6 (0.91%) target vessel revascularisations. Definite stent thrombosis was reported in 3 patients (0.45%) and probable stent thrombosis in 2 patients (0.30%) up to 9-month follow-up.

Conclusions: The results of MILES-UK registry demonstrated that the use of an ultrathin-strut biodegradable polymer sirolimus-eluting coronary stent in all-comer complex patients undergoing PCI was associated with good clinical efficacy and safety.

Stable CAD - CT / MRI imaging, CTO - Invasive imaging and functional assessment

Long-term clinical outcomes of patients with coronary CTO caused by intra-stent restenosis

GOMEZ MONTERROSAS Omar [1,2,3], MARTIN Victoria [3], SCALONE Giancarla [4], FREIXA Xavier [3], BRUGALETTA Salvatore [3], MASOTTI Monica [3], REGUEIRO Ander [3], FLORES-UMANZOR Eduardo [3], NUÑEZ Jose Luis [5], SABATE Manel [3]

(1) Hospital Ángeles - Puebla, Puebla, Mexico; (2) XXI Century National Medical Center, CDMX, Mexico; (3) Hospital Clínic i Provincial de Barcelona, Barcelona, Spain; (4) Ascoli Centro- Tra Rue e Travertino, Province of Ascoli Piceno, Italy; (5) Unity Health Care - Upper Cardozo Health Center, DC, USA

Aims: In this study we aim firstly to identify predictors of selecting percutaneous coronary intervention to treat chronic total occlusion due to in-stent restenosis; and secondly, to compare long-term clinical outcomes of patients treated with coronary artery bypass graft, percutaneous coronary intervention (PCI) or optimal medical therapy.

Methods and results: Between June 2010 and January 2014 a total of 1,290 chronic total occlusion patients were included in a prospective registry. Eighty-six patients presented with chronic total occlusion due to in-stent restenosis. Clinical follow-up was obtained up to April 2019. Major adverse cardiac events were defined as the composite endpoint of cardiac death, acute myocardial infarction or target lesion revascularisation. Fifty-four patients were treated by PCI (63%), 22 received optimal medical treatment (25%) and 10 (12%) were treated by coronary artery bypass graft. Patients treated by PCI were older and presented higher values of left ventricular ejection fraction. From the anatomical point of view, calcification and ostial location were more frequently observed in the optimal medical treatment group, whereas SYNTAX scores were higher in the coronary artery bypass graft arm. At multivariate analysis, age and SYNTAX score were the only independent predictors of selecting PCI. At long-term follow-up (mean 101 months), the major adverse cardiac events rate was higher in the coronary artery by-pass graft arm mainly driven by a higher incidence of target lesion revascularisation.

Conclusions: PCI could be an effective and safe procedure to treat CTO-ISR. Larger prospective trials are required to confirm these clinical results.

Stable CAD - Invasive imaging and functional assessment

Constant resistance ratio: a new resting index validated by iFR using a pressure microcatheter

LI Chenguang [1], LI Chenguang [1], YANG Junqing [2], DONG Shaohong [3], DONG Liang [4], CHEN Jiyan [2], LI Shen [1], HAU William Kongto [5], BARBATO Emanuele [6], WANG Jian'an [4], GE Junbo [1]

(1) Zhongshan Hospital Fudan University, Shanghai, China; (2) Guangdong Provincial People's Hospital, Guangzhou, China; (3) Shenzhen People's Hospital, Shenzhen, China; (4) The Second Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China; (5) The Chinese University of Hong Kong, Hong Kong, China; (6) University of Naples Federico II, Naples, Italy

Aims: Instantaneous wave-free ratio (iwFR) has been shown to be non-inferior to fractional flow reserve (FFR) for guiding revascularisation in randomised trials. Here, we propose a new resting index: constant resistance ratio (cRR), which can be reliably calculated from the pressure waveforms independent of ECG. We hypothesised that the diagnostic performance and numerical values of cRR are in high agreement with iwFR. To validate this, we performed a retrospective study using a pressure microcatheter (PMC) system, through which both cRR and iwFR were derived from the original waveforms.

Methods and results: The diastolic "wave-free" period, which is the foundation of iwFR, can be reliably identified by calculating the time derivative of Pd/Pa and finding the longest period when it equals zero. The mean Pd/Pa within such constant (and minimum) resistance periods is defined as cRR. Retrospective invasive coronary pressure measurements using a PMC system from 86 patients (87 vessels) at four medical centres were used to perform the validation study comparing the diagnostic and numerical agreement of cRR with iwFR. From quantitative coronary angiography, the mean reference vessel diameter was 3.1±0.5 mm and mean diameter stenosis was 49±12%. All pressure tracings included in the study met the following criteria: (1) with >20 resting cardiac cycles recorded, (2) of clinically acceptable drift (≤0.03), and (3) without ventricularisation or damping. The primary endpoint was the Bland-Altman bias between cRR and iwFR. Secondary endpoints included the diagnostic agreement, correlation, and receiver operating characteristic (ROC) analysis. The mean cRR and iwFR values were 0.93±0.05 and 0.93±0.05, respectively. The Bland-Altman analysis showed a minimal mean bias of -0.0001 between cRR and iwFR, with [-0.012, 0.012] 95% limits of agreement. The Pearson correlation coefficient between the two indices was 0.994. Using 0.89 as the cutoff for both cRR and iwFR, the diagnostic accuracy of cRR was 97% [95% CI: 90%-99%], with an area under the ROC curve of 0.994.

Conclusions: This study shows that the proposed new resting index cRR is numerically equivalent to iwFR, and the two indices are also identical in terms of diagnostic agreement.

Euro20A-OP090
Abstract | Oral presentation

CTO - Tools, devices and techniques

Safety and efficacy of paclitaxel DEB use in CTO – a single centre experience

STANISLAUS Rohith [(1)], STANISLAUS Rohith [(1)], M. SUNDRAM Rhuban [(1)], MOHAMED NAZEEB Mohamed Nazrul [(1)], TEY Yee Sin [(1)], THUM Chan Ho [(1)], PALANIAPPAN Ganapathi [(1)], HANI KAMSANI Suraya [(1)], ZAINAL Zulaikha [(1)], AZMI YAHAYA Shaiful [(1)], NURRUDDIN Amin Ariff [(1)]

(1) National Heart Institute, Federal Territory of Kuala Lumpur, Malaysia

Aims: A chronic total occlusion (CTO) is defined as the complete obstruction of a coronary artery, exhibiting TIMI 0 or TIMI 1 flow, with an occlusion duration of >3 months. The prevalence has been described as high as 30% and 13% of cases exhibit more than one CTO. We aimed to study the safety and efficacy of DEB angioplasty in dealing with CTO lesions in the coronary arteries with respect to 12-month MACE of target lesion revascularisation (TLR), myocardial infarction (MI) and cardiac death.

Methods and results: Between 2015 and 2018, our centre had a total of 2,248 cases where a drug-eluting balloon (DEB) was implemented in the treatment of coronary artery disease (CAD). These cases were analysed retrospectively and it was noted that 182 (8.1%) of these had CTO. There was some overlap as some patients had more than one CTO lesion; and in total there were 190 CTO lesions which were treated with DEB. Out of the total number of lesions 145 (76.3%) were *de novo* lesions and 45 (23.7%) were due to in-stent restenosis (ISR). A residual stenosis post deployment of the DEB was considered successful if it was < 30% by visual assessment and if there were no flow-limiting dissections. A high number of CTO cases were noted in males 157 (86%), hypertensive patients 137 (75%), patients with dyslipidaemia 109 (60%), diabetic patients 105 (58%) and history of smoking accounted for 79 (43%) of cases. It was also noted that the mean age group was 58.3±9.9 years which is indicative that the disease process is chronic as expected. Only 15 (8.2%) of cases had a diagnosis of acute coronary syndrome (ACS) prior to coronary angiogram and a majority of these cases were driven by either angina or functional testing. It was noted that diffuse vessel disease is the most common vessel characteristic and was seen in 177 (93.2%) of cases; this correlates with the higher age group with significant co-morbidities. The left anterior descending artery 85 (44.7%) followed by the right coronary artery 70 (36.8%) were the most common coronary vessels involved. Predilatation of the lesions was performed in all cases with a pressure of 12±4.6 atmospheres, where the mean vessel diameter predilatation was 2.2±0.5mm. The mean inflation time was 62.2±28.5 seconds. The mean DEB diameter and dilatation pressure were 2.6±0.4 mm and 7.8±2.7 atmospheres, respectively. Flow limiting dissection was noted in 3 (1.1%) of cases and was treated with bail-out DES, however only 18 (6.7%) of cases had dissections after DEB inflation. Major adverse cardiac events (MACE) was described as target lesion revascularisation (TLR), myocardial infarction (MI) and cardiac death, where we documented a total of 4 (2.3%) cases at 1-year follow-up. This was driven by TLR, a total of 4 non-cardiac deaths were also observed at 1 year. The majority of the patients were on dual antiplatelet therapy for 12 months, a total of 147 (80.8%).

Conclusions: DEB angioplasty is a safe technique in dealing with CTO in both *de novo* lesions as well as ISR. MACE was seen only in 4 (2.3%) patients at 12-month follow-up. It was also noted that the level of residual stenosis post DEB deployment was 10.8±12.8%, which falls within the globally accepted standards.

Stents and scaffolds - Tools, devices and techniques

FANTOM II trial: safety and performance study of the Fantom sirolimus-eluting bioresorbable coronary scaffold – first report: four-year clinical outcomes

ABIZAID Alexandre [1], ABIZAID Alexandre [1], CARRIE Didier [2], FREY Norbert [3], DUDEK Darius [5], CHEVALIER Bernard [6], HOLM Niels [9], LANSKY Alexandra [7,9], GAMBONE Louise [7,9], ANDERSON Jeffrey [8], LUTZ Matthias [3]

(1) Dante Pazzanese, State of São Paulo, Brazil; (2) CHU Toulouse, Toulouse, France; (3) Universitätsklinikum Schleswig-Holstein, Kiel, Germany; (4) SP ZOZ Szpital Uniwersytecki w Krakowie, Kraków, Poland; (5) Hôpital Privé Jacques Cartier, Massy, France; (6) Yale School of Medicine, CT, USA; (7) Reva Medical, CA, USA; (8) Yale Cardiovascular Research Group, New Haven, CT, USA; (9) Aarhus Universitetshospital, Skejby, Aarhus Municipality, Denmark

Aims: The primary objective of the FANTOM II study was to evaluate the safety and performance of native coronary artery stenting using the Fantom sirolimus-eluting bioresorbable coronary ccaffold by assessing the incidence of major adverse cardiac events (MACE) and late lumen loss. The Fantom scaffold is a fully resorbable scaffold, manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque and comprises thin struts (125 microns) that facilitate device delivery and precise target lesion treatment.

Methods and results: The FANTOM II study is a prospective, multicentre trial which enrolled 240 patients with single *de novo* coronary stenosis with reference vessel diameter 2.5 to 3.5 mm diameter and lesion length ≤20 mm. Major adverse cardiac events (MACE) through 48 months follow-up were assessed. Angiographic follow-up was performed in consecutive patient cohorts at 6 months (n=117) and 9 months (n=123). Acute delivery success, acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol were 97.9% (235/240), 95.8% (230/240), 99.1% (228/230) and 99.6% (227/228), respectively. The mean in-stent late lumen loss at 6 months and 9 months was 0.25±0.40 mm and 0.33±0.36 mm respectively, and in-segment binary restenosis occurred in 2.0% and 7.6% of patients respectively.

Conclusions: The Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favourable safety and effectiveness performance at 4 years of follow-up. Longer-term follow-up through 5 years is ongoing to examine the late outcomes with this novel device.

Stable CAD - Invasive imaging and functional assessment

Characterisation of the human coronary microvascular response to multiple hyperaemic agents

STEVEN miner [1,2,3], NARDONE massimo [2], MCCARTHY Mary [1], ARDERN Chris [2], EDGELL Heather [2], TOLEVA Olga [4], NIELD Lynne [3], MINER Steven [1,2,3]

(1) Southlake Regional Health Centre, ON, Canada; (2) York University, ON, Canada; (3) University of Toronto - St. George Campus, ON, Canada; (4) University of Manitoba, MB, Canada

Aims: It is unclear whether coronary microvascular dysfunction (CMD) represents one disease or a group of mechanistically distinct phenotypes. The objective of this work was to characterise the index of microvascular resistance (IMR) responses to multiple hyperaemic agents in the human coronary circulation.

Methods and results: Thermodilution-derived IMR was determined sequentially during intravenous adenosine, intracoronary acetylcholine, and intravenous dobutamine in patients with cardiac symptoms but non-obstructive angiograms. 166 patients were studied (32 with adenosine alone, 46 with adenosine and acetylcholine, and 88 with all three agents). An adenosine IMR>25, acetylcholine IMR>31, and dobutamine IMR>29 were used to define elevated IMR responses. Correlation between all three pharmacological stimuli demonstrated weak-to-moderate association (adenosine vs acetylcholine IMR: $r=0.29$; $p<0.01$; adenosine vs dobutamine IMR: $r=0.32$; $p<0.01$; acetylcholine vs dobutamine IMR: $r=0.27$; $p=0.01$). Additionally, 1) elevated adenosine IMR responses were associated with increasing age and BMI, hypertension, diabetes mellitus, hyperlipidaemia, depression, obstructive sleep apnoea, thyroid-stimulating hormone, creatinine, and left ventricular hypertrophy, 2) elevated acetylcholine IMR responses were associated with male sex, uric acid, creatinine, and left ventricular hypertrophy, and 3) elevated dobutamine IMR responses were associated with hypertension and left atrial volume index. Excluding patients with an abnormal adenosine IMR, patients with either an elevated acetylcholine and/or dobutamine IMR had greater left ventricular hypertrophy and left atrial volumes, greater burden of exertional chest pain, and higher risk exercise stress tests.

Conclusions: Microvascular-specific IMR responses to different hyperaemic agents are weakly associated, while the predictors for agent-specific IMR responses varied. These data suggest that CMD represents a group of mechanistically distinct phenotypes.

Euro20A-OP094
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

Long-term clinical outcomes after implantation of Absorb BRS in a real-world setting, with predilatation and guided by intravascular imaging

TARBINE Sergio [1], COSTANTINI Costantino R [1], TARBINE Sergio [1], COSTANTINI Costantino O [1], DENK Marcos [1], FREITAS Marcelo [1], MARCIO Luize [1], FOLADOR Joao [1], MACEDO Rafael [1], STONE Gregg W. [2]

(1) Hospital Cardiológico Costantini, State of Paraná, Brazil; (2) Icahn School of Medicine at Mount Sinai, NY, USA

Aims: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (BRS) has been previously demonstrated with clinical data. However, these trials included patients with simple lesions. The ABSORB III trial demonstrated an excess of adverse events following BRS implantation. Aiming to evaluate clinical outcomes, we analysed the treatment of real-world patients using optimal techniques and intravascular image guidance in all cases, at long-term follow-up from a single centre.

Methods and results: This was an observational retrospective study, in a single Brazilian centre, from December 2014 to December 2017, including 128 patients treated with BRS implantation. Safety and efficacy outcomes were analysed in the in-hospital and late follow-up stages 3.56 yrs±0.8 years. All patients underwent a minimum follow-up of 1.9 years and a maximum of 5 years. Mean age was 58.2 years, 85.9% of the patients were men, and 28.1% were diabetic. Regarding clinical presentation, 54.6% had stable angina or silent ischaemia. Intravascular imaging (IVUS-OCT) was used in all cases. Lesion preparation included balloon angioplasty, and when necessary cutting balloon and rotational atherectomy. Device success was achieved in 100% of cases with 99.2% overall procedure success rate (1 case of subacute thrombosis). Long term major adverse cardiovascular events rate was (including hospital stage): cardiac death 0%, stent thrombosis 1.5%, myocardial infarction 1.5%, target lesion revascularisation 8.59%, target vessel revascularisation 10.94%.

Conclusions: The analysis of this cohort of patients, in a real-world setting with more complex scenarios, showed so far to be safe and effective at late follow-up using an enhanced technique, including intravascular imaging in all cases. Whether these results are durable beyond 5 years will be reported.

Euro20A-OP095
Abstract | Oral presentation

Other Coronary interventions - Other

The predictors of stent thrombosis and sudden cardiac death after DES implantation for left main distal bifurcation lesions; the Milan and New-Tokyo (MITO) registry

WATANABE Yusuke [(1)], WATANABE Yusuke [(1)], MITOMO Satoru [(1)], NAGANUMA Toru [(1)], MATSUOKA Satoshi [(1)], NAKAMURA Sunao [(1)]

(1) New Tokyo Hospital, Chiba, Japan

Aims: There are scarce available data about stent thrombosis and sudden cardiac death, life threatening events after drug-eluting stent (DES) implantation for unprotected left main (ULM) bifurcation lesions.

Methods and results: We identified 1,832 consecutive patients who received DES implantation for ULM bifurcation lesions at high volume centres in Japan and Milan. Four hundred and forty-one patients were excluded from the initially identified subjects because of non-bifurcation lesion (n=235), a non-atherosclerotic cause (n=27), left main to left circumflex crossover stenting (n=51) and insufficient clinical data (n=128; follow-up duration < 6months [n=106] and unreliable stent data [n=22]). A total of 1,391 patients were included in this study. We evaluated the primary endpoint, defined as a composite of any stent thrombosis and sudden cardiac death during follow up. We identified the predictors of the life-threatening event using Cox regression analysis. Any stent thrombosis or sudden cardiac death occurred in 69 patients. The 69 patients had much more morbidity compared to the 1,322 patients in whom any stent thrombosis or sudden cardiac death did not occur. The patients who had any stent thrombosis or sudden cardiac death were more likely to be female and showed a higher frequency of diabetes millitus, hypertension, chronic kidney disease, dialysis, peripheral artery disease, lower ejection fraction, the prevalence of true bifurcation and calcified lesions. Cox regression analysis identified the following factors as the independent predictors of any stent thrombosis or sudden cardiac death; dialysis (adjusted HR 3.04, 95% CI: 1.61-5.73, p=0.001), ejection fraction (adjusted HR 0.96, 95% CI: 0.94-0.98, p<0.001), diabetes mellitus (adjusted HR 1.68, 95% CI: 1.02-2.76, p=0.04), chronic kidney disease (adjusted HR 1.88, 95% CI: 1.07-3.33, p=0.029), proximal optimisation technique (adjusted HR 0.46, 95% CI: 0.26-0.83, p=0.010) and calcified lesion requiring rotational atherectomy (adjusted HR 2.15, 95% CI: 1.15-4.04, p=0.017).

Conclusions: Patients with renal dysfunction with or without dialysis, decreased ejection fraction, diabetes millitus and calcified lesions requiring rotational atherectomy were independently associated with any stent thrombosis or sudden cardiac death after PCI for ULM distal bifurcation lesions. Proximal optimisation technique significantly reduced the adverse events.

Euro20A-OP099
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

Thin composite-wire strut zotarolimus-eluting stents versus ultrathin strut sirolimus-eluting stents in the randomised BIONYX trial at two years

BUITEN Rosaly [1], BUITEN Rosaly [1], PLOUMEN Eline [1], ZOCCA Paolo [1], JESSURUN Gillian [2], SCHOTBORGH Carl [3], ROGUIN Ariel [4], DANSE Peter [5], BENIT Edouard [6], AMINIAN Adel [7], VON BIRGELEN Clemens [1]

(1) Medisch Spectrum Twente, Enschede, the Netherlands; (2) Scheper Ziekenhuis, Emmen, the Netherlands; (3) Haga ziekenhuis, The Hague, the Netherlands; (4) Rambam Hospital, Haifa, Israel; (5) Rijnstate Arnhem, Arnhem, the Netherlands; (6) Jessa Ziekenhuis, Hasselt, Belgium; (7) centre hospitalier universitaire, Charleroi, Belgium

Aims: The current-generation thin composite-wire strut durable-polymer zotarolimus-eluting stent (Resolute Onyx) is widely used in clinical practice, but no follow-up data beyond 1-year have been published. The aim of the present study was to assess 2-year safety and efficacy of this zotarolimus-eluting stent, compared to the ultrathin strut biodegradable-polymer sirolimus-eluting stent (Orsiro) in all-comers. The paper includes a prespecified small-vessel subgroup analysis.

Methods and results: A total of 2,488 participants in the randomised BIONYX trial (NCT02508714) were treated in 7 coronary intervention centres in Belgium, Israel, and the Netherlands. The main endpoint target vessel failure was a composite of safety (cardiac death or target vessel-related myocardial infarction) and efficacy (clinically indicated target vessel revascularisation), and was analysed using Kaplan-Meier methods. The trial found non-inferiority of this novel zotarolimus-eluting stent versus the sirolimus-eluting stent regarding 12-month target vessel failure rates. Two-year follow-up data were available in 2,460 of 2,488 patients (98.9%). Target vessel failure occurred in 93/1,243 (7.6%) patients assigned to zotarolimus-eluting versus 87/1,245 (7.1%) patients assigned to sirolimus-eluting stents (HR 1.07, 95% CI: 0.80-1.43, P-logrank=0.66). There was no significant between-stent difference in individual components of this endpoint. The incidence of stent thrombosis was low for both treatment arms (0.4% vs 1.1%, P-logrank=0.06). In patients stented in small vessels (quantitative coronary angiography-based reference vessel diameter < 2.5 mm), there was no between-stent difference in target vessel failure, which occurred in 8.2% of patients treated with zotarolimus-eluting vs 8.7% of patients treated with sirolimus-eluting stents (HR 0.93, 95% CI: 0.59-1.46, P-logrank=0.75). Target lesion revascularisation rates were similar and occurred in 4.0% vs 4.4%.

Conclusions: At 2-year follow-up, the novel Resolute Onyx zotarolimus-eluting stent showed in all-comers similar safety and efficacy as compared to the Orsiro sirolimus-eluting stent. The analysis of patients who were treated in small vessels also suggested no advantage for one stent over the other.

STEMI - Tools, devices and techniques

An analysis of time to electrocardiogram and STEMI reperfusion target times: a single tertiary site prospective analysis

MARTIN Lorelle [1,2], LEWIS Virginia [2], SHAKER Amanda [2], MURPHY Maria [1,2], EDVARDSSON David [2], CLARK David [1,3], FAROUQUE Omar [1,3]

(1) Austin Hospital, VIC, Australia; (2) La Trobe University, Melbourne Campus, VIC, Australia; (3) University of Melbourne, VIC, Australia

Aims: The evidence supporting the ≤10-minute parameter for receiving a 12-lead ECG from first medical contact (FMC) to diagnose STEMI is limited. Our objective was to examine the effect time to ECG had on STEMI reperfusion target times. Our primary aim was to measure the optimal 'FMC-ECG' time associated with highest probability of meeting the ≤90-minute target. Our secondary aim was to establish the independent effect 'FMC-ECG' time and explanatory variables of interest had on 'ECG-reperfusion' time.

Methods and results: We analysed a consecutive and prospective cohort of 873 STEMI patients receiving primary percutaneous coronary intervention at a large Australian tertiary hospital from July 2009 - December 2017. The cohort was stratified into two subsets, "hospital presenters" or "pre-hospital notification (PHN) presenters", to capture the contemporary ability to diagnose STEMI and activate systems of care prior to hospital arrival. We applied two separate methodologies to address each aim for both subsets. Firstly, 'FMC-ECG' time was plotted against the estimated probability of achieving reperfusion targets using smoothing splines and logistic regression respectively. Plotting this allowed us to locate where the rate of change of the curve's slope was the greatest and therefore identify an optimal 'FMC-ECG' time. Secondly, quantile regression was conducted to estimate the independent effect "FMC-ECG' time and other explanatory variables had on 'ECG-reperfusion' time. For patients presenting to hospital, we estimated a 'Door-ECG' time of seven minutes was associated with a 60% probability of achieving reperfusion targets. For PHN presenters, we estimated a 'field FMC-ECG' time of six minutes was associated with a 71% probability of achieving the reperfusion targets. For hospital presenters, quantile regression demonstrated a 'Door-ECG' time greater than seven minutes and presenting out of hours were associated with prolonged 'ECG-reperfusion' times. For PHN presenters, we found age ≥75 years, presenting out of business hours, intubated prior to cardiac catheter laboratory, and distance to hospital were associated with prolonged 'ECG-reperfusion' times. Conversely, a field 'FMC-ECG' time >18 minutes and being male were associated with reduced 'ECG-reperfusion' times.

Conclusions: A 'FMC-ECG' time between 6-7 minutes or less was associated with the highest probability of achieving reperfusion targets, depending on presentation mode. Further analysis is required to explore the impact these results have on long-term outcomes using a multi-site cohort.

Stable CAD - Invasive imaging and functional assessment

Impact of renal insufficiency on the relationship of non-hyperaemic index and FFR

JONG Chien-Boon [1], JONG Chien-Boon [1], LU Tsui-Shan [3], WU Chih-Cheng [1], HUANG Ching-Chang [2], PATRICK LIU Yan-Tyng [2]

(1) National Taiwan University Hospital Hsin-Chu Branch, Hsinchu City, Taiwan; (2) National Taiwan University, Taipei City, Taiwan; (3) National Taiwan Normal University, Taipei City, Taiwan

Aims: Functional assessment of coronary artery stenosis by FFR is performed under hyperaemic conditions. However, inducing hyperaemia carries some cost and risk. The acute drop of Pd/Pa after intracoronary nitroglycerine (NTG-Pd/Pa) had been shown to be an acceptable estimate of FFR. In patients with chronic kidney disease (CKD), discordance between IFR and FFR was observed. Nonetheless, the impact of CKD on the diagnostic accuracy of NTG-Pd/Pa was not clear. The aim of this study was to evaluate the optimal cutoff of NTG-Pd/Pa to predict positive FFR in different stages of CKD patients.

Methods and results: A total of 867 vessels receiving FFR evaluation were retrospectively reviewed from the database of two university hospitals. The mean age of the cohort was 67 years and 27% of them had CKD. Receiver operating characteristic (ROC) curves were used to estimate the diagnostic performance of NTG-Pd/Pa and to identify the appropriate cutoff value of NTG-Pd/Pa to predict positive FFR results in different stages of CKD. The best threshold of NTG-Pd/Pa to predict ischaemic FFR values varied from 0.89, 0.86, 0.83 and 0.84 with the non-CKD, CKD stage 3a, CKD stage 3b-5 and ESRD groups, and 74%, 87%, 92% and 87% accuracy rate respectively. Pooled early/non-CKD subgroup showed optimal NTG-Pd/Pa cutoff of 0.89 with an accuracy of 74%. Pooled advanced subgroup (CKD stage 3b-5 and ESRD) improved the accuracy up to 89% with the optimal cutoff of 0.84. In early or non-CKD patients, NTG-Pd/Pa > 0.91 (n=298, 40.3%) had a negative predictive value (NPV) of 94.7%, sensitivity of 94.0% and NTG-Pd/Pa<0.84 (n=85, 11.5%) had a positive predictive value (PPV) of 81.2%, specificity of 97.0%. In patients with advanced CKD, the NTG-Pd/Pa > 0.89 (n=65, 51.2%) had a NPV of 98.1%, sensitivity of 96.6% and NTG-Pd/Pa<0.84 (n=17, 13.4%) had a PPV of 88.2%, specificity of 98.0%. Using the hybrid of NTG-Pd/Pa and FFR strategy, 51.8% vessels in early/non-CKD patients and 64.6% vessels in advanced CKD patients could avoid the use of adenosine with ≥95% agreement with FFR results.

Conclusions: The best cutoff value of NTG-Pd/Pa predicting positive FFR became lower with deteriorating renal function. Using a hybrid strategy, hyperaemia by adenosine could be avoided in nearly two-third of CKD patients. The results of this study suggested that the current ischaemic threshold of resting index should be re-evaluated in patients with advanced CKD.

Other Coronary interventions - Calcified lesions

Acute and mid-term results of PCI with orbital atherectomy system

KOIKE Jumpei [(1)], NAKAMURA Shigeru [(1)]

(1) Kyoto Katsura Hospital, Kyoto, Japan

Aims: Severely calcified lesions present many challenges to percutaneous coronary intervention (PCI). Recently, a newly developed atherectomy device, Diamondback coronary orbital atherectomy system (OAS) has been approved.

Methods and results: 141 consecutive cases (173 lesions) who underwent PCI with OAS in our hospital from February 2018 to August 2019 were enrolled. We assessed the clinical outcomes after OAS of severely calcified lesions; procedure success, angiographic complications, in-hospital MACE (cardiac death, myocardial infarction (MI: CK > 3×ULN), and target vessel / lesion revascularisation (TVR/TLR)) and mid-term results at 6 months after PCI. Restenosis factors were also examined. We compared the difference in procedure and lesion factors between the restenosis lesions and no restenosis lesions. Mean age was 78 years and 72% patients were male. Coronary risk factors were: hypertension (81%), hyperlipidaemia (67%), diabetes (50%), smokers (15%), CKD (38%) and haemodialysis (13%). Optical frequency domain imaging (OFDI) was used as imaging device in 73% of all patients. We performed OAS at low revolution speed in all cases and made an addition at high revolution speed in 71% lesions. 11% lesions additionally needed rotational atherectomy because OAS could not pass through the lesion or the lesion needed additional ablation with large rotational atherectomy bar. 83% lesions were finally treated with drug-coated balloon (DCB), and stents were implanted in 12% lesions. Procedural success rate was 97%. In complications, coronary perforation occurred in 1% lesion, persistent slow flow in 2%. Overall free from in-hospital MACE was 97%. There were 1 cardiac death (2%), 3 nonQ-MI (2%) and no TLR. Follow-up angiography was performed in 54 of 85 lesions (62%). Restenosis was observed in 5 lesions (9%). There was no significant difference in final device, predilatation balloon and occurrence of slow flow between 5 lesions with restenosis and 49 lesions without restenosis.

Conclusions: OAS has been shown to have high procedure success rate and low restenosis rate in a large proportion of lesions treated by DCB (83%). OAS as a lesion preparation tool may offer a new treatment for the patients with severe calcified lesions. Close consideration of which lesions are suitable for OAS is required.

Euro20A-OP108
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Real-time IVUS guidance: a novel technique for accurate placement of ostial stents

HARDING Scott [1], HARDING Scott [1], WEBBER Bruce [2], FAIRLEY Sarah [1], ORMISTON John [2]

(1) Wellington Hospital, New Zealand, Wellington, New Zealand; (2) Intracare (formerly Mercy Angiography), Auckland, New Zealand

Aims: Accurate placement of coronary stents at ostial locations is challenging. We have developed a novel technique for ostial stent placement utilising real time intravascular ultrasound (IVUS) guidance. We report our bench testing and initial clinical experience.

Methods and results: In this technique the stent is placed into the target vessel while an IVUS catheter is placed over a coronary guide wire into either the side branch at bifurcations or in the aorta in aorto-ostial lesions to allow real time imaging and guidance of ostial stent placement. The OptiCross imaging catheter and POLARIS system were used due to the low-profile of the OptiCross catheter. The appearances of the balloon and stent edge on IVUS were validated in a bench model. Placement of 10 consecutive stents into the ostial LAD using real time IVUS guidance was then assessed in a left main bifurcation bench model. The stents and IVUS were placed into the model simultaneously through an 8F guiding catheter. All stents were deployed successfully. The average distance from stent to LAD ostium was 0.47±0.20 mm. Real time IVUS guidance of ostial stent placement using OptiCross imaging catheters and the POLARIS system was then performed in 13 patients and 14 lesions. The average age was 71.9±6.4 years, 53.8% were male, with 61.5% presenting with ACS. Femoral access and an 8Fr guide catheter was used in 7 patients and radial access with a 7.5 Fr Sheathless Eaucath in 6 patients. When using the 7.5 Fr Sheathless Eaucath the stent needed to be delivered into the ostial lesion first followed by passage of the IVUS catheter into the side branch or aorta due to size constraints. The target lesion was RCA aorto-ostial in 4, LM aorto-ostial in 2, ostial circumflex in 1 and ostial LAD in 7 patients. Three lesions were chronic total occlusions and 4 lesions required rotational atherectomy. A mixture of Synergy, Resolute Onyx, Cre8 Evo and XIENCE Alpine drug-eluting stents were used. The mean stent diameter was 3.75±0.82 mm and mean length 17.9±6.3 mm. All stents were post-dilated with mean NC balloon size of 3.9±0.88mm. All stent deployments were successful. Angiographic and procedural success was achieved in 100%. Post stenting IVUS examination was performed in all cases. The mean distance the stent edge protruded from the ostium assessed on IVUS was 0.37±0.36 mm. The maximum stent protrusion was 1.1mm. In one case the stent was placed 0.2 mm inside the ostium, in all other cases there was complete coverage of the ostium.

Conclusions: We have developed a novel technique utilising real time IVUS guidance that allows accurate placement of stents in ostial locations.

Euro2OA-OP111
Abstract | Oral presentation

Stable CAD - Invasive imaging and functional assessment

Guiding myocardial revascularisation by algorithmic interpretation of FFR pullback curves: a proof of concept study

ARGACHA Jean-François [1], ARGACHA Jean [1], DECAMP Jean [2], VANDELOO Bert [1], BABIN D [3], LOCHY Stijn [1], VAN DEN BUSSCHE Karen [1], AZZANO Alessia [1], SONCK Jeroen [4], DE HEMPTINE Quentin [5], XAPLANTERIS Panos [5], SCHOORS Danny [1], MAGNE Julien [6], SEGERS Patrick [7], COLLET Carlos [4], COSYNS Bernard [1]

(1) UZ Brussel, Jette, Belgium; (2) Centre for Quantum Technologies, Centre for Quantum Technologies, Singapore; (3) TELIN, Ghent, Belgium; (4) Olv Ziekenhuis, Aalst, Belgium; (5) CHU Saint-Pierre de Bruxelles, Brussels, Belgium; (6) CHU Dupuytren Limoges, Limoges, France; (7) BioMMeda, Ghent, Belgium

Aims: Distribution of epicardial resistance along the vessel is a key determinant of post-PCI fractional flow reserve (FFR). Interpretation of FFR pullback curves by visual inspection remains complex and subjective. Computer science may facilitate interpretations of such curves. We hypothesise that a virtual stenting algorithm analysing FFR pullback curves increases operator reliability in interpreting epicardial disease distribution, and refines coronary angiogram and distal FFR based PCI indication.

Methods and results: A virtual stenting algorithm (VSA) was developed to perform a fully automated analysis of the FFR pullback curve. VSA provides: 1) a quantitative analysis of vessel disease distribution, 2) an evaluation of PCI appropriateness, 3) a virtual stent positioning to maximise the post-PCI gain in coronary resistance and 4) a prediction of the post-PCI FFR. VSA capacity to affect conventional evaluation of stable coronary artery disease was tested in a retrospective, monocentric study of 34 patients undergoing FFR-guided PCI. Vessels with intermediate disease on coronary angiogram (CA) and a distal FFR<0.8 were reviewed by 5 experienced interventional cardiologists (raters) who were asked to assess vessel disease distribution into focal, combined or diffused categories, and, if required, to report their PCI strategy. Each rating was performed under 3 different settings: based on CA and distal FFR (S1); based on CA and FFR pullback curve (S2); and based on CA and VSA analysis (S3). 165 ratings of 39 vessels (77% LAD) were performed. From S1, a focal, combined or diffuse disease distribution was reported in respectively 40, 43.6 and 16.4%, with a fair agreement between rater consensus and operator (kappa 0.36, CI 95% 0.14-0.58). Compared to S1, inter-rater reliability in vessel disease assessment was increased by S2 (kappa 0.38 vs 0.32), and by S3 (kappa 0.4 vs 0.32). The overall agreement in final assessment of vessel disease distribution by raters was higher with computer than with operator (67 vs 42%, p<0.01). Compared to S2, S3 reclassified vessel disease category in similar proportion (15 vs 19.4%, NS), but included more reclassification toward a focal than a diffuse disease (14 vs 1.2%, respectively, p<0.01). Consequently, most reclassification from S3 was towards an eligible PCI than a non-eligible PCI (34.2 vs 3.8%, p<0.05). Regarding final assessment of PCI appropriateness by raters, a trend towards an increased overall agreement with computer than with operator was observed (80 vs 70%, NS).

Conclusions: The present study reports for the first time the effect of a computer science approach of FFR pullback curves on interventional cardiologist reliability in the diagnosis and treatment of stable coronary artery disease. FFR pullback interpretation by a VSA increases inter-rater reliability in vessel disease assessment and reclassifies patient selection for PCI. Such innovative approaches standardise evaluation of PCI treatment appropriateness and stent positioning. Clinical benefit of VSA on post-PCI FFR requires further clinical validation in a prospective study.

Euro2OA-OP112
Abstract | Oral presentation

STEMI - Invasive imaging and functional assessment, NSTEMI - Tools, devices and techniques

Investigation of collagen content and cap thickness of ruptured plaque caps in human coronary autopsy specimens

GRAINGER Stephanie [1], GRAINGER Stephanie [1], GREINER Cherry [1], SAYBOLT Matthew [3], GILLIGAN Alexandra [1], FARROW Samantha [1], WILENSKY Robert [2]

(1) Infraredx, MA, USA; (2) Hospital of the University of Pennsylvania, PA, USA; (3) Hackensack Meridian Health Jersey Shore University Medical Center, Neptune City, NJ, USA

Aims: Thickness of the fibrous cap over a lipid core plaque is considered a primary measure of likelihood of fibroatheroma rupture. However, caps of equal thickness may be composed of different quantities of collagen with variable organisation, and thus have varying propensities to rupture. Previous work showed a poor correlation between collagen amount, determined from greyscale pixel intensities of polarised imaging of picrosirius red stained slides, and plaque cap thickness. This study used a more robust collagen-positive pixel counting method, with particular clinical focus on ruptured plaques.

Methods and results: Forty human autopsy hearts were enrolled after identification of a minimum quantity of cholesterol (minimum of 8 total quadrants per segment (each quadrant = 90 and 2 mm length)) through scanning with NIRS-IVUS (Infraredx, Inc., Bedford, MA). Each segment (n=102 coronary segments) was fixed and divided into 2 mm blocks, resulting in 2,182 blocks. Two 7 micron thin sections from each block were stained with picrosirius red and Movat's pentachrome. Picrosirius red slides were imaged with a linear polariser and captured over 360 degrees of rotation to create composite polarised images. This method compensated for underestimation of collagen, which is known to occur with standard linear polarisation techniques. Pathological contouring of the lipid regions (identified using Movat's pentachrome images) was performed on the unpolarised picrosirius red images. Cap thickness was measured in all regions of histology-verified lipid core plaques in 1 degree increments from the catheter centre. Collagen was assessed in the same localised regions using co-registered polarised picrosirius red images. Collagen quantification per 1 degree was based on the number of pixels in the cap region above a certain intensity threshold on 16-bit greyscale images. The entire data set was mined for sections indicating evidence of possible current ruptures, or healed ruptures. Seven slides were identified in each rupture group, and the 1 degree regions corresponding to the lowest 10th percentile of collagen quantification were identified to focus on the site of rupture on each slide. All active rupture sites had less than 300 collagen positive pixels per degree (range 7 to 211 pixels), despite ruptured cap thickness values ranging upwards of 200 microns (range 31 to 607). The range of thickness values corresponding to rupture sites corresponds to a much larger range than the traditional 65 micron threshold for thin capped fibroatheromas. As expected, healed ruptures showed more collagen variation. Intact thin capped fibroatheromas also showed collagen metric values within the same range as the ruptured regions (inner quartile ranges: 24.0 (thin capped fibroatheromas), 24.9 (ruptures)), but more importantly, low amounts of organised collagen (i.e. less collagen positive pixels) were observed across the entire range of cap thicknesses.

Conclusions: Overall, a poor correlation exists between cap thickness and organised collagen composition in fibrous caps, as observed with polarised picrosirius red imaging. Ruptured caps show a defined maximum amount of collagen content, despite a range of cap thicknesses. This finding suggests that the clinical relevance of a vulnerable plaque should also consider the amount of organised collagen over simply a dimensional measure of cap thickness.

Stents and scaffolds - Tools, devices and techniques

Use of sirolimus-coated balloon in de novo small vessel coronary lesions; mid-term follow-up from a two-centre registry

ATHUKORALA Sampath [1], LOKU WADUGE Bhagya Harindi [1], KALOGERAS Konstantinos [2], PANOULAS Vasileios [1], WATKIN Richard [1], LEE Kaeng [1], PULIKAL George [1], MENT Jerome [1], BHATIA Gurbir [1], FREESTONE Bethan [1], BASAVARAJAIAH Sandeep [1]

(1) Heartlands Hospital, Birmingham, United Kingdom; (2) Harefield Hospital, London, United Kingdom

Aims: Drug-coated balloons (DCB) in Europe are mainly used in restenotic lesions and this is endorsed by the European Society of Cardiology, which gives class IA recommendations. However, some of the recent data suggest it can also be considered in a subset of *de novo* lesions, especially small vessels (<3.0 cm). Most DCB elute paclitaxcel, but there is no data on DCB eluting limus, which is the drug of choice in currently-available drug-eluting stents. In this study, we report outcomes from the use of limus-eluting DCB (MagicTouch, Concept Medical, India) in *de novo* small vessel coronary lesions.

Methods and results: We included all patients treated with MagicTouch DCB between March 2018 and June 2019. The results are reported as cardiac death, target vessel myocardial infarction, target lesion revascularisation and MACE (combination of cardiac death, target vessel MI and TLR). During the study period, 219 patients (with 243 lesions) with *de novo* lesions were treated with MagicTouch DCB. The mean age of patients was 66±10.7 years, 209 (77%) were male, 34% (n=75) had diabetes, 16% (n=34) had chronic kidney disease and 54% were in the setting of acute coronary syndrome (n=118). Predilatation was performed in 92% (222 lesions). Bail-out stenting (with DES) was required in 13% lesions (n=32), of which 18 were due to dissections and 14 were due to recoil >30% following DCB use. The mean diameter and length of DCB was 2.29 mm and 24 mm respectively. During a median follow-up of 313 days (10 months) cardiac death was reported in 3 patients (1.4%). Target vessel MI was in 1.4% (n=2), TLR per lesion was 6.5% (n=16) and the MACE rate was 5.5% (n=12). There were no documented cases of acute vessel closure.

Conclusions: The mid-term outcome from the first ever study on sirolimus-eluting balloon in *de novo* small vessel lesions appears promising with low rates of hard endpoints, repeat rates of revascularisation and MACE rates despite a complex group of patients (50% ACS, 34% diabetics and 14% CKD) and lesion subsets (small vessel and diffuse disease). We need longer follow-up, which is ongoing.

Euro2OA-OP116
Abstract | Oral presentation

Left main and multivessel disease - Tools, devices and techniques

Are higher operator volumes for unprotected left main stem PCI associated with improved patient outcomes? A survival analysis of 6,748 cases from the British Cardiovascular Intervention Society national database

KINNAIRD Tim [5], KINNAIRD Tim [1], ANDERSON Richard [1], GALLAGHER Sean [1], SHARP Andrew [1], FAROOQ Vasim [1], LUDMAN Peter [2], CURZEN Nick [3], BANNING Adrian [4], MAMAS Mamas [1]

(1) University Hospital of Wales, Cardiff, United Kingdom; (2) Queen Elizabeth Hospital Birmingham, Birmingham, United Kingdom; (3) Southampton General Hospital, Southampton, United Kingdom; (4) John Radcliffe Hospital, Oxford, United Kingdom; (5) Royal Stoke University Hospital, Stoke-on-Trent, United Kingdom

Aims: Registry data does not closely correlate higher operator volumes with improved patient outcomes for unselected PCI. However, operator volume for selected more complex PCI may be important, but the association between operator volume and survival after unprotected left main-stem PCI (uLMS-PCI) is poorly defined.

Methods and results: We used the British Cardiovascular Intervention Society national PCI database to explore the relationship between operator volume and 12-month survival after uLMS-PCI. Data were analysed from all uLMS-PCI procedures performed in England and Wales between 2012 and 2014. Individual operator volume was totalled and operators divided into four quartiles of volume (Q1-Q4). Individual logistic regressions were performed for each of the MACE events to quantify the independent association between operator quartile and outcomes. To correct for potential baseline imbalances, we used a propensity score estimation for multiple treatments using generalised boosted models. Multivariate logistic regression was used to examine the associates of 12-month mortality. A total of 6,748 uLMS-PCI procedures were analysed. Median uLMS-PCI operator volume for the whole cohort was 6 (range 1-161, Q1 (median=2, range 1-3), Q2 (median=5, range 4-7), Q3 (median=11, range 8-15), Q4 (median=26, range 16-161). Higher volume operators undertook uLMS-PCI in patients with greater comorbid burden including age ($p<0.001$ for trend), diabetes mellitus ($p=0.006$), previous MI ($p=0.03$ for trend), previous PCI ($p=0.01$), and peripheral vascular disease ($p=0.002$) and number of diseased vessels ($p<0.001$) compared to lower volume operators. Procedural complexity increased with operator volume with left main bifurcation disease more likely ($p<0.001$), rotational atherectomy ($p<0.001$) or imaging use more likely ($p<0.001$) and more stents used ($p<0.001$). Despite increase patient and procedural complexity femoral access was less frequently used as operator volume increased ($p<0.001$). After adjustment, the observed in-hospital survival (odds ratio 0.30, 95% confidence interval 0.14-0.56), in-hospital MACE (OR 0.40, 0.24-0.66) and 12-month survival (OR 0.53, 0.36-0.79) were significantly lower in Q4 operators compared to Q1 operators. Adjusted non-PCI related complications including major bleeding and acute kidney injury were similar across the operator quartiles implying that adjustment methodology was robust. On logistic regression, these observations were consistent acorss several important sub-groups including clinical presentation and uLMS anatomy. In adjusted analysis, the minimum LMS-PCI volume associated with improved survival was 17 cases/year. Individual operator volume was closely correlated with 12-month survival (OR 0.999/case, $p<0.0001$).

Conclusions: Higher uLMS-PCI volume operators were observed to have improved 12-month survival compared to lower volume operators with 17 uLMS-PCI/year observed as the minimum number associated with beter outcomes.

Euro2OA-OP117
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

The effects of shockwave lithotripsy on DES

ADA Cuneyt [1], ADA Cuneyt [1], WONG Christopher [1], KRITHARIDES Len [1], LO Sidney [2], YONG Andy [1]

(1) Concord Hospital, NSW, Australia; (2) Liverpool Hospital, NSW, Australia

Aims: The Shockwave lithotripsy balloon is only indicated for previously unstented segments. However, case reports describing use within under-expanded stents are becoming more common in the medical literature. The aim of this study was to use electron microscopy (EM) to assess the physical effects of shockwave lithotripsy on the structure of various types of polymer-free and polymer-coated drug-eluting stents.

Methods and results: Stents that were tested in this experiment included a polymer-free 3mm Cre8 (Alvimedica, Turkey) stent, a bioabsorbable polymer 3mm Synergy (Boston Scientific, USA) stent, and the durable polymer 3mm Resolute Integrity (Medtronic, Ireland) and 3mm XIENCE Alpine (Abbott Laboratories, USA) stents. All stents were deployed ex-vivo to 3mm and baseline EM scans were performed at both low (27x) and high (220x) magnification. EM was performed using a JCM-6000 (Jeol, Japan). A 3mm Shockwave C2 catheter (Shockwave Medical, USA) was then used to deliver pulses within the stents in a water bath at body temperature. EM scanning at both magnifications were repeated after 20 pulses, 50 pulses and 80 pulses. Stent disruption was quantified based on a stent architectural deformation assessment (ADA) grade, which is defined as follows: Grade 0 - no damage; Grade I – presence of cracking, pitting or blister formation with no peeling of polymer or drug; Grade II – presence of partial thickness peeling of polymer or drug; Grade III – presence of full-thickness peeling of polymer with visible underlying metal surface; Grade IV – visible disruption to the metal architecture of the stent. Minor stent imperfections were seen with all stents on high EM magnification at baseline, including minimal polymer cracking and pitting of the drug reservoir. After 20 Shockwave pulses, no new defects were seen in any of the stents. After 50 pulses, ADA Grade I defects were seen with the Resolute stent and ADA Grade II defects were seen with the Synergy stent. No new defects were seen with the XIENCE and Cre8 stents. After 80 pulses, ADA Grade II defects were seen with the Resolute and XIENCE stents, while ADA Grade III defects were seen with the Synergy stent. No new defects were seen with the Cre8 stent.

Conclusions: Operators will need to be aware that lithotripsy pulses within stented segments can lead to disruption of stent architecture. While further confirmatory studies are necessary, 80 pulses of lithotripsy did not cause perceptible disruption to the Cre8 stent and the polymer-free stent appeared to be less susceptible to the damaging effects of lithotripsy. Finally, 20 pulses of lithotripsy did not cause perceptible disruption to the surface architecture of any of the stents tested in this study.

Euro20A-OP118
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

20-year trends in clinical outcomes of randomised controlled trials for PCI: systematic review and meta-regression analysis of 48 trials including 94,831 patients

ASANO Taku [(1)], ASANO Taku [(1)], ONO Masafumi [(1)], SAITO Akira [(1)], TAKAOKA Yoshimitsu [(1)], KANIE Takayoshi [(1)], KOMIYAMA Nobuyuki [(1)]

(1) St. Luke's International Hospital, Tokyo, Japan

Aims: The technology of percutaneous coronary intervention (PCI) was developed after the advent of coronary stents. However, the impact of the technological development on clinical outcomes is still unclear, and remarkable improvement in clinical outcomes after PCI has not been observed in the trials comparing PCI with medical therapy or coronary bypass graft. The current analysis aims to investigate trends in clinical outcomes after PCI following the emergence of coronary stents, using the randomised controlled trials (RCTs) comparing coronary stents.

Methods and results: We performed a systematic review of RCTs investigating coronary stents in non-specific populations (excluding the trials particularly enrolling patients with diabetes or myocardial infarction etc.) conducted between 1996 and 2016 (publication between 1997 and 2019) with independent clinical event adjudication. The random-effect meta-regression analysis including 90 arms with 94,831 patients in 46 RCTs was performed, investigating the 20-year trends in clinical outcomes such as death, cardiac death, myocardial infarction, target lesion revascularisation (TLR) and stent thrombosis at one and five years after the index procedure. The sensitivity analysis was performed by limiting to 20 all-comer trials. In the meta-regression analysis, we did not observe significant change in the incidences of cardiac death and myocardial infarction after PCI over 20 years (p-values for cardiac death: 0.666 at one year, 0.256 at five years and p-values for myocardial infarction: 0.121 at one year, 0.376 at five years; R2 for cardiac death: <0.01 at one year and five years and R2 for myocardial infarction: <0.01 at one year and five years), whereas the incidences of clinically indicated TLR (p-value <0.001, R2 =0.40 at one year, p-value =0.002, R2 =0.22 at five years) and stent thrombosis decreased steeply in the first decade and slightly in the second decade (p-value =0.040, R2 =0.09 at one year; p-value =0.017, R2 =0.17 at five years). The sensitivity analysis limiting all-comer populations revealed consistent results.

Conclusions: The development of PCI had an impact on the 20-year trends in TLR and ST, although there were no trends in cardiac death and myocardial infarction.

Stents and scaffolds - Tools, devices and techniques

Effect of procedural technique on cardiovascular outcomes following second-generation drug-eluting resorbable magnesium scaffold implantation

OZAKI Yuichi [1], OZAKI Yuichi [1], GARCIA-GARCIA Hector [1], MELAKU Gebremedhin [1], JONER Michael [2], GALLI Stefano [3], VERHEYE Stefan [4], LEE Michael [5], WAKSMAN Ron [1], HAUDE Michael [6]

(1) MedStar Washington Hospital Center, DC, USA; (2) Technische Universität München, Munich, Germany; (3) Università Cattolica del Sacro Cuore, Metropolitan City of Milan, Italy; (4) ZNA Cardiovascular Center Middelheim, Antwerp, Belgium; (5) Queen Elizabeth Hospital, Kowloon, Hong Kong; (6) Lukaskrankenhaus GmbH, Neuss, Germany

Aims: The feasibility and safety of second-generation drug-eluting magnesium scaffolds (Magmaris) in patients with coronary artery disease have been demonstrated in the BIOSOLVE trials. However, the procedural factors related to target lesion failure (TLF) and clinically-driven target lesion revascularisation (CD-TLR) after Magmaris implantation have not yet been studied. The aim of this study was to assess TLF and CD-TLR over one year following Magmaris implantation using a dedicated technique (so called "4 Ps" strategy).

Methods and results: The BIOSOLVE-IV trial specifically recommended the 4Ps implantation technique. 4Ps stands for: patient selection, proper sizing, predilatation, post-dilatation. All the patient and lesion characteristics, preparation, and sizing of the device were analysed for TLF and CD-TLR through one-year follow-up. Variables in the BIOSOLVE IV trial that were associated with TLF/CD-TLR were also explored in the BIOSOLVE-II and BIOSOLVE-III trials. A total of 384 patients were pooled from the BIOSOLVE II-IV trials. Some patients were excluded because more than 2 devices were used or Magmaris was not implanted, and others were excluded post-balloon as angiographic view was not available, resulting in 315 patients to be analysed for this study. The total number of TLF and CD-TLR through one year were 14 and 10 patients, respectively. Out of the 315 patients, the number of patients in the undersized, properly sized and oversized vessel groups were 13, 81 and 221, respectively. One of 13 TLF patients (7.7%) was in the undersized vessel group, 4 of 81 patients (4.9%) were in the properly sized vessel group, and 9 of 221 patients (4.1%) in oversized. In terms of CD-TLR, 1 of 13 patients (7.7%) in undersized, 2 of 81 patients (2.5%) in properly sized, and 7 of 221 patients (3.2%) in oversized were observed. All the cases with TLF had more than 20% (the 4 P's implantation protocol recommended < 20%) diameter stenosis (DS) after predilatation. %DS after predilatation in patients with TLF and CD-TLR was significantly greater than those without TLF and CD-TLR. Furthermore, minimum lumen diameter after predilatation in patients with TLF was significantly lower than in those without TLF and CD-TLR. In patients with properly sized scaffolds, %DS after predilatation was similar in patients with and without TLF and CD-TLR. However, greater post-balloon %DS was observed in patients with TLF and CD-TLR than without in patients with non-properly sized scaffold.

Conclusions: Improper sizing and poor lesion preparation prior to Magmaris implantation appear to be related to TLF during 1-year follow-up.

Euro2OA-OP123
Abstract I Oral presentation

Stable CAD - Invasive imaging and functional assessment

High-dose escalation of intracoronary adenosine and determinants for ischaemia in assessment of FFR

JONG Chien-Boon [1], JONG Chien-Boon [1], WU Chih-Cheng [1], PATRICK LIU Yan-Tyng [2], HUANG Ching-Chang [2]

(1) National Taiwan University Hospital Hsin-Chu Branch, Hsinchu City, Taiwan; (2) National Taiwan University Hospital, Taipei City, Taiwan

Aims: Maximal hyperaemia for fractional flow reserve (FFR) may not be achieved with current recommended doses for intracoronary adenosine (100 and 200 µg in the right and left coronary arteries, respectively). Real-world data on a large cohort of patients are needed to validate the effect and safety of doses higher than the current recommendation. This study aims to report the effect and safety of high-dose intracoronary adenosine (up to 800 µg) on patients in real-world practice.

Methods and results: Data of 892 patients and 1,200 vessels were extracted from the medical databases of two university hospitals. Increasing doses (100, 200, 400, 600, and 800 µg) of adenosine were administered as intracoronary bolus unless the ischaemic threshold was achieved (FFR ≤0.8) or complete atrioventricular block developed. The percentage of FFR ≤0.8 after higher-dose escalation was compared with those at conventional doses, and the predictors for reallocation after higher doses were analysed. In the 1,044 vessels in which the protocol was administered, 38.6% achieved the ischaemic threshold at the conventional dose and an additional 8.3% achieved the threshold after high-dose escalation. High-dose escalation was well-tolerated without major complications. Borderline FFR (0.81-0.85) at conventional dose, stenosis >60% and triple-vessel disease increased the likelihood of reallocation, but chronic kidney disease decreased it. For FFR value in the borderline range, 46% of the vessels were reallocated after high-dose escalation.

Conclusions: Escalation of intracoronary adenosine up to 800 µg optimised the sensitivity of FFR. Higher-dose adenosine may be recommended especially for borderline FFR values near the ischaemic threshold.

Stents and scaffolds - Tools, devices and techniques, CTO - Tools, devices and techniques

One-year clinical outcomes of ultrathin biodegradable polymer coated sirolimus-eluting stents in total occlusion: a multicentre, all-comer analysis

AJMERA Prakash [(1)], AJMERA Prakash [(1)], POTHINENI Ramesh [(2)], CHAWLA Kamal Kumar [(1)], MANTRAVADI Sai Sudhakar [(3)], JARIWALA Pankaj Vinod [(4)], VIJAN Vinod [(5)], VIJAN Vikrant [(5)], POTDAR Anil [(6)], INAMDAR Manohar K [(7)], PATHAK Abhijit [(8)]

(1) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (2) Dr. Ramesh Cardiac and Multispeciality Hospital, Vijayawada, India; (3) Gleneagles Global Hospitals, Telangana, India; (4) Yashoda Hospitals - Somajiguda, Telangana, India; (5) Vijan Cardiac & Critical Care Centre, Maharashtra, India; (6) Parisoha Foundation Pvt. Ltd, Mumbai, India; (7) Ashwini Hospital, Maharashtra, India; (8) Swasthya Hospital And Medical Research Center, Maharashtra, India

Aims: Since the inception of PCI, total occlusions have been listed under the most troublesome interventions to cardiologists. Technical & technological advancements have provided some aid in successful treatment of total occlusions. This analysis was aimed to present the safety and clinical performance of ultrathin-strut (60 µm) biodegradable polymer-coated Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) sirolimus-eluting stents (SES) in patients with total occlusions.

Methods and results: Two real-world, all-comer, multicentre registries maintained between May 2016 and March 2018 containing 1,203 and 1,269 patients implanted with only Supraflex Cruz (Sahajanand Medical Technologies Pvt Ltd, Surat, India) SES were utilised for the analysis. Patients with totally occluded lesions were included in this analysis. The primary endpoint was the incidence of target lesion failure, a composite of cardiac death, target vessel myocardial infarction, and target lesion revascularisation at one year. Stent thrombosis as per the Academic Research Consortium was considered as the safety endpoint. A total of 420 patients were included in this analysis. The mean age of the patients was 55.3±10.8 years and 302 (71.9 %) were male. Hypertension, hypercholesterolaemia, and diabetes mellitus were major risk factors affecting 189 (45.0 %), 147 (35.0 %), and 131 (31.2 %) patients, respectively. There were 162 (38.6 %) patients with unstable angina and 66 (15.7 %) with stable angina. Fifty-one (12.1 %) patients had NSTEMI and 141 (33.6 %) had STEMI. In 420 patients with 436 total occlusions, 524 Supraflex Cruz SES were implanted. Of the total occlusions, 192 (44.0 %) were in left anterior descending artery, 175 (40.1 %) were in right coronary artery, 67 (15.4 %) in left circumflex artery, and 2 (0.5 %) in left main artery. The mean stent length and diameter were 27.3±9.1 mm and 2.9±0.3 mm, respectively. Follow-up details of 407 (96.9 %) were available at one year. Primary outcome, target lesion failure, occurred in 21 (5.2 %) patients at one year, consisting of 5 (1.2 %) cardiac death, 7 (1.7 %) target-vessel myocardial infarction, and 9 (2.2 %) target lesion revascularisation. We observed 2 (0.5 %) cases of overall stent thrombosis at one-year follow-up.

Conclusions: In complex lesion characteristics like total occlusions, Supraflex Cruz SES was clinically safe with low rates of clinical outcomes at one-year follow-up.

Euro20A-OP125
Abstract | Oral presentation

Bifurcation lesion - Invasive imaging and functional assessment

Reliability and safety of a side branch jailed second-generation optical pressure guidewire in physiology-guided bifurcation PCI in-vitro model

RUBIMBURA Vladimir [1], RUBIMBURA Vladimir [1], VAN'T VEER Marcel [2,3], DE BRUYNE Bernard [4], JOHNSON Nils [5], MULLER Olivier [1]

(1) CHUV Centre hospitalier universitaire vaudois, Lausanne, Switzerland; (2) Catharina Ziekenhuis, Eindhoven, the Netherlands; (3) Eindhoven University of Technology, Eindhoven, the Netherlands; (4) Olv Ziekenhuis, Aalst, Belgium; (5) Weatherhead P E T Imaging Center, TX, USA

Aims: To compare fractional flow reserve (FFR) measurements between two second-generation optical pressure guidewires in bifurcation treatment: a jailed wire (JW) advanced into the side branch before stenting and a second free-floating wire (FW) introduced into the side branch after bifurcation stenting. The free-floating wire served as the reference standard.

Methods and results: An in-vitro bifurcation hydrodynamic model placed pressure sensors in the main vessel, main branch, and side branch. The proximal pressure sensor in the main vessel was used for equalising the pressure wires. Diameters of the proximal main vessel, side and main branches were 4.0 mm, 3.0 mm and 3.0 mm, respectively. After equalisation of the pressure wires, the JW was advanced into the side branch and the FW into the main branch. A workhorse guidewire was placed in the side branch too. A 3.0x22mm stent was implanted at its nominal pressure over the bifurcation, jailing the JW in the side branch. A proximal optimisation technique (POT) was performed using a non-compliant 4.0x12mm balloon at nominal pressure. The FW then was withdrawn and advanced into the side branch to the same position as the JW. A 2.5x15mm balloon was used to open the struts of the jailed side branch. At each step of the procedure, FFR measurements from the JW and FW were recorded: before stenting, after stenting, after POT technique, after crossing of the FW into the side branch, and during inflation of the 2.5x15mm balloon. The FW was then withdrawn and drift was checked. The time necessary to retrieve the workhorse wire and JW was recorded and drift was checked on the pressure wire. Assuming a drift of the optical pressure guidewire <3 mmHg/h, we estimated that 44 measures (22 JW and 22 FW) were necessary to demonstrate equivalence of the JW compared to the FW using a 0.02 margin. No statistical difference between FFR values was noticed after crossing the FW into the side branch: 0.97±0.02 and 0.97±0.01 from the JW and FW respectively. During balloon inflation in the side branch, no statistical difference was observed between FFR values of the JW and FW: 0.78±0.13 and 0.79±0.13, respectively. In 86% of the measures (42 comparisons), FFR difference from the JW and FW was ≤0.01 and in 2 cases equal to -0.02. No significant difference was observed of the mean FFR values between the JW and FW in all the other steps of the bifurcation stenting procedure. The mean time to retrieve the wires was not statistically different: 2.8±0.98s, 3.09±1.22s and 2.0±0.55s for the JW, balance middleweight wire, and Whisper medium support wire, respectively. Only one case of drift (Pd/Pa >0.02) was recorded in a FW (2.3%). No structural damage was observed on the jailed wires using optical microscopy.

Conclusions: In bifurcation stenting, the FFR values of a second-generation optical pressure guidewire jailed in the side branch are reliable compared to a free-floating wire inserted after stent implantation. Jailed pressure wires can be retrieved safely without major structural damage.

Other Coronary interventions - Calcified lesions

Impact of calcified lesion complexity on procedural and angiographic outcomes after lesion preparation with rotational atherectomy or modified balloons: a subgroup analysis from the PREPARE-CALC trial

HEMETSBERGER Rayyan [1], HEMETSBERGER Rayyan [1], TOELG Ralph [1], BYRNE Robert [2], MANKERIOUS Nader [1], ROBINSON Derek R. [3], ALLALI Abdelhakim [1], SULIMOV Dimitry [4], KASTRATI Adnan [5], ABDEL-WAHAB Mohamed [4], RICHARDT Gert [1]

(1) Segeberger Kliniken GMBH / Herz- und Gefäßzentrum, Bad Segeberg, Germany; (2) Mater Private Hospital, Dublin 7, Ireland; (3) Department of Mathematics, University of Sussex, Brighton, United Kingdom; (4) Heart Center Leipzig, University of Leipzig, Leipzig, Germany; (5) Deutsches Herzzentrum München, Munich, Germany

Aims: Optimal lesion preparation of severely calcified stenosis is essential before stent implantation. The randomised PREPARE-CALC trial demonstrated superiority of a strategy of lesion preparation with rotational atherectomy (RA) prior to drug-eluting stent (DES) implantation compared to a modified balloon (MB; cutting/scoring) angioplasty strategy. Beyond calcification, other features of lesion complexity may influence device deliverability and strategy success. The aim of this analysis was to investigate the impact of lesion complexity on the success of the strategies of upfront RA vs MB.

Methods and results: The PREPARE-CALC population was stratified according to operator-adjudicated lesion complexity into type-C lesions or non-type-C lesions. The endpoints were strategy success (defined as successful stent delivery and expansion with attainment of <20% in-stent residual stenosis in the presence of TIMI 3 flow without crossover or stent failure), need for bail-out RA, acute lumen gain, late lumen loss (LLL) and target lesion revascularisation (TLR) at 9-months follow-up. Out of 200 patients, 143 (71%) had at least one type-C lesion and 57 (29%) had non-type-C lesions. Of patients with type-C lesions, 65 (46%) were allocated to the MB arm, whereas of patients with non-type-C lesions 35 (61%) were allocated to the MB arm. Baseline characteristics were well balanced between patients allocated to the MB or RA arm, regardless of lesion complexity. Strategy success in patients with type-C lesions was higher with upfront RA as compared with MB (97% vs 72%; p<0.001), whereas in patients with non-type-C lesions both strategies were equally successful (100% vs 97.1%; p=1.0). The need for bail-out RA was higher in patients with type-C lesions (n=15, 10.5%) as compared with non-type-C lesions (n=1, 1.8%). Acute lumen gain did not differ after RA or MB in type-C lesions (1.7±0.4 mm vs 1.7±0.5 mm, p=0.59) nor in non-type-C lesions (1.7±0.3 mm vs 1.8±0.4 mm, p=0.48). Similarly, at nine months LLL did not differ after RA or MB in type-C lesions (0.24±0.43 mm vs 0.15±0.42 mm, p=0.19) nor in non-type-C lesions (0.16±0.31 mm vs 0.19±0.32 mm, p=0.76). TLR rates were low and not significantly different after treatment with RA or MB in type-C lesions (2.6% vs 7.7%, p=0.25) or in non-type-C lesions (0% vs 5.7%, p=0.52).

Conclusions: In severely calcified, but otherwise less-complex coronary lesions, the treatment strategy with RA or MB before DES implantation resulted in comparable acute strategy success rates, whereas in complex type-C lesions an upfront RA is a more successful strategy as compared to MB.

Stents and scaffolds - Tools, devices and techniques

One-year clinical outcomes of 9,771 patients undergoing complex PCI treated with unrestricted use of Ultimaster bioresorbable polymer sirolimus-eluting stent

MAMAS Mamas [(1)], MAMAS Mamas [(1)]

(1) Royal Stoke University Hospital, Stoke-on-Trent, United Kingdom

Aims: Previous studies suggested that complex percutaneous coronary intervention (PCI) was associated with a higher risk of ischaemic events. However, data with new-generation DES in our daily practice are limited. The aim of this study was to evaluate the impact of the complexity of PCI on ischaemic and bleeding adverse events in patients who were treated with unrestricted use of Ultimaster™ a thin strut sirolimus-eluting stent (SES) with abluminal bioresorbable polymer.

Methods and results: The present analysis is a sub-study of the e-Ultimaster registry (NCT02188355), which is a prospective, multicentre, worldwide, all-comers registry enrolling 36,916 patients. So far, 34,538 patients who reached one-year follow-up or died were included in this analysis. The primary endpoint was target lesion failure (TLF) at 1 year (defined as a composite of cardiac death, target-vessel related myocardial infarction [TV-MI] and clinically-driven target lesion revascularisation [CD-TLR]), and patients were stratified according to complex PCI, which was defined as PCI fulfilling at least one of the following procedural features: multivessel PCI, ≥3 stents implanted, ≥3 lesions treated, bifurcation PCI with ≥2 stents, total stent length> 60mm, or chronic total occlusion (CTO). All endpoint related events were adjudicated by an independent Clinical Event Committee. Among 34,538 patients included in the present analysis, 9,771 (28.3%) underwent complex PCI. Patients undergoing complex PCI were older and more frequently had comorbidities (diabetes, hypertension, hypercholesterolaemia, current smoker, renal impairment, and low left ventricular ejection fraction) and history of MI and revascularisation, as compared to those undergoing non-complex PCI ($p<0.001$ for all). The rate of patients who continued DAPT at one year was 70.5 % in the complex PCI and 65.2% in the non-complex PCI group. The crude rate of the primary endpoint of TLF at one year was significantly higher in the complex PCI group compared with the non-complex PCI group (4.3% vs 2.6%, $p<0.001$). Of note, as the number of complex PCI features increased, a greater risk of TLF was observed (2.6 % for non-complex PCI vs 4.0% for 1 or 2 risks vs 5.3% for ≥ 3 risks). In terms of individual components of the primary endpoint, the complex PCI group resulted in a higher risk of cardiac death (1.6% vs 1.1%, $p<0.001$), TV-MI (1.2% vs 0.7%; $p<0.001$), and CD-TLR (2.3 % vs 1.3%; $p<0.001$). The rate of definite or probable stent thrombosis was infrequent but significantly higher in patients with complex PCI than in the non-complex PCI group (0.87% vs 0.52%; $p<0.001$). Notably, the risk of major bleeding was significantly higher in the complex PCI group than the non-complex PCI group (0.89% vs 0.47%; $p<0.001$).

Conclusions: In this large worldwide registry of PCI, overall ischaemic event rates at one year in patients undergoing complex PCI were in general low. However, those patients still had a higher risk of ischaemic, as well as bleeding events, as compared with patients undergoing non-complex PCI. In this higher-risk population with complex PCI, further improvement of PCI outcomes is required, potentially with an individualised approach for revascularisation strategy and post-procedural antiplatelet regimen to mitigate ischaemic events without increasing bleeding risk.

Euro2OA-OP132
Abstract | Oral presentation

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Individual patient data analysis of the BIOFLOW study programme comparing bioresorbable polymer sirolimus-eluting stents to a durable polymer everolimus-eluting stents

TÖLG Ralph [1], TÖLG Ralph [1], SLAGBOOM Ton [2], WALTENBERGER Johannes [3], LEFÈVRE Thierry [4], SAITO Shigeru [5], KANDZARI David [6], KOOLEN Jacques [7], RICHARDT Gert [1]

(1) SEGEBERGER KLINIKEN GMBH, Bad Segeberg, Germany; (2) OLVG, locatie Oost, Amsterdam, the Netherlands; (3) SRH Zentralklinikum Suhl gGmbH, Suhl, Germany; (4) Private Hospital Jacques Cartier, Massy, France; (5) Shonan Kamakura General Hospital, Kanagawa, Japan; (6) Piedmont Heart Institute, Atlanta, USA; (7) Catharina Ziekenhuis Eindhoven, Eindhoven, the Netherlands

Aims: This analysis of pooled individual patient data (IPD) aimed to evaluate the safety and efficacy of a bioresorbable polymer sirolimus-eluting stent system (BP-SES; Orsiro) compared to a durable polymer everolimus-eluting stent system (DP-EES; XIENCE) in the pooled population as well as in high risk subgroups.

Methods and results: IPD with up to 12 months follow-up of the randomised controlled trials BIOFLOW-II (NCT01356888), -IV (NCT01939249) and -V (NCT02389946), as well as the all-comers registry BIOFLOW-III (NCT01553526), were pooled. 3,717 subjects (2,923 with BP-SES and 794 with DP-EES) with 5,328 lesions (4,225 lesions with BP-SES and 1,103 with DP-EES) were included in the IPD. The primary endpoint was target lesion failure (TLF) at 12-month follow-up. Subgroups analysed included diabetes, age (≥ 65 years), gender, complex lesions (B2/C), small vessels (reference vessel diameter ≤ 2.75 mm), stent size ≤ 3.0 mm diameter, multivessel treatment, renal disease and patients with acute coronary syndrome (ACS). A mixed effects logistic regression was used to correct for potential confounders. Overall TLF at 12 months was 5.2% (151/2923) in the BP-SES group vs 7.6% (60/794) in the DP-EES group (OR=0.67 with 95% CI: [0.49; 0.91]; p=0.0098). Target vessel myocardial infarction (TV-MI) was 3.1% (90/2923) vs 5.7% (45/794) (OR=0.53 with 95% CI: [0.37; 0.76]; p=0.0005). In the stratified subgroup analysis, TLF and TV-MI rates were significantly lower in small vessels, stents ≤ 3.0 mm, complex lesions, and in the BP-SES group. In patients with small target vessels, regression analysis revealed an independent stent effect in favor of BP-SES for TLF (OR=0.52 with 95% CI: [0.33; 0.81]; p=0.0043) and TV-MI (OR=0.58 with 95% CI: [0.36; 0.92]; p=0.0364). As BP-SES stent sizes vary in strut thickness, the regression analysis was repeated for patients treated with stents ≤ 3.0 mm diameter with only 60 µm strut thickness. Interestingly, a similar effect in favor of BP-SES was seen in those patients for TLF (OR=0.65 with 95% CI: [0.44; 0.96]; p=0.0292) and TV-MI (OR=0.66 with 95% CI: [0.43; 1.03]; p=0.0652).

Conclusions: Results of this IPD analysis suggest that the BP-SES with ultrathin struts is as safe and efficacious as DP-EES in various risk groups of patients suffering from coronary artery disease. Especially patients with small target vessels (RVD ≤ 2.75 mm) and patients treated with stents ≤ 3.0 mm diameter with strut thickness of only 60 µm may benefit from treatment with BP-SES over DP-EES.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Other

Long-term safety of paclitaxel DEB-only angioplasty for de novo coronary artery disease

MERINOPOULOS Ioannis [1,2], MERINOPOULOS Ioannis [1,2], GUNAWARDENA Tharusha [1,2], WICKRAMARACHCHI Upul [1,2], RICHARDSON Paul [1], PERPEROGLOU Aris [3], VASSILIOU Vassilios [1,2], ECCLESHALL Simon [1]

(1) Norfolk & Norwich University Hospital NHS Foundation Trust, Norwich, United Kingdom; (2) Norwich Medical School, UEA, Norwich, United Kingdom; (3) University of Essex, Colchester, United Kingdom

Aims: Concerns have been raised over paclitaxel drug-coated balloon (DCB) use for peripheral arterial disease due to potentially increased late mortality, and the FDA initiated an investigation for the peripheral use of paclitaxel DCB. We investigated whether there was evidence of a potential signal of increased late mortality in patients with stable *de novo* coronary artery disease (CAD) treated with paclitaxel DCB.

Methods and results: We retrospectively searched our clinical database for all patients treated with either paclitaxel DCB or non-paclitaxel second-generation drug-eluting stents (DES) for stable, *de novo* CAD from 2011-2018. In order to see a true potential effect of the paclitaxel itself and to have an homogenous group, we excluded patients with previous PCI and patients being treated for ACS. Patients with recurrent PCI following their index procedure were excluded if the subsequent PCI strategy differed from index. Survival data were obtained though the Office of National Statistics. A total of 429 patients treated with paclitaxel DCB only and 1,088 patients treated with non-paclitaxel second-generation DES were identified. The average age was 66.9±10.2 years, 76.2% male in the DCB group; 66.8±10 years, 76.6% male in the DES group. The groups were well balanced regarding demographics (age, sex, hypertension [HTN], hypercholesterolaemia, myocardial infarction [MI], diabetes, stroke, heart failure, peripheral vascular disease [PVD], CABG or family history of CAD) and prognostic lesions targeted (left main coronary artery, left anterior descending artery or multivessel PCI). The DES group had significantly more patients with chronic obstructive pulmonary disease and smoking history while the DCB group had significantly more patients with atrial fibrillation (AF). Mean vessel diameter and lesion length were significantly larger in DES group (3.39±0.59mm vs 3.06±0.56mm and 30.03±16.5mm vs 26.05±11.9mm, correspondingly; $p<0.001$ for both). However, mean vessel diameter for DCB was greater that 3mm, indicating that large vessels were targeted. The patients were followed for an average of 31.6±16.3 months for the DCB group and 44.4±18.4 months for the DES group. We obtained mortality data for 1,515 out of 1,517 patients. There were 12 deaths (2.8%) in the DCB group and 77 deaths (7.1%) in the DES group. Univariate Cox regression identified the following poor prognostic factors: increasing age, HTN, PVD, MI, heart failure, smoking, AF and creatinine; while family history of CAD and hypercholesterolaemia were associated with better prognosis. None of the angiographic characteristics were associated with worse outcome. The Kaplan-Meier estimator curve for five year follow up did not show a signal of increased late mortality with DCB to support the paclitaxel late mortality theory, even when excluding the deaths occurring in the first 24 months of follow-up. There was a trend for better survival with DCB (hazard ratio=0.765, 95% confidence interval: 0.56-1.04, $p=0.08$). The 30-day, 1, 2 and 3 year mortality for DCB and DES groups were 0% vs 0.3%, 1.1% vs 1.6%, 3.4% vs 3.8% and 5.5% vs 6.5%, respectively, all $p>0.05$. On multivariate Cox regression only age, increased creatinine and smoking history remained significant poor prognostic factors.

Conclusions: Real-world data from a centre with a high volume of coronary paclitaxel DCB-only angioplasty does not support late mortality with paclitaxel DCB during five years of follow-up, even when adjusted for all prognostically important factors.

Euro20A-OP136
Abstract | Oral presentation

Stents and scaffolds - Invasive imaging and functional assessment, Other Coronary interventions - Other

Impact of stent size on procedural outcomes in small coronary arteries with long lesions

SAHIN Anil [1,2], TIGEN Kursat [1], SAHIN Anil [1,2], DOGAN Zekeriya [1], CINCIN Altug [1], GUREL Emre [1], SUNBUL Murat [1], KANAR Batur [1], ALIS Deniz [2], SAYAR Nurten [1], OZBEN Beste [1]

(1) Marmara University Faculty of Medicine, Istanbul, Turkey; (2) Mehmet Akif Ersoy Göğüs Kalp Damar Cerrahisi Eğitim Araştırma Hastanesi, Istanbul, Turkey

Aims: Limited data is available on the outcomes of stent implantation in long (≥28 mm) and small (≤2.5 mm) coronary vessels. The aim of this study was to investigate the impact of stent size selection on acute outcomes in long and small coronary lesions.

Methods and results: Patients with stable coronary artery disease or acute coronary syndrome who had undergone percutaneous coronary revascularisation to native coronary arteries with stents ≤2.5mm in size and ≥28mm in length were retrospectively included in the study. Post-procedural analysis and events such as side branch occlusion, intramural haematoma, vessel rupture, distal thrombus embolism, edge dissection, in-hospital stent thrombosis, myocardial infarction and death were recorded. One hundred and sixty-one consecutive patients (127 male, mean age: 62.7±9.0 years) were included. Most of the lesions were mid or distal segments of the coronary arteries and stent oversizing > 25% compared to distal vessel diameter was detected in 51 patients. Edge dissection was detected in 30 patients. Edge dissection, vasospasm and distal embolism were more frequently observed in procedures with stent oversizing. TIMI flow grade I-II rates were significantly higher in patients with edge dissection and in patients presenting with acute coronary syndromes. Stent oversizing was an independent predictor of edge dissection and a stent oversizing of >25% predicted edge dissection with a sensitivity of 83.3% and a specificity of 84.7%.

Conclusions: Coronary intervention in small coronary arteries with long lesions is related with high risk of edge dissection and increased coronary complications, especially in procedures with stent oversizing.

Stents and scaffolds - Invasive imaging and functional assessment

Reduction of lipid core burden index in non-culprit lesions at two-year follow-up after STEMI: a randomised study of BRS vs optimal medical therapy

KEFER Joelle [1], KEFER Joelle [1], BEAULOYE Christophe [1], CHENU Patrick [1], GURNE Olivier [1], RENKIN Jean [1]

(1) Cliniques universitaires Saint-Luc UCLouvain, Woluwe-Saint-Lambert, Belgium

Aims: Near-infrared sprectoscopy is able to detect lipid rich plaque by using the maximum 4 mm lipid core burden index > 250. Until now, data are scarce on plaque modification-oriented therapies to mitigate the risk of future cardiac events associated with non-culprit vulnerable plaques after acute coronary syndrome. Bioresorbable vascular scaffold (BRS) could potentially optimise plaque remodelling. The aim of the present study was to compare the evolution of lipid core burden index in non-culprit lesions treated either by BRS or optimal medical therapy at 2-year follow-up after STEMI.

Methods and results: Thirty-three non-obstructive non-culprit lesions among twenty-nine patients (24 males, 56±12 yrs) were included in the study. Fifteen of these lesions (9 in the left anterior descending, 4 in the right and 2 in the circumflex coronary artery) were lipid-rich plaque with an FFR>0.80 and were randomly assigned to either the BRS arm (group 1; N=7) or optimal medical therapy (group 2; N=8). At baseline, there were no differences between plaque characteristics (FFR 0.85±0.04 vs 0.89±0.06, diameter stenosis 39±11 vs 34±9%, plaque burden 54±10 vs 47±8%, lipid core burden index 479±165 vs 428±152, p=NS for all comparisons between group 1 and 2, respectively). Seven BRS were implanted 3±1 days after the STEMI among 6 patients within the group 1 without complications, under optical coherence tomography guidance, showing a good expansion and apposition of all scaffolds. At 2-year angiographic follow-up, the FFR became signifcantly lower in group 1 than in group 2 (0.88±0.04 vs 0.94±0.02; p=0.009) while the plaque burden (50±7 vs 36±12%; p=0.03) and the lipid core burden index (234±125 vs 20±21; p=0.003) was significantly higher in group 1 vs group 2. During the clinical follow-up (median duration 762 days, interquartile range 712-1055), there was 100% survival, zero stent thrombosis and a target lesion revascularisation in one case of each group. All but one patient were on statin therapy at last follow-up and the mean LDL-cholesterol value was similar between group 1 and 2 (72±20 vs 57±17 mg/dl, respectively; p=0.08).

Conclusions: The present study shows that BRS is less effective than optimal medical therapy in reduction of lipid core burden index in non-culprit lesion at 2-year follow-up after STEMI. Larger studies are needed to evaluate the ability of near-infrared spectroscopy-guided therapy to optimise plaque remodelling and to mitigate the risk of future cardiac events after STEMI.

Euro2OA-OP138
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques, CTO - Tools, devices and techniques

Clinical outcomes of 1,722 patients after successful treatment of CTO lesions with bioresorbable polymer sirolimus-eluting stent(s): insights from an all-comer and worldwide registry

RUMOROSO Jose Ramon [(1)], SUBINAS Asier [(1)], SADABA Mario [(1)]

(1) Hospital Universitario de Galdakao, Galdakao, Spain

Aims: The success rate of chronic total occlusion (CTO) percutaneous coronary intervention (PCI) has substantially been improved, together with the maturation and refinement of equipment and techniques. However, there is a limited data of clinical outcomes after treatment of CTO with new-generation drug-eluting stents. The aim of this study is to evaluate clinical outcomes in patients with successfully treated CTO lesions with bioresorbable polymer sirolimus-eluting stent(s)

Methods and results: The e-Ultimaster registry is a large, prospective, worldwide registry investigating 1-year outcome of patients treated with a thin strut (80 μm) bioresorbable polymer sirolimus-eluting stents (Ultimaster). The primary endpoint of target lesion failure (TLF) at one year was defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent Clinical Event Committee adjudicated all endpoint-related clinical outcomes. The current analysis was performed on 34,538 patients who reached one-year follow-up or died. Among them at least one CTO lesion was successfully treated in 1,722 patients (5.02%). Patients with CTO lesions were younger (63.8±10.7 vs 64.3±11.3 years old, p=0.031), frequently male (80.6% vs 75.8%, p<0.001), had lower EF (51.0±13.2 vs 54.0±11.6%, p<0.001), and had a higher prevalence of comorbidities (diabetes mellitus; 31.7% vs 27.9%, p<0.001, hypercholesterolaemia; 60.0% vs 55.8%, p=0.001, previous myocardial infarction; 34.3% vs 21.7%, p<0.001, previous PCI; 33.6% vs 25.5%, p<0.001, and previous CABG; 10.1% vs 5.5%, p<0.001), compared to patients without CTO lesions. The most frequently treated vessel with CTO lesions was the RCA (48.3%), followed by the LAD (44.3%). The number of study stents implanted was 1.9±1.1 with a total stent length of 49.1±31.7mm in patients with CTO lesions, whereas patients without CTO lesions received 1.4±0.8 stents with a total stent length of 31.5±20.6mm (both p<0.001). Regarding the CTO lesion approach, a retrograde approach was performed in 17.8% of the procedures. The average radiation dose was 2272mGy and the contrast volume was 228ml. Microcatheters were used in 21.7% of the procedures and imaging (IVUS or OCT) was used in 11.1% of the patients. TLF rates at one year were not different between patients with or without CTO lesions (3.31% vs 3.08%, p=0.57). In addition, the rates of cardiac death (1.22% vs 1.24%, p=0.99), TV-MI (1.05% vs 0.86%, p=0.42), CD-TLR (1.57% vs 1.61%, p=0.99), and definite or probable stent thrombosis (0.99% vs 0.60%, p=0.055) were similar in patients with or without CTO lesions. Patients with CTO lesions treated with the retrograde approach (n= 184) had a significantly higher TLF rate at one year (7.61%), compared to patients with CTO treated with the antegrade approach (n= 851) (2.82%, p=0.004), which was mainly driven by a higher rate of periprocedural TV-MI during the index hospitalisation (4.89% vs 0.24%, p<0.001).

Conclusions: In this large multicentre registry, one-year clinical event rates after successful treatment of CTO with polymer sirolimus-eluting stent(s) were low and similar to those patients without CTO. However cautious interpretation is necessary because only patients underwent successful CTO treatment were included in this registry. The retrograde approach was associated with a high rate of periprocedural TV-MI, which warrants careful follow-up during hospitalisation after CTO procedure.

Stents and scaffolds - Tools, devices and techniques

Final five-year results of the REMEDEE registry: real-world experience with the dual-therapy COMBO stent

KERKMEIJER Laura [1], KERKMEIJER Laura [1], CHANDRASEKHAR, Jaya [1], KALKMAN Deborah [1], WOUDSTRA Pier [1], MENOWN Ian [2], SURYAPRANATA Harry [3], DEN HEIJER Peter [4], IÑIGUEZ Andrés [5], VAN 'T HOF Arnoud [6], ERGLIS Andrejs [7], ARKENBOUT Karin [8], MULLER Philippe [9], KOCH Karel [1], TIJSSEN Jan [1], BEIJK Marcel [1], DE WINTER Robbert [1]

(1) Amsterdam UMC - Locatie AMC, Amsterdam, the Netherlands; (2) Craigavon Area Hospital, Craigavon, United Kingdom; (3) Radboudumc, Nijmegen, the Netherlands; (4) Amphia Hospital, Breda, the Netherlands; (5) Álvaro Cunqueiro Hospital, Vigo, Spain; (6) Isala ziekenhuis, Zwolle, the Netherlands; (7) Pauls Stradiņš Clinical University Hospital, Riga, Latvia; (8) Tergooi - Blaricum, Blaricum, the Netherlands; (9) Institut National de Cardiochirurgie et de Cardiologie Interventionnelle, Luxembourg, Luxembourg

Aims: The COMBO stent combines an abluminal biodegradable coating eluting sirolimus with a luminal anti-CD34+ antibody layer to attract endothelial progenitor cells in order to promote vessel healing and therefore possibly prevent neointima formation and restenosis. We aimed to assess long-term safety and performance of the dual-therapy COMBO stent in a large unselected population and in pre-specified subgroups.

Methods and results: The prospective, multicentre, investigator-initiated, REMEDEE Registry evaluates clinical outcomes after COMBO stent treatment in daily clinical practice. One thousand patients were enrolled between June 2013 and March 2014. Patients had a mean age of 65 years (±11), 26% were females and 18% of patients had diabetes mellitus (DM). In 30% of patients, there was an urgent indication for PCI, 60% of lesions were AHA/ACC lesion type B2 or C. At 5 years, target lesion failure (TLF) (composite of cardiac death, target vessel myocardial infarction or target lesion revascularisation) was present in 145 patients (14.8%). Definite or probable ST occurred in 0.9%, with no additional case beyond 3 years of follow-up. In males, the 5-year TLF-rate was 15.6% versus 12.6% in females (p=0.22). Patients without diabetes mellitus (DM) had TLF-rate of 11.4%, non-insulin treated DM 22.7% (p=0.001) and insulin-treated DM 41.2% (p<0.001). Patients presenting with NSTE-ACS had a higher incidence of TLF compared to non-ACS (20.4% vs 13.3%; p=0.008), while incidence with STE-ACS was comparable to non-ACS (10.7% vs 13.3%; p=0.43).

Conclusions: The dual-therapy COMBO stent has shown good clinical results up to four-year follow-up. For the first time, five-year performance of the COMBO stent in a large unselected population will be presented. ClinicalTrials.gov Identifier: NCT01874002

Euro2OA-OP141
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Comparison of a biodegradable polymer sirolimus-eluting stent with durable polymer everolimus-eluting stents after rotational atherectomy. A single-centre observational study

MANKERIOUS Nader [1], MANKERIOUS Nader [1], HEMETSBERGER Rayyan [1], TRABOULSI Hussein [1], TOELG Ralph [1], ABDEL-WAHAB Mohamed [2], RICHARDT Gert [1], ALLALI Abdelhakim [1]

(1) Segeberger Kliniken GMBH / Herz- und Gefäßzentrum, Bad Segeberg, Germany; (2) Universitätsklinikum Leipzig, Leipzig, Germany

Aims: New-generation drug-eluting stents (DES) have shown superiority over early-generation DES in virtually all percutaneous coronary intervention (PCI) settings, including rotational atherectomy. Recently, a biodegradable polymer sirolimus-eluting stent (Orsiro) was shown to be superior to durable polymer DES particularly in small vessels treated with the ultrathin struts (60 µm). Our aim is to compare the long-term outcomes of the Orsiro DES with durable polymer DES in terms of target lesion failure after rotational atherectomy.

Methods and results: A total of 624 patients who underwent rotational atherectomy at our centre between June 2007 and December 2018 were divided according to the type of implanted DES into 121 patients treated with Orsiro DES and 164 patients with durable polymer DES (Promus and XIENCE DES). Patients who were treated with other stent types and those who presented with acute myocardial infarction or chronic total occlusion were excluded. Incidence of long-term target lesion failure as a composite of cardiac death, target vessel myocardial infarction or clinically driven target lesion revascularisation was investigated. Patients and procedural characteristics were balanced between the two groups, except for more frequent single coronary artery disease, left anterior descending artery as a target vessel, post-stenting balloon dilatation and the use of intravascular imaging modalities in the Orsiro DES group. The rate of in-hospital major adverse cardiac events was significantly higher in the durable polymer DES group (p=0.022), driven by numerical higher rates of cardiac death and periprocedural myocardial infarction. After two years, the Orsiro DES group showed lower rates of target lesion failure (10%) as compared to durable polymer DES group (18%). However after adjustment for potential confounders, this difference did not reach statistical significance (adjusted HR: 0.55, CI: 0.26-1.16, p=0.115). Notably, the rate of target lesion failure was significantly lower within the ultrathin struts (60 µm) sub-group confined only to small Orsiro DES (diameter ≤ 3mm) as compared to the same size thin-strut (80 µm) durable polymer DES sub-group (adjusted HR: 0.19, CI: 0.04-0.87, p=0.032), driven by lower rates of clinically driven target lesion revascularisation (log-rank p=0.022). Total stent length (adjusted HR: 1.02, CI: 1.01-1.03, p=0.007) and diabetes mellitus (adjusted HR: 2.69, CI: 1.25-5.78, p=0.011) emerged as independent predictors of target lesion failure in the whole cohort.

Conclusions: In the whole rotational atherectomy cohort, Orsiro DES had numerical lower rates of long-term target lesion failure as compared to durable polymer DES. Small Orsiro DES with the ultrathin-strut property caused significant reduction in long-term target lesion failure rates. Total stent length and diabetes mellitus remained predictors of target lesion failure.

Left main and multivessel disease - Tools, devices and techniques

Treatment of left main lesions using DES with bioresorbable polymer: one-year patient outcomes

ROUTLEDGE Helen [1], ROUTLEDGE Helen [1]

(1) Worcestershire Royal Hospital, Worcester, United Kingdom

Aims: Based on currently available evidence, 2018 ESC guidelines recommended that PCI is an appropriate alternative to CABG in treating left main (LM) disease with low (SYNTAX score 0-22) to intermediate (SYNTAX score 23-32) anatomical complexity. The aim of this study is to assess the worldwide practice and performance of a thin-strut sirolimus-eluting stent with bioresorbable polymer in a subgroup of patients with LM coronary artery disease.

Methods and results: e-Ultimaster is a prospective, multicentre registry which enrolled patients treated with Ultimaster DES worldwide. Of the 34,538 patients that reached 1-year follow-up or died, 1,099 patients were treated in LM, among which 514 patients were treated only in LM, while 585 patients were treated in LM plus one or more vessels (LM+MV). Most of the patient characteristics were similar between two groups, with a mean age of 69.2±11.0 and 68.9±10.9years, BMI of 27.2±5.1 and 27.6±5.6kg/m^2, 74.7% and 71.6% with hypertension, 59.6% and 63.3% with hypercholesterolaemia in the LM and LM+MV group respectively (p>0.05 for all). There is no difference in the % of patients who had previous PCI (39.5% vs 36.9%) or CABG (22.0% vs 18.0%) in the LM and LM+MV group (P>0.05). Regarding lesion characteristics, 44.8% of patients in the LM group had lesions longer than 25mm, while more than half of the patients (56.1%) in the LM+MV group had long lesions (p<0.01). Among treated lesions, 32.2% of LM and 32.6% of the LM+MV group had moderate or severely calcified lesions. Among treated patients, 53.4% had a SYNTAX score <22, while 32.5% had a SYNTAX score 23-32. Regarding the procedure, approximately 68% of the procedures were performed via radial access in both groups, while imaging (OFDI or IVUS) was used in 36.5% of the procedures in LM and 27.1% in the LM+MV group. In the LM and LM+MV groups, direct stenting was performed in 29.4% and 51.3% (p<0.001) of the lesions, while post dilatation was performed in 69.7% and 74.9% (p=0.06) of the lesions, respectively. The number of Ultimaster stents implanted per patient was 1.4±0.7 in the LM only group and 2.2±1.2 in the LM+MV group, and the total length of successfully implanted Ultimaster stents was 30.0±21.3mm and 48.9±32.2mm. At 3-month and 1-year follow-up, 92.7% and 69.2% of treated LM patients were on DAPT, and the majority of patients were angina-free at one year (90.0%). At one year, the clinical outcomes in LM alone vs the LM+MV group are the following: cardiac death 4.1% vs 5.5%, target vessel MI 1.2% vs 2.7%, target lesions revascularisation 4.1% vs 4.3%, target vessel revascularisation 4.7% and 5.3% respectively (P>0.05 for all). The definite and probable stent thrombosis rates are 1.0% vs 1.9% (p=0.31), and the composite endpoint of target lesion failure is 8.0% vs 10.8% (p=0.12). Target vessel failure is 8.6% vs 11.3% (p=0.16) at one year.

Conclusions: In complex patients treated for LM disease, with or without additional treated vessels, the Ultimaster DES showed good clinical outcomes at one year. The LM patients treated in this registry reflecting daily practice are more complex than recommended in current ESC guidelines, as only 53% of patient had a low (<22) SYNTAX score. In view of the current controversy surrounding LM treatment, more evidence is needed to further strengthen the indication for PCI treatment of left main disease. In general the results of this study indicate that the thin-strut sirolimus-eluting Ultimaster stent with bioresorbable polymer offers a good option for treating LM patients.

Stents and scaffolds - Tools, devices and techniques

BIOVITESSE – Multicentre prospective first-in-man study of a new polymer-free, DES with ultrathin struts: nine-month late lumen loss results of cohort 2

RAEBER Lorenz [2], RAEBER Lorenz [2], HAENER Jonas [2], WAKSMAN Ron [8], LUESCHER Thomas [1,7], MOCCETTI Marco [6], ROFFI Marco [3], STORTECKY Stefan [2], FOURNIER Stephane [4], GARCIA-GARCIA Hector M. [8], SIEGRIST Patrick [5]

(1) Royal Brompton Hospital, London, United Kingdom; (2) Inselspital, Universitätsspital Bern, Bern, Switzerland; (3) Hôpitaux Universitaires de Genève (HUG), Geneva, Switzerland; (4) CHUV Centre hospitalier universitaire vaudois, Lausanne, Switzerland; (5) University Hospital of Zürich, Zürich, Switzerland; (6) Fondazione Cardiocentro Ticino, Lugano, Switzerland; (7) Center for Molecular Cardiology, University of Zurich, Schlieren Campus, Zurich, Switzerland; (8) MedStar Washington Hospital Center, DC, USA

Aims: A potent anti-proliferative mTOR inhibitor has been developed by Biotronik which is one thousand-fold more lipophilic than sirolimus. In pre-clinical testing, stents coated with a polymer-free, abluminal-biased coating including this drug achieved effective reduction in neoinitimal hyperplasia at a low dose. The aim of the BIOVITESSE first-in-man study was to assess the safety and efficacy of this novel polymer-free drug-coated coronary stent (DCS) combining the proven PROKinetic Energy stent with this new limus drug in subjects with chronic coronary syndrome (CCS).

Methods and results: The BIOVITESSE study consists of 2 consecutive cohorts treated with a novel polymer-free DCS. In cohort 2, a total of 33 patients with CCS and *de novo* lesions were enrolled at five centres in Switzerland from June 2018 to January 2019, and underwent repeat angiography and optical coherence tomography (OCT) at 9 months. The primary endpoint was in-stent late lumen loss (LLL) at 9 months as assessed by angiography. Secondary endpoints included OCT data and cardiovascular events at 12 months. All patients underwent clinical follow-up at 1, 9 and 12 months. All angiography and OCT data were analysed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee. Patients had a mean age of 61.8±9.7 years. Hyperlipidaemia (84.8%) and hypertension (75.7%) were the predominant risk factors and a history of previous myocardial infarction was frequent (30.0%). A total of 28 patients (84.8%) presented with CCS and 5 patients (15.2%) with unstable angina. Procedural success was 100% and angiographic follow-up was obtained in 97% of patients. At 9 months, the primary endpoint in stent LLL was 0.31±0.30 mm and strut coverage as assessed by OCT was 98.9±2.1%. There was only one event of clinically driven target lesion revascularisation up to 12-month follow-up. No myocardial infarction, no cardiac death and no stent thrombosis occurred at all during the follow-up time.

Conclusions: It can be concluded that this novel polymer-free stent is safe and its late lumen loss results are comparable to other drug-coated stents.

Euro2OA-OP144
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

Long-term clinical data of the BIOSOLVE-II study with a drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries – BIOSOLVE-II

HAUDE Michael [(1)], HÜSEYIN Ince [(2)], ABIZAID Alexandre [(3)], TOELG Ralph [(4)], LEMOS Pedro Alves [(5)], VON BIRGELEN Clemens [(6)], CHRISTIANSEN Evald Høj [(7)], DE BRUYNE Bernard [(8)], NEUMANN Franz-Josef [(9)], KAISER Christoph [(10)], WAKSMAN Ron [(11)]

(1) Medizinische Klinik I, Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany; (2) Vivantes Klinikum im Friedrichshain and Am Urban, Berlin, Germany; (3) Instituto de Cardiologia, Dante Pazzanese, Sao Paulo, Brazil; (4) Herzzentrum Segeberger Kliniken GmbH, Bad Segeberg, Germany; (5) Instituto do Coração – HCFMUSP, University of Sao Paulo, Sao Paulo, Brazil; (6) Department of Cardiology, Medisch Spectrum Twente, Thoraxcentrum Twente, Enschede, the Netherlands; (7) Department of Cardiology, Aarhus University Hospital, Aarhus, Denmark; (8) Cardiology Department, Cardiovascular Research Center Aalst, OLV Hospital, Aalst, Belgium; (9) Klinik für Kardiologie und Angiologie II, Universitäts-Herzzentrum Freiburg - Bad Krozingen, Bad Krozingen, Germany; (10) Department of Cardiology, University Hospital Basel, Basel, Switzerland; (11) Interventional Cardiology, MedStar Washington Hospital Center, Washington DC, USA

Aims: In order to assess the long-term safety, clinical performance and bioabsorption process of the sirolimus-eluting bioabsorbable magnesium scaffold (DREAMS 2G), 5-year clinical data and multi-modality imaging outcomes up to 3-year follow-up are reported.

Methods and results: A total of 123 subjects from 13 sites in Europe, Brazil and Singapore with 123 *de novo* lesions have been enrolled in the BIOSOLVE-II study. Clinical follow-ups are scheduled at 1, 6, 12, 24, 36 and 60-months. Angiographic follow-ups are planned at 6 months and are voluntarily at 12 months and 36 months. A subgroup of 30 subjects undergo additional IVUS and OCT assessments at 6 months and voluntarily again at 12 months and 36 months. Vasomotion testing is performed with acetylcholine, followed by nitroglycerine at 6 months and 12 months, if subjects consent. Dual antiplatelet therapy was recommended for 6 months. Primary endpoint is in-segment late lumen loss (LLL) at 6-month follow-up. The angiographic results are analysed by an independent corelab and all clinical events are adjudicated by an independent clinical events committee. Target lesion failure (TLF) rate at 36 months remained low, occuring in 8 patients (6.8%), and is comparable to second-generation drug-eluting stents. TLF rate includes 5 clinically-driven target lesion revascularisations (TLRs), 1 periprocedural target-vessel myocardial infarction (MI) and 2 cardiac deaths. No definite or probable scaffold thrombosis was observed up to 36 months. Serial angiographic images were available for 25 subjects. In-segment LLL at 12 months was 0.35±0.23 mm vs 0.46±0.25 mm at 36 months. In order to evaluate if the difference in LLL between 12 and 36 months is related to natural progression of the disease or late effects of the device, an additional comparative angiographic analysis of the target vessel versus a non-target vessel (vessel without stenosis) was performed. To exclude any bias caused by minor differences in the reference vessel diameter (RVD), the LLL was normalised by the RVD for this analysis. These results showed that the normalised LLL remained stable from 12 to 36 months and is similar between target and non-target segments.

Conclusions: The 3-year clinical results of the DREAMS 2G demonstrate an excellent safety profile with a low TLF rate comparable to second-generation drug-eluting stents and no definite or probable scaffold thrombosis. The change in LLL can be attributed to the overall progression of the disease rather than very late effects of the DREAMS 2G beyond its resorption time.

Euro20A-OP145
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

Safety and performance of the resorbable magnesium scaffold Magmaris in a real-world setting – first cohort subjects at 12-month follow-up of the BIOSOLVE-IV registry

LEE Michael Kang-Yin [1], LEE Michael Kang-Yin [1], WLODARCZAK Adrian [2], MONTORSI Piero [3], TORZEWSKI Jan [4], BENNETT Johan [5], HAUDE Michael [6], STARMER Gregory [7], BUCK Thomas [8], WIEMER Marcus [9], VERHEYE Stefan [10]

(1) Queen Elizabeth Hospital, Hong Kong, Hong Kong; (2) Miedziowe Centrum Zdrowia SA, Lubin, Poland; (3) Centro Cardiologico Monzino, Milan, Italy; (4) Cardiovascular Center Oberallgaeu-Kempten, Oberallgaeu, Germany; (5) University Hospitals Leuven, Leuven, Belgium; (6) Staedtische Kliniken Neuss-Lukaskrankenhaus GmbH, Neuss, Germany; (7) Cairns Hospital, Cairns, Australia; (8) Klinikum Westfalen, Knappschaftskrankenhaus, Dortmund, Germany; (9) Johannes Wesling Hospital, Minden, Germany; (10) Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium

Aims: The aim of this registry is to investigate the clinical performance and long-term safety of the resorbable magnesium scaffold Magmaris in a real-world setting. Up to 2,054 subjects in up to 120 clinical sites in Europe, Asia and Asia-Pacific countries will enrol in this registry. This registry has two cohorts: the first cohort includes 1,075 subjects and the second cohort will include 979 subjects. Primary endpoint of this registry is powered for the first cohort subjects. This analysis includes the 12-month follow-up data of the first cohort subjects (1,075).

Methods and results: In this prospective, multicentre, controlled, global registry, the first 1,075 subjects with 1,121 *de novo* coronary artery lesions were enrolled between September 2016 and September 2018. Primary endpoint of the registry is target lesion failurev(TLF) assessed at 12-month follow-up. Clinical follow-up visits are scheduled at 6, 12, 24, 36, 48 and 60 months. 806 men (75.0%) and 269 (25.0%) women were enrolled in 23 countries. The mean age was 61.3±10.5 years. The mean lesion length and reference vessel diameters were 14.9±4.2 mm and 3.2±0.3 mm, respectively. Based on the analysed data, 67.3% of the subjects had hypertension, 66.3% had hypercholesterolaemia, 61.1% had a smoking history, and 21.2% of the subjects were diabetic. The percentage of subjects who presented with an NSTEMI was 19.2%. The percentage of type B2/C lesions was 15.2%. At 12 months, 96.9% (1042/1075) follow-up compliance was achieved. Analysed data of the first cohort of BIOSOLVE-IV undergoing 12-month clinical follow-up showed a low TLF rate (4.3%) with a low rate of target vessel myocardial infarction (1.1%), which is comparable to second-generation permanent drug-eluting stents (DES). Analysis of clinically driven target lesion revascularisation resulted in a rate of 3.9% and cardiac death in a rate of 0.2%. Definite or probable scaffold thrombosis rate was 0.5%. Excluding cases with premature antiplatelet or anticoagulant discontinuation, the scaffold thrombosis rate was 0.1%.

Conclusions: The Magmaris scaffold showed an excellent safety profile up to 12 months, comparable to second-generation DES.

CTO - Tools, devices and techniques

Poor distal vessel quality is an independent predictor for the wire manipulation time within 30 minutes on percutaneous coronary intervention for CTO

OCHIUMI Yusuke [(1)], SUZUKI Yoriyasu [(1)], MURATA Akira [(1)], ITO Tatsuya [(1)]

(1) Toyohashi Heart Center, Toyohashi, Japan

Aims: To predict the probability of a successful intervention, the Japan-CTO (J-CTO) score has been widely available. However, poor distal vessel quality (PDV) hasn't been evaluated for the predictor. The present study aimed to verify whether PDV is an independent predictor for a successful guidewire crossing through the chronic total occlusion (CTO) lesion set to within 30 minutes, as used for the J-CTO score.

Methods and results: We examined 193 consecutive CTO–PCIs (percutaneous coronary intervention) performed from January 2013–December 2017. The endpoint including the technical outcomes in these patients with and without PDV was analysed. Moreover, we re-evaluated the predictors for CTO–PCI difficulty according to the J-CTO score. The average J-CTO score in patients was 1.6±1.1. One hundred and eighty-one (93.8%) obtained overall technical success, comprising 101 (55.8%) with and 80 (44.2%) without PDV. The prevalence of successful outcomes with only antegrade wire techniques or antegrade single-wire escalation was significantly lower in patients with PDV than in those without PDV (only antegrade wire techniques: 46.5% vs 83.8%, respectively; p<0.0001) (single-wire escalation: 32.7% vs 75.0%, respectively; p=0.0087). The percentages of successful outcomes for the various techniques were significantly higher in the CTO lesions with PDV than in those without PDV (use of retrograde approach: 53.5% vs 16.3%, respectively, p<0.0001; IVUS-guided technique: 5.9% vs 0%, respectively, p=0.027; RCART: 29.7% vs 7.5%, respectively, p=0.0002). The percentage of procedures with endpoints of successful wire manipulation time of ≤30 min was also significantly lower in the CTO lesions with PDV than in those without PDV (24.8% vs 61.3%, p<0.0001). Multivariate analyses demonstrated that blunt stump, calcification, bending, retry lesion, and PDV were independent predictors of unsuccessful guidewire crossing of ≤30 min (odds ratio [OR]: 0.31, 95% confidence interval [CI]: 0.13–0.71, p=0.0039; OR: 0.34, 95% CI: 0.16–0.71, p=0.0035; OR: 0.17, 95% CI: 0.05–0.60, p=0.0034; OR: 0.18, 95% CI: 0.06–0.54, p=0.0008; and OR: 0.19, 95% CI: 0.09–0.41, p<0.0001, respectively). The area under the receiver operating characteristic curve for the probability of successful guidewire crossing within 30 minutes for J-CTO score was 0.77 and for new a scoring system with PDV added to the J-CTO score was 0.81.

Conclusions: PDV may be the predictor for successful GW crossing within 30 minutes. A new scoring system where PDV adds to the factors could be applied for difficulty grading and procedural time prediction on CTO-PCI.

2020 PCR e-Course Coronary interventions

Euro20A-OP148
Abstract | Oral presentation

Stents and scaffolds - Tools, devices and techniques

A prospective, randomised multicentre study to assess the safety and effectiveness of the Orsiro sirolimus-eluting stent in the treatment of subjects with up to two de novo coronary artery lesions – BIOFLOW IV: five-year clinical results

WITZENBICHLER Bernhard [1], WITZENBICHLER Bernhard [1], SLAGBOOM Ton [4], TÖLG Ralph [2], HAUDE Michael [3], MASOTTI Monica [5], SALMERON Ruiz [6], WITKOWSI Adam [7], SAITO Shigeru [9]

(1) Helios Amper-Klinikum Dachau, Dachau, Germany; (2) SEGEBERGER KLINIKEN GMBH, Bad Segeberg, Germany; (3) Rheinland Klinikum Neuss GmbH - Lukaskrankenhaus, Neuss, Germany; (4) OLVG, locatie Oost, Amsterdam, the Netherlands; (5) Hospital Clínic de Barcelona, Barcelona, Spain; (6) Hospital Universitario Virgen de la Macarena, Sevilla, Spain; (7) Institute of Cardiology, Warsaw, Poland; (8) MedStar Washington Hospital Center, DC, USA; (9) Okinawa Tokushukai Shonan Kamakura General Hospital, Okinawa, Japan

Aims: The aim of the BIOFLOW-IV study is to compare the safety and effectiveness of the Orsiro sirolimus-eluting stent (SES) with the XIENCE Prime/XIENCE Xpedition everolimus-eluting stent (EES) in a prospective multicentre randomised controlled non-inferiority trial in a mixed population of Caucasian and Japanese subjects.

Methods and results: A total of 575 subjects (age 64.7±9.6 years) were enrolled in the intention-to-treat population at 46 sites in Europe, Israel, Japan and Australia. All subjects were randomly assigned (2:1) to receive Orsiro (n= 385) or XIENCE (n=190), respectively. The randomisation was stratified for diabetes. Hypertension (75.1%) and hypercholesteremia (69.0%) were the major cardiovascular risk factors in the overall population. 30.6% of the subjects presented with a history of myocardial infarction. Clinical follow up visits were performed at 1, 6 and 12 months, and annually up to 60 months post index procedure. All angiographic index images were analysed by an independent corelab. All clinical events were adjudicated by an independent clinical events committee. Statistical analysis was performed for the total study population. Both randomisation groups showed comparable baseline results with regard to demographics, medical history and risk factors, and lesion characteristics. The primary endpoint TVF (Universal Definition) rate at 12 months (including a time window of 14 days) was 5.1% in the Orsiro group vs 6.6% in the XIENCE group. Non-inferiority between the two treatment groups was confirmed with p=0.0003. At 48 months (including a time window of 30 days), the TVF failure estimates were 11.8% (Orsiro) vs 10.6% (XIENCE) (p=0.6446) for the overall cohort. Definite or probable stent thrombosis failure estimates were 0.8% in the Orsiro group vs 0.0% in the XIENCE group (p=0.5544). 60-month results show a TVF rate of 12.3% (Orsiro) compared to 10.8% (XIENCE) (p=0.6521). Definite and probable stent thrombosis rates remained unchanged.

Conclusions: The ultrathin Orsiro SES with biodegradable polymer was non-inferior to the XIENCE EES with durable polymer at 12 months for TVF. There were no statistically significant differences in other clinical endpoints at the annual follow-up visits between the two treatment groups in a mixed population of Japanese and Caucasian subjects.

Stable CAD - CT / MRI imaging

CT-based assessment of myocardium at risk: validation versus absolute flow measurement

KEULARDS Danielle [1], KEULARDS Danielle [1], FOURNIER stephane [2,3], VAN 'T VEER Marcel [1], COLAIORI iginio [2], ZELIS Jo [1], EL FARISSI mohamed [1], ZIMMERMANN frederik [1], COLLET carlos [2], DE BRUYNE bernard [2], PIJLS Nico [1]

(1) Catharina Ziekenhuis Eindhoven, Eindhoven, the Netherlands; (2) Onze Lieve Vrouwziekenhuis, Aalst, Belgium; (3) Lausanne University Hospital, Lausanne, Switzerland

Aims: The prognostic importance of a coronary stenosis depends on its functional severity and the myocardial mass. Functional severity can be assessed by fractional flow reserve, estimated non-invasively by FFR-CT. Calculation of myocardial mass at risk by that same CT-algorithm, however, has not been validated so far. The aim of the present study was to compare the distribution of myocardial mass of the three main territories as assessed by that CT-algorithm to the corresponding distribution of blood flow measured invasively, which is known to correspond closely to perfusion territory.

Methods and results: Thirty-five patients with normal or near-normal coronary arteries underwent CT scanning for myocardial mass assessment and invasive absolute coronary blood flow measurement in all three major coronary arteries by continuous thermodilution. The mean difference between mass estimation by CT and by coronary blood flow was 5.3% for the LAD area, 2.0% for the LCx area and 3.1% for the RCA area. The correlation between invasively measured flow in the LCA and RCA territory versus CT-calculated myocardial mass was 0.90 ($p<0.001$, $R2 = 0.81$).

Conclusions: Our study confirms a close relationship between the extent of the perfusion territory calculated by the particular CT-algorithm and invasively measured coronary blood flow in (near-) normal coronary arteries. Therefore, not only the presence and severity of a coronary stenosis (FFRCT) but also the extent of myocardium at risk (CT mass) can be assessed simultaneously by one single CT-investigation.

Stable CAD - Invasive imaging and functional assessment

Intracoronary cardiogram triggered pressure ratio (ICE-T) as an index of diagnosis of myocardial ischaemia

NAKAYAMA Masafumi [1], NAKAYAMA Masafumi [1], UCHIYAMA Takashi [1], TANAKA Nobuhiro [2], MIWA Shunsuke [1], HIJIKATA Nobuhiro [1], KOBORI Yuichi [1], IWASAKI Kiyotaka [3]

(1) Toda Chūō General Hospital, Saitama, Japan; (2) Tokyo Medical University Hachioji Medical Care Center, Tokyo, Japan; (3) Waseda University, Tokyo, Japan

Aims: Isoelectric lines of the intracoronary electrocardiogram (IC-ECG) may represent intervals without regional myocardial electrical potential. We hypothesised that the IC-ECG-based pressure index was more stable and precise than the instantaneous flow reserve (iFR). We investigated the usefulness of the IC-ECG-based pressure index for diagnosing myocardial ischaemia.

Methods and results: Thirty-seven consecutive patients with coronary stenosis requiring physiological assessment were enrolled. iFR at rest and under hyperaemia was measured at 51 and 40 lesions, respectively. The IC-ECG-triggered distal pressure (Pd)/aortic pressure (Pa) ratio (ICE-T) was defined as the average Pd/Pa ratio in the period corresponding to the isoelectric line. Similarly, the electrocardiogram-triggered Pd/Pa ratio (ECG-T) was calculated. The index value and fluctuation of pressure parameters (Pd/Pa, Pa, and Pd) during the analysis interval of each index both at rest and during hyperaemia were compared. Receiver operating characteristic (ROC) curve analysis of resting indices was performed to predict a fractional flow reserve (FFR) value of ≤0.80. The ICE-T value was significantly lower than iFR-online both at rest and during hyperaemia, but the ECG-T value was similar to the iFR-online value. The fluctuations of ICE-T and ECG-T pressure parameters were significantly smaller than the iFR calculation. Diagnostic accuracy was the highest in ICE-T (ICE-T 90.0%, ECG-T 85.0%, and iFR-online 72.5%, respectively). ICE-T showed significantly higher accuracy than iFR-online (p=0.008). ROC curve analyses showed that the ICE-T predicted FFR value of ≤ 0.80 best (area under curve, ICE-T 0.897, ECG-T 0.865, iFR 0.810).

Conclusions: We identified the period in IC-ECG in which the resting Pd/Pa was low and constant and demonstrated that ICE-T had superior accuracy over iFR for diagnosing myocardial ischaemia. The IC-ECG-based algorithm may improve the accuracy of myocardial ischaemia diagnosis, without increasing invasiveness, as compared with pressure-dependent indices.

Stable CAD - Invasive imaging and functional assessment

Contrast-FFR plus intracoronary nitroglycerine acute drop accurately predicts FFR

GUTIÉRREZ-BARRIOS Alejandro [1], GUTIERREZ Alejandro [1], NOVAL-MORILLAS Inmaculada [1], CAMACHO-FREIRE Santiago [2], IZAGA-TORRALBA Elena [1], LIVIA Gheorghe [1], CALLE-PEREZ German [1]

(1) Puerta Del Mar, Cádiz, Spain; (2) Hospital Universitario Juan Ramón Jiménez, Huelva, Spain

Aims: Our aim was to investigate whether radiographic contrast plus intracoronary nitroglycerin acute drop (cFFR-NTG) can predict functional assessment of coronary stenosis offering superior diagnostic agreement with FFR compared to non-hyperaemic indexes and contrast mediated FFR (cFFR).

Methods and results: From June 2016 to June 2019, 266 consecutive patients with 329 angiographic coronary stenoses, functionally evaluated by pressure wire during routine clinical practice, were prospectively enrolled at the two participating centres in Spain. The study consisted of five sequential steps separated by at least 30 seconds until the return of Pd/Pa ratio to baseline value. 1) Resting baseline Pd/Pa was assessed after an initial period of at least 30 seconds after the last contrast injection. 2) Resting iFR or RFR were assessed in a sample of 72 lesions. 3) Contrast-FFR assessment. A single injection of at least 7cc of contrast in the left coronary system and 6cc in the right system was performed per protocol. 4) cFFR-NTG was calculated as the lowest ratio after coronary injection of a 0.2 mg bolus of nitroglycerin plus a contrast injection of at least 4cc (4-6cc) of radiographic contrast (acute drop). 5) FFR was obtained after continuous peripheral intravenous adenosine infusion or intracoronary administration. The reproducibility of cFFR and cFFR-NTG measurement was assessed in a group of 45 and 40 patients, respectively. The coefficient of variation for reproducibility of the 2 measures of both indexes was 1.4% and 1.0% respectively. Comparison of ROC curves was performed using the DeLong method. The ROC curves for cFFR-NTG using an FFR≤0.80 showed a higher accuracy in predicting FFR (AUC 0.97) than resting Pd/Pa (AUC 0.90, $p<0.01$) and cFFR (AUC 0.93.5, $p<0.01$). A significant ($p<0.01$) strong correlation was found between FFR and the four analysed indexes: Pd/Pa($r=0.78$); iFR/RFR ($r=0.73$); cFFR($r=0.89$) and cFFR-NTG($r=0.93$). cFFR-NTG showed the closest agreement at Bland-Altman analysis. According to the Youden index the optimal cutoff values for an FFR>0.8 of resting Pd/Pa, iFR/RFR, cFFR and cFFR-NTG were >0.91, >0.89, >0.85 and >0.84 respectively. The cFFR-NTG cut off value >0.84 showed the highest negative predictive value (88%), specificity (91%), sensitivity (94%) and accuracy (92%) of the studied indexes. cFFR-NTG/FFR hybrid approach showed a significant lower number of lesions requiring adenosine than Pd/Pa and cFFR hybrid approaches($p<0.01$).

Conclusions: The most accurate index in predicting the functional significance of coronary stenosis using FFR as reference was cFFR-NTG. This index is quick, reliable, cheap, easy to perform and it is not the limited proprietary software of one vendor, and may play a role in the setting of physiological assessment of coronary stenosis.

Euro20A-OP152
Abstract | Oral presentation

CTO - Adjunctive pharmacotherapy

Extended role of allied healthcare professionals in complex higher risk (and indicated) patients (CHIP) and complex CTO PCI: value of conscious sedation

MACPHEE-LEECH Lauren [1], MACPHEE-LEECH Lauren [1]

(1) John Radcliffe Hospital, Oxford, United Kingdom

Aims: Nurse-led conscious sedation is currently widely utilised in a number of cardiac procedures. However, its role during PCI has not been explored, likely due to the relatively short duration of most procedures. The use of conscious sedation in CHIP and complex CTO PCI could improve patient experience, reduce procedure time and potentially reduce the number of repeat procedures due to early termination of procedures as a result of patient discomfort. Thus, there is the potential to enhance patient experience and cath lab efficiency and running costs.

Methods and results: We performed a single centre retrospective audit reviewing the last 50 EP procedures utilising conscious sedation and compared them to the last 50 CTO PCI procedures. We compared procedure duration and the quantity of sedation and opiates used. The data show that the mean time for an EP case was 1 hour 59 minutes, compared to the CTO cases being 2 hours 31 minutes. Despite shorter procedure times during the EP cases, larger amounts of sedation and analgesia were utilised.

Conclusions: Given that most cath labs, including our own, have nurses trained in the administration of conscious sedation currently in post, there are no significant barriers to its utilisation. We believe such an approach has the potential to enhance patient experience and enhance cath lab efficiency. We are currently assessing its role in CHIP and complex CTO PCI in a prospective audit focussing on patient safety and satisfaction.

Stents and scaffolds - Invasive imaging and functional assessment

Ten-year clinical outcomes of late-acquired stent malapposition after coronary stent implantation

LEE Seung-Yul [1], LEE Seung-Yul [1], HONG Myeong-Ki [2], AHN Jung-Min [3], PARK Seung-Jung [3]

(1) Wonkwang University Medical Center, Jeollabuk-do, Republic of Korea; (2) Severance Hospital, Seoul, Republic of Korea; (3) Asan Medical Center, Seoul, Republic of Korea

Aims: The goal of this study was to determine the impact of late-acquired stent malapposition (LASM) on long-term clinical outcomes in patients treated with coronary stent implantation.

Methods and results: We investigated major adverse cardiac events (MACE) over 10 years after 6-month intravascular ultrasound (IVUS) examination using our previous studies database. A total of 732 patients treated with bare-metal stents (BMS; 54 LASM versus 678 non-LASM) and 529 patients treated with first-generation drug-eluting stents (DES; 82 LASM versus 447 non-LASM), who did not have clinical events or censoring at the time of follow-up IVUS, were included for the present analysis. MACE was defined as the composite of cardiac death, target vessel-related myocardial infarction, target lesion revascularisation and stent thrombosis. Multivariable adjustment and inverse probability weighting were performed to consider baseline differences. After multivariable adjustment, LASM was related to a greater risk of MACE (hazard ratio [HR]=1.666, 95% confidence interval [CI]=1.041-2.665, p=0.0333) and very late stent thrombosis (HR=3.529, 95% CI=1.153-10.798, p=0.0271) than non-LASM in patients treated with first-generation DES, but not in those treated with BMS. Results were consistent after inverse probability weighting. Among patients with LASM of first-generation DES, no very late stent thrombosis occurred in patients who continued to receive dual antiplatelet therapy.

Conclusions: The relationship between LASM and MACE might depend on the type of implanted stent during the long-term follow-up, highlighting the clinical significance of polymers and drugs in DES systems.

Left main and multivessel disease - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Comparison of single-stent vs dual-stent techniques for unprotected left main bifurcation PCI: a propensity-score analysis of the DELTA 2 multicentre registry

BENEDUCE Alessandro [1], BENEDUCE Alessandro [1], MORONI Francesco [1], TRIVELLIZZI Alfredo M. [1], GIUSTINO Gennaro [2], BRIEDE Ieva [3], SAWAYA Fadi J. [4], DAEMEN Joost [5], KAWAMOTO Hiroyoshi [6], MONTORFANO Matteo [1], CHIEFFO Alaide [1]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy; (2) Mount Sinai Medical Center, NY, USA; (3) Pauls Stradiņš Clinical University Hospital, Riga, Latvia; (4) Hôpital Privé Jacques Cartier, Massy, France; (5) Erasmus Medical Center, Rotterdam, the Netherlands; (6) New Tokyo Hospital, Chiba, Japan

Aims: Optimal bifurcation PCI strategy for distal left main lesions is still a matter of debate. The aim of this study was to compare clinical outcomes of 1-stent vs 2-stent PCI strategy with new-generation DES for unprotected distal left main interventions in the DELTA 2 multicentre registry.

Methods and results: A subgroup analysis from the multicentre DELTA 2 registry was performed. The primary objective was a composite of all-cause death, MI and CVA. Secondary endpoints included clinically-driven target lesion revascularisation and stent thrombosis. Of 3,986 patients included in the DELTA 2 registry, 3,372 underwent PCI for distal left main involvement. Overall, 2,258 patients (75%) were treated using a 1-stent (provisional) technique, while 753 patients (35%) were treated using a 2-stent technique, encompassing T-stenting/TAP (46%), crush/mini-crush (27%), culotte (23%) and V-stenting (4%). True bifurcation lesions were observed in 1,412 patients (47%) and were more frequently treated using the 2-stent technique (84% vs 37%, p<0.001). The use of IVUS was significantly higher in patients treated with the 2-stent technique (50% vs 37%, p<0.001). Multivessel disease (87% vs 78%, p<0.001) and the use of femoral access route (63% vs 53%, p<0.001) were also significantly more prevalent in the 2-stent group. Conversely, diabetes (31% vs 26%, p=0.016), previous PCI (47% vs 40%, p=0.003) and previous CABG (11% vs 5%, p<0.001) were significantly more prevalent in the 1-stent group. After propensity score adjustment, at 3-year follow-up, there was no significant difference in the primary composite endpoint, while the rate of MACCE was significantly higher in patients treated with the 2-stent technique (29% vs 19%, adjusted HR 1.24, 95% CI: 1.04-1.52, p=0.038), as well as the rate of clinically-driven TLR (13% vs 7%, adjusted HR 1.61, 95% CI: 1.18-2.19, p=0.003). There was no difference regarding the specific technique used. At Cox multivariate analysis, the 2-stent technique was an independent predictor of MACCE (p<0.001) and TLR (p=0.016).

Conclusions: Among patients undergoing unprotected left main bifurcation PCI with new-generation DES in a large real-world population, the use of a 1-stent (provisional) technique was associated with lower rates of MACCE and clinically-driven TLR at 3-year follow-up compared to a 2-stent technique.

Euro20A-OP006
Abstract | PCR's Got Talent

Stable CAD - Invasive imaging and functional assessment

Invasive assessment of the causes of persistent angina in patients with previous ischaemic heart disease and complete revascularisation

SIGISMONDI ANDREA [(1)], SIGISMONDI Andrea [(1)], ROA GARRIDO Jessica [(1)], ORTIZ CRUCES Samuel [(1)], SANCHEZ FERNANDEZ Irene [(1)], GOMEZ FERNANDEZ Prudencia [(1)], LANDERO GARCIA Francisco Javier [(1)], GRACIA HIRALDO Maria Eugenia [(1)], BOBO MASSO Esteban [(1)], CARDENAL PIRIS Rosa [(1)], DIAZ FERNANDEZ Jose Francisco [(1)]

(1) Hospital Juan Ramón Jiménez - Huelva, Huelva, Spain

Aims: Patients with coronary artery disease and previous complete revascularisation can suffer angina and can present ischaemia in invasive functional testing without progression of the stenosis in the epicardial coronaries. We proposed to invasively assess the possible underlying causes of persistent/recurrent angina in patients with coronary disease and complete revascularisation.

Methods and results: We recruited 42 patients, from January 2018 until April 2019, with angina and/or positive invasive functional testing for ischaemia and angiographic coronary stenosis <70%. In these patients we assessed the fractional flow reserve and the induction of vasospasm by injection of acetylcholine. The mean age of the patients was 64.88±10,01 years, 47.6% were diabetic and 23.7% were active smokers. The most treated vessel was the left anterior descending artery (78.6%) followed by the left circumflex artery (42.9%), right coronary artery (39%) and left main coronary artery (23.8%). Epicardial stenosis, assesed by the criterion of a fractional flow reserve (FFR) <0.8, was found in 33% of the patients with a mean FFR of 0.83±0.8; reduced coronary flow (coronary flow reserve <2) in 40.5% with a mean coronary flow reserve 3.58±3.21; high index of microvascular resistance (> 25) in 45.2% with a mean index of microvascular resistance 27.4±18.92; positive acetylcholine test in 69% (52.4% with diffuse spasm). In only 3 patients the cause of the chest pain was not found.

Conclusions: In patients with angina and previously treated coronary disease, if there is not progression of the epicardial disease, the most frequent cause of chest pain is endothelial dysfunction, followed by microvascular stenosis. Applying these tests, only in less than 10% of patients the cause of the persistence of chest pain is not found.

STEMI - Invasive imaging and functional assessment, NSTEMI - Invasive imaging and functional assessment

Identification of three novel phenotypes of cardiogenic shock

ZWECK Elric [1,2], ZWECK Elric [1,2], THAYER Katherine L [1], HELGESTAD Ole K L [3,16], AYOUTY Mohyee [4], GARAN A Reshad [5], HERNANDEZ-MONTFORT Jaime [6], MAHR Claudius [7], WENCKER Detlef [8], SINHA Shashank S [9], VOROVICH Esther [10], ABRAHAM Jacob [11], O'NEILL William [12], JOSIASSEN Jacob [13], HASSAGER Christian [13,14], JENSEN Lisette O [3], HOLMVANG Lene [13,14], SCHMIDT Henrik [3], RAVN Hanne B [13,14], MØLLER Jacob E [3,16], BURKHOFF Daniel [15], KAPUR Navin K [1]

(1) Tufts Medical Center, MA, USA; (2) Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; (3) Odense Universitetshospital, Odense Municipality, Denmark; (4) Tufts University School of Medicine, Boston, MA, USA; (5) Beth Israel Deaconess Medical Center (BIDMC), MA, USA; (6) Cleveland Clinic Florida, FL, USA; (7) University of Washington, WA, USA; (8) Baylor Scott & White Medical Center - Plano, TX, USA; (9) Inova Heart and Vascular Institute, VA, USA; (10) Northwestern Medicine, IL, USA; (11) Providence Heart Institute, Portland, OR, USA; (12) Henry Ford Hospital, MI, USA; (13) Rigshospitalet, Copenhagen Municipality, Denmark; (14) University of Copenhagen, Copenhagen, Denmark; (15) Cardiovascular Research Foundation, NY, USA; (16) OPEN, Open Patient data Explorative Network, Odense Municipality, Denmark

Aims: Cardiogenic shock (CS) is a heterogenous syndrome, mostly emerging from acute myocardial infarction (AMICS) or acute-on-chronic heart failure (HFCS). CS mortality remains unacceptably high despite several novel therapeutic options. Deep phenotyping of diseases can pave the way for more individualised trials and treatment but has never been tried in CS. We hypothesise that there are distinct clusters/phenotypes of CS which are identifiable using unbiased machine learning techniques and allow for risk stratification of CS patients.

Methods and results: Clusters were identified in an AMICS derivation cohort from the Cardiogenic Shock Working Group Registry (CSWG-MI, n=408) and subsequently tested in AMICS patients from the Danish Retroshock Registry (DRR, n=947) and an HFCS cohort (CSWG-HF, n=480) for external validation. We used a combination of different machine learning techniques (e.g. hierarchical clustering, consensus-k means clustering, random forest classification) to identify and validate emerging clusters internally and externally and to optimise cluster granularity whilst achieving minimised bias. AMICS patients in CSWG-MI and DRR clustered independently into three clusters, when the same clustering algorithm was applied. CSWG-HF patients were also assigned to these clusters using a random forest classifier. We subsequently assigned labels to the phenotypes based on their clinical appearance: "non-congested CS" whose patients exhibit higher cardiac output and lower cardiac filling pressures compared to the other clusters; "cardiorenal CS", comprised of older patients with several comorbidities, impaired kidney function and primarily left ventricular impairment; and "cardiometabolic CS", standing out with right ventricular failure, elevated serum lactate and alanine aminotransferase (ALT) levels and the overall worst cardiac function. Despite pre-clustering differences of the cohorts, phenotype composition within each cohort was similar, revealing reproducible trends of demographic, metabolic, and haemodynamic parameters. Mean age was 62.3±14 vs 69.3±11.5 vs 63.7±13.2 years ($p<0.001$), lactate was 2.5 [1.5, 4.2] vs 1.8 [1.4, 2.5] vs 6.6 [4.9, 9.7] mmol/l ($p<0.001$), glomerular filtration rate was 81.4±16.4, 30.4±13.8, 50.8±17 mL/min/1.73m² ($p<0.001$), ALT was 49 [23, 86] vs 52.5 [23.8, 111] vs 110 [57, 273] U/L ($p<0.001$), and right atrial pressure was 13±5.8 vs 15±7.2 vs 16.8±6.6 mmHg ($p=0.001$) in "non-congested CS" vs "cardiorenal CS" vs "cardiometabolic CS" in CSWG-MI. The "cardiorenal" phenotype was more frequently observed in HFCS than in AMICS patients (53.8% vs 35.3% and 30.9%, $p<0.001$) while the "cardiometabolic" phenotype was less common in HFCS patients (13.8% vs 29.2% and 36%, $p<0.001$). In-hospital mortality was 21-26% for the "non-congested", 41-45% for the "cardiorenal", and 55% for the "cardiometabolic" CS, respectively ($p<0.001$ for difference between phenotypes). In CSWG-HF, mortality for the respective phenotypes was 9%, 30%, and 53% ($p<0.001$).

Conclusions: We hereby identified three unbiased phenotypes of CS, that emerged in independent cohorts from different countries. These clusters will allow past and future CS trials to stratify their patients and outcomes by phenotype to achieve more specific results and thereby establishing a basis for more individualised healthcare. Using the CS phenotypes in the clinical setting may lead to development of treatment strategies tailored to improve outcomes for unique subsets of CS patients.

Left main and multivessel disease - Adjunctive pharmacotherapy

Safety and efficacy of one-month DAPT followed by 23-month ticagrelor monotherapy in patients undergoing staged PCI

KAWASHIMA Hideyuki [1,2], KAWASHIMA Hideyuki [1,2], TOMANIAK Mariusz [3], ONO Masafumi [1,2], WANG Rutao [1], HARA Hironori [1,2], TAKAHASHI Kuniaki [2], GAO Chao [1], MODOLO Rodrigo [2,4], ONUMA Yoshinobu [1], SERRUYS Patrick [1]

(1) University Hospital Galway, Galway, Ireland; (2) University of Amsterdam, Amsterdam, the Netherlands; (3) University of Warsaw, Warsaw, Poland; (4) University of Campinas, State of São Paulo, Brazil

Aims: Optimal antiplatelet treatment regimens in patients undergoing staged percutaneous coronary intervention (PCI) have not yet been specifically evaluated. Our study investigated whether patients undergoing staged PCI might benefit from a novel aspirin-free antiplatelet regimen compared with a standard dual antiplatelet therapy (DAPT) regimen using the all-comers GLOBAL LEADERS population.

Methods and results: This is a *post hoc* sub-analysis of the multicentre, prospective, and open-label randomised controlled GLOBAL LEADERS trial, comparing the experimental strategy of 1-month DAPT (aspirin and ticagrelor) followed by 23-month ticagrelor monotherapy and the reference regimen of 12-month DAPT, followed by 12-month aspirin monotherapy in patients undergoing staged and non-staged procedures. The primary endpoint was the composite of all-cause death or new Q-wave myocardial infarction at 2 years, and the key secondary endpoint was bleeding according to Bleeding Academic Research Consortium criteria type 3 or 5. Of 15,968 randomised patients, a total of 1,651 patients underwent staged PCI according to the trial protocol definition. At 2 years, the risks of the primary and key secondary endpoint were similar between the 2 regimens. In CCS patients undergoing staged PCI, the experimental strategy tended to increase the risk of all-cause death (4.1% vs 1.7%, HR 2.465; 95% CI: 0.888-6.845, p=0.083), and it was not seen in patients with non-staged PCI (Pinteraction=0.042). In ACS patients undergoing staged PCI, the risks of BARC type 3 or 5 (1.8% vs 4.5%, HR 0.387; 95% CI: 0.179-0.836, p=0.016) and BARC type 2, 3, or 5 bleeding (5.7% vs 11.2%, HR 0.496; 95% CI: 0.317-0.776, p=0.002) were significantly lower in the experimental group, especially with regard to BARC type 2, 3, or 5 bleeding; That observation was not made in patients with non-staged PCI (Pinteraction=0.011).

Conclusions: In patients with staged PCI, one-month DAPT followed by 23-month ticagrelor monotherapy is associated with different safety profile depending on clinical presentation, with an increased risk of all-cause death in CCS and a reduced bleeding rates in ACS, achieved without any trade-off in the risk of ischaemic events.

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Abstract | PCR's Got Talent

Left main and multivessel disease - Tools, devices and techniques, CTO - Tools, devices and techniques

Effectiveness of high-flow percutaneous mechanical circulatory support or IABP for complex higher-risk but indicated patients undergoing PCI

YBARRA Luiz [1,2], YBARRA Luiz Fernando [1,2], BONNET Marc [1], DAUTOV Rustem [1,3], ALJOHANI Khaled [1], ESMAIEL Abdullah [1], SPAZIANO Marco [1], MARTUCCI Giuseppe [1], PIAZZA Nicolo [1], DANDONA Sonny [1], RINFRET Stéphane [1]

(1) McGill University Health Centre, QC, Canada; (2) London Health Sciences Centre, ON, Canada; (3) The Prince Charles Hospital, QLD, Australia

Aims: There is a paucity of data on complex higher-risk but indicated patients undergoing percutaneous coronary intervention (PCI).

Methods and results: We performed a prospective single-centre cohort study collecting baseline and procedural characteristics, and in-hospital outcomes in complex higher-risk but indicated patients undergoing PCI. Patients perceived at lower risk were managed with intra-aortic balloon pump (IABP) and those at higher-risk with high-flow mechanical circulatory support. From January 2016 to December 2019, 94 complex higher-risk but indicated patients underwent PCI under haemodynamic support (high-flow mechanical circulatory support: 54 [53 on Impella CP and 1 on Tandem Heart]; IABP: 36). Overall, 81% were previously turned down for coronary artery bypass surgery (CABG) or had already had CABG (high-flow mechanical circulatory support: 89% vs IABP: 69%, p=0.01). In non-CABG patients, SYNTAX score was very high (high-flow mechanical circulatory support: 44±11 vs IABP: 41±16, p=NS). High-flow mechanical circulatory support patients had more history of heart failure (57% vs 28%, p<0.01) and had lower ejection fraction (25±12 vs 40±15, p<0.01). The need for retrograde chronic total occlusion PCI and acute heart failure were more common in the high-flow mechanical circulatory support group (39% vs 7.8%, p=0.01 and 45% vs 24%, p=0.04, respectively). SYNTAX score reduction was high in the entire cohort (34±13). Despite higher-risk features, the high-flow mechanical circulatory support group had similar in-hospital mortality (high-flow mechanical circulatory support: 11% vs IABP: 13%, p=NS), but major bleeding and acute kidney injury were more common with high-flow mechanical circulatory support. Univariate baseline predictors of in-hospital death included age and female sex. Patients who survived to discharge had more often an ejection fraction <30% (66%) than those who died (27%) (p=0.01).

Conclusions: In complex higher-risk but indicated patients, substantial reduction in SYNTAX score was achieved after supported PCI. Selective use of high-flow mechanical circulatory support seems to mitigate the acute adverse effect of low ejection fraction on a high observed in-hospital mortality.

STEMI - Adjunctive pharmacotherapy

Aspirin, ticagrelor and heparin pre-transfer versus similar precatherisation treatment in STEMI on pre-PCI TIMI flow

D'ENTREMONT Marc-André [1], DENTREMONT Marc-André [1], LAFERRIÈRE Chloë [1], NGUYEN Michel [1], BÉRUBÉ Simon [1], COUTURE Étienne [1], VERRAULT-JULIEN Louis [1], LEMAIRE-PAQUETTE Samuel [1], GARANT Marie-Pierre [1], KARZON Anthony [1], DESGAGNÉS Noémie [1]

(1) CHUS Fleurimont, QC, Canada

Aims: Whether early combined antithrombotic therapy with aspirin, ticagrelor and unfractionated heparin (UFH) in STEMI patients can improve clinical outcomes is unknown. The only RCT comparing prehospital to in-catherisation laboratory administration of ticagrelor did not demonstrate an increase in pre-PCI TIMI flow in the IRA. Data regarding the efficacy of UFH in this clinical setting is lacking. The objective of this novel study was to evaluate the effects of early pre-treatment with aspirin, ticagrelor and UFH on pre-PCI TIMI flow in the IRA in acute STEMI patients.

Methods and results: This retrospective cohort study was conducted in a spoke and hub STEMI network where patients diagnosed in peripheral hospitals and patients diagnosed by ambulance personnel in the prehospital setting are transferred to the hub hospital for emergent primary PCI. We retrospectively compared 488 STEMI patients receiving aspirin, ticagrelor and UFH pre-treatment at the peripheral hospital before transfer (PHT) versus 233 prehospital triage setting (PTS) STEMI patients receiving in-ambulance aspirin, followed by ticagrelor and UFH pre-treatment in the catherisation laboratory. The primary outcome was the presence of a pre-PCI TIMI flow 2-3 in the IRA and the secondary outcome was the presence of definite in-hospital stent thrombosis. The median times from ticagrelor and UFH administration to angiography in the PHT group and the PTS group were 80 minutes (95% CI: 68.5-93.9) and 10 minutes (95% CI: 5-15.5), respectively ($p<.0001$). Using inverse probability of treatment weighting to minimise heterogeneity between the two groups, there was a significant difference for the primary outcome (44.7% vs 18.9%, $p<.0001$) and for definite in-hospital stent thrombosis (0.6 vs 2.6%, $p=0.03$) in the PHT vs the PTS group, respectively. Rates of major bleeding events as defined by the Bleeding Academic Research Consortium (BARC) were low and not significantly different between groups. Each 10-minute delay between ticagrelor and heparin administration and angiography was associated with a reduced pre-PCI TIMI flow (OR 0.89, 95% CI: 0.85-0.93).

Conclusions: STEMI patients receiving aspirin, ticagrelor and UFH before peripheral hospital transfer have a significantly greater pre-PCI TIMI flow and a lower rate of definite in-hospital stent thrombosis compared to patients receiving in-ambulance aspirin in the prehospital setting followed by ticagrelor and heparin in the catherisation laboratory without greater bleeding risk. A hypothesised mechanism for this improvement may be explained by the longer time interval between ticagrelor pre-treatment and angiography, thus falling into a more effective therapeutic window of ticagrelor. Furthermore, UFH may play a synergistic role with ticagrelor and aspirin in decreasing the pre-PCI thrombus burden. Further studies are warranted to assess whether such results can be reproduced in a randomised prehospital triage population.

Stents and scaffolds - Tools, devices and techniques

Hybrid PCI: combination DES and DEB therapy to treat complex coronary disease

KHOKHAR Arif [1], KHOKHAR Arif [1], GALLO Francesco [1], LARICCHIA Alessandra [1], PONTICELLI Francesco [1], RUGGIERO Rossella [1], STICCHI Alessandro [1], FERRARO Massimo [2], MANGIERI Antonio [1], GIANNINI Francesco [1], COLOMBO Antonio [1,2]

(1) Maria Cecilia Hospital, Province of Ravenna, Italy; (2) EMO GVM - Centro Cuore Columbus, Metropolitan City of Milan, Italy

Aims: Simultaneous use of DES and DEB is increasingly being considered as a hybrid approach to PCI. This strategy offers significant advantages in treating complex bifurcation and long diffuse coronary disease, however limited data exists. We sought to determine the long-term outcomes following combined use of DES with DEB in the same coronary vessel.

Methods and results: We retrospectively evaluated all patients who underwent simultaneous DES and DEB implantation (hybrid PCI) in the same coronary vessel between February 2007 and May 2019. The cohort was split according to whether hybrid PCI was used to treat bifurcation (BIF) or non-bifurcation (nBIF) disease, which included long diffuse disease and bail-out stenting. A range of different generation DES and DEB were implanted for stable coronary artery disease. Follow-up consisted of clinical evaluation and invasive angiography when clinically indicated. The endpoints analysed were rates of restenosis, target lesion revascularisation (TLR) and target vessel revascularisation (TVR). Hybrid PCI of the same vessel was performed in 250 vessels (225 patients, median age 68 years, 95% male). 27% had diabetes, 61% hypertension, 53% hypercholesterolaemia, 80% previous PCI and 33% previous AMI. Hybrid PCI was most commonly performed in the left anterior descending artery and its branches (112/250, 45%), followed by the circumflex artery (64/250, 26%), right coronary artery (59/250, 23%), left main stem (9/250, 4%) and other vessels (6/250, 2%). In the LAD, the median length of DES and DEB implanted was 24mm (IQR 16-30) and 30mm (IQR 30-40) respectively. A hybrid approach was used to treat bifurcation disease in 58/250 (23%) vessels and lesions were complex with 92% being type B2/C and 13% being calcified. Angiographic success with TIMI 3 flow was achieved in all treated vessels. There were four procedural complications (one dissection and three coronary perforations), which were all successfully managed with no in-hospital deaths. Angiographic follow-up was available in 98/225 (44%) of patients. Angiographically-determined significant restenosis was seen in 40/98 (16%) of cases and there was no significant difference in rates between the two groups (BIF 39.1% vs nBIF 41.3%, p=0.851). At a median follow-up of 13 months (IQR=26), rates of TLR and TVR were 16.4% and 20% respectively. Similar rates of TLR (BIF 16.1% vs nBIF16.5%, p=0.94) and TVR (BIF 16.1% vs nBIF 21.1%, p=0.4) were seen in both groups. On Cox regression analysis, previous PCI (hazard ratio (HR) 4.8, 1.6-14.1; p<0.01) presence of diabetes (HR 2.57, 1.28-5.16; p<0.05) and ostial disease (HR 6.33, 1.46-27.5; p<0.05) were strong predictors of both TLR and TVR in all patients.

Conclusions: Combining DES and DEB therapy in the same vessel is a safe and effective strategy to treat complex coronary disease, whilst limiting the length and number of implanted stents. This hybrid approach resulted in acceptable long-term rates of restenosis, TLR and TVR with no significant difference observed between bifurcation or non-bifurcation disease.

CTO - Invasive imaging and functional assessment

OCT follow-up after successful recanalisation of coronary CTO

AMAT-SANTOS Ignacio J. [1], SANTOS-MARTINEZ Sandra [1], REDONDO Alfredo [1], ALONSO Carlos [1], CAMPO Alberto [1], GUTIÉRREZ Hipólito [1], RAMOS Benigno [1], DELGADO ARANA Jose Raul [1], GÓMEZ Itziar [1], SAN ROMAN Jose A [1], AMAT-SANTOS Ignacio J. [1]

(1) University Clinical Hospital of Valladolid, Valladolid, Spain

Aims: To characterise the healing process of successfully treated coronary chronic total occlusions (CTOs) through systematic optical coherence tomography (OCT) follow-up.

Methods and results: All patients who underwent successful percutaneous recanalisation of coronary CTOs in our institution from July 2018 to July 2019 underwent angiographic and OCT analysis at 6-month follow up. Images were centrally analysed in a corelab. A total of 89 patients underwent percutaneous coronary intervention (PCI) of a CTO. Successful recanalisation was achieved in 80 cases (89%). Briefly, dual catheter technique was used in 87.6% of the cases, with successful antegrade and retrograde recanalisation in 87.5% and 12.5% of the cases, respectively, and final result assessment with intravascular ultrasound in 33.8% of the cases. No procedural or in-hospital deaths occurred, one patient had cardiac tamponade that was percutaneously solved and one more had retroperitoneal haematoma that required vascular surgery. At a mean time of 7.1±1.9 months after the procedure, all patients underwent clinical follow up with angiographic and OCT analysis in 71 patients (88.75% of the successful cases). One patient presented non-cardiovascular death, and one more an NSTEMI due to new lesion in a different vessel. Angiographic analysis revealed one case of asymptomatic occlusion of the treated CTO; the vessel was treated and OCT revealed subclinical thrombosis due to severe under-expansion of the prior stent. Of the analysed struts, 73% were endothelialised, minimal and mean lumen areas were 7.4±1.4 and 8.7±1.7 mm^2, respectively, and strut malapposition was found in 17.2%. No cases of binary restenosis were found. Fifteen patients (18.7%) presented a finding by OCT that led to intervention. In 7 cases (8.7%) under-expansion of the stents implanted to treat the CTO was found and required post-dilation in 6 cases (lithoplasty in 2 cases), and new stent implantation in 2 cases. In addition, 8 cases presented new lesions proximal (3 cases, 3.75%) or distal (5 cases, 6.25%) to the treated segment requiring stenting (6 cases, 7.5%) of drug-eluting balloon dilation (2 cases, 2.5%).

Conclusions: OCT at 6-month follow up of coronary CTOs demonstrated a high rate of findings requiring intervention (18.7%), including need for new stenting in 10%. These findings suggest a need for greater use of intravascular imaging at the end of successful recanalisation of CTOs, and a clinical benefit of angiographic and intracoronary imaging analysis at short-term follow-up even in asymptomatic patients.

STEMI - Tools, devices and techniques

Pressure-controlled intermittent coronary sinus occlusion improves the vasodilatory microvascular capacity and reduces myocardial injury in patients with STEMI

SCARSINI Roberto [1], SCARSINI Roberto [1], TERENTES-PRINTZIOS Dimitrios [1], KOTRONIAS Rafail [1], LANGRISH Jeremy [1], LUCKING Andrew [1], KHARBANDA Rajesh [1], CHANNON Keith [1], DE MARIA Giovanni Luigi [1], ADRIAN Banning [1]

(1) John Radcliffe Hospital, Oxford, United Kingdom

Aims: Pressure-controlled intermittent coronary sinus occlusion (PICSO) demonstrated to be effective in reducing the infarct size in ST-elevation myocardial infarction (STEMI) and its possible role in patients undergoing primary percutaneous intervention (PPCI) is under evaluation in the randomised PICSO-AMI I trial. PICSO improves the microcirculatory function in STEMI patients. However, its exact mechanism of action remains unclear. We hypothesise that an important determinant of PICSO effect is the increase of microvascular vasodilatory capacity in the infarct-related artery.

Methods and results: 34 patients with STEMI (27 anterior STEMI and 7 inferior STEMI) underwent PPCI and were included in the Oxford Acute Myocardial Infarction – PICSO (OxAMI-PICSO) study. Median age was 63 (55-70) years and 82% were male. Thermodilution-derived index of microcirculatory resistance (IMR) and coronary flow reserve (CFR) were assessed before stent implantation (immediately after flow restoration) and at completion of PPCI. Vasodilatory microcirculatory capacity was assessed using the resistive reserve ratio (RRR). Per protocol, PICSO was considered in case of severe coronary microcirculatory dysfunction, defined as IMR >40 Units. Infarct size (IS) and microvascular obstruction (MVO) were assessed using cardiac magnetic resonance imaging at 48 hours and 6 months of follow up. A control group derived from an historical cohort of STEMI patients with IMR >40 Units was enrolled for comparison (n=50). At baseline, median values of IMR (58.9 [49.2-74.1] vs 73.6 [49.6-81.3], p=0.23), CFR (1.03 [1.00-1.43] vs 1.1 [1.00-1.40], p=0.86) and RRR (1.21 [1.02-1.57] vs 1.40 [1.12-1.64], p=0.11) were similar between PICSO group and controls. PICSO significantly improved the microvascular vasodilatory capacity (post-PICSO RRR=1.87 [1.62-2.53, p<0.001), whereas RRR did not change significantly after PPCI in the control group (1.44 [1.08-2.23], p=0.16). RRR was significantly higher in PICSO patients compared with controls at completion of PPCI (p=0.003). At 48 hours PICSO patients had significantly smaller MVO (3.0 [0.0-6.5] vs 5.0 [1.4-9.3] % of myocardium, p=0.047) but similar IS% (36.0 [21.0-43.5] vs 41.0 [31.5-46.0], p=0.086) compared with controls. At 6 months the final IS% was significantly smaller (26.0 [17.0-30.0] vs 31.5 [28.0-37.0], p=0.003) in patients who underwent PICSO-assisted PPCI.

Conclusions: PICSO increased the microvascular vasodilatory capacity in STEMI patients undergoing PPCI. PICSO-assisted PPCI may be considered to improve the microvascular function and reduce the myocardial injury in STEMI patients with severe coronary microcirculatory dysfunction.

Stable CAD - Bypass surgery, Stents and scaffolds - Tools, devices and techniques

Safety and efficacy of embolic protection devices in saphenous vein graft interventions: a propensity score analysis – multicentre SVG PCI PROTECTA study

WANHA Wojciech [1], WANHA Wojciech [1], MIELCZAREK Maksymilian [2], GILIS-MALINOWSKA Natasza [2], ROLEDER Tomasz [3], LADZINSKI Szymon [1], MILEWSKI Marek [1], CIECWIERZ Dariusz [2], GASIOR Pawel [1], PAWLOWSKI Tomasz [1], JANUSZEK Rafal [4], KOLODZIEJCZAK Michalina [5], BARTUS Stanislaw [4], GRUCHALA Marcin [2], SMOLKA Grzegorz [1], NAVARESE Eliano Pio [6], DUDEK Dariusz [4], OCHALA Andrzej [1], KEDHI Elvin [1], JAGUSZEWSKI Milosz [2], WOJAKOWSKI Wojciech [1]

(1) Medical University of Silesia, Katowice, Poland; (2) Medical University of Gdansk, Gdansk, Gdansk, Poland; (3) Regional Specialist Hospital, Research, and Development Center, Wroclaw, Poland; (4) Jagiellonian University Medical College, Kraków, Poland; (5) Antoni Jurasz University Hospital, Bydgoszcz, Poland; (6) Interventional Cardiology and Cardiovascular Medicine Research, Mater Dei Hospital, Bari, Bari, Italy

Aims: Data regarding the efficacy of embolic protection devices (EPDs) in saphenous vein graft (SVG) percutaneous coronary intervention (PCI) is controversial. The primary objective of the study was to compare 1-year clinical outcomes of SVG PCI with and without EPDs in an all-comer population.

Methods and results: This was a multicentre registry comparing PCI with and without EPDs in consecutive patients undergoing PCI of SVG. The group consisted of 792 patients, including 266 (33.6%) patients with MI. The primary composite endpoint was MACCE defined as death, myocardial infarction (MI), target vessel revascularisation (TVR), and stroke assessed at one year. After propensity score analysis, there were no differences in MACCE (21.9% vs 23.9%; HR 0.91, 95% CI: 0.57-1.45, p=0.681, respectively) nor in secondary endpoints of death, MI, TVR, target lesion revascularisation (TLR) and stroke at one year in EPDs PCI group vs no-EPDs PCI group. Similarly, there were no differences between groups in the study endpoints at 30 days follow up. However, a sub-analysis comparing SVG PCI with Spider-EPDs vs no-EPDs groups, presented a trend towards lower risk of death in the device group (2.1% vs 7.8% HR 0.26, 95% CI: 0.06-1.07, p=0.062, respectively).

Conclusions: There was no clinical benefit for routine use of EPDs during SVG PCI in short- and long-term follow-up. However, a favourable outcome was observed for Spider-EPD guided SVG PCI, which warrants further device-oriented studies.

CTO - CT / MRI imaging

Viability and functional recovery after CTO PCI

DE WINTER Ruben W. [1], SCHUMACHER Stefan P. [1], EVERAARS Henk [1], STUIJFZAND Wijnand J. [1], VAN DIEMEN Pepijn A. [1], BOM Michiel J. [1], VAN LOON Ramon B. [1], VAN ROSSUM Albert C. [1], OPOLSKI Maksymilian P. [2], NAP Alexander [1], KNAAPEN Paul [1]

(1) Amsterdam UMC - Locatie VUmc, Amsterdam, the Netherlands; (2) Instytut Kardiologii im. Prymasa Tysiąclecia Kardynała Stefana Wyszyńskiego, Warsaw, Poland

Aims: Current guidelines advocate viability assessment to guide percutaneous coronary intervention (PCI) of chronic coronary total occlusions (CTO). The aim of the present study was to evaluate viability as well as global and regional functional recovery after successful CTO PCI using quantitative cardiac magnetic resonance (CMR) imaging.

Methods and results: 132 patients with sequential CMR at baseline and 3 months after successful CTO PCI were prospectively recruited between 2013 and 2018. Segmental wall thickening (SWT) and percentage late gadolinium enhancement (LGE) were quantitatively measured per segment. Viability was defined as dysfunctional myocardium (<2.84mm SWT) with no or limited scar (≤50% LGE). Significant improvements in left ventricular (LV) ejection fraction (from 48.1±11.8 to 49.5±12.1%, p<0.01), LV end-diastolic volume (from 99.1±31.8 to 95.7±30.2ml, p<0.01), and LV end-systolic volume (from 54.4±30.5 to 51.2±29.3ml, p<0.01) were observed after CTO PCI. CTO segments with viability (N=216, (31%)) demonstrated a significantly higher increase in SWT (0.80±1.39mm) compared to CTO segments with preprocedural preserved function (N=456 (65%), 0.07±1.43mm, p<0.01) or extensive scar (LGE >50%, N=26 (4%), -0.08±1.09mm, p<0.01). Improvement in SWT was comparable between segments with viability if further stratified to 0, >0-25, and >25-50% hyperenhancement (p=0.94). Patients with ≥2 CTO segments viability showed more SWT increase in the CTO territory compared to patients with 0-1 segment viability (0.49±0.93 vs 0.12±0.98mm, p=0.03).

Conclusions: Improvements in LV function and volumes were significant but modest following CTO PCI. Detection of dysfunctional myocardial segments without extensive scar (≤50% LGE) as a marker for viability may aid in identifying subjects with significant regional functional recovery after CTO PCI.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Safety of pressure wire-based coronary revascularisation deferral in patients with chronic kidney disease

TRAVIESO GONZALEZ Alejandro [(1)], TRAVIESO-GONZALEZ Alejandro [(1)], CASTRO MEJIA Alex Fernando [(1)], JERÓNIMO BAZA Adrián [(1)], PEREZ VIZCAYNO María José [(1)], JIMÉNEZ QUEVEDO Pilar [(1)], NOMBELA FRANCO Luis [(1)], FERNÁNDEZ ORTIZ Antonio [(1)], MEJÍA RENTERÍA Hernán [(1)], ESCANED Javier [(1)], GONZALO Nieves [(1)]

(1) Hospital Clínico San Carlos, Madrid, Spain

Aims: To assess the safety of pressure wire-derived indices to defer revascularisation in patients with chronic kidney disease (CKD).

Methods and results: From a single-centre retrospective cohort of 439 patients whose revascularisation was deferred after physiological assessment with FFR or iFR, we examined incidence of MACE (a composite of all-cause death, myocardial infarction and unplanned revascularisation) in patients with chronic kidney disease (defined as eGFR<60 ml/min/1.73m^2) and without it, and across different stages of CKD. Additionally, we assessed the incidence of target vessel revascularisation and target vessel myocardial infarction as pre-specified, vessel-related, secondary outcomes. Analyses were performed either unadjusted and adjusted by other potentially relevant variables (sex, age, hypertension, diabetes, smoking status, clinical presentation, and percentage of angiographic stenosis). At 4 years of follow-up, the primary endpoint occurred in 30 of 120 (25.0%) of the patients with CKD and in 46 of 319 (14.4%) of the patients without it (adjusted HR=1.56, 95% CI: 0.96 – 2.53, p=0.071). The incidence of MACE was even higher in patients with an eGFR<30 ml/min/1.73m^2: 7 of 16 (43.8%, adjusted HR=3.10, 95% CI: 1.08-8.92, p=0.036), and a positive linear relationship between the stage of CKD and the incidence of adverse cardiovascular events was found (p=0.002 for trend). The higher risk of MACE was driven especially by higher rates of death and revascularisation, being the incidence of myocardial infarction (MI) similar in both groups. However, this increased MACE rate in patients with renal dysfunction was not related to the previously deferred vessel: no differences were observed in the incidence of target vessel revascularisation (5.8% in CKD patients vs 5.9% in non CKD, p=0.347) and target vessel myocardial infarction (0.8% vs 4.6%, p=0.666). Additionally, no significant differences were observed in the incidence of MACE when comparing FFR and iFR as the deferral technique, either in patients with CKD (p=0.302) or without it (p=0.624).

Conclusions: Patients with CKD in whom pressure wire evaluation led to deferral of coronary revascularisation develop more MACE in the long term, compared to patients with normal renal function. Yet, the increase in MACE in patients with CKD was seldom related to deferred vessels, thus suggesting an epiphenomenon of an intrinsically higher cardiovascular risk of CKD patients.

Stable CAD - Invasive imaging and functional assessment, Bifurcation lesion - Invasive imaging and functional assessment

Evaluation of stent apposition in POT: diagnostic accuracy of a method based on Progression of contrast mediUm to evaluate coronary opaciFication and Flow (POT Puff) vs OCT

AMINFAR Farang [(1)], AMINFAR Farhang [(1)], RUBIMBURA Vladimir [(1)], ROGUELOV Christan [(1)], DUPRE Marion [(1)], PAGNONI Mattia [(1)], FOURNIER Stephane [(1)], EECKHOUT Eric [(1)], RANGE Gergoire [(1)], MULLER Olivier [(1)], ADJEDJ Julien [(1,2)]

(1) CHUV Centre hospitalier universitaire vaudois, Lausanne, Switzerland; (2) Institut Arnault Tzanck, St Laurent du Var, France

Aims: PCI involving bifurcations accounts for about one third of cases. PCI of coronary bifurcations is largely finalised with a POT which consists of inflating a shorter and wider balloon adapted to the mother branch size. We hypothesised that contrast progression during the POT could be a sign of stent apposition in the mother branch. To validate this simple angiographic sign, called POT Puff, as a stent apposition marker in the mother branch, we performed an observational study comparing POT Puff signs with the gold standard of stent apposition, OCT.

Methods and results: In two centres, we performed contrast injection during the POT in stable patients who underwent PCI of any bifurcation lesion excluding left main, followed by an OCT. We called POT Puff positive if contrast medium progressed through the inflated balloon and POT Puff was negative if contrast progression was completely stopped by the inflated balloon. The OCT analysis was performed by an independent operator. The number of struts in the mother branch was counted and sorted as: no malapposition below 200 microns and malapposition above 200 microns to the intimal surface. We included 50 consecutive coronary bifurcations in 49 patients with a POT Puff sign and OCT without complications. The prevalence of malapposition in the mother branch confirmed by OCT was 26% (14 cases). The POT Puff sign was positive in 24% (12 cases) and negative in 76% (38 cases). Sensitivity, specificity, positive predictive value and negative predictive value were respectively 69% (44-94, 95% confidence of interval), 92% (83-100), 75% (51-100) and 89% (81-99). Area under the ROC curve was 0.806 (0.645-0.966).

Conclusions: Our study suggests that prevalence of stent malapposition in the mother branch is frequent and that the POT Puff sign is simple, accurate and cost-free to detect stent malapposition as compared with OCT. POT Puff should be used in every PCI of non-left-main bifurcation finalised with a POT to assess mother branch stent apposition.

Stents and scaffolds - Invasive imaging and functional assessment

Prognostic value of quantitative flow ratio measured immediately after DEB angioplasty for in-stent restenosis

CAI Xiaoqing [(1)], CHEN Yundai [(1)]

(1) 301 Hospital Xiyuan Parking Lot, Haidian, China

Aims: The study aimed to evaluate the risk factors and predictors of recurrent restenosis after drug-coated balloon (DCB) angioplasty for drug-eluting stent (DES) restenosis among patients enrolled in the RESTORE ISR China randomised trial.

Methods and results: Patients undergoing the RESTORE ISR China randomised trial with follow-up angiography were enrolled and classified into the recurrent restenosis group and the non-recurrent restenosis group. The binary classifications followed QCA standards of ISR: diameter stenosis≥50% in the in-segment area at follow-up angiography as recurrent restenosis. Clinical and angiographic characteristics of these two groups were analysed and compared, and the QFR value both before lesion preparation and after final DCB angioplasty were also measured and compared. 226 lesions in 208 patients with a follow-up angiography at 9 months were enrolled. Recurrent restenosis was detected in 43 patients (20.7%) and in 49 lesions (21.7%). A multivariable regression analysis showed the QFR value after DCB angioplasty (OR 0.88; 95% CI: 0.83 to 0.93; p<0.0001 for 0.01 increase), lesion length (OR 1.08; 95% CI: 1.01 to 1.15; p=0.017 for 1 mm increase), and vessel calibre (OR 0.35; 95% CI: 0.13 to 0.89; p=0.027 for 1 mm increase) were independent risk factors of recurrent restenosis after DCB angioplasty. The area under the curve (AUC) of receiver operating characteristic (ROC) indicated that QFR value after DCB angioplasty was the primary risk predictor in predicting recurrent restenosis in DCB angioplasty.

Conclusions: QFR value after DCB angioplasty, lesion length and vessel calibre were independent risk factors of recurrent restenosis after DCB angioplasty. Furthermore, QFR value after DCB angioplasty was a novel and promising predictor in evaluating prognosis after DCB angioplasty of DES ISR.

Stable CAD - Invasive imaging and functional assessment, Stents and scaffolds - Invasive imaging and functional assessment

Residual quantitative flow ratio for estimating post-PCI FFR

VAN DIEMEN Pepijn [(1)], SCHUMACHER Stefan [(1)], BOM Michiel [(1)], DRIESSEN Roel [(1)], EVERAARS Henk [(1)], DE WINTER Ruben [(1)], VAN ROSSUM Albert [(1)], OPOLSKI Maksymilian [(2)], DANAD Ibrahim [(1)], KNAAPEN Paul [(1)]

(1) Amsterdam UMC - Locatie VUmc, Amsterdam, the Netherlands; (2) Instytut Kardiologii im. Prymasa Tysiąclecia Kardynała Stefana Wyszyńskiego, Warsaw, Poland

Aims: Quantitative flow ratio (QFR) accurately computes fractional flow reserve (FFR) using cine contrast images obtained during invasive coronary angiography (ICA). Residual QFR (rQFR) is a novel tool incorporated in QFR analysis that assesses outcome after percutaneous coronary intervention (PCI) by virtually removing stenosis and estimating post-PCI FFR. We sought to assess the correlation between rQFR and post-PCI FFR and its ability to predict a suboptimal PCI result defined by post-PCI FFR.

Methods and results: A total of 135 patients (164 vessels) with stable coronary artery disease that underwent PCI and subsequent post-PCI FFR measurements will be evaluated for inclusion in the study. For this preliminary data-analysis, 57 patients (65 vessels) were analysed. QFR analysis based on pre-PCI ICA images was performed up to the point where post-PCI FFR was measured. Furthermore lesion location was matched with stent location to allow for the virtual removal of stenosis similar to the performed PCI and computation of rQFR. A rQFR and post-PCI FFR <0.90 were considered to indicate a (prognostically) suboptimal PCI result. Six vessels were excluded due to; inappropriate ICA angles (N=1), a subtotal lesion with poor contrast opacification of the vessel (N=2), poor contrast injection (N=2) or presence of an ostial right coronary artery lesion (N=1), resulting in 59 (91%) vessels with successful QFR analysis, of which 31 (53%) had a suboptimal post-PCI FFR result. Overall, pre-PCI FFR (0.69±0.15) was higher than QFR (0.63±0.19, p=0.011), whereas post-PCI FFR (0.89±0.07) was lower than rQFR (0.94±0.06, p<0.001). A moderate correlation between rQFR and post-PCI FFR was observed (Pearson correlation coefficient: 0.39, p=0.002). Lastly, rQFR demonstrated an excellent positive predictive value (PPV) (100%) for determining a suboptimal PCI result, whereas overall accuracy (71%) was hampered by a moderate negative predictive value (NPV) (65%).

Conclusions: These results, although exploratory of nature, indicate that rQFR can be used to assess optimal stent location in order to obtain a satisfying PCI result. If rQFR is <0.90 stent location should be reconsidered as post-PCI FFR will almost certainly remain suboptimal, due to the presence residual stenosis. On the other hand, if rQFR is above 0.90 stent location seems appropriate. This does, however, not necessarily commensurate to an optimal PCI result e.g., although speculative, due to stent malapposition, an edge dissection, or unfavourable lesion characteristics such as extensive calcifications or long length.

Stable CAD - Invasive imaging and functional assessment

Non-hyperaemic pressure ratios correlate with both coronary flow reserve and resistive reserve ratio

ADA Cuneyt [1,2], ADA Cuneyt [1,2], WONG Christopher [1,2], FEARON William [3], SVANERUD Johan [4], LO Sidney [5], KRITHARIDES Len [1], NG Martin [2], YONG Andy [1]

(1) Concord Hospital, NSW, Australia; (2) Royal Prince Alfred Hospital, NSW, Australia; (3) Stanford University, CA, USA; (4) Coroventis Research AB, Uppsala, Sweden; (5) Liverpool Hospital, NSW, Australia

Aims: NHPRs are increasingly being used in the catheterisation laboratory to evaluate epicardial coronary lesions. They have been shown to correlate with CFR. However, it remains unknown whether NHPRs correlate with RRR, which informs on microcirculatory vasodilatory capacity. In this study, we aim to elucidate the inter-relationship between all of the commercially available NHPRs and both epicardial and microcirculatory vasodilatory capacity (CFR and RRR).

Methods and results: Patients scheduled for coronary angiography were prospectively recruited for the study and those found to have intermediate coronary lesions with 30-90% diameter stenosis underwent the study protocol. Exclusion criteria included prior MI in the target territory, STEMI within 72 hours, previous CABG and contraindications to adenosine. Coronary physiology measurements were performed using a pressure/temperature sensor guidewire placed in the distal segment of the target vessel. The mean transit time was assessed using thermodilution and was recorded both at rest and during adenosine induced hyperaemia (140mcg/kg/min), as were the aortic (Pa) and distal (Pd) pressure traces. The FFR (Pd/Pa during hyperaemia), CFR (resting transit time/hyperaemic transit time), corrected index of microcirculatory resistance (IMR: Pa x hyperaemic transit time x (1.34xPd/Pa - 0.32)) and resistive reserve ratio (RRR: IMR at rest/IMR during hyperaemia) were derived. The resting Pd/Pa and resting full-cycle ratio (RFR) were obtained automatically from the Coroflow system. Other NHPRs including the instantaneous wave-free ratio (iFR), diastolic pressure ratio (dPR) and diastolic hyperaemia-free ratio (DFR) were derived offline after the procedure by an expert who was blinded to the initial measurements. There were 92 vessels included from 81 patients with a median diameter stenosis of 48%, FFR of 0.84, IMR of 22 and RRR of 3.35. RRR was divided into high and low groups using the median RRR. Compared to the high RRR group, those with a low RRR had significantly lower NHPRs, but no significant difference in FFR. The median, interquartile range and p value in the low RRR vs high RRR groups respectively are as follows: iFR 0.88±0.12 vs 0.94±0.08, p=0.001, RFR 0.88±0.11 vs 0.93±0.08, p=0.001, DFR 0.90±0.12 vs 0.95±0.10, p=0.01, dPR 0.89±0.12 vs 0.94±0.08, p=0.003 & Pd/Pa 0.92±0.08 vs 0.95±0.07, p=0.007, FFR 0.82±0.15 vs 0.87±0.17, p=0.189). All NHPRs correlated with RRR (iFR r=0.340, p=0.001, RFR r=0.317, p=0.002, DFR r=0.230 p=0.028, dPR r=0.292 p=0.005 & Pd/Pa r=0.243 p=0.02). The NHPR-RRR correlation was stronger in those with an IMR≥25 and not present in those with IMR<25. All NHPRs also correlated with CFR (iFR r=0.549, p=0.000, RFR r=0.522, p=0.000, DFR r=0.450 p=0.000, dPRr=0.504 p=0.000 & Pd/Pa r=0.444 p=0.000). FFR correlated with CFR (r=0.336, p=0.001) but not RRR (p=0. 356). Importantly, IMR did not correlate with NHPRs or FFR.

Conclusions: NHPRs are associated with both the coronary flow reserve and resistive reserve ratio, but are independent of the minimum achievable microcirculatory resistance (IMR). These associations have important implications in the understanding and use of NHPRs in the clinical setting.

Stable CAD - Invasive imaging and functional assessment

Objective identification of stenoses inducing myocardial ischaemia using sequential iFR, FFR and intracoronary flow measurements

STEGEHUIS Valérie [1], STEGEHUIS Valérie [1], WIJNTJENS Gilbert [1], NIJJER Sukhjinder [2], DE WAARD Guus [5], VAN DE HOEF Tim [1], SEN Sayan [2], PETRACO Ricardo [2], ECHAVARRÍA-PINTO Mauro [3], MEUWISSEN Martijn [4], DANAD Ibrahim [5], KNAAPEN Paul [5], ESCANED Javier [6], DAVIES Justin [2], VAN ROYEN Niels [7], PIEK Jan [1]

(1) Amsterdam UMC - Locatie AMC, Amsterdam, the Netherlands; (2) Imperial College London, London, United Kingdom; (3) ISSSTE General Hospital of Querétaro, Qro., Mexico; (4) Amphia Hospital, Breda, the Netherlands; (5) Amsterdam UMC - Locatie VUmc, Amsterdam, the Netherlands; (6) Hospital Clínico San Carlos, Madrid, Spain; (7) Radboud University Medical Center, Nijmegen, the Netherlands

Aims: Although ischaemic heart disease (IHD) has a multilevel origin, the diagnostic approach is mainly focused on focal obstructive disease as assessed by pressure-derived indices. The prognostic value of invasive coronary flow implies that identification of perfusion abnormalities is critical for correct clinical decision making. We evaluated the diagnostic potential of a sequential approach using instantaneous wave-free ratio (iFR), fractional flow reserve (FFR) and coronary flow reserve (CFR) to determine the number of lesions associated with flow abnormalities after initial pressure measurements

Methods and results: We assessed 366 intermediate lesions from 222 patients with simultaneous intracoronary pressure and flow velocity measurements. Contemporary clinical iFR, FFR and CFR cut-points for myocardial ischaemia were applied. 118 (32%) lesions were FFR+ and 136 lesions (37%) were iFR+. Subsequent CFR assessment resulted for FFR in a total of 91 (25%) FFR+/CFR+ and for iFR a total of 111 (30%) iFR+/CFR+ lesions. After an iFR, FFR and invasive flow velocity assessment approach, this would have eventually yielded 20% of lesions (74 out of 366) as ischaemic.

Conclusions: Ultimately, 20% of intermediate lesions are associated with flow abnormalities after applying a pressure and flow velocity sequential approach. If iFR is borderline, FFR has limited additional value, in contrast with CFR. These results emphasise the use of coronary physiology in assessing stenosis severity, but may also further question the contemporary reputation of a pressure-based approach as a gold standard for the detection of myocardial ischaemia in IHD.

STEMI - Adjunctive pharmacotherapy

Primary PCI in the very elderly: a realistic intervention? A study of outcomes in patients aged 85 years and older with STEMI

AUBINIERE-ROBB Louise [1], AUBINIERE-ROBB Louise [1], REID George [2], MURPHY Aengus [3]

(1) University of Sheffield Medical School, Sheffield, United Kingdom; (2) Queen Elizabeth University Hospital, Glasgow, United Kingdom; (3) Monklands Hospital, Airdrie, United Kingdom

Aims: Primary percutaneous coronary intervention (PPCI) as management for acute STEMI is a well-established, evidence-based treatment offered across the UK. Evidence of benefit in the very elderly is sparse. With an aging population, the demand on PPCI services for STEMI in the elderly is likely to increase. Our aim was to establish real life outcomes in patients aged 85 years and older who receive PPCI for acute STEMI.

Methods and results: Data was collected retrospectively on all patients aged 85 years and older who were referred and accepted for PPCI to our centre between 2013 and 2018 inclusive. This represented 4.8% (N=172) of all accepted PPCI referrals over the six-year period. 164 patients proceeded to invasive angiography, of whom 143 patients received PPCI. PPCI was successful in over 95% of cases. Median hospital stay of all patients was 7 days (range 1 – 190). 131 patients survived STEMI admission (79.9%). 95% of patients who survived admission were discharged to their own home, and 52% were functionally independent. One-year mortality was 33.7% (n=55). Median survival of all patients post-STEMI was 2.55 years.

Conclusions: Advanced age should not be used as an exclusion criterion in isolation for PPCI. Rather, a personalised approach that takes into account all clinically relevant patient factors should be adopted to guide PCI decision-making. Despite relatively long hospital stays and high 1-year mortality, there are still potential good quality life years to be gained following intervention. Our findings therefore suggest that emergency revascularisation therapy as first-line treatment for STEMI in the very elderly should be considered routinely.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Volumetric quantification of absolute coronary flow to assess flow reserve

IZAGA-TORRALBA Elena [1], GUTIÉRREZ-BARIOS Alejandro [1,2], IZAGA-TORRALBA Elena [1], RIVERO Fernando [3], CALLE-PEREZ German [1,2], ALFONSO Fernando [3], GHEORGHE Livia [1,2]

(1) Hospital Universitario Puerta del Mar, Cádiz, Spain; (2) INiBICA, Cadiz, Spain; (3) Hospital de La Princesa, Madrid, Spain

Aims: Coronary flow reserve (CFR) can be invasively assessed by Doppler or by thermodilution (CFRthermo). However both methods are based on indirect measurements. A new method to quantify coronary absolute flow (AF) has been validated. This technique requires a continuous infusion of saline through a dedicated catheter at a flow rate that induces hyperaemia (≥15mL/min). We sought to evaluate the feasibility of this method to quantify resting AF using a continuous low-flow rate of saline and to determine the absolute CFR by dividing the maximum AF by the resting AF and its agreement with CFRthermo.

Methods and results: Thirty-four patients with suspected coronary disease were prospectively recruited during a period of 7 months in two centres. The most frequently studied vessel was the left anterior descending (71%). Pd/Pa was recorded before starting, during resting (10-12mL/min) and during hyperaemic (18-20mL/min) saline infusion to check that AF measurement at rest was feasible and that hyperaemia was not induced using low flow rate infusion. During low flow saline infusion the mean Pd/Pa did not modify (0.95±0.032 before starting and 0.95±0.033 at the end), the coefficient of variation of the initial and final Pd/Pa value was <0.01% and the r-coefficient of the two measurements was 0.98. By comparison, during maximal hyperaemia induced by saline infusion the coefficient of variation was 5.2% (initial Pd/Pa was 0.95±0.03 and FFR at the end of the infusion was 0.89±0.05). CFR thermo was calculated from the ratio of inverse mean transit times at rest and at hyperaemia and compared with absolute CFR (CFRabs) that was calculated from the ratio of AF at maximum hyperaemia induced by a continuous saline infusion and AF at rest measured using a continuous saline infusion (10-12mL/min). CFR thermo and CFRabs could be successfully assessed in all the patients (100%). There were no significant adverse events. In one patient in whom the RCA was the measured artery, a symptomatic bradycardia was successfully resolved by changing the infusion rate to 15mL/min, completing the measurements without clinical consequence. Mean values obtained were: hyperaemic AF 197.6±67 mL/min; resting AF 77.7±25 mL/min; CFR thermo 2.42±1 and CFRabs 2.61±0.85. A strong correlation was found between CFR thermo and CFRabs (r=0.88, p<0.01). Bland-Altman analysis showed a mean difference of 0.19±0.5. The average absolute difference between both indexes was 14±12%. In 14% of all cases, the difference between both parameters was ≥25%.

Conclusions: The present study confirms the feasibility and safety of CFRabs. This index showed a strong correlation with CFR thermo.

Stable CAD - Diabetes, Other Coronary interventions - Other

Results of PCI with second-generation DEB in diabetic patients at long-term follow-up

ABELLÁN-HUERTA José [(1)], ABELLÁN-HUERTA José [(1)], SÁNCHEZ-PÉREZ Ignacio [(1)], LÓPEZ-LLUVA María Thiscal [(1)], LOZANO-RUIZ-POVEDA Fernando [(1)], PÉREZ-DÍAZ Pedro [(1)], PIQUERAS-FLORES Jesús [(1)], MASEDA-URIZA Ramón [(1)], FRÍAS-GARCÍA Raquel [(1)]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Drug-coated balloons (DCB) constitute one of the therapeutic tools used in percutaneous coronary interventions (PCI) of both stent restenosis and *de novo* coronary lesions, mainly in bifurcations and small vessels. Diabetic patients represent an unfavourable subgroup because of their higher restenosis and adverse events rates. Nowadays, the results of PCI with DCB at a long-term follow-up are unclear in this subset of patients. Our aim was to evaluate the efficacy and safety of PCI with second-generation drug-coated balloons (DCB) in diabetics at long term follow-up.

Methods and results: We prospectively included 205 lesions in 175 diabetic patients (68.5± 11.7 years, 63.7% male) treated with DCB between March 2009 and January 2019. We evaluated the presence of major cardiac events (MACE) after a clinical follow up (median 33 months): death, non-fatal myocardial infarction, target lesion revascularisation (TLR) and thrombosis. The 48.6% of the patients had stable coronary artery disease, and 51.4% acute coronary syndromes (43.1% non-STEMI and 8.3% STEMI). 86.3% of the patients had hypertension and 67.3% had dyslipidaemia. The 17.1% of the lesions were bifurcations. The target lesion diameter was 2.5 mm or less in 47.8% of the cases. The coated drug was paclitaxel in 92.5% of the lesions, and sirolimus in the remaining 7.5%. Of the 205 lesions, 39.9% were *de novo* lesions and 60.1% were restenosis (40.4% restenosis of bare-metal stent [BMS] and 19.7% of drug-eluting stent [DES]). 82.7% of the lesions were treated with DCB, 6.2% with DCB and BMS and 11.1% with DCB and DES. The angiographic success rate was 98.4%. There were no significant differences regarding baseline characteristics in these three groups nor in the MACE rate after follow-up (p=0.6). The rate of death was 9.2% (5.4% cardiovascular death, 7.4% non-cardiovascular death), the rate of non-fatal MI was 5.4% and the TLR rate was 6.4% during follow-up. No cases of thrombosis were observed, immediately after the procedure nor during follow up. 16.9% of patients had an angiographic follow-up. We observed a higher rate of TLR during follow-up in bifurcation lesions (14.3% vs 7.7%; p=0.05) as well as a higher need for additional stent after PCI in bifurcation lesions (20% vs 5.5%; p=0.17).

Conclusions: In diabetic patients, percutaneous coronary intervention of *de novo* coronary lesions and in-stent restenosis (both BMS and DES) with second-generation drug-eluting balloons provide very favourable outcomes at a long-term follow-up. However, complex lesions such as bifurcations were associated with a higher need of additional stents after the initial PCI and a higher rate of TLR during follow-up.

Other Coronary interventions - Calcified lesions

Anatomical and procedural determinants of rotational atherectomy failure

TOMASIEWICZ Bruno [(1)], TOMASIEWICZ Bruno [(1)], KÜBLER Piotr [(1)], ZIMOCH Wojciech [(1)], KOSOWSKI Michal [(1)], RAKOTOARISON Oscar [(1)], WANHA Wojciech [(2)], OCHALA Andrzej [(2)], WOJAKOWSKI Wojciech [(2)], RECZUCH Krzysztof [(1)]

(1) Wroclaw Medical University, Wroclaw, Poland; (2) Medical University of Silesia, Katowice, Poland

Aims: Most established predictors of outcome after rotational atherectomy (RA) of heavily fibro-calcified lesions are related to patients' general risk and clinical related factors. Specific predictors of RA failure associated with either coronary and culprit lesion anatomy or the RA procedure are still to be determinated. The aim is to assess anatomical and procedural predictors of unsuccessful RA in an all-comers population.

Methods and results: A total of 534 consecutive patients after RA were included in a double-centre observational study. The analysis focused on procedural factors and lesion anatomical characteristics including length, tortuosity, length and severity of calcifications, sequential character, and the need to use strong support during the procedure. Composite primary endpoint consisted of: rota-wire introduction failure, RA failure (no successful widening of the lesion), periprocedural complications and procedure-related mortality. Primary endpoint occurred in 76 (14.2%) patients, including: rota-wire introduction failure in 13 (2.4%), rotational atherectomy failure in 51 (9.6%), periprocedural complications in 39 (7.3%), procedure-related death in 9 (1.7%) patients. In univariable analysis the determinants of RA failure were high SYNTAX score (>27) (p=0.009), severe calcifications (p=0.017), angulation on lesion (p=0.043), sequential lesion (p=0.00008), the need to use strong support (p=0.0001), calcium length more than 20 mm (p=0.01), lesion length more than 20 mm (p=0,01), chronic total occlusion lesion (p=0,01). Multivariable analysis revealed sequential lesions (OR 2.07, CI 1.09 – 3.92; p=0.026) and need of strong support (OR 2.29, CI 1.32 – 3.98; p=0.003) as independent predictors of composite endpoint.

Conclusions: The presence of sequential lesions and the need for strong support are independent determinants of unsuccessful RA. Further research is necessary to establish a kind of practical score predicting the risk of RA failure.

Stable CAD - Invasive imaging and functional assessment

The progression of atherosclerosis with respect to vulnerable plaque distribution in non-culprit non-ischaemic native coronary lesions of diabetic patients – data from the COMBINE OCT-FFR study

ROLEDER Tomasz [1], ROLEDER Tomasz [1], BERTA Balazs [2,3], HERMANIDES Renicus S [2], IJSSELMUIDEN Alexander [4], ALFONSO Fernando [5], KAUER Floris [6], ESCANED Javier [7], DE LUCA Giuseppe [8], WOJAKOWSKI Wojciech [9], KEDHI Elvin [10]

(1) Regional Specialist Hospital in Wroclav, Research and Development Center, Wroclav, Poland; (2) Isala ziekenhuis, Zwolle, the Netherlands; (3) Diagram B.V., Zwolle, the Netherlands; (4) Amphia Hospital, Breda, the Netherlands; (5) Hospital de La Princesa, Madrid, Spain; (6) Albert Schweitzer Ziekenhuis, Dordrecht, the Netherlands; (7) Hospital Clínico San Carlos, Madrid, Spain; (8) Azienda Ospedaliera-Universitaria "Maggiore della Carità", Eastern Piedmont University, Novara, Italy; (9) Medical University of Silesia, Katowice, Poland; (10) AZ Sint-Jan, Bruges, Belgium

Aims: In order to study the natural evolution of atheroma progression, we studied the distribution of high-risk plaques in non-ischaemic native coronary lesions with respect to lesion morphology in diabetic patients enrolled in the COMBINE trial

Methods and results: COMBINE (OCT-FFR, NCT02989740) study is a multicentre, prospective natural history study that assesses non-culprit lesions to better predict adverse events in diabetes. OCT analysis identifies plaque composition, estimates calcium arc (o), lipid arc (o), and measures thickness of the fibrous cap (μm) covering the lipid core. Moreover, OCT records the presence of typical plaque vulnerability traits like thin fibrous cap atheroma (TCFA), plaque erosion (PE), plaque rupture (PR), and healed plaques. A dedicated software estimated the interpolated percentage area stenosis (AS, %) and lesion length (mm). Based on the distribution, all analysed lesions were divided into three quantiles (Qn) according to AS(≤57 [n=154], 58-68 [n=158], ≥69 [n=151]) and lesion length (≤16.6 [n=156], 17.1-28.1 [n=158], ≥28.2 [n=149]). OCT imaged 463 lesions for 391 patients of COMBINE study. Lesion length was the longest (20.86±11.91, 23.34±10.66, 25.87±10.81, p<0.01) in the 3rd Qn of AS. TCFA (23 [15%], 32 [20%], 41 [27%], p=0.03) and healed plaques (16 [12%], 34 [21%], 38 [25%], p=0.01) also occurred more often in the 3rd Qn of AS. Calcium arc (144±92, 169±94, 178±103, p=0.01) and lipid arc (178±72, 201±73, 212±73, p=0.01) were the smallest in the 1st Qn of AS. Fibrous cap thickness was the thinnest (161±107, 150±114, 116±72, p=0.01) in the 3rd Qn of lesion length. TCFA (18 [11%], 31 [20%], 47 [32%], p=0.01) and PE (3 [2%], 4 [3%], 13 [19%], p=0.01) occurred more often in the 3rd Qn of lesion length. Calcium arc (142±88, 170±98, 178±102, p=0.01) and lipid arc (186±74, 196±75, 209±72, p=0.05) were the smallest in the 1st Qn of lesion length. There were no differences in PR with respect to AS (12 [8%], 19 [12%], 20 [13%], p=0.27) and lesion length (12 [8%], 21[13%], 18 [12%], p=0.25).

Conclusions: TCFA and plaque erosions occur more often in longer lesions, and TCFA is observed in more stenotic lesions. Healed plaques were only observed in the most stenotic lesions advocating for plaque rupture and healing as the main process of vessel narrowing. These results suggest that the progress of vessel stenosis goes along with increased plaque vulnerability and ischaemia in non-culprit lesions in diabetic patients.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

DEB vs contemporary DES for the treatment of DES in-stent restenosis: insights from the DAEDALUS study

GIACOPPO Daniele [1], GIACOPPO Daniele [1], CASSESE Salvatore [1], ALFONSO Fernando [2], XU Bo [3], CHRISTOPH Naber [4], HENRIQUES José [6], PERÉZ-VYZCAINO José [5], PARK Seung-Jung [6], KASTRATI Adnan [1], BYRNE Robert [1]

(1) Deutsches Herzzentrum München, Munich, Germany; (2) Hospital de La Princesa, Madrid, Spain; (3) Chinese Academy of Medical Sciences, Beijing, China; (4) Elisabeth-Krankenhaus Essen, Essen, Germany; (5) Hospital Clinico Universitario San Carlos, Madrid, Spain; (6) AMC, Amsterdam, the Netherlands; (7) Asan Medical Center, Seoul, Republic of Korea

Aims: Drug-eluting balloons (DEB) and drug-eluting stents (DES) have emerged as the most effective treatments for in-stent restenosis. In the main analysis of the DAEDALUS study, DEB was compared with first- and second-generation DES for the treatment of bare-metal stent- or DES-in-stent restenosis. At long-term follow-up, DES was more effective and similarly safe compared with DEB. In this prespecified analysis, we sought to compare DCB exclusively with contemporary second-generation DES for the treatment of DES-in-stent restenosis, which nowadays is becoming the usual anatomic subset of interest.

Methods and results: The DAEDALUS study was a collaborative, individual patient data meta-analysis including all 10 available randomised clinical trials (1,976 patients, 2,080 lesions) comparing DEB alone versus DES alone for the treatment of in-stent restenosis. The primary efficacy endpoint was target lesion revascularisation; the primary safety endpoint was a composite of all-cause death, myocardial infarction, or target lesion thrombosis. Risk estimates were drawn by one-stage Cox mixed-effects models accounting for the original stratification of patients across trials. In this prespecified major analysis, we included only patients randomised to DEB or second-generation DES for the treatment of DES-in-stent restenosis. At 1-year follow-up, DCB was associated with a significant increase in the risk of target lesion revascularisation compared with DES (14.4% vs 5.7%, p<0.0001; HR 1.96, 95% CI: 1.16-3.32); results remained consistent after multivariable adjustment accounting also for multiple lesions per patient (HRadj 2.06, 95% CI: 1.17-3.64). At 1-year follow-up, the risk of all-cause death, myocardial infarction, or target lesion thrombosis was similar between DEB and DES (4.4% vs 4.2%, p=0.919; HR 1.03, 95% CI: 0.55-1.93); results remained consistent after multivariable adjustment accounting also for multiple lesions per patient (HRadj 0.95, 95% CI: 0.47-1.91).

Conclusions: At 1-year follow-up, DCB is significantly less effective and similarly safe compared with contemporary DES for the treatment of DES-in-stent restenosis.

Bifurcation lesion - Tools, devices and techniques

Mid-term survival of patients with bifurcation lesions – practical insights from an all-comer registry

VASSILEV Dobrin [(1)], VASSILEV Dobrin [(1)], MILEVA Niya [(1)], NIKOLOV Pavel [(1)], DIMITROV Georgi [(1)], KARAMFILOFF Kiril [(1)], NAUNOV Vladimir [(1)], RIGATELLI Gianluca [(3)], COLLET Carlos [(2)], GIL Robert [(4)], SERRUYS Patrick [(5)]

(1) Aleksandrovska University Hospital, Sofia, Bulgaria; (2) Olv Ziekenhuis, Aalst, Belgium; (3) Rovigo Medica, Province of Rovigo, Italy; (4) Medical Centre of Postgraduate Education, Warsaw, Poland; (5) Imperial College London, London, United Kingdom

Aims: There is sparse data about impact of different clinical and angiographic factors on mortality in coronary bifurcation lesion subtypes. The aim of the current study was to analyse predictors of mortality in patients with coronary bifurcation stenoses.

Methods and results: All patients with coronary bifurcation stenoses were included in thid prospective registry from July 2014. All patients were prospectively followed for their vital status and cause of death, if it occured. The inclusion criterion was angiographic bifurcation lesions in a native coronary artery with diameter ≥ 2.5 mm and ≤ 4.5 mm and SB diameter ≥ 2.0 mm. We excluded patients with ST-segment elevation myocardial infarction, left main lesion, haemodynamic instability and those with non-cardiac co-morbidity conditions with a life expectancy of less than one year. Percutaneous coronary intervention (PCI) was performed according to current guidelines. Provisional stenting was the default strategy in all patients; POT was the recommended technique for all patients and kissing-balloons inflation was left to operator discretion. Side branch was stented in case of flow compromise after stenting, persisting ischaemia in this region, type ≥C dissection. All patients received dual antiplatelet therapy with ADP-antagonist and aspirin for at least 12 months. Seven hundred and ninety-four consecutive patients with coronary bifurcation stenoses were included. The mean age was 67±10 years, 70% males, 98% hypertensive, 38% diabetic, 94% dyslipidemic (or on treatment with statin), 40% smokers, renal failure (GFR<60 ml/kg/min) 31%, COPD 13%, PAD 10%, cancer 7%, 26% with previous myocardial infarction, 49% with previous PCI. An LAD was involved in 67% (530/794) and 58% had true bifurcation lesions (Medina xx1). The rate of all-cause death at median 33 months (IQR 18-52 months) was 15.1% (n=120/794). On multivariate Cox regression analysis in a model including age, NYHA functional class, diabetes, cancer, COPD, renal failure, haemoglobin concentration, hematocrit, LV ejection fraction, mitral regurgitation degree, bifurcation main branch BARI score (%LV mass at risk), total APPROACH score (total %LV mass at risk), side branch %DS>70%, and LAD lesion location, the independent predictors of death were: age (HR=1.033, CI 1.010-1.057, p=.005), haemoglobin concentration (HR=.986, CI.973-.999, p=.030), mitral regurgitation degree (HR=1.489, CI 1.085-2.043, p=.014), main branch BARI score (HR=1.030, CI 1.004-1.056).

Conclusions: We identified several predictors of mid-term mortality after stenting coronary bifurcation lesions. The only independent lesion factor related to survival was myocardial territory obeyed from the main branch.

STEMI - Invasive imaging and functional assessment, NSTEMI - Invasive imaging and functional assessment

Predictive value of the quantitative flow ratio in detecting vulnerable plaques in non-flow limiting lesions: a combined analysis of the PROSPECT and IBIS 4 studies

SAFI Hannah [1,2], SAFI Hannah [1,2], BOURANTAS Christos [1,2,3], RAMASAMY Anantharaman [1,3], TUFARO Vincenzo [1], TORII Ryo [2], REIBER Johan [4], MATHUR Anthony [1,3], ONUMA Yoshinubo [5], MAEHARA Akiko [6], SERRUYS Patrick [7], STONE Peter [8], BAUMBACH Andreas [1,3], STONE Gregg [6], RÄBER Lorenz [9]

(1) Barts Health NHS Trust, London, United Kingdom; (2) University College London, London, United Kingdom; (3) The William Harvey Research Institute, London, United Kingdom; (4) Medis medical imaging systems, Leiden, the Netherlands; (5) Erasmus Medical Center, Rotterdam, the Netherlands; (6) Columbia University, NY, USA; (7) Imperial College London, London, United Kingdom; (8) Harvard Medical School, MA, USA; (9) Inselspital, Universitätsspital Bern, Bern, Switzerland

Aims: Fractional flow reserve (FFR) is the gold standard for assessing lesion severity and planning treatment and may also provide useful prognostic information even in non-flow limiting lesions. FFR however does not provide any information about plaque morphology which also has value in identifying high-risk lesions. Studies have shown that the QFR, recently introduced to assess lesion severity, provides useful prognostic information; nevertheless, the additive value of this technique over intravascular imaging in detecting lesions that are likely to progress and cause events is yet unclear.

Methods and results: We analysed data acquired from 60 patients recruited in the PROSPECT and IBIS 4 studies. The baseline IVUS-virtual histology (VH) and angiographic data in 17 non-culprit lesions with a vulnerable phenotype (i.e., thin cap or thick cap fibroatheroma) that caused major adverse cardiac events or required revascularisation (MACE) at 5-year follow-up was compared to 78 vulnerable plaques that remained quiescent. The segments studied by IVUS-VH were identified in coronary angiography and processed using the QFR software that estimated the fixed (fQFR) and contrast flow (cQFR) values. The mean age of the studied population was 57.1 years; 8.0% were female and 13.0% were diabetic. At 5-year follow-up 11 events had occurred (3 myocardial infarctions and 8 admissions because of unstable angina) and 6 lesions required revascularisation for disease progression. All the studied lesions were non-flow-limiting by QFR (range 0.81-1.00). MACE lesions had a greater plaque burden (PB; 70.4% [63.5%, 72.2%] vs 61.0% [53.3%, 67.6%], p=0.001) and a smaller minimum lumen area (MLA; 3.59 mm^2 [3.16 mm^2, 4.51 mm^2] vs 5.04 mm^2 [3.77 mm^2, 6.52 mm^2], p=0.003), and smaller cQFR (0.94 [0.90, 0.98] vs 0.99 [0.95, 1.00], p=0.002) and fQFR (0.95 [0.93, 0.98] vs 0.99 [0.96, 1.00], p=0.005) compared with quiescent lesions. By univariate analysis MLA (HR: 0.51, 95% CI: 0.32-0.79, p=0.003), PB (1.11, 95% CI: 1.05-1.18, p=0.001), lesion length (HR: 1.10, 95% CI: 1.01-1.09, p=0.010), MLD (HR:0.34, 95% CI: 0.12-0.92, p=0.033), cQFR (HR: 0.43, 95% CI: 0.21-0.89, p=0.022) and fQFR (HR: 0.36, 95% CI: 0.16-0.81, p=0.031) were predictors of MACE. In multivariate analysis a low but normal QFR (>0.80 to <0.97) was the only independent prediction of MACE (HR: 3.53, 95% CI: 1.16-10.75, p=0.027).

Conclusions: In non-flow limiting lesions with a vulnerable phenotype, QFR may provide additional prognostic information beyond plaque morphology for predicting MACE throughout 5 years. Confirmatory research is needed to evaluate the predictive accuracy of QFR and combined intravascular imaging to identify vulnerable plaques.

STEMI - Tools, devices and techniques

Duration of left ventricular unloading before reperfusion is inversely associated with infarct size in anterior STEMI: a sub-analysis of the STEMI-DTU pilot trial

KAPUR Navin [1], KAPUR Navin [1], MOSES Jeffrey [2], UDELSON James [1], STONE Gregg [3], KARAS Richard [1], O'NEILL William [4]

(1) Tufts Medical Center, MA, USA; (2) Columbia University, NY, USA; (3) Cardiovascular Research Foundation, NY, USA; (4) Henry Ford Hospital, MI, USA

Aims: Infarct size is associated with the risk of heart failure and death after ST-segment elevation myocardial infarction (STEMI). The STEMI Door-to-Unload (STEMI-DTU) Pilot study randomised patients with anterior STEMI to left ventricular (LV) unloading with an Impella CP followed by either immediate reperfusion (U-IR) or unloading plus a 30-minute delay before reperfusion (U-DR). U-DR was shown to be feasible, safe, and did not increase infarct size compared with U-IR. We now tested whether the duration of LV unloading is inversely associated with infarct size in patients with anterior STEMI.

Methods and results: The relationship between symptom onset to balloon angioplasty time (ischaemic time), duration of LV unloading, and percent infarct size normalised to the area at risk (determined by 3 to 5-day cardiac magnetic resonance, CMR) was analysed in patients enrolled in the STEMI-DTU Pilot study. Sum of precordial STE measured in millimeters (mm) was used as an indicator of larger anterior STEMI. Only patients with CMR data and confirmed STEMI were analysed (n=38/50). Symptom onset to balloon time was similar in the U-DR vs U-IR groups (225±76 vs 211±176 minutes, p=0.76). Infarct size at 3-5 days trended lower in the U-DR group (48±16% vs 57±16%, U-DR vs U-IR, p=0.08). Moreover, symptom onset to balloon times were significantly longer in the U-DR group among patients with total STE >6 mm (227±82 vs 174±57 minutes, p=0.03, n=28) or STE >7 mm (258±72 vs 168±58 minutes, p<0.01, n=23). Despite this, significantly smaller infarct sizes were observed in the U-DR arm among patients with STE >6 mm (65±25% vs 47±17%, p<0.01) or STE >7 mm (66±11% vs 49±16%, p<0.01). No correlation between symptom to balloon time and infarct size was observed at any timepoint. The duration of LV unloading was inversely associated with 3-5 day infarct size among patients with STE >6mm (R=-0.46, p=0.01) and STE >7 mm (R=-.52, p<0.01).

Conclusions: The duration of LV unloading prior to reperfusion may be inversely related to infarct size in patients with large anterior STEMI. Especially in patients with large anterior STEMI, first unloading the LV and delaying reperfusion for 30 minutes may be superior to LV unloading and immediate reperfusion to reduce infarct size irrespective of total ischaemic time. These findings are being tested in the large-scale STEMI-DTU Pivotal trial, which is currently randomizing 688 patients with anterior STEMI to LV unloading for 30 minutes before reperfusion (Door-to-Unload) versus reperfusion alone without delay or LV unloading (Door-to-Balloon).

Other Coronary interventions - Calcified lesions

Intravascular lithotripsy in complex calcified coronary lesions: 12-month clinical outcome of a patient from a prospective, observational register study

AKSOY Adem [1], SALAZAR Carlos [2], BECHER Marc Ulrich [1], TIYERILI Vedat [1], ZIMMER Sebastian [1], SINNING Jan-Malte [1], NICKENIG Georg [1], ESCANED Javier [2], WERNER Nikos [3]

(1) Heart Center Bonn, University Bonn, Bonn, Germany; (2) Hospital Clinico San Carlos IdiSSC, Universidad Complutense, Madrid, Spain; (3) Heart Center Trier, Krankenhaus der Barmherzigen Brüder, Trier, Germany

Aims: Percutaneous coronary intervention (PCI) of calcified lesions is associated with a higher prevalence of target vessel revascularisation and myocardial infarction. Intravascular lithotripsy (IVL) has been recently proposed for the treatment of calcified coronary lesions. IVL can modify calcified plaques and permits low pressure PTCA and subsequently lower rate of complication. This study sought to report 12-months clinical outcome and strategy success of IVL on calcified lesions in an all-comers cohort of patients from a prospective, observational multicentre register.

Methods and results: Patients with moderate and severely calcified coronary lesions were screened in three centres starting May 2018. Up to March 2019, 71 patients with 78 lesions were eligible for IVL. Patients were assigned to the following groups: A) primary IVL therapy for patients with calcified coronary *de novo* coronary lesions (n= 39 lesions), B) secondary lithoplasty therapy for patients with moderate or severe calcified coronary lesions in which conventional non-compliant balloon dilatation failed (n= 22 lesions) and C) tertiary lithoplasty therapy in patients with in-stent stenosis due to stent underexpansion after previous stenting (n= 17 lesions). The primary endpoint of the current analysis was the occurrence of major adverse cardiac events (MACE) at 12-month follow-up defined as the composite of death, myocardial infarction, and target vessel revascularisation (TVR). The secondary endpoint was strategy success, defined as successful stent delivery and expansion with attainment of <20% in-stent residual stenosis of the target lesion. At the time of abstract submission 12-month follow-up for 42 patients with 47 calcified lesions was completed. Average diameter of calcified stenosis was 82.5±9.9 % at baseline and decreased significantly to 17.7±12.53 % (p-value: 0.01) after PCI. MLD was 1.3±0.5 mm at baseline and significantly increased after Shockwave procedure (2.9±0.6 mm, p-value < 0.001). Strategy success was reached in 38 of 42 (90.4%) patients. Device delivery and lithoplasty treatment of target lesion could be performed in all cases. In 4 lesions type B dissection occurred, which were successfully treated with stent implantation. Four Shockwave balloons ruptured after 20, 40, 60, and 70 shocks, respectively, mostly after repositioning of the balloon within the calcified lesion without further sequelae. Overall seven of 42 patients (16.7%) died. Four patients (9.5%) were admitted to hospital with acute syndrom. Two patients (4.8%) needed target lesion revascularisation. Follow-up is ongoing and will be completed in 2020.

Conclusions: Despite high rates of initial strategy success, nearly a quarter of patients enrolled in register experienced MACE.

Other Coronary interventions - Other

The influence of anxiety and depression at discharge on the risk of acute cardiac readmission, revascularisation or all-cause mortality within one year after PCI: findings from the national DenHeart study

BORREGAARD Britt [1,4], BORREGAARD Britt [1,4], NIELSEN Stine [1,4], LASSEN Jens Flensted [1,4], JENSEN Lisette Okkels [1,4], BERG Selina Kikkenborg [2,7], MØLLER Jacob Eifer [1,2,4], CHRISTENSEN Anne Vinggaard [2,7], EKHOLM Ola [4], MOLS Rikke Elmose [3], THORUP Charlotte Brun [5], RASMUSSEN Trine Bernholdt [6]

(1) Odense Universitetshospital, Odense Municipality, Denmark; (2) Rigshospitalet, Copenhagen Municipality, Denmark; (3) Aarhus Universitetshospital, Skejby, Aarhus, Denmark; (4) Syddansk Universitet, Odense Municipality, Denmark; (5) Aalborg Universitetshospital Syd, Aalborg Municipality, Denmark; (6) Gentofte Hospital, Hellerup, Denmark; (7) Copenhagen University, Copenhagen, Denmark

Aims: Survival rates among patients with coronary artery disease have increased since the introduction of treatment with percutaneous coronary intervention (PCI), but the effect of psychological factors such as symptoms of anxiety and depression on adverse outcomes are sparsely described. Thus, the aim was to investigate the association between symptoms of anxiety and depression and a composite endpoint of the first event of an acute cardiac readmission, revascularisation or all-cause mortality within one year after PCI.

Methods and results: A national cross-sectional survey at hospital discharge (responders, n=3,362) was performed with register-based follow-up among patients having undergone elective or emengency PCI. Mental health was measured at discharge using the Hospital Anxiety and Depression Scale, HADS, and divided into symptoms of anxiety (HADS-A) and symptoms of depression (HADS-D). The associations between mental health (HADS-A and HADS-D) and the composite endpoint were assessed with Cox proportional hazards models with time-to-first-event as underlying timescale. The results are presented as hazard ratios (HR) with 95% confidence intervals (CI), and adjusted for sex, age, heart failure, COPD, renal disease, ventricular arrhythmia and diabetes. At discharge, 32% reported symptoms of anxiety (HADS-A ≥ 8) and 19% reported symptoms of depression (HADS-D ≥ 8). After one year, 35.8% had experienced the composite endpoint of the first event of an acute cardiac readmission, revascularisation or all-cause mortality (separately; 35.0%, 7.9% and 2.2%, respectively). Proportions of patients experiencing the composite event significantly differed among patients reporting symptoms of anxiety compared to patients without symptoms of anxiety (40.5% vs 33.1%, p≤0.001) and among patients reporting symptoms of depression compared to those, who did not (46.1% vs 33.0%, p≤0.001). In the regression analyses, both symptoms of anxiety (HADS-A ≥ 8) and depression (HADS-D ≥ 8) were associated with an increased risk of experiencing the composite endpoint of the first event of an acute cardiac readmission, revascularisation or all-cause mortality (HADS-A ≥ 8: HR 1.24 95% CI: 1.10-1.40; HADS-D ≥ 8: HR 1.45 95% CI: 1.26-1.66). Based on analyses of the continuous scores of HADS-A and HADS-D, a one-point increase in scores was associated with a 3% and 5% higher risk of experiencing the composite event, respectively. The results were driven by readmissions and mortality.

Conclusions: After PCI, nearly one-third of the patients report symptoms of anxiety and one-fifth symptoms of depression at discharge. Symptoms of anxiety and depression significantly increased the risk an acute cardiac readmission, revascularisation or all-cause mortality within one year after PCI.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Incidence and mechanisms of largely uncovered struts in current generation DES: insight from the TRANSFORM-OCT study

BERNELLI Chiara [1], BERNELLI Chiara [1], PELLEGRINI Dario [2], CEREDA Alberto [3], YAMAC Hatice [2]

(1) Santa Corona Hospital: First Aid, Province of Savona, Italy; (2) ASST Papa Giovanni XXIII, Province of Bergamo, Italy; (3) Sondrio Hospital, Province of Sondrio, Italy

Aims: The presence of uncovered struts (US) may be associated with delayed vessel healing, stent failure and potential adverse clinical events. Factors associated with development of largely (>30%) US with current-generation drug-eluting-stents (DES) detected by optical coherence tomography (OCT) remain unclear. Aim of the study was to evaluate the incidence, the mechanisms and the temporal evolution of largely-US.

Methods and results: Study population consisted of the patients enrolled in the TRANSFORM-OCT, a randomised controlled trial that assigned 90 subjects to PCI with either abluminal bioabsorbable polymer everolimus- or durable polymer zotarolimus-eluting-stents. OCT imaging was obtained before, immediately after procedure and at 3 and 18 months. Patients were then divided in 2 groups according to the amount of US identified at 3 months post-procedure, to identify those with ≥30% of US ("largely uncovered group") of <30% of US ("not largely uncovered group"). Unpaired Student's t-tests were performed for continuous variables and chi-square or Fisher's exact tests for categorical variables. Multivariable linear and logistic regression analyses were respectively used for continuous and categorical variables. Among 90 patients evaluated, largely-US were detected in 34.4% lesions/patients treated. Uncovered struts occurred more frequently in bigger vessels with larger mean lumen area (5.51±1.1 vs 4.27±1.5 mm^2, p=0.001). Notably, lesions with US had a significant higher percentage of plaque rupture (41.9 vs 18.6%, p=0.02), presence of thin-cap fibroatheroma (TCFA [58.1% vs 51.7% p=0.03]) and red-mixed thrombus (41.9% vs 17.2 %, p=0.01) as compared with lesions without US. As expected, US showed a greater percentage of malapposed struts (6.08±5.3 vs 3.5±3.6, p=0.02) and malapposition area (0.18±0.15 vs 0.11±0.08 mm^2, p=0.02) at the index procedure. At 3 and 18 months the rate and the amount of US and malapposed struts was significantly reduced. Indeed, at 3 months lesions in the largely uncovered group had 48.4±12% uncovered struts, vs 13.3±7% in the not largely uncovered group (p<0.001). However, the rate of malapposed struts at 3 months was only 7.95±7.5% and 1.69±1.6% (p<0.001), respectively, thus meaning that the vast majority of uncovered struts were well-apposed to the vessel wall. At 18 months, this rate improved even more, with uncovered struts being 8.4±10% and 1.8±3% (p<0.001), respectively, and malapposed struts being only 1.4±3.3 and 0.16±0.43% (p 0.006). The percentage of covered struts, the presence of plaque rupture and MLA post-implantation were the only factors independently associated with US both at 3 and 18 month.

Conclusions: Largely-US at 3 months occurs in about 1/3 of lesions treated with current generation DES. US are more frequent in larger vessels containing TCFA, plaque rupture and thrombus. US usually coexist with stent malapposition. Besides vessel characteristics, high-pressure implantation technique and novel thin-strut stents might have a crucial role in reducing the potential risk of vessel delayed healing and stent failure. In this scenario, OCT besides being useful in understanding mechanisms related to strut uncoverage, could play a fundamental role in preventing and reducing their occurrence, through PCI guidance and optimisation.

CTO - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

PCI of in-stent CTO – A median long-term follow-up from a single-centre experience

MOHAMMED Ishaq [1], BASAVARAJAIAH Sandeep [1], WATKIN Richard [1], MICHAEL Pitt [1], MENT Jerome [1], LEE Kaeng [1], FREESTONE Bethan [1], PULIKAL George [1], BHATIA Gurbir [1], ATHUKORA Sampath [1]

(1) heartlands hospital main, Birmingham, United Kingdom

Aims: In both elective and emergency settings the implantation of stents is increasing worldwide. In-stent CTOs are becoming an increasingly common finding. Percutaneous coronary intervention (PCI) for in-stent restenosis (ISR) CTOs remains a challenge with relatively higher rates of complications as compared to *de novo* CTOs even though the success rates have gone close to 90%. Although there is plethora of data on ISR, there are limited data on in-stent chronic total occlusion (CTO). In this study, we explore the median long-term follow up outcome of patients who had PCI to in-stent CTO at our centre.

Methods and results: We evaluated all patients who underwent PCI to in-stent CTO between 2011 and 2017 at our centre. As per the standard CTO definition, we included all the in-stent CTOs of at-least 3-months duration. The endpoints used were; cardiac death, target vessel MI, stent thrombosis and target vessel revascularisation. Sixty-one patients with a mean age of 67.26±10.7 years [69% were male] underwent PCI for in-stent CTO between 2011 and 2017. Ninety-three percent of patients were symptomatic, 32% were diabetic, 7% were active smokers at the time of PCI, 27% had chronic kidney disease and 26% had left ventricular systolic dysfunction (ejection fraction <50%). Forty percent of the lesions were treated in the setting of acute coronary syndromes. The mean J-CTO score was 2.81. Ninety-three percent of the cases were treated with antegrade approach. Success rate was 88.9%. Forty-eight percent of patients received DES and the remaining 52% were treated with drug-coated balloons. Duration of dual antiplatelet therapy ranged from 1 month to 24 months depending on the treatment strategy received. At median follow-up of 34.27±10.4 months, mortality rate due to cardiac death was 3.2% (2 patients died); one occurred 2 years and the other occurred 3 years after procedure. Both patients were on single antiplatelet therapy at the time of death. There were no documented cases of target vessel MI or stent thrombosis (definite and probable). TVR was 14.7% (n=9) and the MACE rate (combination of cardiac death, target vessel myocardial infarction and TVR) was 16.4%. At 2.5-year follow-up 91.3% of successfully treated patients demonstrated significant clinical improvement.

Conclusions: In-stent CTOs are becoming more common. The challanges of opening an in-stent CTO are similar to CTO PCI. This is the first report of the outcomes of in-stent CTOs in the literature with median long-term follow-up nearing almost 3 years and the outcomes are comparable to international CTO registries and acceptable given the complex group of patients and also lesion complexity.

STEMI - Tools, devices and techniques

Dynamic microvascular flow resistance (dMVR) measurement using the Controlled Flow Infusion (CoFI) method in a porcine STEMI model with reduced TIMI flow outcome post-stenting and subsequent microvascular obstruction by injecting endogenous microthrombi

CESAROVIC Nikola [1], CESAROVIC Nikola [1], LIPISKI Miriam [2], HOH Tobias [3], WASCHKIES Conny [3], JONER Michael [4], SCHWARTZ Robert [5], HOEM Jon [6], GERTEIS Esther [6], BLUDAU Oliver [6], ROTHMAN Martin [6]

(1) Translational Cardiovascular Technologies, ETH Zürich and German Heart Center Berlin, Zurich, Switzerland; (2) Division of Surgical Research, University Hospital Zurich, Zurich, Switzerland; (3) Institute for Biomedical Engineering, University and ETH Zurich, Zurich, Switzerland; (4) Deutsches Herzzentrum München, München, Germany, Munich, Germany; (5) Minneapolis Heart Institute and Foundation, Minneapolis, USA; (6) CorFlow Therapeutics AG, Baar, Switzerland

Aims: Microvascular obstruction (MVO) remains a major problem in acute coronary syndromes, with potent impact on both short- and long-term prognosis. No clinical pharmacology-based trials to date show efficacy against MVO, regardless of strategy. Because of these pharmacologic failures, this study evaluated a multi-modal therapeutic approach against MVO using a combined pharmacologic and fluid-dynamic approach.

Methods and results: STEMI was created in 8 healthy domestic pigs using 90-minute proximal LAD balloon occlusion, followed by balloon deflation followed by stenting and reperfusion (mimicking standard PCI procedure). After stenting, an injection of endogenous micro-thrombi was administered directly in to the left anterior descending artery (LAD). In all animals TIMI flow assessment of the distal LAD (microembolisation site) was performed by angiography. Controlled flow infusion was administered by brief epicardial (within the stent) balloon occlusion with direct infusion of either tirofiban 30 ml (25µg/kg) in 3 flow sequences (N= 4 animals) or no therapeutic flow infusion (N= 4 animals). Simultaneous back pressure from the infusion was recorded. At 4 hours post reperfusion, contrast enhanced cardiac MRI (CMR) was performed to evaluate MVO presence and extent. Following the imaging procedure, the animals were sacrificed, and the hearts explanted for gross pathology and histological evaluation. Final data will be available upon presentation.

Conclusions: MVO is a critical, multifaceted problem, with uniformly poor therapeutic response displayed across many pharmacologic trials. The combination of target-delivered, potent, local antiplatelet agent delivered with restorative haemodynamic infusion using Controlled Flow Infusion may improve therapeutic results, while simultaneously providing important diagnostic physiology. Further preclinical studies are warranted by these early data.

Other Coronary interventions - Calcified lesions

Intravascular imaging on the treatment of calcified lesions with coronary lithotripsy

CUBERO-GALLEGO Hector [1], CUBERO-GALLEGO Hector [1], MILLAN Raul [2], GOMEZ-LARA Josep [3], FUERTES-BARAHONA Monica [4], AMAT-SANTOS Ignacio [5], SALVATELLA Neus [2], TIZON-MARCOS Helena [2], GOMEZ-HOSPITAL Joan Antoni [3], MORIS Cesar [1], VAQUERIZO Beatriz [2]

(1) Hospital Universitario Central de Asturias, Oviedo, Spain; (2) Hospital del Mar, Barcelona, Spain; (3) Hospital Universitario de Bellvitge, L'Hospitalet de Llobregat, Spain; (4) Hospital Universitario Joan XXIII, Tarragona, Spain; (5) Hospital Clínico Universitario de Valladolid, Valladolid, Spain

Aims: Coronary lithotripsy is a new technique that involves the use of high-energy mechanical pulses, delivered by a semicompliant balloon, to crack coronary calcium. The main objective of this study was to provide further insight about the effects of the lithoplasty balloon on significant calcified coronary lesions to optimise stent implantation using intracoronary imaging: intravascular ultrasound (IVUS) and optical coherence tomography (OCT).

Methods and results: This was a prospective, multicentre registry, which included consecutively all cases with calcified coronary lesions that underwent coronary lithotripsy with the Coronary Rx Lithoplasty System (Shockwave Medical, Inc., Fremont, CA) between August 2018 and August 2019. IVUS/OCT data were analysed at an independent central core lab by experienced analysts, who were blinded to the clinical data, using proprietary offline software (LightLab Imaging, St Jude Medical Inc., St. Paul, Minnesota, US). This registry included 57 patients (66 lesions); a relatively elderly population (72.6±9.4 years) with high proportions of patients with diabetes (56%), chronic kidney disease (35%) and multivessel disease (84%). All lesions were classified as type B/C. On average, coronary lithotripsy required the use of 1.17±0.41 balloons delivering 3 therapies (range, 2.5-4) with a mean of 60 pulses. Successful coronary lithotripsy was achieved in 98% of cases. Intravascular imaging techniques (IVUS/OCT) were performed at the discretion of the operator in 38 (57.57%) patients, but only 16 cases showed minimum criteria to be properly analysed. The analysis of intravascular imaging was performed at 2 time points: after predilating with a semicompliant balloon before the coronary lithotripsy; and after stent implantation. IVUS images were analysed in 7 cases (44%) and OCT images were analysed in 9 cases (56%). Before coronary lithotripsy, calcification length on intravascular imaging was 26.9±15.1 mm; calcium angle was 309.38±73.25º; and minimal lumen diameter and minimal lumen area were 1.66±0.32 mm and 2.32±0.69 mm², respectively; with a mean lumen eccentricity of 0.74±0.04. After inflating the lithoplasty balloon to reference vessel diameter, stents were delivered to all target lesions. After stent implantation, the minimal lumen diameter was 2.6±0.2 mm and the mean lumen area was 7.24±1.38 mm². Lesion preparation with coronary lithotripsy led to an increase in the minimum lumen area and in the acute lumen area gain after stent implantation of 3.2±0.58 mm² and 3.10±1.05 mm², respectively, with further improvement in the mean lumen eccentricity index post-stenting (0.83±0.03). In this group of patients where intravascular imaging was performed, there were no complications.

Conclusions: This is a real-world multicentre registry, which supports the feasibility, safety, and short-term efficacy of the lithoplasty balloon for the treatment of calcified lesions in a high-risk population. In addition, intravascular imaging by IVUS/OCT supports the efficacy of coronary lithotripsy improving lesion compliance with a probably circumferential plaque modification in the presence of significant calcification to optimise stent expansion and apposition.

Left main and multivessel disease - Bypass surgery

Ten-year all-cause death following percutaneous or surgical revascularisation in patients with prior cerebrovascular disease: insights from the SYNTAXES study

TAKAHASHI Kuniaki [1], THUIJS Daniel J.F.M. [2], MOHR Friedrich-Wilhelm [4], MORICE Marie-Claude [3], HOLMES David R. [5], ONUMA Yoshinobu [7], KAPPETEIN Arie Pieter [2], HEAD Stuart J. [2], SERRUYS Patrick W. [7]

(1) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (2) Erasmus MC, Rotterdam, the Netherlands; (3) Hôpital Privé Jacques Cartier, Massy, France; (4) Heart Centre Leipzig, Leipzig, Germany; (5) Mayo Clinic, MN, USA; (6) Baylor University Medical Center, Dallas, USA; (7) National University of Ireland Galway, Galway, Ireland

Aims: Patients with prior cerebrovascular disease (CEVD) are often referred to percutaneous coronary intervention (PCI) instead of coronary bypass artery grafting (CABG). However, there have been limited data supporting this preference. The aim of the present study was to evaluate a relative benefit of PCI versus CABG in terms of all-cause death at 10 years according to prior CEVD.

Methods and results: The SYNTAX Extended Survival (SYNTAXES) study assessed vital status up to 10 years in patients with three-vessel disease (3VD) and/or left main coronary artery disease (LMCAD) who were originally enrolled in the SYNTAX trial. The relative efficacy of PCI vs CABG in terms of 10-year all-cause death was assessed according to prior CEVD, defined as prior stroke, transient ischaemic attack, or carotid artery disease. The pre-specified primary endpoint was all-cause death at 10 years. In the SYNTAXES study, the status of prior CEVD was available in 1,791 (99.5%) patients, of whom 253 patients had prior CEVD (78 patients had prior stroke, 84 patients had prior transient ischaemic attack, and 148 had prior carotid artery disease). Patients with prior CEVD were older and had more comorbidities (medically treated diabetes, on insulin, metabolic syndrome, peripheral vascular disease, chronic obstructive pulmonary disease, impaired renal function, and congestive heart failure), compared with those without prior CEVD. In the overall population, patients with prior CEVD, when compared with those without prior CEVD, had a significantly higher risk of all-cause death at 10 years (41.1% vs 24.1%; hazard ratio: 1.92; 95% confidence interval: 1.54-2.40; $p<0.001$). The risk of all-cause death at 10 years was similar between patients with PCI and CABG irrespective of the presence of prior CEVD (Pinteraction=0.624).

Conclusions: Prior CEVD was associated with a significantly increased risk of all-cause death at 10 years. The risk of all-cause death at 10 years in patients with PCI vs CABG was similar irrespective of the known CEVD. These results did not support preferential referral to PCI rather than CABG in patients with prior CEVD.

Stents and scaffolds - Tools, devices and techniques

Haemodynamic analysis of new version mirage BRS and metallic Ultimaster stents: a new era begins with shear stress analysis in stent assessment

TENEKECIOGLU Erhan [1], TENEKECIOGLU Erhan [1], TORII Ryo [3], KATAGIRI Yuki [4], DIJKSTRA Jouke [2], REIBER Johan [2], BOURANTAS Christos [3], ONUMA Yoshinobu [1], SERRUYS Patrick [5]

(1) Erasmus MC, Rotterdam, the Netherlands; (2) Leiden University Medical Center (LUMC), Leiden, the Netherlands; (3) UCL, London, United Kingdom; (4) AMC, Amsterdam, the Netherlands; (5) Imperial College London, London, United Kingdom

Aims: OCT based computational fluid dynamics (CFD) studies have bestowed enormous information for coronary flow behaviors. Stent implantation causes local flow disruptions which can end up in thrombus formation and exuberant neointimal hyperplasia. Restoring vasomotricity and cyclic strain makes bioresorbable scaffold (BRS) glamorous in front of metallic stents. After unprecedented results from Absorb, with circular thinner struts, Mirage seems flashing as an alternative door to knock. Our aim was to compare haemocompatibility of Mirage with Ultimaster DES using CFD techniques using preclinical models.

Methods and results: After implantation of 3x18mm Ultimaster stent (strut thickness: 85µm) (n=6) and 3×18mm Mirage (strut thickness:105 µm) (n=6), three-dimensional (3D) reconstructions were performed and followed by CFD studies. Following non-Newtonian pulsatile flow simulation, CFD analysis unravelled that post-implantation shear stress distribution was not different between Mirage BRS and metallic DES Ultimaster. Using mixed effect analysis; mean ESS, median ESS, maximum ESS and minimum ESS were found comparable between Mirage and Ultimaster stents (0.84±0.11 Pa vs 0.87±0.09 Pa, p=0.32). The endothelisation at 28-day histological analysis showed comparable endothelial coverage in Mirage BRS and Ultimaster stents.

Conclusions: The new thinner version of Mirage bioresorbable scaffold demonstrated similar local micro-haemodynamics to the metallic Ultimaster stent. Despite thinner quadratic struts of Ultimaster, the circular struts of Mirage caused less flow disruption.

STEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Device-related complications after Impella mechanical circulatory support implantation: an IMP-IT observational multicentre registry substudy

ANCONA Marco [1], CHIEFFO Alaide [1], ANCONA Marco [1], BURZOTTA Francesco [2], PAZZANESE Vittorio [1], BRIGUORI Carlo [3], PIVA Tommaso [4], TRANI Carlo [2], GIUSTINO Gennaro [5], MONTORFANO Matteo [1], TARANTINI Giuseppe [6]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy; (2) Gemelli, Metropolitan City of Rome, Italy; (3) Mediterranea Cardiocentro, Naples, Naple, Italy; (4) Ospedali Riuniti di Ancona, Ancona, Italy; (5) Mount Sinai Medical Center, NY, USA; (6) Padova Ospedale, Province of Padua, Italy

Aims: The IMP-IT Registry (IMPella Mechanical Circulatory Support Device in Italy) is an investigator-initiated, nationwide, all-comer, multicentre registry evaluating the trends in use and clinical outcomes of Impella in the setting of cardiogenic shock (CS) and high-risk PCI (HR-PCI). The aim of the present study is to report the incidence, the predictors and clinical impact of device-related complications (DRC) in the IMP-IT registry.

Methods and results: A total of 406 patients across 17 Italian centres from 2004 to June 2018 have been included in this registry: 229 for CS (56.4%) and 177 for HR-PCI (43.6%) indication. DRC were defined as a composite endpoint of access-site bleeding, limb ischaemia, vascular complication requiring treatment (endovascular or surgical), haemolysis (both major and minor), aortic injury (such as aortic dissection) and left ventricular perforation. DRC incidence in the overall population was 25.6%: the rate was significantly higher in the CS group (37.1%) than in the HR-PCI group (10.7%) ($p<0.0001$). The most frequent complication was haemolysis, whose rate was 11.8% and occurred almost exclusively in CS population. Access-site bleeding was observed in 9.6% of the overall population, with no significant difference between the CS (10.9%) and the HR-PCI (7.9%) group. Limb ischaemia was observed in 34 patients (8.3% of the overall population), with significantly higher rate in the CS group (12.6%) than in the HR-PCI group (2.8%), ($p<0.0001$). A vascular intervention (either surgical or percutaneous) was required in 5.2% of the overall population. One case of left ventricular perforation and one case of aortic injury were reported. Cardiogenic shock at presentation appears as the strongest independent predictors of DRC (odds ratio 4.96, 95% confidence interval 2.42 – 10.16, $p<0.0001$). Other independent predictors of DRC were peripheral artery disease, atrial fibrillation, active smoking, right ventricular dysfunction, and left ventricular ejection fraction. Predictors of each DRC have than been assessed. On multivariate analysis, cardiogenic shock was the strongest independent predictor of haemolysis together with pulmonary hypertension. Indeed, the only independent predictor of limb ischaemia was peripheral artery disease, while the only independent predictor of access site bleeding was the concomitant use of extracorporeal membrane oxygenation (ECMO). On univariate analysis, DRC was correlated to one-year mortality (hazard ratio 1.60, 95% confidence interval: 1.14-2.26); however, at multivariate analysis, DRC was not confirmed to be an independent predictor of one-year mortality (hazard ratio 0.87, 95% confidence interval: 0.57-1.32).

Conclusions: In the IMP-IT registry, the rate of DRC was 25.6%, with CS being the strongest independent predictor. The incidence of haemolysis was 11.8%: cardiogenic shock and pulmonary hypertension were the strongest independent predictors of haemolysis. The incidence of limb ischaemia was 8.3%, aligned with previous reports; peripheral artery disease was the only independent predictor of limb ischaemia. DRC was not an independent predictor of one-year mortality at multivariate analysis.

Other Coronary interventions - Other

Vital prognosis derived from the updated logistic clinical SYNTAX score in patients with prior CABG surgery undergoing PCI

HIRONORI Hara [1], HARA Hironori [1], KOGAME Norihiro [1], TAKAHASHI Kuniaki [1], ONO Masafumi [1], KAWASHIMA Hideyuki [1], GAO Chao [2], WANG Rutao [2], FAROOQ Vasim [3], ONUMA Yoshinobu [4], SERRUYS Patrick W. [4,5]

(1) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (2) Radboud Universiteit, Nijmegen, the Netherlands; (3) Manchester Royal Infirmary, Manchester, United Kingdom; (4) National University of Ireland Galway, Galway, Ireland; (5) Imperial College London, London, United Kingdom

Aims: The anatomical SYNTAX score evaluated the anatomical complexity of coronary artery disease and predicted the medium-term prognosis of patients undergoing percutaneous coronary intervention (PCI). The anatomical CABG SYNTAX score was derived from classical anatomical SYNTAX score in patients with prior coronary artery bypass graft (CABG), and the logistic clinical SYNTAX score was developed by incorporating clinical factors into the anatomical SYNTAX score. We aimed to investigate the prognostic values of these SYNTAX-derived scores for all-cause mortality after PCI in patients with prior CABG.

Methods and results: Using the GLOBAL LEADERS trial database, we calculated the anatomical CABG SYNTAX score and logistic clinical SYNTAX score in 205 patients with prior CABG undergoing PCI. The all-cause mortality rate at 2 years was evaluated, and the predictive values for all-cause mortality were assessed using receiver operating characteristic curve analysis and integrated discrimination improvement. Applying the logistic clinical SYNTAX score categorised according to the median value (0.372), high score patients showed a significantly higher all-cause mortality rate at 2 years, compared to low score patients (p=0.0016), unlike the anatomical CABG SYNTAX score. The AUC values for 2-year all-cause mortality of the anatomical CABG SYNTAX score and logistic clinical SYNTAX score were 0.582 and 0.806 (p<0.001), respectively. A higher predictivity of the logistic clinical SYNTAX was also demonstrated by integrated discrimination improvement (0.121, p<0.001).

Conclusions: The logistic clinical SYNTAX score showed a higher predictive value for 2-year all-cause mortality than the anatomical CABG SYNTAX score and should be documented prior to PCI in order to properly inform the patient about his vital prognosis and the need to intensify his optimal pharmacological treatment as an adjunctive therapy to PCI.

Other Coronary interventions - Other

Radiation safety and risk estimates for cancer to nursing staff in the cath lab

ISON Glenn [1,2], ISON Glenn [1,2], KRISHNAMOORTHY Roopa [1]

(1) St George Hospital, NSW, Australia; (2) Hurstville Private Hospital, NSW, Australia

Aims: The occurrence of cancers is related to a number of factors, including age, sex, location and ethnicity, as well as exposure to environmental agents such as ionizing radiation. Whilst we have a good understanding of deterministic effects at high radiation levels, the calculation of possible damage at low levels is difficult. Cardiac cath lab nurses work in this low-level category. We will determine to look at the latest Biological Effects of Ionizing Radiation V (BEIR VII) report to analysis occupational risk.

Methods and results: The Biological Effects of Ionizing Radiation VII study was based on populations exposed from the Chernobyl accident, Hiroshima and Nagasaki, nuclear industry workers, workers from the Mayak facility, Chernobyl clean-up workers, airline and aerospace employees, and medical and dental occupational exposures. An average cath lab nurse's lifelong radiation exposure, using the US calculated population average, is 82% from natural background (cosmic radiation, natural radioactivity). Of the remaining 18 % from human-made exposure, personal diagnostic medical X-rays and nuclear medicine account for about 79%. Elements in consumer products, such as tobacco, the domestic water supply, building materials, and to a lesser extent, smoke detectors, televisions, and computer screens, account for another 16%. The remaining 5 % is from nuclear fallout and traveling by jet aircraft (add 0.01 mSv for each 1000 miles travelled), living near a coal-fired power plant (plant emissions— add 0.0003 mSv), being near X-ray luggage inspection scanners (add 0.00002 mSv), or living within 50 miles of a nuclear power plant (add 0.00009 mSv). This does not take into account the added occupational exposure in the cath lab. We endeavoured to calculate the risk multiplier of the usual yearly nurse radiation exposure to the BEIR VII model to quantify added cancer risk to our nursing staff. Over the last 4 years our full-time nurses averaged 96.25 µSv per year on their under-lead gown dosimeters. This is way below the allowed 20,000µ Sv a year for a deterministic result. Other labs may have a lower or higher average. The linear low radiation no-threshold BEIR VII model predicts that approximately one individual per thousand would develop cancer from an acute exposure to 0.1 Sv. From this our 15 cath lab nurses would need over 100 years to reach this level. In perspective approximately 420 out of 1000 individuals would be expected to develop a form of solid cancer or leukemia from normal causes in a lifetime. Whilst this is a great result for our nurses, a comprehensive review of all biology data shows that cancer risk is a linear progression at lower doses without a safe threshold. So, whilst an occupational cancer risk may be infinitesimal, it is not zero. As such, radiation safety in the lab must be constantly monitored and improved

Conclusions: This hopeful result of low risk of occupational cancers for our nurses in our centre, though based on the usual under-lead torso dose detector measurements, should carry over to their whole body absorbed dose as our cath lab is vigilant with under- and over-table shielding and eye protection but we will be continuing experiments on this. Other centres should also give this great importance as unmeasured, unshielded head, eye, arm and lower leg doses may give rise to cancer effects. Use of radiation risk modelling should be employed by all cardiac cath labs with vigilant oversight of their nursing staff radiation levels.

Bifurcation lesion - Tools, devices and techniques

Regular DES versus dedicated bifurcation drug-eluting BiOSS stents in coronary bifurcation treatment – a six-year follow-up of randomised POLBOS I and POLBOS II clinical trials

GIL Robert [1], GIL Robert [1], BIL Jacek [1], KERN Adam [2], INIGO GARCIA Luis A. [6], FORMUSZEWICZ Radoslaw [3], DOBRZYCKI Slawomir [4], VASSILEV Dobrin [5]

(1) Centralny Szpital Kliniczny MSWiA w Warszawie, Warsaw, Poland; (2) University of Warmia and Mazury in Olsztyn, Olsztyn, Poland; (3) 10 Wojskowy Szpital Kliniczny, Bydgoszcz, Poland; (4) The Medical University of Bialystok, Bialystok, Poland; (5) Alexandrovska University Hospital, Sofia, Bulgaria; (6) Costa del Sol Hospital, Marbella, Spain

Aims: Bifurcation lesions pose a therapeutic challenge during percutaneous coronary intervention (PCI). Results of regular drug-eluting stents (rDESs) in bifurcation treatment are not optimal. The aim of this study was to analyse the 6-year follow-up of BiOSS (Balton, Poland) stents in patients enrolled in two randomised clinical trials POLBOS I (NCT02192840) and POLBOS II NCT02198300).

Methods and results: The BiOSS stent is a coronary-dedicated bifurcation balloon-expandable stent made of 316L stainless steel and coated with a biodegradable polymer as well as the drug. The stent consists of two parts with different diameters connected with two struts of 1.9 - 2.5 mm length each. The aim of randomised POLBOS trials was to compare the BiOSS stents with regular drug-eluting stents (rDES) in patients with stable CAD or NSTE-ACS (POLBOS I: paclitaxel-eluting BiOSS Expert vs rDES; POLBOS II: sirolimus-eluting BiOSS LIM vs rDES). Provisional T-stenting was the default strategy. Angiographic control was performed at 12 months in all patients. The primary endpoint was composed of MACE defined as cardiac death, myocardial infarction or target lesion revascularisation (TLR). Clinical assessment was performed every year after the index procedure. In POLBOS I trial BiOSS Expert was implanted in 120 patients (49.4%), and rDES was implanted in 123 patients. The target vessel was the left anterior descending (LAD) artery (52% vs 70%) followed by the left main stem (LMS) coronary artery (22% vs 15%). In rDES group, 38.2% of patients received paclitaxel-eluting stents. Side branch treatment with rDES was required in 10% of cases in both groups. At 12 months, the incidence of cumulative major adverse cardiovascular events (MACE) was similar in both groups: 13.3% vs 12.2% (p=0.7). The TLR rate was significantly higher in the BiOSS Expert group compared with rDES group (11.5% vs 7.3%; p=0.02). Significantly lower rates of restenosis were observed in final kissing balloon (FKB) subgroups of both the BiOSS Expert (8.1% vs 13.2%; p<0.05) and rDES groups (4.9% vs 9.5%; p<0.05). In POLBOS II 202 patients were randomly assigned 1:1 to treat¬ment of the coronary bifurcation lesions either with the BiOSS LIM stent (n=102) or with rDES (n=100). The target vessel was the LAD (44% vs 43%) followed by the LMS (35.3% vs 38%). Side branch treatment was required in 8.8% (rDES) and 7% (BiOSS). At 12 months, the cumulative MACE incidence was similar in both groups (11.8% [BiOSS] vs 15% [rDES, p=0.08]), as was the TLR rate (9.8% vs 9% [p=0.8]). The binary restenosis rates were significantly lower in the FKBI subgroup of the BiOSS group (5.9% vs 11.8%, p<0.05). At 60 months, the MACE rate was 24.8% in the BiOSS group and 22.1% in the rDES group (p=0.42), whereas TLR rates were 18.9% and 16.7%, respectively (p=0.29).

Conclusions: BiOSS stents provided satisfactory 1-year results which seemed comparable with rDES. Long-term data are pending.

Left main and multivessel disease - Invasive imaging and functional assessment

Is iFR better than FFR in the assessment of left main lesions? Single-centre experience based on the first series of patients

BIL Jacek [(1)], BIL Jacek [(1)], PAWLOWSKI Tomasz [(1)], GIL Robert [(1)]

(1) Centralny Szpital Kliniczny MSWiA w Warszawie, Warsaw, Poland

Aims: Assessment of the left main coronary artery (LM) by coronary angiography has several limitations. Fractional flow reserve (FFR) is useful for the functional evaluation of LM stenoses. Instantaneous wave-free ratio (iFR), a resting index, was developed to simplify functional coronary assessment. However, its performance for LM stenoses has yet to be explored.

Methods and results: We included patients with angiographically intermediate LM stenoses qualified by the Heart Team for functional assessment. The iFR was measured at rest, and the FFR was measured under maximal hyperaemia after 2 minutes of adenosine infusion (140 µg/kg/min) (SynVision, Volcano). We calculated that a sample size of 90 lesions would have provided 90% power at a 5% significance level to detect an area under the curve (AUC) < 0.7 for the iFR to identify FFR-positive stenoses. We included 90 patients (age 69±9 years, women 20%, hypertension 88.9%, diabetes type 2 – 40.9%, prior MI 35.6%, chronic kidney disease 20%). Pure LM stenosis was present in 64.4% of patients, whereas 35.6% of patients had multivessel disease with LM involvement. The mean SYNTAX score was 29.6±5.2. Mean FFR values in LAD and LCx were, 0.82±0.11 and 0.85±0.12, respectively. Mean iFR values in LAD and LCx were 0.88±0.10 and 0.90±0.12, respectively. The comparison between the iFR and the FFR showed a significant correlation (LAD: r = 0.89, LCx: r = 0.83, both p<0.001). The correlation was better in case of pure LM stenosis (LAD: r = 0.95, LCx: r = 0.73, both p<0.001) than in multivessel disease (LAD: r = 0.48, LCx: r = 0.84, both p<0.001). At receiver operating characteristic (ROC) analysis, the iFR revealed a good diagnostic performance when compared to the FFR (AUC = 0.80; p<0.001). A classification agreement between the iFR and the FFR was recorded in 84% of cases. Interestingly, iFR and FFR correlated well with % diameter stenosis of the distal LM in QCA analysis when measured in LAD (LAD: r = -0.81, LCx: r = -0.71, both p<0.001) than in LCx (LAD: r = 0.15, LCx: r = 0.31, both p=NS). At 1-year follow-up clinical data on patients in whom PCI was deferred based on iFR results proved that it was a safe modalitiy. The rates of cardiac death and MI were acceptable.

Conclusions: The present study is one of the first demonstrating that the assessment of LM stenoses with the instantaneous wave-free ratio is a reliable adenosine-free alternative to classic fractional flow reserve.

Other Coronary interventions - Other

Bleeding risk profile in patients on oral anticoagulation undergoing PCI

SCHUKRAFT Sara [1], SCHUKRAFT Sara [1], HUWYLER Tibor [1], OTTINGER-MANKAKA Cindy [1], LEHMANN Sonja [1], COOK Ezia [1], GOY Jean-Jacques [1], TOGNI Mario [1], ARROYO Diego [1], PURICEL Serban [1], COOK Stéphane [1]

(1) Fribourg University, Fribourg, Switzerland

Aims: The aim of this study is to quantify the risk of additional high bleeding risk (HBR) criteria, as defined by the Academic Research Consortium for High Bleeding Risk (ARC-HBR) group, in patients on oral anticoagulation (OAC) and planned to receive DAPT after PCI.

Methods and results: The Cardio-FR registry is a single-centre prospective registry enrolling all consecutive patients undergoing PCI between May 2015 and May 2017 at the University & Hospital Fribourg (Fribourg, Switzerland). All patients on OAC and willing to provide informed consent were included in the study. We defined 2 groups: patients with OAC + additional HBR criteria vs patients with OAC as the only HBR criterion. A second analysis was performed for minor HBR criteria: patients with ≥2 minor HBR criteria vs ≤1 minor HBR criterion. The primary endpoint was any bleeding during the 24-month follow-up. The secondary bleeding endpoint was defined as BARC ≥3 using a hierarchical approach to describe bleeding severity grade. The secondary ischaemic endpoint was a patient-oriented composite endpoint (POCE) of all-cause death, myocardial infarction (MI), and repeat target-vessel revascularisation (TVR). Follow-up was complete in 142 patients of which 102 (72%) had OAC as the only ARC-HBR criterion and 40 (28%) at least one additional HBR major criterion. VKA were prescribed in 76 patients (54%) and 66 patients (46%) had NOAC. OAC was mainly for atrial fibrillation in both groups (63%). The mean number of major HBR criteria in the OAC+HBR group was 2.32±0.57. Two or more minor HBR criteria were present in 67 patients (47%). DAPT was: aspirin + clopidogrel in 123 patients (87%), aspirin + prasugrel in 17 patients (12%), and aspirin + ticagrelor in 1 patient (<1%). Median duration of triple therapy was 1 month. The rate of bleeding complications was higher in patients with OAC+HBR criteria compared to patients with OAC-only (53% vs 20% at 24 months, p<0.01). Interestingly, the difference remained after triple therapy interruption. The rate of BARC ≥3 bleedings at 24 months was also significantly higher in patients with OAC+HBR vs OAC only (35% vs 8%, <0.01). The incidence of POCE was 18% in the OAC+HBR group vs 30% in the OAC-only group (hazard ratio, 2.1; 95% CI: 0.81 to 5.46; p=0.13). In the minor HBR criteria analysis, the overall bleeding rate at 24 months was significantly higher in OAC-HBR as compared to OAC-only (43% vs 16%, hazard ratio, 0.27; 95% CI: 0.12 to 0.56; p<0.01). However, the difference was no longer significant for major BARC ≥3 bleedings (hazard ratio, 0.80; 95% CI: 0.34 to 1.85; p=0.60).

Conclusions: Additional HBR criteria are frequent in unselected patients on OAC undergoing PCI. Both major and minor HBR criteria increase the risk of bleeding but only additional major HBR criteria increase the risk of major bleeding (BARC ≥3) at 24-month follow-up.

NSTEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Two-year experience of magnesium BRS implantation in ACS

LANOCHA Magdalena [1], LANOCHA Magda [1], WLODARCZAK Adrian [1], SZUDROWICZ Marek [1], JASTRZEBSKI Artur [1], PECHERZEWSKI Maciej [1], LESIAK Maciej [2]

(1) Copper Health Center, Lubin, Poland; (2) Poznan University of Medical Sciences, Poznan, Poland

Aims: Bioresorbable vascular scaffolds (BRS), the newest coronary stent technology, were developed to improve long-term outcomes compared to metallic drug-eluting stents. Especially in the setting of the acute coronary (ACS) syndrome, these devices bring hope for improvement of long-term results of percutaneous coronary interventions (PCI).

Methods and results: The study population consisted of the 70 consecutive patients who underwent PCI with the Magmaris BRS in the setting of ACS (NSTEMI -75%, UA - 25%) and were followed up for 24 months. Patients with ST-segment elevation myocardial infarction were excluded from enrolment. Baseline demographic and angiographic characteristics, as well as the 24-month clinical follow up, were prospectively analysed. Patients were enrolled at mean age 61.4±8.4 years, predominantly male (85%) with typical cardiovascular risk factors. *De novo* lesions were treated in LAD (37%), LCX (14%), and RCA (49%), respectively. Angiographic success in the target lesion was 100%. One case of ischaemia-driven target vessel revascularisation (ID-TLR) was reported during index in-hospital stay. No other events were observed (procedural success of 98%). All patients remained on prescribed DAPT for 12 months. Twelve-month follow up revealed 3 cases of scaffold restenosis (ID-TLR) treated by DES implantation (9 months after index PCI, and 2 patients 12 months after index PCI). None other endpoints such as cardiac death or scaffold thrombosis were observed. On a voluntary basis, 12-month control angiography and optical coherence tomography (OCT) assessment were performed in 42 patients (60%) which confirmed the perfect angiographic performance of all implanted magnesium scaffolds. All the patients were followed up for 24 months and no additional device-oriented, or patient-oriented endpoints, were observed during the second year of observation.

Conclusions: Long-term observation of ACS patients treated with magnesium bioresorbable scaffolds confirmed the excellent clinical performance of this new-generation of bioresorbable scaffolds. We believe that implantation of the Magmaris in ACS patients in daily clinical practice is applicable and associated with excellent clinical outcomes.

Bifurcation lesion - Tools, devices and techniques

The patient-oriented clinical outcomes of functionally guided strategy in coronary bifurcation lesions – insights from the FIESTA registry

VASSILEV Dobrin [1], VASSILEV Dobrin [1], MILEVA Niya [1], NIKOLOV Pavel [1], DIMITROV Georgi [1], KARAMFILOFF Kiril [1], NAUNOV Vladimir [1], RIGATELLI Gianluca [3], COLLET Carlos [2], GIL Robert [4], SERRUYS Patrick [5]

(1) Aleksandrovska University Hospital, Sofia, Bulgaria; (2) Olv Ziekenhuis, Aalst, Belgium; (3) Rovigo Medica, Province of Rovigo, Italy; (4) Medical Centre of Postgraduate Education, Warsaw, Poland; (5) Imperial College London, London, United Kingdom

Aims: The purpose of this study is to address the rates of patient-oriented outcomes after functionally-guided (e.g. fractional flow reserve) PCI of coronary bifurcation lesions.

Methods and results: We analysed patients from the FIESTA registry, which was a continuation of FIESTA study (FFR vs icECG in Coronory Bifurcations, ClinicalTrials.gov Identifier: NCT01724957). Patients with stable angina were included. The inclusion criterion was angiographic bifurcation lesions in a native coronary artery with diameter ≥ 2.5 mm and ≤ 4.5 mm and SB diameter ≥ 2.0 mm. We excluded patients with ST-segment elevation myocardial infarction, left main, haemodynamic instability. PCI was performed according to the current guidelines. Provisional stenting was the default strategy in all patients. Fractional flow reserve (FFR) was performed using the PrimeWire or PrimeWire Prestige (Volcano Corp., USA). For all FFR measurements, intracoronary adenosine was given in increasing doses of 60 mcg, 120 mcg, and 240 mcg. The minimum value of FFR measurements was taken for analysis. All patients received dual antiplatelet therapy with ADP-antagonist and aspirin for at least 12 months. A total of 160 consecutive patients with coronary bifurcation stenoses were included. The mean age was 67±10 years, 66% males, 96% hypertensive, 38% diabetic, 96% dyslipidemic (or on treatment with statin), 46% smokers, 19% with previous myocardial infarction, 51% with previous PCI. From these, 74 had positive FFR<0.80 in main vessel of bifurcation lesion (46% functionally significant lesions). The rates of major adverse events at 32±20 months in treated and deferred patients were: all-cause death 16.2% (n=12/74) vs 7.1% (n=6/86), p=0.069; cardiac death 12.2% (n=9/74) vs 5.9% (n=5/86), p=.163; myocardial infarction 1.2% (n=1/74) vs 0%, p=0.282; symptom-related TVR 5.4% (n=4/74). There was no significant difference regarding rates of rehospitalisations, because of symptom recurrence 20% vs 17.6%, p=0.673. On multivariate Cox regression analysis, the only independent predictor of patient-oriented clinical outcomes (cardiac death, MI, TVR), 11.2% (n=18/160) was renal failure (HR=3.983, CI 1.531-10.359, p=0.005).

Conclusions: Deferring bifurcation lesions based on FFR was safe. The rates of patient-oriented clinical outcomes were not significantly different between treated and deferred stenoses based on 4-year follow-up.

Bifurcation lesion - CT / MRI imaging, Other Coronary interventions - Calcified lesions

Advanced atherosclerosis in coronary bifurcations – is CT coronary angiography a tool to assess it?

ILIC Ivan [1], ILIC Ivan [1], VIDAKOVIC Radosav [2], JANICIJEVIC Aleksandra [2], STEFANOVIC Milica [2], KAFEDZIC Srdjan [2], CEROVIC Milivoje [2], MILICEVIC Dusan [2], ZIVANIC Aleksandra [2], BABIC Rade [1]

(1) Institute for cardiovascular diseases Dedinje, Belgrade, Serbia; (2) Clinical Hospital Center Zemun, Belgrade, Serbia

Aims: Coronary bifurcation atherosclerosis depends on its angles, flow and extensive branching. Multislice CT coronary angiography (CTCA) enables non-invasive evaluation of geometry and atherosclerotic plaque characterisation within the coronary arteries. We investigated the ability of CTCA to determine qualitative and quantitative parameters of atherosclerotic plaque in the main branch (MB) of "true" non-left main bifurcation compared to intravascular ultrasound (IVUS).

Methods and results: The study included patients with stable coronary artery disease scheduled for PCI where we analysed MB quantitative parameters and plaque characteristics at the level of bifurcation's "polygon of confluence" and at the point of minimal lumen diameter (MLD) stenosis using 128-slice CT scanner prior to PCI and 40mHz IVUS catheter during the intervention. Patients were not considered for the study if having left ventricular ejection fraction (LVEF) of less than 30% or suffering from renal failure with estimated glomerular filtration rate (GFR) of less than 30 ml/min/m^2. Patients with bifurcation lesion within the culprit artery causing myocardial infarction, grafted surgically or previously treated with PCI, were not considered for the study. The study included 70 patients with 72 native, non-left main bifurcations. Most of the lesions were in the left anterior descending (LAD) – diagonal (D) territory (50/72 (69.4%]) while 31 (43%) were Medina 1,1,1 lesions. Bland-Altman analysis showed important discrepancy in measuring lumen area between CTCA and IVUS (proximal 11.2%; carina 34.8%; distal 30.7%; MLD 69.6%). There was a significant correlation regarding measurements of the vessel area (proximal r=0.272/p=0.043, carina 0.373/0.041, distal 0.334/0.012, MLD 0.321/0.016), which didn't exist for lumen area (proximal r=0.183/p=0.177, carina 0.198/0.143, distal 0.194/0.153, MLD 0.010/0.944). There was a significant correlation between average plaque density on CTCA in Hounsfield units with percentage of calcified atherosclerotic plaque on IVUS virtual histology (proximal r=0.307/p=0.024, carina 0.469/0.008, distal 0.339/0.024, MLD 0.318/0.020) which was not true for other tissue types – fibrous (proximal r=0.008/p=0.955, carina 0.076/0.583, distal 0.204/0.184, MLD 0.203/0.145), lipid (proximal r=-0.222/p=0.107, carina -0.105/0.444, distal 0.036/0.815, MLD -0.176/0.206) and necrotic (proximal r=-0.003/p=0.980, carina 0.067/0.625, distal 0.168/0.276, MLD 0.216/0.120).

Conclusions: CT coronary angiography has certain limitations in quantitative and tissue evaluation of complex coronary bifurcations compared to IVUS due to unfavourable characteristics of advanced, flow limiting, calcified lesions.

Stents and scaffolds - Tools, devices and techniques

First real-world safety and performance analysis of the routine clinical use of the Tyrocore-based sirolimus-eluting bioresorbable coronary scaffold

LUTZ Matthias [1], LUTZ Matthias [1], KRÄMER Marie [1], KUHN Christian [1], ROSENBERG Mark [2], LEIBUNDGUT Gregor [3], FREY Norbert [1]

(1) University Medical Center Schleswig-Holstein, Campus Kiel, Kiel, Germany; (2) Klinikum Aschaffenburg, Kardiologie, Aschaffenburg, Germany; (3) Canton Hospital Basel-Land, Liestal, Switzerland

Aims: The objective of this analysis was to evaluate the safety and performance of native coronary artery stenting using the Fantom bioresorbable scaffold (BRS) in routine clinical practice. Fantom is manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. It is radiopaque with thin struts (125 microns) in the 2nd generation device and as low as 95 micron struts in the third-generation Fantom Encore.

Methods and results: This assessment includes a single centre evaluation of the real-world use of the Fantom BRS in every-day clinical practice. This analysis include more than 80 patients who were consecutively treated with a total of more than 100 implanted scaffolds over a time period of 20 months. More than 15 of the patients included in this evaluation were treated with a total of 20 third-generation Fantom Encore scaffolds, which has a reduced strut thickness compared to the second-generation Fantom scaffold. Reported outcomes include acute technical success, acute procedural success, and a clinical procedural success rate of 97.3%. There were three incidences of restenosis (TLF) with no further major adverse cardiac events (MACE) or scaffold thrombosis through 6-month and 12-month follow-up among the patients that have reached this time point. Six-month and 12-month clinical outcomes for all patients as well as acute results will be presented at the conference. Up to now the 6-month MACE rate is 2 % and there is no scaffold thrombosis.

Conclusions: In this first more than 80 patient report of routine clinical use, the Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favourable safety and efficacy through 6 and 12 months. These results demonstrate the advantages of a thin-strut, radiopaque bioresorbable scaffold on procedural success and early clinical outcomes in routine real-world clinical use.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Safety and efficacy of excimer laser coronary atherectomy for uncrossable coronary lesions

OJEDA Soledad [1], OJEDA Soledad [1], HIDALGO Francisco [1], SUÁREZ DE LEZO Javier [1], GONZÁLEZ Rafael [1], SEGURA José [1], MAZUELOS Francisco [1], LUQUE Aurora [1], ELIZALDE Juan Carlos [1], PERICET Cristina [1], ROMERO Miguel [1], PAN Manuel [1]

(1) Hospital Universitario Reina Sofia, Córdoba, Spain

Aims: Uncrossable lesions constitute a challenge for percutaneous coronary intervention. Despite the development of low-profile balloons and microcatheters, the failure of the procedure is frequent and rotational atherectomy may be the only alternative. However, this device requires a dedicated wire that often cannot be delivered beyond the lesion. The objective of this study is to assess the efficacy and safety of excimer laser coronary atherectomy (ELCA) in balloon/microcatheter uncrossable coronary lesions.

Methods and results: From June 2018 to December 2018, ELCA was used in 15 patients in whom the guidewire successfully crossed the coronary lesion but a microcatheter or a low-profile balloon failed to advance and to dilate the lesion. In all cases we used the CVX-300 Excimer Laser System (Spectranetics Inc., Colorado Springs, CO, USA) in conjunction with the 0.9-mm X80 catheter (Spectranetics Inc.). While flushing with continuous saline, a mean of 4,745±1,661 pulses were delivered, reaching a fluence of 74.3±4.5 mJ/mm^2 and a frequency of 58±13 pulses/sec. The mean age was 73±9 years and 11(73.3%) were men. Six (40%) patients had unstable angina or acute coronary syndrome and the remaining 9 (60%) patients presented stable angina. The lesions were located in the left anterior descending artery in 6 (40%) patients, in the circumflex artery in 4 (26.7%), and in the right coronary artery in 5 (33.3%) patients. All patients had severe lesions with significant calcifications. Additionally, in 4 (26.7%) of them, a coronary chronic total occlusion was present. The refence vessel diameter was 2.89±0.32 mm, the lesion length 26±13 mm and the percentage of stenosis was 92±8%. Technical success was achieved in 12 (80%) patients. In the majority of these cases (n= 7; 58.3%%), the ELCA catheter crossed the lesion completely, while in the remaining 5 (41.7%) patients the catheter could not be advanced beyond the distal lesion. However, it modified the plaque, allowing the subsequent passing of the balloon. After that, the lesions were dilated and successfully treated with drug-eluting stents. In 3 (20%) patients the ELCA failed. In all of these patients, rotational atherectomy was attempted but in only 1 patient, the specific guidewire crossed the lesion and rotational atherectomy was performed. Regarding procedural complications, 3 (20%) patients had myocardial injury detected by troponin elevation without clinical consequences, 1 (6.7%) patient had a stroke (which was not directly attributable to ELCA) and led to subsequent mortality and another patient (6.7%) presented a ventricular fibrillation during the energy applications requiring electrical defibrillation. There were no perforations of the target vessel, coronary dissections or other serious complications related to the device. After a median follow-up of 4 months, no major cardiac events (death, myocardial infarction and target vessel revascularisation) were recorded in the patients successfully treated and all of them remain free of symptoms.

Conclusions: ELCA provides a safe and effective therapy in contemporary percutaneous coronary intervention to treat uncrossable lesions, reaching a success rate of 80% in this complex lesion subset. The main advantage of this technique over other strategies is that ELCA can be performed using any type of coronary guidewire.

STEMI - Tools, devices and techniques

Two-year clinical outcomes of the REVELATION study: paclitaxel-coated balloon angioplasty vs DES in AMI

NIEHE Sander [1], NIEHE Sander [1], VOS Nicola [1], VAN DER SCHAAF Rene [1], AMOROSO Giovanni [1], HERRMAN Jean Paul [1], PATTERSON Mark [1], SLAGBOOM Ton [1], VINK Maarten [1]

(1) OLVG, locatie Oost, Amsterdam, the Netherlands

Aims: The randomised REVELATION trial showed that in the setting of ST-segment elevation myocardial infarction (STEMI), a drug-coated balloon (DCB) strategy was non-inferior to a drug-eluting stent (DES) in terms of fractional flow reserve assessed at 9 months. The aim of the present study is to assess the long term clinical outcome (2 years) of both these strategies.

Methods and results: A total of 120 patients with a non-severely calcified culprit lesion in a native coronary artery and a residual stenosis of <50% after predilatation were randomised to treatment with a DCB or DES. Complete clinical follow-up at two years was available in 109 patients (91%). A major adverse cardiac event (MACE) defined as death, recurrent myocardial infarction, or target-lesion revascularisation, occurred in 3 patients (5.4%) in the DCB group and 1 patient (1.9%) in the DES group, respectively (HR 2.86, 95% CI: 0.30-27.53, p=0.34). Between 9 months and 2 years only one event occurred (TLR), in a patient randomised to DCB who required bail-out stenting.

Conclusions: In this randomised study of DCB versus DES in selected patients presenting with STEMI, long-term outcomes were excellent and comparable between DCB and DES.

CTO - Tools, devices and techniques

Survival benefit of revascularisation versus optimal medical therapy alone for CTO management in patients with diabetes

PÉREZ FUENTES Pedro Ramon [1], PÉREZ FUENTES Pedro [1], FLORES UMANZOR Eduardo [1], SABATE MANEL [1], FREIXA Xavier [1], REGUEIRO CUEVA Ander [1], MARTIN YUSTE Victoria [1], BRUGALETTA Salvatore [1]

(1) Hospital Clínic i Provincial de Barcelona, Barcelona, Spain

Aims: Chronic total occlusion (CTO) is common in patients with diabetes mellitus. Data on the long-term outcomes after treatment of CTOs in this high-risk population are scarce. We aim to compare the long-term clinical outcomes of CTO revascularisation either by coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) vs optimal medical treatment (MT) alone in patients with diabetes.

Methods and results: A total of 538 consecutive patients with diabetes and at least one CTO were identified from 2010 to 2014 in our centre. In the present analysis, patients were stratified according to the CTO treatment strategy that was selected. MT was selected in 52% of patients whereas revascularisation was selected in the remaining 48%. Patients undergoing revascularisation were younger, had higher left ventricular ejection fraction (LVEF), lower ACEF score, and more positive myocardial ischaemia detection results compared to the MT group ($p<0.001$). Patients referred for CABG had higher rates of left main disease compared to the PCI and MT groups (32% vs 4% and 11%, respectively; $p<0.001$). Complete revascularisation was more often achieved in the CABG group, compared to the PCI group (63% vs 35.5% $p<0.001$). Multivariable analysis showed that revascularisation with CABG was associated with lower rates of all-cause and cardiac mortality rates compared to MT, (hazard ratio [HR] 0.44, 95% confidence interval [CI] 0.27-0.73 $p=0.002$ and HR 0.42, 95% CI: 0.21-84, $p=0.015$, respectively). Successful CTO-PCI showed a trend towards benefit in all-cause mortality (HR 0.58, 95% CI: 0.33-1.04, $p=0.06$).

Conclusions: In our registry, CTO revascularisation in diabetic patients, especially with CABG, was associated with lower long-term mortality rates as compared to MT alone.

Other Coronary interventions - Other

Optimal timing of staged PCI of non-infarct-related vessels in patients with ACS and multivessel disease: a Bern PCI registry analysis

OTSUKA Tatsuhiko [1], OTSUKA Tatsuhiko [1], BÄR Sarah [1], KAVALIAUSKAITE Raminta [1], UEKI Yasushi [1], ZANCHIN Christian [1], ZANCHIN Thomas [1], STORTECKY Stefan [1], PILGRIM Thomas [1], WINDECKER Stephan [1], RÄBER Lorenz [1]

(1) Inselspital, Universitätsspital Bern, Bern, Switzerland

Aims: Complete revascularisation among ACS patients with multivessel disease reduces cardiovascular events. However, the optimal timing of PCI in non-infarct-related vessels remains a matter of debate. We aimed to investigate the impact of early (≤4 weeks) versus late (>4 weeks) PCI of non-culprit lesions in patients scheduled for staged PCI after index hospitalisation discharge.

Methods and results: From January 2009 to December 2017, all acute coronary syndrome (ACS) patients undergoing planned staged PCI at Bern University Hospital, Switzerland, were analysed. Patients with cardiogenic shock, early (in-hospital) complete revascularisation of non-infarct related vessels, staged CABG, and multiple staged PCI were excluded from the present analysis. We aimed to compare the primary outcome between patients with early staged PCI group (≤4 weeks) and late staged PCI group (>4 weeks). The timepoint of staged PCI was at the discretion of the operator and was defined in the hospital discharge letter. The primary endpoint was a composite of all-cause death, recurrent myocardial infarction (MI), or urgent PCI in non-infarct-related vessels. Urgent PCI was defined as revascularisation in a non-infarct-related vessel performed earlier than planned because of unstable angina after (index hospitalisation) discharge or worsening congestive heart failure or symptomatic arrhythmia refractory to medication. Between January 2009 and December 2017, total of 9,040 ACS patients were treated. Staged PCI was planned among 1,746 patients and a total of 1,434 patients fulfilled the eligibility criteria for this analysis. The primary composite endpoint at 1 year occurred in 12.1% of late staged PCI patients, and 7.76% of early staged PCI group (HR [95% CI] 0.64 [0.42-0.97]; p=0.035), respectively. There was no difference in all-cause death (late 2.94% vs early 2.01%, HR [95% CI] 0.69 [0.30-1.56]; p=0.37), cardiac death (late 1.56% vs early 1.44%, HR [95% CI] 0.92 [0.34-2.50]; p=0.88), or recurrent MI (late 3.96% vs 4.60%, HR [95% CI] 1.18 [0.67-2.10]; p=0.57) between groups. Urgent PCI in non-infarct-related lesions occurred in 7.36% of patients in late staged PCI group, and 3.45% of patients in the early staged PCI group (HR [95% CI] 0.47 [0.26-0.86]; p=0.015). Definite stent thrombosis occurred at a similar frequency among groups (late 1.20% vs early 1.72% (HR [95% CI] 1.45 [0.55-3.82]; p=0.45), respectively.

Conclusions: In ACS patients with multivessel disease scheduled for a staged revascularisation after the index hospitalisation, a late (>4 weeks) staged PCI was associated with a higher rate of major cardiovascular events as compared to an early staged PCI strategy (≤4 weeks). This difference was mainly driven by more frequent urgent revascularisation procedures.

Other Coronary interventions - Other

Introduction of an evidence-based rapid deflation protocol for haemostasis after transradial procedures is associated with faster haemostasis without increased bleeding complications or patient discomfort: a ward-based observational study

NIELSEN Lisbet [(1)], NIELSEN Lisbet [(1)], NOERGAARD Marianne Wetendorff [(1)], JOSHI Francis Richard [(1)]

(1) Rigshospitalet, opgang 2, Copenhagen Municipality, Denmark

Aims: Radial artery occlusion (RAO) remains a problem after transradial (TR) procedures. Patent or minimal-pressure haemostasis has been shown to reduce the risk of RAO in randomised studies. We aimed to test the effect of the introduction of an evidence-based rapid-deflation minimal-pressure protocol on bleeding complications and radial artery occlusion in our institution. We also aimed to describe patients' experiences of hand pain and paraesthesia.

Methods and results: The study was performed in March (previous practice (PP)) and June 2019 after introduction of a rapid-deflation (RD) protocol. TR Band® was used in all cases. PP was inflation of the TR Band® at end-case with 14mL, removing air to the point of haemostasis and then replacing 4mL. 120 minutes later, air was removed by 2mL increments every 5 minutes. In RD, at end-case, the TR Band® was inflated with 15 mL, air removed to the point of haemostasis and then 2mL replaced. 15 minutes later, air was again removed to the point of haemostasis, and then 2 mL replaced. Residual air was removed from the TR Band® after 90 minutes (5 French) and 120 minutes (6 French). Bleeding and haematoma were registered at 30 and 120 minutes, after removal of the TR Band®, and at discharge. Radial artery occlusion was assessed with colour Doppler ultrasound. Patient comfort scores in terms of pain and paraesthesia in the hand were measured in both groups. The co-primary endpoints were haematoma ≥5 cm (EASY Class ≥II) and radial artery occlusion at discharge. Secondary endpoints included persistent oozing or bleeding from the puncture site requiring manual compression prior to discharge and haematoma >10 cm. There were 110 patients in the PP group and 106 patients in the RD group. 6 Fr Glidesheath Slender® sheaths were used in 97% and 98% of cases, respectively; 31% and 41% of patients had PCI (p=0.18). Unfractionated heparin dosing (1000 IU) was 8 [7-11] versus 9 [7-12], p=0.06. Significant differences were seen in the PP and RD groups with respect to age (65 [53-72] versus 69 [59-75] years, p=0.03), female sex (38% versus 25%, p=0.04), creatinine (78[66-93] versus 84 [74-103] mmol/L, p=0.02), the use of clopidogrel (30% versus 44%, p=0.04) and indication for oral anticoagulation (7% versus 17%, p=0.047). The volume of air on leaving the lab in the PP and RD groups were 12 [11-14] mL versus 11 [10-13] mL (p<0.01); 15 minutes later this was 12[11-14] versus 7[7-10] mL (p<0.01). There was no significant difference in the incidence of haematoma ≥5 cm (3(3%) versus 2(2%), p=1.00). One radial artery occlusion was observed in the PP group. There was no difference in oozing or bleeding requiring manual compression (PP and RD: 5% versus 10%, p=0.18); no significant univariate or multivariate predictors of haematoma ≥5 cm or persistent oozing were identified. There were 2 (2%) >10 cm haematoma in the PP group and none in the RD group (p=0.50). There were no cases of pseudoaneurysm or compartment syndrome. Total time to haemostasis was significantly reduced from 182[167-201] to 138[126-159] minutes (p<0.01). No differences were found in patient-reported pain or paraesthesia; no pain at all was reported in 96% of the PP group and 94%, of the RD group (p=0.53).

Conclusions: Introduction of a Rapid Deflation protocol after TR procedures was associated with faster haemostasis without increased bleeding complications or a negative impact on patient-reported comfort. There was a very low incidence of RAO.

Stents and scaffolds - Adjunctive pharmacotherapy

Validation of bleeding risk criteria (ARC-HBR) in patients undergoing PCI

UEKI Yasushi [1], UEKI Yasushi [1], BÄR Sarah [1], LOSDAT Sylvain [2], OTSUKA Tatsuhiko [1], ZANCHIN Christian [1], ZANCHIN Thomas [1], SIONTIS George [1], PILGRIM Thomas [1], WINDECKER Stephan [1], RÄBER Lorenz [1]

(1) Inselspital, Universitätsspital Bern, Bern, Switzerland; (2) Clinical Trials Unit, Bern, Switzerland

Aims: The Academic Research Consortium for High Bleeding Risk (ARC-HBR) defined consensus-based criteria for patients at high bleeding risk (HBR) undergoing percutaneous coronary intervention (PCI). We aimed to validate the ARC-HBR criteria for the bleeding outcomes using a large cohort of patients undergoing PCI.

Methods and results: Between 2009 and 2016, patients undergoing PCI were prospectively included in the Bern PCI Registry. Patients were considered to be at HBR if at least 1 major criterion or 2 minor criteria were met and the ARC-HBR score was calculated by adding 1 point for any major and 0.5 point for any minor criterion. The primary endpoint was Bleeding Academic Research Consortium (BARC) 3 or 5 bleeding at 1 year; ischaemic outcomes were assessed using the device-oriented composite endpoints (DOCE) of cardiac death, target-vessel myocardial infarction, and target lesion revascularisation. Among 12,121 patients, those at HBR (n=4,781, 39.4%) had an increased risk of BARC 3 or 5 bleeding (6.4% vs 1.9%; p<0.001) and DOCE (12.5% vs 6.1%; p<0.001) compared with those without HBR. There was a graded risk increase for BARC 3 or 5 bleeding as a function of ARC-HBR score (0: 1.6%, 0.5: 2.9%, 1: 4.6%, 1.5: 4.9%, 2: 8.5%, 2.5: 9.0%, ≥3: 10.9%). The degree of risk and prognostic value were related to the risk factors composing the criteria.

Conclusions: Patients at HBR defined by the ARC-HBR criteria had a higher risk of BARC 3 or 5 bleeding as well as DOCE. The bleeding risk was proportional to the risk score and related to its individual components.

Other Coronary interventions - Other

Predictors and long-term outcomes of incomplete revascularisation in PCI

ABUD Marcelo [1], ABUD Marcelo [1], ORDOÑEZ BUZZINO Santiago [1], VACAVALVERDE Ignacio [1], LAMELAS Pablo Manuel [1], SPALETRA Pablo Marcelo [1], PEDERNERA Gustavo Omar [1], MASCOLO Pablo [1], PADILLA Lucio Tiburcio [1], BELARDI Jorge Atilio [1], CURA Fernando Adrián [1]

(1) ICBA Instituto Cardiovascular, Buenos Aires, Argentina

Aims: The aim of this study is to evaluate the predictors of incomplete revascularisation and long-term clinical outcomes in an all-comers contemporary cohort of patients treated with percutaneous coronary intervention.

Methods and results: Patients who underwent percutaneous coronary intervention between January 2009 and June 2019 were retrospectively analysed and classified into two groups, depending on whether complete or incomplete revascularisation (IR) has been achieved. We defined complete revascularisation upon the anatomical definition, which includes the treatment of all vessels > 2.25 mm with at least one significant stenosis > 50%. Those patients with cardiogenic shock (blood pressure < 100 mmHg, heart rate > 100 bpm, poor peripheral perfusion with inotropic requirement and/or mechanical circulatory assistance) were excluded from the analysis. The primary outcome was the composite of major cardiovascular events consisting of all-cause mortality, acute non-fatal myocardial infarction (AMI) and stroke at 5 years, whichever came first. The observed prevalence of incomplete revascularisation (IR) was 47.5%. This group of patients were older with higher cardiovascular risk factor burden. Regarding the extension and anatomical characteristics, IR patients presented a higher SYNTAX score (26 [RIC 16 - 37] vs 12 [RIC 6 - 20], p<0.0001), as well as higher prevalence of CTO, bifurcation lesions and more severe (77.3 mm [RIC 70 - 90] vs 75.9 mm [70 - 90], p 0.006) and diffuse (17.8 mm [RIC 12 - 24.6] vs 16 mm [12 - 22.7], p 0.015) lesions. The independent predictors of IR were: age>80 years (OR 1.56), emergency indication (OR 1.65), intermediate and high SYNTAX score (OR 5.03), diabetes melliitus (Non-IR: OR 1.22; IR: OR 1.45), previous CABG (OR 1.94), CKD (OR 1.69), LVEF<30% (OR 1.53) and the presence of CTO (OR 1.78). The LM compromise was a factor associated with lower IR (OR 0.59). IR was associated to higher risk of MACE (14.3% vs 7.1%, HR 1.66 [95% CI: 1.44-1.910], p<0.0001) driven by all-cause mortality. The risk of MACE in patients with IR was higher in all SYNTAX score categories (pint 0.357), as well as in the presence or absence of DBT (pint 0.456).

Conclusions: Incomplete revascularisation is highly prevalent in current PCI practice and its prevalence is higher with higher SYNTAX scores. It is associated to poor prognosis with higher rates of MACE, mainly driven by all-cause mortality. This was seen across all SYNTAX score categories. Independent predictors of IR were: age>80 years, emergency indication, intermediate and high SYNTAX score, diabetes melliitus, previous CABG, CKD, LVEF<30% and the presence of CTO. The LM compromise was a factor associated with lower IR in our observation.

Other Coronary interventions - Other

Innovations in occupational radiation protection for interventional cardiologists: the PODIUM project approach to personal dosimetry

OCONNOR Una [1], OCONNOR Una [1], SZIRT Richard [1], MURPHY Ross [1], WALSH Colin [1], GORMAN Dermot [1], ALMEN Anja [2], DUCH Maria Amor [3], GINJAUME Merce [3], ABDELRAHMAN Mahmoud [4], VANHAVERE Filip [4]

(1) St. James's Hospital, Dublin 8, Ireland; (2) Lund University, Lund, Sweden; (3) Polytechnic University of Catalonia, Barcelona, Spain; (4) SCK•CEN, Mol, Belgium

Aims: Individual monitoring of radiation workers is essential to ensure compliance with legal dose limits and for the ALARA (As Low As Reasonably Achievable) principle of radiation protection. This is of particular importance in Interventional Cardiology, with cardiologists among the most intensive users of fluoroscopically-guided interventional procedures. However, there are challenges with current monitoring programmes. The aim of the PODIUM (Personal Online Dosimetry using Computational Methods) project is to perform personal dosimetry in real-time without the need to wear physical dosimeters.

Methods and results: We applied and validated the innovative PODIUM methodology in the interventional cardiology/radiology setting in three European hospitals. This involved collecting data from radiation dose structured reports (RDSR) along with real movements of interventional clinicians using camera technology. This data was then transferred to the software application for dose calculation. Real clinician movement was obtained using a Microsoft Kinect™ camera mounted above the X-ray TV monitor. Ethics and consent issues were paramount in the study design due to the use of camera technology. Cardiologists were asked to wear a combination of currently available active and passive personal dosimeters to measure their dose per case for common examinations including PCI and Coronary Angiograms. Measured dose was compared with the PODIUM simulated results, in some cases using three different Monte-Carlo simulation codes. Our preliminary results show differences of approximately 30 – 50% between calculated and measured staff doses, in terms of the personal dose equivalent quantity Hp(10). An online application has also been developed to calculate individual levels of occupational exposure.

Conclusions: This preliminary study showed extremely encouraging results with a satisfactory margin of error between calculated and measured staff doses. Some challenges and limitations remain such as accurately tracking the C-arm movement and the ceiling mounted lead-glass screen. The next chapter of this study is to continue to improve the camera system and work has commenced on a 2-camera system. The Interventional radiology/cardiology environment is one of the most complex situations for personal dosimetry and it was ambitious yet highly worthwhile to test the proof-of-concept PODIUM approach in this field. It is clear that there is great promise and interest in continuing to develop this type of innovative solution. Acknowledgements. PODIUM is part of CONCERT. This project has received funding from the Euratom research and training programme 2014-2018 under grant agreement No. 662287.

Stents and scaffolds - Tools, devices and techniques

Sirolimus-coated balloon versus novel sirolimus-eluting stents in treatment of patients with high bleeding risk

TESTA Luca [1], DANI Sameer [2]

(1) IRCCS Pol. S. Donato, Milan, Italy; (2) Apollo Hospitals & Apollo CVHF Heart Institute, Ahmedabad, India

Aims: Current data on the performance of drug-coated balloon (DCB) angioplasty in the treatment of coronary stenosis hold promise. Merits of DCBs over stent technologies include homogeneous drug delivery, immediate drug release, no permanent implant left behind and shorter DAPT. We compared the clinical outcomes of sirolimus-coated balloons (SCB) (Magic Touch SCB, Concept Medical) vs novel sirolimus-eluting stents (SES) which have a unique coating technology (Abluminus DES+, Concept Medical), in patients with high bleeding risks.

Methods and results: We analysed 1,888 total patients (217 patients treated with MagicTouch SCB and 1,671 patients treated with Abluminus DES+) who had high bleeding risk. We assessed and compared major adverse cardiac events (MACE) at 1 year. MACE was defined as composite of target lesion/vessel revascularisation (TLR/TVR), target vessel myocardial infarction (TV-MI) and cardiac death. In the MagicTouch SCB group, the majority of patients presented with unstable angina (64.1%) while in the Abluminus DES+ group, most patients had ST-elevated MI (64.1%). The baseline characteristics of the patients in both groups were comparable. Most patients treated with SCB were prescribed a minimum 3 months DAPT while patients treated with DES were prescribed with minimum of 12 months DAPT. All patients completed 1-year follow-up. The incidence of MACE was recorded as 5.1% vs 2.6%, HR 2.033, 95% CI: 1.047-3.949; p=0.03, at 1 year in the SCB group vs the DES group, while TLR/TVR were 4.6 vs 1.1%, HR 4.340, 95% CI: 2.033-9.402, p=p<0.001. Cardiac death occurred in (0.0 vs 1.0, HR 0.041, 95% CI: 0.00-43.252, p=0.369) for MagicTouch SCB and Abluminus DES+ groups respectively. Rates of TV-MI are numerically similar in both groups (0.5% vs 0.5%, HR 0.927, 95% CI: 0.120-7.688, p=0.971). Moreover, 0.7 % patients implanted with DES presented with stent thrombosis which was clearly absent in patients treated with SCB group.

Conclusions: Though the sirolimus-coated balloon (non-stent drug delivery) was associated with higher restenosis rates when compared to DES patients with high bleeding risks, it could be a valid option when short DAPT is needed. A randomised controlled trial is an indispensable tool to further support the results.

Bifurcation lesion - Tools, devices and techniques

BioMime Branch -1: a randomised comparison of sirolimus-eluting coronary side branch stent systems and everolimus-eluting coronary stent systems to assess safety and performance in patients with de novo coronary bifurcation lesions

SELVAMANI Sethuraman [(1)], SELVAMANI Sethuraman [(1)], DAVIDSON Deepak [(2)], ARNEJA Jaspal [(3)], GUNASEKARAN Sengottuvelu [(4)], CHANDRA Praveen [(5)]

(1) Meenakshi Mission Hospital & Research Centre, Tamil Nadu, India; (2) Caritas Hospital, Kerala, India; (3) Arneja Heart and Multispeciality Hospital, Maharashtra, India; (4) Apollo Hospital Chennai, Tamil Nadu, India; (5) Medanta -The Medicity, Haryana, India

Aims: The study is designed to compare safety and performance of sirolimus-eluting bifurcation stents with everolimus-eluting coronary stent systems in patients with *de novo* coronary bifurcation lesions.

Methods and results: BioMime Branch-1 is a prospective, active-control, open-label, multicentre, randomised clinical trial. A total of approximately 183 patients with coronary bifurcation lesions will be enrolled and currently 24 have been recruited and randomly assigned (2:1) to receive either the sirolimus-eluting bifurcation stent in the side branch or the other drug-eluting stent in the main branch vs the everolimus-eluting coronary stent system in the side branch and main branch. The primary safety endpoint is incidence of ischaemia-driven target lesion failure at a 6-month follow-up. Secondary safety endpoints are major adverse cardiac events which is the composite of cardiac death, myocardial infarction and ischaemia-driven target vessel revascularisation at a 6-month follow-up. The study is currently recruiting and among 24 enrolled patients (n=18 in the sirolimus-eluting coronary side branch stent system arm and n=6 in the everolimus-eluting coronary stent system arm with a mean age of 58.33±6.74 and 53±9.14 years, respectively), a total 45 target lesions were treated. Out of 45 lesions, 33 lesions in the sirolimus-eluting coronary side branch stent system and 12 lesions in the everolimus-eluting coronary stent system were treated; procedural success, technical and device success was 100% in all the cases. At a 6-month follow-up, the incidence of ischaemia-driven target lesion failure and ischaemia-driven target vessel revascularisation were similar in the sirolimus-eluting stent group (0.0%) as compared with the everolimus-eluting stent group (0.0%). Ischaemia-driven target lesion revascularisation was reported in none of the patients between the groups at a 6-month follow-up. No mortality rate (cardiac and non-cardiac deaths) or stent thrombosis were observed in the sirolimus-eluting stent group and everolimus-eluting stent group to 6-month follow-up. Since the study is ongoing, the updated patient's data at respective follow-up will be provided during the conference.

Conclusions: In the multicentre, BioMime Branch-1 trial, results were found to be similar in the sirolimus-eluting coronary side branch stent system and everolimus-eluting coronary stent system at 6-month follow-up. (CTRI/2017/10/010239)

Stents and scaffolds - Adjunctive pharmacotherapy, Other Coronary interventions - Other

Hybrid PCI strategy with paclitaxel DEB in combination with DES. A single-centre experience

TEY Yee Sin [(1)], TEY Yee Sin [(1)], NURUDDIN Amin Ariff [(1)], PALANIAPPAN Ganapathi [(1)], THUM Chan Ho [(1)], STANISLAUS Rohith [(1)], NG Min Yeong [(1)], TEH Khai Chih [(1)], KAMSANI Suraya Hani [(1)], MOHAMED NAZEEB Mohamed Nazrul [(1)], KOLANTHAIVELU Jayakhanthan [(1)], ZAINAL Zulaikha [(1)], JALALUDDIN Mohd Saad [(1)]

(1) National Heart Institute, Federal Territory of Kuala Lumpur, Malaysia

Aims: We aimed to assess the outcome of hybrid percutaneous coronary intervention strategy with drug-eluting balloon in combination drug-eluting stent. Hybrid strategy is defined as stenotic lesion treated with paclitaxel-coated SeQuent Please NEO DEB combined with DES at the main artery supplying the territory.

Methods and results: A single centre, retrospective study was conducted on all patients that underwent coronary angioplasty with hybrid strategy between January 2015 and December 2018. Patients' baseline characteristics, angiographic data and 12-month follow-up outcomes were studied. Endpoint analysis included in-hospital outcome and major adverse coronary event (MACE) at 1-year follow-up. MACE was defined as a composite of cardiac-related mortality, myocardial infarction (MI), clinically-driven target vessel revascularisation (TVR), target lesion revascularisation (TLR) and stroke. Data were collected by using case report forms and reviewing patient's case notes, totalling 2,248 cases and 2,759 lesions treated with DEB during study period. Five hundred and ninety-six (26.5%) patients had a total of 680 (24.6%) lesions treated with hybrid strategy. Mean age was 59.6±9.8 years and the majority were male (85.6%, n=510). Most patients had hypertension (75.5%, n=450) and diabetes mellitus (61.7%, n=368). Two-thirds of patients (63.6%, n=379) were known to have coronary artery disease while half of patients (48.7%, n=290) had previous history of myocardial infarction. 95.5% of cases (n=569) were performed electively and 4.5% of cases (n=27) were done during primary angioplasty. The majority of treated lesions were in left anterior descending artery territory (49.4%, n=336) followed by right coronary artery (31.2%, n=212) and left circumflex (15.7%, n=107) territory. Treated lesions were predominantly type C lesions (67.4%, n=458). 72.8% coronary lesions were *de novo* in nature (n=495) and 27.2% were in-stent stenosis lesion (n=185). Mean percentage of stenotic lesions was 90.0±11.4% with mean estimated lesion length of 34.8±24.6mm. There was 1.3% (n=8) in-hospital mortality of which all were cardiac related. 0.3% (n=2) had acute vessel occlusion resulting in acute myocardial infarction required TLR during index admission. Clinical follow-up at 1-year was available in 572 (96%) patients. MACE was 1.7% (n=10) of which 50% (n=5) was cardiac related. 0.3% (n=2) had target vessel MI. 2.6% (n=15) patients required TVR and 1.7% (n=10) required TLR. None of the patients required bypass graft at 1-year. Our predicted probability of survival was 98% at 1-year.

Conclusions: Our centre experience demonstrates that hybrid PCI strategy can be applied in diffuse or multiple lesions of a single artery supplying the same territory with acceptable clinical outcome. However, a randomised study is needed to demonstrate its efficacy and long-term outcome to compare this hybrid strategy with DES alone in the treatment of coronary arteries with multiple or diffuse lesions.

Stents and scaffolds - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

New stent positioning system assisted PCI

KOMKOV Artem [1,2,3], KOMKOV Artem [1,2,3], SAMOCHATOV Denis [1,2], OSIEV Aleksandr [5], SEMISYNOV Ilya [4], MONOSOV Dmitriy [4], MAZAEV Vladimir [3]

(1) City Clinical Hospital 67, Moscow, Russian Federation; (2) National Medical Research Center of Traumatology and Orthopedics named after NN Priorova, Moscow, Russian Federation; (3) National Medical Research Center for Preventive Medicine, Moscow, Russian Federation; (4) Leningrad Regional Hospital, Saint Petersburg, Russian Federation; (5) Medsi, Moscow, Russian Federation

Aims: To verify usability and efficacy of stent positioning assistance system in patients undergoing PCI using OCT with the eye of lesion and stent implantation site.

Methods and results: All patients undergoing to this study had severe lesions in coronary arteries so PCI with stent implantation was performed in each case. All lesion predilatation was done to prepare plaques for sufficient stent expansion and easier way to use positioning assistance device. Patients with highly calcified coronary arteries were excluded due to unpredictable stent manipulation even after good balloon expandsion. We used OCT pullback before stent implantation to check plaque length and lesion structure, measure vessel diameter and size of the stent for implantation. Exact location for stent placement was defined by markers on OCT images. After predilatation and OCT pullback, the new assistant for stent positioning was mounted on a stent delivery system before introduction on the guidewire. The assistance device was fixed on the stent delivery system very close to the Y-connector when the stent was delivered to lesion site. The stent was moved to the correct position by rotation of the device back handle. High-resolution fluoroscopy or angiographic programs for better stent visualisation were used to improve stent positioning. Final result was checked by angiography and post-PCI OCT pullback. In 1 case we also used IVUS before and after PCI to evaluate lesion site and implanted stent. Eight vessels were investigated in 6 patients by 1 experienced operator (more than 50 cases using the assisting device), and 2 interventional cardiologist used the stent positioning device for the first or second time. Half of cases were performed by the experienced operator and the another half by first/second time device-using operators after short proctor briefing. Patients were 62.2±8.6 years old. All of them were male. 5 patients had stable coronary artery disease and 1 had AMI. Second stent edge-to-edge implantation was performed in 2 vessels, non-bifurcational and non-ostial lesions in 3 vessels, bifurcational lesions in 3 vessels (1 with IVUS control also). Distance error of stent placement from the defined site of implantation based on OCT data was 0.5±0.4 mm in cases performed by operators using the device first/second time and 0.2±0.2 mm in cases of the experienced operator.

Conclusions: Using the stent positioning assistance system is very efficient tool for high precision stent implantation. The system can be safely used even by inexperienced operators with satisfactory results. More investigations for the long-term outcomes and prospective control need to be verified in larger groups.

Other Coronary interventions - Calcified lesions

Super high-pressure OPN NC percutaneous transluminal coronary angioplasty balloon performance in complex coronary lesions: results of a multicentre registry

ORTIZ CRUCES Samuel [1], ORTIZ CRUCES Samuel [1], RHEUDE Tobias [2], CAMACHO FREIRE Santiago Jesús [1], FUSARO Massimiliano [2], GÓMEZ MENCHERO Antonio Enrique [1], CASSESE Salvatore [2], ROA GARRIDO Jessica [1], CARDENAL PIRIS Rosa [1], KASTRATI Adnan [2], DÍAZ FERNÁNDEZ José Francisco [1]

(1) Hospital Juan Ramón Jiménez - Huelva, Huelva, Spain; (2) Deutsches Herzzentrum München, Munich, Germany

Aims: Calcified coronary lesions remain a challenging scenario for patients undergoing PCI with elevated rates of periprocedural complications and adverse long-term events. We sought to assess the efficacy and safety of a super high-pressure non-compliant (NC) PTCA balloon (OPN; SIS Medical AG, Frauenfeld, Switzerland).

Methods and results: This is a multicentre all-comers registry including a total of 392 patients (412 lesions) treated with OPN at two centres from February 2010 to August 2019. Clinical data and angiographic characteristics, including safety endpoints (i.e., major adverse cardiovascular events [MACE, defined as cardiovascular death, AMI, target-lesion revascularisation], balloon rupture, perforations, stent or vessel thrombosis) were assessed. The mean age of the population was 69±9 years, 73% were male, and 66% had diabetes mellitus. The patients presented most commonly with NSTEMI (32.3%), followed by unstable angina (28.6%). The types of lesions were: 62.5% severely calcified coronary lesions, 31.6% in-stent restenosis and 4.5% chronic total occlusion (CTO). Intracoronary imaging technique was used in 19% (15% IVUS and 4% OCT). OPN was used for lesion preparation in 64.9%, and for post-dilatation in 34.3%. An average of 3.03 balloons were used in case of predilatation. In most cases (84%) complementary balloons (i.e. NC, scoring or cutting balloons) were chosen before deciding to use OPN. Rotablation was done in 14% of the patients. The efficacy and the safety of the OPN balloon were excellent with an angiographic success rate of 94% without any intraprocedural fatal complication (0.6% balloon rupture without perforation, 1.3% flow limiting dissection, 0.6% contained haematoma, 0.6% hypotube rupture). MACE rate at 5-year follow-up was 23.2% (5% cardiovascular death, 11% non-fatal myocardial infarction, 12% target-lesion revascularisation, 1% stent thrombosis).

Conclusions: Super high-pressure OPN NC balloon is effective and safe for optimal lesion preparation in complex coronary artery disease. Further randomised trials are demanded to compare different balloon-based lesion preparation strategies.

Stable CAD - Invasive imaging and functional assessment, Other Coronary interventions - Calcified lesions

The impact of guidewire bias on the efficacy of an orbital atherectomy system in calcified coronary lesions assessed by optical coherence tomography

TANAKA Kentaro [(1)], OKUTSU Masaaki [(1)], TAHARA Satoko [(1)], NAKAMURA Sunao [(1)]

(1) New Tokyo Hospital, Chiba, Japan

Aims: Detailed mechanisms of effective calcified plaque ablation by the Diamondback 360 Orbital Atherectomy System (OAS) *in vivo* are not well studied. The purpose of this study was to assess the efficacy of the OAS with optical coherence tomography (OCT).

Methods and results: Our study was a single centre, retrospective observation of 21 calcified coronary lesions treated with OAS assessed by OCT between April and November 2019. OCT imaging was acquired during pre- and post-ablation of OAS, and after stent implantation. At lesion level analysis, mean calcium area and calcium arc were 4.38±1.95mm^2 and 192±56 degrees in the ablated segment length of 21.3±8.0 mm. Mean lumen area increased from 4.34±2.30 mm^2 to 4.89±2.00 mm^2 with a lumen volume increase of 10.67±5.50mm^3 by ablation with OAS, and lumen area of 7.66±2.30 mm^2 was gained after stent implantation. Non-calcified plaque ablation was observed in 20.5±32.2% of total ablated area. At cross sectional level analysis, ablated calcified plaque area had a negative correlation of length between luminal surface of calcified plaque and OCT catheter position (i.e. guidewire bias) at pre-ablation ($r= -0.50$, $p>0.001$), in total of 574 cross-sectional frames with co-registration of pre- and post-ablation OCT images. Closer or attached position of OCT catheter to the plaque (the length $\leq$ 0.5mm) resulted in effective ablation of calcified plaque. ($p>0.001$) Similar trend was observed even in larger (>8.0 mm^2) lumen area ($r= -0.57$, $p>0.001$). Lumen area, lumen diameter and lumen eccentricity index in pre-ablation OCT had no significant correlation with ablated calcified plaque area.

Conclusions: OCT image acquisition, especially the positional relation between the OCT catheter and the calcified plaque to be ablated before the OAS procedure can be useful to maximise the efficacy of the OAS in calcified coronary lesions.

CTO - Tools, devices and techniques

Survival prediction for patients with coronary CTO

STELMASHOK Valeriy [1], STELMASHOK Valeriy [1], MROCHEK Alexander [1], POLONETSKY Oleg [1], STRYGO Nikolai [1]

(1) Republican Scientific and Practical Centre «Cardiology», Minsk, Belarus

Aims: To develop the prognostic survival model for patients with coronary artery chronic total occlusion.

Methods and results: From 2009 to 2013 in our single centre study an attempt of coronary artery chronic total occlusion (CTO) recanalisation by antegrade approach was performed in 217 patients. There were 158 patients with successful CTO revascularisation and 59 patients with unsuccessful attempt. This groups of patients did not differ in terms of demographic and clinical data. We evaluated cardiac mortality as the endpoint for our surviving model. The average follow-up period after coronary CTO recanalisation/attempt was 82.6 months (interquartile range: 74.0-101.0 months), maximal observational period 120 months (10 years). Overall one-, three-, and five-year survival rates were 98.6±0.8%, 97.1±1.2%, 95.9±1.4%, respectively. At the end of the observation period, the prognostic survival rate for all patients was 83.7±4.6%. The clinical, demographic, echocardiographic, angiographic parameters, CTO recanalisation success/failure factor were selected for univariate analysis. Based on the results of this analysis five potential predictors were selected for the multivariate model: body mass index, left ventricle end-systolic size, end-diastolic and end-systolic volumes, CTO recanalisation success/failure factor. The constructed multivariate model had high statistical significance (c2= 29.58, p<0.001). Important predictors associated with outcome were end-diastolic volume more than 180 ml (HR 0.17, 95% CI: 0.06-0.43, p<0.001) and CTO recanalisation success/failure factor (HR 2.74, 95% CI: 1.06-7.07, p=0.038).

Conclusions: End-diastolic volume more than 180 ml and unsuccessful attempt of coronary CTO recanalisation are strong predictors of cardiovascular mortality (c2=29.58, p<0.001 for overall significance model). In our research end-diastolic volume more than 180 ml increased cardiovascular mortality to 83% and successful coronary CTO revascularisation reduced cardiovascular mortality by 2.74 times.

STEMI - Adjunctive pharmacotherapy, Other Coronary interventions - Other

The comparison between balloon angioplasty vs stent implantation for stent thrombosis: the REAL-ST registry

YABUSHITA Hiroto [1]

(1) New Tokyo Hospital, Chiba, Japan

Aims: Stent thrombosis (ST) is an infrequent but potentially fatal complication of percutaneous coronary intervention. However, there is little data on optimal strategy for ST. This study aimed to compare strategies between balloon angioplasty (BA), including drug-coated balloon (DCB), and stent implantation in patients treated for ST.

Methods and results: Between January 2004 and December 2015, 655 consecutive patients who were diagnosed with definite ST were included (264 early ST, 88 late ST and 303 very late ST patients). Of these, 357 patients were treated with BA and/or DCB, 263 patients were treated with stent implantation (excluding 35 patients). Primary endpoints included cardiac death, target lesion revascularisation (TLR) and myocardial infarction (MI) at 5 years. Furthermore, we performed Cox regression analysis for cardiac death. Mean age was 68.5±10.3 years, male gender in 80.3%, diabetes mellitus in 46.6%, haemodialysis (HD) in 7.0%, and on dual antiplatelet therapy in 61.6%. There were no significant differences regarding the patient and lesion characteristics between the groups. Cardiac death occurred in a total of 17.1% (20.4% in the BA and DCB group vs 12.5% in the stent group, p=0.01), TLR occurred in a total of 17.4% (16.0% in the BA and DCB group vs 19.4% in the stent group, p=0.38) and MI occurred in a total of 7.0% (6.5% in the BA and DCB group vs 7.6% in the stent group, p=0.69). The occurrence of cardiac death was significantly higher in the BA and DCB group as compared to the stent group (p=0.01). On the other hand, recurrent ST occurred in a total of 5.5% patients (6.2% in the POBA and DCB group and 4.6% in the stent group, p=0.35). When final TIMI grade 3 was obtained, even in the POBA and DCB group, cardiac death occurred less as compared to those with TIMI grade 0, 1 and 2 (14.7% in TIMI 3, vs 41.1% in TIMI 0, TIMI 1, and TIMI 2, p<0.01). The Cox regression analysis demonstrated that HD and final TIMI grade 3 were independent predictors for cardiac death (HD: HR, 0.40 [95% CI: 0.21-0.78], p<0.01; final TIMI grade 3: HR, 0.33 [95% CI: 0.22-0.49], p<0.01).

Conclusions: Stent implantation might be a better treatment than POBA and DCB in patients with ST. Moreover, when final TIMI grade 3 was obtained, clinical outcome was feasible even in POBA and DCB treatment.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Acute procedural and long-term outcomes in patients with guide extension catheter device use

THORP Andrew [1], THORP Andrew [1], DESAI Chirag [1], WILSON Jeffrey [1], GEDELA Maheedhar [1], SINGH Aditya [1], VARGA Zoltan [1], SIMPSON Brian [1], PETRASKO Phillip [1], KREMER Andrew [1], STYS Adam [1], STYS Tomasz [1]

(1) Sanford USD Medical Center and Hospital, SD, USA

Aims: Guide extension catheter devices such as GuideLiner® allow for increased support, deep seating for distal delivery of intracoronary devices, and selective delivery of contrast. This study analyses the procedural outcomes utilising this study.

Methods and results: Data was obtained for all percutaneous coronary interventions (PCI) performed at the Sanford Cardiovascular Institute between January 2011 and June 2019. Radiation exposure, contrast volume, procedure duration, and adverse cardiac events were compared for patients who required use of a guide extension catheter versus those who did not, as per provider preference. For this study, adverse cardiac events were defined as the occurrence of myocardial infarction (MI), coronary artery bypass grafting (CABG), or death at 30 and 365 days post-PCI. Cases were performed using the Acist™ contrast delivery systems and utilised either single or bi-plane fluoroscopic systems, depending on provider judgement. Comparisons were made by linear regression, and a p-value of <0.05 was considered significant. A total of 9,526 PCIs performed with a total of 6,757 unique patients aged 18 and older during the study period. A total of 3,113 (32.68%) of these cases required use of a guide extension catheter (GuideLiner®) per provider preference. Patients who required use of guide extension were more likely to require less contrast exposure (101.70±72.23 vs 104.94±61.01 mL) but slightly higher radiation dose (1,672.15±1,798.35) and procedure time (51.92±30.57 mins vs 44.82±25.30 mins) ($p<0.05$ for all). Patients who required guide extension use had a greater rate of MI at 30 days (86 [2.8%] vs 129 [2.0%]) and 1 year (51 [2.5%] vs 83 [1.8%]), $p<0.05$. GuideLiner patients had fewer CABG at 30 days (1 [0.03%] vs 17 [0.03%]) and slightly higher rates of CABG at 1 year (29 [0.9%) vs 26 [0.4%], $p<0.05$). Guideliner patients had similar rates of death at 30 days compared to non-Guideliner patients (35 [1.6%] vs 85 [1.9%], $p=0.4484$), but greater rates of death at 1 year (104 [4.8%] vs 172 [3.7%], $p<0.05$).

Conclusions: Patients who required guide extension use were exposed to less contrast volume. A generally higher rate of adverse cardiac events seen in the guide extension catheter group likely reflects greater overall patient disease complexity and warrants further investigation.

Stents and scaffolds - Tools, devices and techniques

PCI with Agent paclitaxel-coated balloon: a real-world multicentre experience

IANNOPOLLO Gianmarco [1,5], IANNOPOLLO Gianmarco [1,5], GIANNINI Francesco [1,3], PONTICELLI Francesco [1], PAGLIARO Beniamino [1], TZANIS Giorgio [1], GALLONE Guglielmo [1], MONTORFANO Matteo [1], COLOMBO Antonio [1,2], DURANTE Alessandro [4]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy; (2) Columbus Clinic Center, Metropolitan City of Milan, Italy; (3) Cotignola Ospedale Villa Cecilia, Province of Forlì-Cesena, Italy; (4) ospedale Valduce, Province of Como, Italy; (5) Maggiore, Metropolitan City of Bologna, Italy

Aims: The AgentTM paclitaxel-coated balloon is a new drug-coated balloon (DCB), with limited real-world available data. Our study sought to assess the safety and efficacy of this new DCB during percutaneous coronary intervention (PCI) in different coronary lesion types in a prospective registry.

Methods and results: All-comer patients undergoing PCI with use of Agent DCB in 3 Italian centres between September 2014 and March 2018 were included in this registry. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, recurrent non-fatal myocardial infarction (MI) and target lesion revascularisation (TLR). DCB procedural lesion success was also evaluated. Among 354 patients (with 450 lesions treated with 508 DCBs) included in the registry, Agent DCBs were used for the treatment of in-stent restenosis (ISR), small vessel disease (SVD), bifurcation lesions (BL) and "stent-like result" (SLR) lesions obtained after balloon predilatation in 34%, 29%, 26%, 11%, respectively. The implant of Agent DCBs was safe and with a high DCB lesion success (92%). One-year MACE was 5.7% in the overall population. Higher MACE (8.3%) was observed in the ISR group, as compared to SVD group (3.6%, p=0.028), with a trend of higher events rates as compared to both BL (3.7%, p=0.09) and SLR groups (5.5%, p=0.54).

Conclusions: The use of Agent DCB during PCI appears safe and effective in a large real-world registry. These results were maintained in all subgroups with a slightly higher trend of events rates in the ISR setting, consistent with the higher risk nature of this subset.

STEMI - Tools, devices and techniques

The rationale of complete revascularisation of STEMI patients with multivessel coronary artery disease on long-term readmission rate, revascularisation, heart failure and cardiovascular mortality

SUSTERSIC Miha [1], SUSTERSIC Miha [1], MRAK Miha [1], BUNC Matjaz [1]

(1) University Medical Center, Ljubljana, Ljubljana, Slovenia

Aims: Up to 50% of STEMI patients have multivessel coronary artery disease (MVD) with worse long-term prognosis than patients with culprit only involvement. They represent a great burden to the health care system because of readmissions due to myocardial ischaemia, heart failure and major adverse cardiac events. The aim of our study was to evaluate the impact of complete revascularisation (CR) of STEMI patients with MVD on readmission due to proven myocardial ischaemia and revascularisation, heart failure and cardiovascular (CV) mortality.

Methods and results: Consecutive STEMI and MVD patents from January 2009 to April 2011 treated with primary coronary intervention (PCI) were included in the study. Coronary angiograms were reviewed to fulfil the MVD criteria (≥ 50% stenosis of at least one non-culprit coronary artery with diameter greater than 2 mm). The follow-up data on readmissions, revascularisations due to proven myocardial ischaemia, heart failure and cardiovascular mortality - which comprised the primary combined endpoint - were gained until April 2017 and compared between patients with CR and incomplete revascularisation (IR) during index hospitalisation. Data analysis was done using software package R and the hypotheses were tested at pre-specified p=0.05 at 95% confidence interval (CI). 235 patients with STEMI and MVD were identified, 70 (30%) in the CR group and 165 (70%) in the IR group, median follow up time was 7.03 years (QD 6 – 8.24 years). Baseline characteristics, comorbidities, left ventricular ejection fraction, therapy at inclusion and laboratory values were not different between CR and IR group at inclusion. In the IR group the residual SYNTAX score (8.7±6.4) after PCI of the culprit was significantly higher than in the CR group (6.4±4.6) (p=0.011). Reasons for readmissions and revascularisation rates were not different between the CR and IR groups (p=0.543). The occurrence of primary combined endpoint was significantly lower in the CR than in the IR group (22 vs 77, log rank p=0.017) after 8 years of follow up, but competing risk analysis revealed that components of primary combined endpoint on their own (readmissions, revascularisations and heart failure, p=0.238 and CV mortality, p=0.08) did not reach the level of significance. Readmissions did not influence CV mortality in the CR group while they significantly impacted CV mortality in the IR group (log rank p=0.49 vs log rank p=0.03). PCI related complications occurred 2.84 more often during readmission than at index hospitalisation (OR 2.84, 95% CI: 1.231-6.562, p=0.014).

Conclusions: CR during index hospitalisation appears to be a better treatment option for patients with STEMI and MVD regarding combined endpoint comprising readmission due to proven myocardial ischaemia and revascularisation, heart failure and CV mortality during long term follow up.

Stable CAD - CT / MRI imaging, Other Coronary interventions - Calcified lesions

Quantification of calcium burden by coronary CT angiography compared to OCT

MONIZZI Giovanni [1,2], MONIZZI Giovanni [1,2], SONCK Jeroen [1], NAGUMO Sakura [1], BUYTAERT Dimitri [1], GRANCINI Luca [2], VANDERHEYDEN Marc [1], DE BRUYNE Bernard [1], ANDREINI Daniele [2], BARTORELLI Antonio [2], COLLET Carlos [1]

(1) Olv Ziekenhuis, Aalst, Belgium; (2) Monzino Cardiology Center, Metropolitan City of Milan, Italy

Aims: Coronary artery calcifications are frequently observed in patients referred for cardiac catheterisation. They can lead to suboptimal stent expansion and have been linked with poor prognosis following elective PCI. Quantifying the calcific burden also aids guiding PCI strategy. Using OCT, the calcified volume can be determined. CT is a sensitive non-invasive tool to detect coronary calcifications and maybe useful to guide PCI strategies. The aim of the study was to investigate the accuracy of CT-derived calcium volume with OCT as a reference in patients undergoing PCI.

Methods and results: Eighty calcified plaques (39 vessels) from patients undergoing OCT-guided PCI with coronary CT angioghraphy acquired as a standard of care were included. Coronary CT angiography and OCT images were matched using fiduciary points. Calcified plaques were reconstructed in three dimensions to calculate calcium volume. A Passing-Bablok regression analysis and the Bland-Altman method were used to assess agreement between imaging modalities. Overall, 35 left anterior descending arteries and 4 right coronary arteries were analysed. Median calcium volume by CT angiography and OCT were 18.23 mm^3 [IQR 8.09, 36.48] and 10.03 mm^3 [IQR 3.6, 22.88]. The Passing-Bablok analysis showed a proportional difference without a systematic difference (Slope 1.61, 95% CI: 1.45 to 1.84, and Intercept 0.08, 95% CI: -1.37 to 1.21); with a mean difference of 9.69 mm^3 (LOA -10.2 mm^3 to 29.6 mm^3). No differences were observed in minimal lumen area (2.84 mm^2 [IQR 2.03, 3.74] for CT and 2.55 mm^2 [IQR 1.91, 4.43] for OCT), Slope 0.85, 95% CI: 0.63 to 1.2 and Intercept 0.58, 95% CI: -0.42 to 1.08.

Conclusions: Coronary CT angiography volumetric calcium evaluation overestimates calcium volume by 60% compared to OCT. Accounting for CT overestimation may allow for an appropriate interpretation of calcific burden in the non-invasive setting. Coronary CT angiography may emerge as a tool to quantify calcium burden for invasive procedural planning.

STEMI - Invasive imaging and functional assessment, Stents and scaffolds - Invasive imaging and functional assessment

Revisiting OCT criteria for optimal stent implantation in STEMI: a MATRIX OCT substudy

YACOB Omar [1], YACOB Omar [1], GARCIA-GARCIA Hector [1], KAZUHIRO Dan [1], SOUD Mohammad [2], FRIGOLI Enrico [3], KARAGIANNIS Alexios [3], VALGIMIGLI Marco [3]

(1) MedStar Washington Hospital Center, DC, USA; (2) Rutgers University - Newark Campus, NJ, USA; (3) University of Bern, Bern, Switzerland

Aims: Optical coherence tomography (OCT) provides unprecedented visualisation of plaque/stent features which has allowed stent optimisation during percutaneous coronary intervention (PCI) in subjects with acute coronary syndrome. Our objective was to investigate the relationship of stent expansion using OCT, with clinical outcomes in ST-segment elevation myocardial infarction (STEMI) patients.

Methods and results: STEMI patients from the MATRIX (Minimizing Adverse Haemorrhagic Events by TRansradial Access Site and angioX) treatment-duration registry were selected and stent expansion, by end-procedural OCT assessment, was compared to the clinical outcomes. Stent expansion index is defined as minimum stent area (MSA) divided by average lumen area (average of proximal and distal reference lumen area). The population was classified into 2 groups based on the stent expansion index: well-expanded ≥90% (N=72, 51%) and under-expanded <90% (N=67, 49%), and for each group MSA (<4.5mm^2), dissection (>200 µm in width and < 5 mm from stent segment), malapposition (>200 µm distance of stent from vessel wall) and thrombus (area >5% of lumen area) were compared. A total of 151 patients with STEMI were assessed and appropriate OCT analysis was obtained in 92% of the subjects which revealed a 30-day major adverse cardiovascular event (MACE) rate of 4.6 %. A significant number of the proximal vessels had a lumen area <4.5mm^2 (16.9%, p<0.001) in the well-expanded subjects as it was also associated with a greater thrombus burden (56.7%, p=0.042).

Conclusions: Irrespective of the OCT stent optimisation criteria findings in STEMI patients, the MACE at 30-day follow-up was low; furthermore, well-expanded stents led to a greater residual thrombotic burden within the stent, but seem to have insignificant clinical impact. Acknowledged stent optimisation criteria, traditionally associated with worse outcomes in stable patients, do not seem to be associated with worse outcomes in a STEMI population. A larger and prospective clinical trial is warranted to further investigate the best optimisation criteria in this population.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

BRS in routine PCI: long-term results

MORI Ricardo [1], MORI Ricardo [1], NUÑEZ GIL Iván [1]

(1) Hospital Clínico San Carlos, Madrid, Spain

Aims: Recent publications suggest that bioabsorbable vascular scaffolds (BVS) carry an excess of thrombotic complications. Our goal was to describe the results in real-life and in the long-term, in a series of patients who received a BVS-Absorb.

Methods and results: Two hundred and thirteen consecutive patients who received at least 1 Absorb BVS between May 2012 and December 2016 were analysed. The primary objective was the incidence of the compound event "target vessel failure" that included infarction or target vessel revascularisation and cardiac death. Seventy-five percent of patients were men with a mean age of 61.4 years. They had a high prevalence of dyslipidaemia (62.44%) and smoking (65.26%). The most common cause of admission was myocardial infarction without ST-elevation (53.52%). A total of 233 coronary lesions were treated, with an average of 1.3±0.3 lesions per patient. The implant was successful in 99.5% of cases. Predilatation was performed in 89.3% and post-dilation in 33.5% of cases. The use of intracoronary imaging (optical coherence tomography [OCT] and/or intravascular ultrasonography [IVUS]) to optimise the BVS implant was performed in 86 patients (40.38%). With a mean follow-up of 42.5 months, the incidence of target vessel failure was 6.57% during the first 24 months and 7.98% at the end of the follow-up. Regarding the device, this included 6 cases (2.81%) of thrombosis (definitive, probable or possible) and 10 cases (4.69%) of restenosis. Patients with a history of diabetes mellitus (HR 1.72 95% CI: 1.01-2.95 p=0-05) and/or chronic oral anticoagulation (HR 5.71 95% CI: 1.12-28.94 p=0.04) had a higher risk of target vessel failure. The use of intracoronary imaging (OCT and/or IVUS) during the BVS implantation had a considerable trend toward significance as a protective factor (HR 0.32 95% CI: 0.11-1.03 p=0.06).

Conclusions: In this series of patients, in real life conditions, the incidence of target vessel failure was comparable to that previously described in randomised clinical trials. The events were more frequent during the first 2 years of follow-up, in the presence of greater cardiovascular comorbidity and in the absence of intracoronary imaging during the implantation.

Other Coronary interventions - Calcified lesions

Intravascular lithotripsy for the management of undilatable coronary stent: the SMILE registry

IELASI Alfonso [1], IELASI Alfonso [1], MOSCARELLA Elisabetta [2], TESTA Luca [3], GIOFFRÈ Gaetano [4], MORABITO Gaetano [5], CORTESE Bernardo [6], COLANGELO Salvatore [7], TOMAI Fabrizio [8], ARIOLI Francesco [9], MAIOLI Mauro [10], LEONCINI Massimo [11], TUMMINELLO Gabriele [12], BENEDETTO Stefano [13], PENNESI Matteo [14], TESPILI Maurizio [1]

(1) Istituto Clinico Sant'Ambrogio, Metropolitan City of Milan, Italy; (2) Azienda Ospedaliera Sant'Anna e San Sebastiano di Caserta, Province of Caserta, Italy; (3) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy; (4) Sant'Eugenio Hospital, Metropolitan City of Rome, Italy; (5) Sant'Anna Hospital, Province of Catanzaro, Italy; (6) Clinica San Carlo - Casa di Cura Polispecialistica, Metropolitan City of Milan, Italy; (7) Ospedale San Giovanni Bosco, Metropolitan City of Turin, Italy; (8) European Hospital, Metropolitan City of Rome, Italy; (9) Ospedale Fatebenefratelli e Oftalmico, Metropolitan City of Milan, Italy; (10) Ospedale S. Stefano, Province of Prato, Italy; (11) Sanremo Hospital, Province of Imperia, Italy; (12) Ospedale Sant'Andrea di Vercelli, Province of Vercelli, Italy; (13) Galliera Hospitals - Cup, Metropolitan City of Genoa, Italy; (14) Careggi University Hospital, Metropolitan City of Florence, Italy

Aims: To evaluate the feasibility, effectiveness and safety of intravascular lithotripsy (IVL) for the treatment of coronary stent under-expansion.

Methods and results: A multicentre, retrospective cohort analysis was performed in consecutive patients undergoing IVL to treat under-expanded stents following non-compliant balloon expansion failure. Primary endpoint was successful IVL dilatation defined as IVL balloon delivery and application at the target site followed by an increase of at least 1 mm^2 in minimal stent cross-sectional area (MSA) on intracoronary imaging or an increase of at least 20% in minimal stent diameter (MSD) by quantitative coronary analysis (QCA). Thirty-nine under-expanded stents (34 patients) were included. Two cases (5.1%) of multiple stent layers and one (2.5%) acutely under-expanded stent, were treated. The median IVL balloon diameter was 3.1 mm (IQR:2.5-3.5 mm) while the number of pulses emitted was 56.7 (IQR: 30-80). IVL was successful in 34 cases (87.1%), with significant improvement in MSD (post:3.23 mm [IQR:3-3.5 mm] vs pre:0.81 mm [IQR:0.35-1.2], p<0.00001) and MSA (post:7.61 mm^2 [IQR:6.43-7.79 mm^2] vs pre:3.35 [IQR:2.8-4 mm^2], p<0.00001). Non-fatal periprocedural ST-elevation myocardial infarction occurred in one case (2.5%) due to IVL balloon rupture. No cardiac death, target lesion revascularisation and stent thrombosis occurred at follow-up.

Conclusions: Our study demonstrated that in case of refractory stent under-expansion, IVL could be a feasible and safe tool to disrupt the underlying resistant plaques and improve stent expansion in otherwise undilatable lesions. Larger studies with longer-term follow-up are needed to confirm our results.

Stents and scaffolds - Tools, devices and techniques

Paclitaxel DEB for the treatment of de novo small vessel disease or restenotic coronary artery lesions: 12-month results of the prospective, multicentre, single-arm PREVAIL study

LATIB Azeem [1,2], LATIB Azeem [1,2], AGOSTONI Pierfrancesco [3], DENS Jo [4], LANCELLOTTI Patrizio [5], PATTERSON Mark [6], TAM Frankie [7], SHEN Cheryl [8], WETZELS Gwenn [8], TESTA Luca [9]

(1) Ospedale San Raffaele, Metropolitan City of Milan, Italy; (2) Montefiore Medical Center: Einstein Campus, NY, USA; (3) St. Antonius Ziekenhuis, Nieuwegein, the Netherlands; (4) Ziekenhuis Oost-Limburg A. V., Genk, Belgium; (5) Chu De Liège, Liège, Belgium; (6) OLVG location East, Amsterdam, the Netherlands; (7) Queen Mary Hospital, Pok Fu Lam, Hong Kong; (8) Medtronic Inc, CA, USA; (9) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy

Aims: Drug-coated balloons (DCB) are potentially an alternative to drug-eluting stents in certain lesion subsets. The PREVAIL study was designed to evaluate the safety and effectiveness of the next-generation Prevail paclitaxel-coated percutaneous transluminal coronary angioplasty (PTCA) balloon catheter for the treatment of coronary *de novo* lesions, small vessel disease or in-stent restenosis in patients with symptomatic ischaemic heart disease.

Methods and results: PREVAIL was a prospective, multicentre, single-arm study that enrolled patients with stable or unstable angina and/or clinical evidence of ischaemia who had a first in-stent restenotic lesion or *de novo* small vessel disease amenable to treatment with DCB. Patients were treated with the Prevail DCB during the index procedure and clinical follow-up assessments were performed at 30 days, 6 months and 12 months post procedure; angiography was performed before and after the procedure, and at 6-month follow-up. The primary endpoint was in-stent (in-balloon) late lumen loss at 6 months post procedure as previously reported. The purpose of this analysis is to report final 12-month clinical outcomes. The analysis was performed on the intent-to-treat population, which included 50 subjects with 53 target lesions. All patients were treated with the Prevail DCB. Mean age was 64.9±9.2 years and 82.0% of the subjects were male. The proportion of subjects with one diseased major coronary artery (>50% stenosis) was 62.0%; the remaining patients had two (22.0%) or three (16.0%) diseased major coronary arteries. The mean number of treated lesions per subject was 1.4±0.6 and mean lesion length was 17.0±6.6 mm. Target lesions were 45.3% *de novo* and 54.7% in-stent restenosis, and 56.6% of subjects had small vessel disease. Two subjects (3.8%) required bail-out implantation of a drug-eluting stent during the index procedure. There were no deaths, myocardial infarctions, or stent thrombosis events within 12 months. The incidence of clinically driven target lesion revascularisation (TLR) at 12 months was 6.0%, and that of clinically driven non-target lesion target vessel revascularisation (non-TL TVR) was 4.0%. The incidence of target vessel failure (TVF) at 12 months was 10.0%, target lesion failure (TLF) was 6.0%, and major adverse cardiac events (MACE) was 6.0%.

Conclusions: The PREVAIL study demonstrates consistent outcomes from the 6-month primary endpoint results. The safety profile did not deviate from what is generally expected in this patient population; there were no deaths, myocardial infarctions, or stent thrombosis events within 12 months, with low rates of MACE, TVF and TLF.

Stents and scaffolds - Adjunctive pharmacotherapy, Other Coronary interventions - Other

Benefits and risks of extended DAPT beyond one year in high ischaemic or bleeding risk patients after DES implantation

WANG Haoyu [(1)], WANG Haoyu [(1)], DOU Kefei [(1)], YANG yuejin [(1)], XU Bo [(1)], GAO Runlin [(1)], WANG Shuze [(2)]

(1) Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; (2) University of Michigan, MI, USA

Aims: Dual-antiplatelet therapy (DAPT) exceeding 1 year may increase a bleeding risk despite reducing the risk of ischaemic events. The benefits and harms of prolonging DAPT with aspirin and clopidogrel beyond 1 year after percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation for patients with high-risk for bleeding or an ischaemic event remain unknown.

Methods and results: Between January 2013 and December 2013, all consecutive patients undergoing PCI were prospectively included in the Fuwai PCI Registry. We evaluated 7,521 patients who were at high risk for ischaemic or haemorrhagic complications and were event free (no death, myocardial infarction [MI], stroke, stent thrombosis [ST], any revascularisation, or major bleeding) at 1 year after the index procedure. Subjects were divided into 2 groups: DAPT (aspirin plus clopidogrel) >1-year group (n=5,252) and DAPT≤1-year group (n=2,269). Patients at high-risk for ischaemic or bleeding events were defined as having at least one additional clinical feature and one angiographic feature according to TWILIGHT trial criteria. The clinical criteria for high risk were an age of at least 65 years, female sex, troponin-positive acute coronary syndrome, established vascular disease, diabetes mellitus that was being treated with medication, and chronic kidney disease. Angiographic criteria included multivessel coronary artery disease, a total stent length of more than 30 mm, a thrombotic target lesion, a bifurcation lesion treated with two stents, an obstructive left main or proximal left anterior descending lesion, and a calcified target lesion treated with atherectomy. The primary outcome was major adverse cardiac and cerebrovascular events (MACCE: a composite of all-cause death, MI, or stroke). During a median follow-up of 30 months after the index procedure, DAPT>1-year was associated with a reduction in risk for MACCE compared with DAPT≤1-year (1.5% vs 3.8%; adjusted hazard ratio [HR]: 0.36; 95% confidence interval [CI]: 0.27-0.50; p<0.001) after multivariable adjustment. This difference was largely driven by a lower risk of all-cause mortality. In contrast, the risk of Bleeding Academic Research Consortium (BARC) type 2, 3 or 5 bleeding was statistically similar between the 2 groups (1.0% vs 1.1%; adjusted HR: 0.81; 95% CI: 0.50-1.30; p=0.373). After propensity score matching, incidence of MACCE was still lower in the DAPT>1-year group than the DAPT≤1-year group (1.6% versus 4.5%; hazard ratio, 0.34; 95% confidence interval, 0.22-0.52; p<0.001) and the rates of BARC type 2, 3 or 5 bleeding was not different between the 2 groups (1.1% versus 0.9%; adjusted hazard ratio, 1.12; 95% confidence interval, 0.57-2.18; p=0.744). In subgroup analysis, the treatment effect of prolonged DAPT was consistent across subgroups regardless of acute coronary, syndrome, DAPT score, or type of used drug-eluting stent.

Conclusions: DAPT continuation with aspirin and clopidogrel beyond 1-year after DES implantation resulted in a significantly lower rate of MACCE, with no higher risk of clinically relevant bleeding in patients who were at high-risk for ischaemic or bleeding events. Our results suggest that prolonged DAPT may improve clinical outcomes after PCI for high-risk patients if they were free of ischaemic or bleeding events at 1 year.

Other Coronary interventions - Other

Risk-benefit profile of DAPT continuation beyond one year after PCI in patients with high ischaemic risk features as endorsed by 2018 ESC/EACTS myocardial revascularisation guidelines

WANG Haoyu [1], WANG Haoyu [1], GAO Runlin [1], YANG Yuejin [1], XU Bo [2], DOU Kefei [1]

(1) Department of Cardiology, Coronary Heart Disease Center, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China; (2) Department of Cardiac Catheterization Laboratories, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

Aims: The 2018 ESC/EACTS myocardial revascularisation guidelines endorsed high risk features of ischaemic events. The benefits and harms of continuing DAPT with aspirin and clopidogrel beyond 1 year after percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation for patients with high ischaemic risk (HIR) remain unknown.

Methods and results: Between January 2013 and December 2013, all consecutive patients undergoing PCI were prospectively included in the Fuwai PCI Registry. We evaluated 4,578 patients who were at ESC/EACTS-endorsed HIR criteria and were event free (no death, myocardial infarction [MI], stroke, stent thrombosis [ST], any revascularisation, or major bleeding) at 1 year after the index procedure. Subjects were divided into 2 groups: >1-year DAPT group (n=3278) and ≤1-year DAPT group (n=1300). Patients at ESC/EACTS-endorsed HIR criteria were defined as diffuse (defined as lesion length ≥20 mm) multivessel disease in patients with diabetes, chronic kidney disease, ≥3 stents implanted, ≥3 lesions treated, bifurcation with 2 stents implanted, total stent length>60 mm, and treatment of CTO, and history of ST-elevation myocardial infarction. The primary outcome was major adverse cardiac and cerebrovascular events (MACCE: a composite of all-cause death, MI, or stroke). During a median follow-up of 30 months after the index procedure, >1-year DAPT with aspirin and clopidogrel was associated with a reduction in risk for MACCE compared with ≤1-year DAPT (1.9% vs 4.6%; adjusted hazard ratio [HR]: 0.39, 95% confidence interval [CI]: 0.28-0.57; p<0.001) in multivariable Cox regression model. This difference was largely driven by a lower risk of all-cause mortality (0.2% vs 3.0%; adjusted HR: 0.07, 95% CI: 0.03-0.15, p<0.001). The clinical benefit of DAPT>1-year was also consistent after IPW adjustment and propensity score matching. In contrast, the risk of BARC type 2, 3 or 5 bleeding showed no significant difference between the 2 groups (1.1% vs 0.9%; adjusted HR: 0.81, 95% CI: 0.50-1.30; p=0.373). Results regarding major bleeding were consistent after IPW adjustment and propensity score matching. Additionally, DAPT>1-year was an independent predictor of reduced risk of MACCE, and its benefit was consistent across multiple subgroups.

Conclusions: DAPT continuation with aspirin and clopidogrel beyond one year in patients with ESC/EACTS-endorsed HIR features after DES implantation resulted in a significantly lower rate of MACCE, without clear evidence of increased major bleeding. These data highlight long-term DAPT with aspirin and clopidogrel may be considered in HIR patients if they were free of ischaemic or bleeding events at 1 year.

Stents and scaffolds - Tools, devices and techniques

Shorter duration from the index PCI correlates with higher recurrent target lesion revascularisation rate after the DEB angioplasty

SATO Tomohiko [1],

(1) New Tokyo Hospital, Chiba, Japan

Aims: Drug-coated balloon (DCB) is widely utilised to treat in-stent restenosis (ISR), and is known to bring about favourable outcome comparable to another drug-eluting stent (DES) implantation. Focal ISR lesion was known to result in favourable outcome, but other factors to predict recurrent ISR are not clear. Clinically, shorter duration from the index PCI may relate to recurrent TLR. We aimed to evaluate this correlation.

Methods and results: Among patients who received PCI for *de novo* lesion with second-generation DES from April 2014 to December 2016 in our institute, 187 patients encountered ISR, and were treated with DCB angioplasty. We defined this duration between the index PCI and DCB angioplasty as duration-A. They received coronary angiography after median 1 year for follow-up or symptomatic reason, and some of them encountered recurrent ISR and received further target lesion revascularisation (TLR). We analysed this recurrent TLR rate as the primary outcome. 187 ISR, overall recurrent TLR rate was 0.33. Multi-variable analysis found that focal type of restenosis (Mehran IA+IB+IC types) (HR 0.56, 95% CI: 0.33-0.96, p=0.03) and duration-A were independent factors related to the recurrent TLR. If we define the early ISR group as having duration-A less than 1.6 years (n=131) (the value was determined by receiver operating characteristic curve), and the late ISR group as having duration-A more than 1.6 years (n=56), TLR rates were 0.40 and 0.16, respectively. Multi-variable analysis found the hazard ratio of early ISR group was 5.05 (95% CI: 2.14-11.9, p=0.0002).

Conclusions: Shorter duration from the index PCI was the independent predictor for recurrent TLR. These patients may need careful follow-up. On the other hand, those who received TLR with DCB later after the index PCI may be less likely to encounter recurrent TLR.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Impact of previous CABG in patients presenting with an ACS: current trends and clinical implications

RIBEIRO Joana Maria [1], RIBEIRO Joana Maria [1], TEIXEIRA Rogério [1,2], SISERMAN Alexandrina [1], PUGA Luís [1], LOPES João [1], SOUSA José Pedro [1], LOURENÇO Carolina [1], BELO Adriana [3], GONÇALVES Lino [1,2], On behalf of the Portuguese Registry of Acute Coro [3]

(1) Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal; (2) Faculdade de Medicina da Universidade de Coimbra, Coimbra, Portugal; (3) Centro Nacional de Colecção de Dados em Cardiologia – Sociedade Portuguesa de Cardiologia,, Lisboa, Portugal

Aims: Among patients presenting with an acute coronary syndrome (ACS), those with previous coronary artery bypass grafting (CABG) are a particular subset. The purpose of this study was to investigate the prognostic impact of previous CABG in ACS patients and to identify the current trends in their clinical management.

Methods and results: We performed a cohort analysis of patients prospectively enrolled in the Portuguese Registry of Acute Coronary Syndrome between 2010–2019 with known previous CABG status. We compared patients with and without previous CABG for four main domains: 1=baseline characteristics, 2=treatment strategies, 3=in-hospital outcomes, and 4=one-year outcomes. The co-primary endpoints were in-hospital and one-year mortality. Secondary endpoints included in-hospital re-infarction, stroke and major bleeding, and a composite endpoint (CE) of death and hospital re-admission due to heart failure (HF) at one-year follow-up. Since scientific recommendations have significantly evolved in the last decade, we analysed the time trends in mortality and therapeutic regimens with a focus on antithrombotic medications. To confirm our results and minimise the baseline differences between groups, we also performed propensity-score matched analyses for all the endpoints. A total of 19,334 (962 CABG and 18,372 non-CABG) and 9,402 (479 CABG and 8923 non-CABG) patients were included in the analyses of in-hospital and mid-term outcomes, respectively. CABG patients were older and had a higher incidence of comorbidities. They were less likely to undergo invasive angiography (74.9 vs 84.6%, p<0.001), but were equally likely to receive dual antiplatelet therapy (91.0 vs 90.8%, p=0.823). In-hospital mortality was similar between groups (3.6 vs 3.4%, p=0.722), as were in-hospital re-infarction, stroke and major bleeding. Unadjusted one-year mortality and the CE were higher in the CABG group (hazard ratio [HR] 1.48, 95% confidence interval [CI] 1.09–2.01, p=0.012 and HR 1.60, 95% CI: 1.33–1.94, p<0.001, respectively). After propensity-matching and multivariate analysis there was a trend towards a reduced mortality (HR 0.63, 95% CI: 0.37–1.09, p=0.098) and a significantly lower incidence of the CE (HR 0.70, 95% CI: 0.50–0.99, p=0.043) in the CABG group. Compliance with the guidelines was good with a use of dual antiplatelet therapy >80% in both groups across the study time frame (and slightly increasing over time). Moreover, use of new $P2Y_{12}$-inhibitors and oral anticoagulation increased throughout the years, while mortality decreased.

Conclusions: Among patients with acute coronary syndrome, a previous history of coronary artery bypass grafting was associated with a high burden of comorbidities and a high-risk profile but was not an independent predictor of adverse events. Treatment decisions should be made on a case-by-case basis, and should not be based on previous coronary artery bypass grafting status alone.

STEMI - Tools, devices and techniques

Stenting of patients with spontaneous coronary artery dissection reduces morbidity and mortality in ACS. An observational retrospective study from India

SHARMA Raghav [(1)], NARSIMHAN ARVIND Yuvaraj [(1)], KUMAR N Prathap [(1)]

(1) Civil Hospital Ambala Cantt, Haryana, India

Aims: Spontaneous coronary artery dissection (SCAD) is an infrequent cause of acute coronary syndrome and sudden cardiac death. Treatment varies from conservative approach to revascularisation. This study was planned to study the profile and benefits of revascularisation in ACS patients with underlying SCAD.

Methods and results: In observational and retrospective data collection, data of all patients admitted to the department of cardiology from December 2017 to September 2019 were evaluated. Total 8,524 patients reporting during this period underwent coronary angiography. 3,434 patients (out of total 8,524) had elective coronary angioplasty. Remaining 2,000 patients reported with ACS (STEMI, NSTEMI and unstable angina). Out of this patient population, patients with angiographic evidence of SCAD were further subjected to evaluation and data analysis. Primary endpoint of the study was success of PTCA and secondary endpoints were procedural complication, in-hospital death and MACE scoring. Out of 2,000 patients reported with ACS, total of 56 patients had angiographic evidence of underlying SCAD. 27 of these 56 patients were diagnosed with acute STEMI and 29 were diagnosed with unstable angina or NSTEMI. Subgroup analysis showed mean age of 56.64 years with minimum 30 to maximum 80 years. Out of these 56 patients, total 46 patients were reported in the study. Dissections were categorised as Type I, Type II or Type III. Total 13 patients were subjected to Type I and 14 patients were subjected to Type II. Among the STEMI subgroup, total 23 patients had dissection in just a single vessel, most of them being the culprit vessel. In the NSTEMI subgroup, 22 patients had SCAD in a single vessel and remaining 7 patients had SCAD in two or more vessels. Majority of males reported in the study were smokers. As per primary objective of the study, successful PTCA was achieved in all patients. There were no procedural complications, in hospital mortality or any MACE in any of the patients.

Conclusions: Male smokers had high incidence of SCAD with multivessel involvement. SCAD may not heal spontaneously most of the time and patients remain symptomatic with compromised quality of life. Stenting of patients presenting with ACS with underlying SCAD will improve quality of life and reduce morbidity and mortality.

Left main and multivessel disease - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Feasibility of combined procedure of TAVI and complex PCI with intravascular lithotripsy: a single-centre experience

CARPENITO Myriam [1], CARPENITO Myriam [1], RICOTTINI Elisabetta [1], NUSCA Annunziata [1], MELFI Rosetta [1], MANGIACAPRA Fabio [1], MIGLIONICO Marco [1], GALLO Paolo [1], GRIGIONI Francesco [1], USSIA Gian Paolo [1]

(1) Campus Biomedico Trigoria, Metropolitan City of Rome, Italy

Aims: Patients with severe aortic stenosis undergoing TAVI often present a significant coronary artery disease (CAD) with complex lesions and extensive calcification, requiring PCI. Recently intravascular lithotripsy has been introduced for PCI of calcified lesions through a balloon catheter using pulsatile mechanical energy. Limited data exist on the outcome of patients undergoing combined TAVI and complex PCI. We present a case series based on the experience of our centre with the aim to provide support to the feasibility of combined procedure of TAVI and intravascular lithotripsy-assisted PCI.

Methods and results: We analysed data from patients with complex coronary lesions undergoing PCI and TAVI between January 2019 to December 2019. When indicated PCI with intravascular lithotripsy (Shockwave, Medical Inc) was performed in the same procedure as TAVI. Procedural time, amount of contrast medium and length of intensive care unit and in-hospital stay were collected and compared with mean results of TAVI-alone procedures in our centre. In-hospital and 30-day major adverse cardiac events were also evaluated. A total of 34 consecutive patients (38% male; age 83±7 years) underwent transfemoral TAVI procedure during the index timeframe. 3 patients (9%) received TAVI and intravascular lithotripsy-assisted PCI during the same procedure. These patients presented at least one high-risk feature, such as reduced left ventricle ejection fraction (LVEF) (N=1), chronic kidney disease (N=1), multivessel coronary artery disease (N=1) and left main lesion (N=1). Complete revascularisation was achieved in all cases. No procedural complications were recorded. Procedural time was 83±16 min, with no significant increase compared to mean of TAVI procedure in our centre (62±22 min; p=0.11). Use of contrast medium did not differ among the only TAVI group patients (169±75.5) and those who received combined procedure (165±100; p=0.93). Patients treated with combined procedure did not present a longer intensive care unit (1 vs 1.54±1.47; p=0.53) or in-hospital length of stay (9.6±3.6 vs 6.9±3.2; p=0.17). No major adverse cardiac events were recorded during in-hospital stay and at 30-day follow-up.

Conclusions: Our early experience suggests that a strategy of combined treatment with TAVI and intravascular lithotripsy-assisted PCI is feasible for treatment of patients with both severe aortic stenosis and severe calcified coronary artery disease without increasing procedural time and complexity. Further studies are needed to validate this treatment strategy in larger population.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Vascular complications of IABP during PCI and clinical outcomes – an analysis of the British Cardiovascular Society national PCI database

KINNAIRD Tim [1], KINNAIRD Tim [1], ANDERSON Richard [1], GALLAGHER Sean [1], FAROOQ Vasim [1], SHARP Andrew [1], COPT Samuel [4], SIRKER Alex [3], LUDMAN Peter [2], CURZEN Nick [6], MAMAS Mamas [5]

(1) University Hospital of Wales, Cardiff, United Kingdom; (2) Queen Elizabeth Hospital Birmingham, Birmingham, United Kingdom; (3) St Bartholomew's Hospital, London, United Kingdom; (4) Biosensors Europe SA, Morges, Switzerland; (5) Royal Stoke University Hospital, Stoke-on-Trent, United Kingdom; (6) Southampton General Hospital, Southampton, United Kingdom

Aims: A femoral vascular complication (VC) has been correlated with adverse clinical outcomes in patients undergoing PCI. Although use of an intra-aortic balloon pump (IABP) has been observed to increase femoral VCs during PCI, the impact of this complication in the setting of an IABP on clinical outcomes is unclear.

Methods and results: We used the British Cardiovascular Society National PCI Database to study the impact of a VC complicating PCI on outcomes. Patients who underwent PCI with IABP support were categorised into those with or without a VC. Multivariate logistic regression was used to identify independent predictors of a VC. Propensity scoring using the inverse probability of treatment weights model was used to correct for baseline imbalances between the two cohorts to quantify the association between a VC and outcomes. Sensitivity analyses were conducted to study the impact of a VC in several important sub-groups. Between 2007 and 2014, of a total of 669,210 PCI procedures were performed in England and Wales, with 10,610 of these supported by use of an IABP (1.6% of total PCI). There was no significant temporal trend in the use of IABP support during PCI. In total there were 224 femoral VCs (2.3%) with major haemorrhage, femoral artery aneurysm and femoral artery dissection the most common events. There was a significant reduction in the annualised rates of a VC from 4.1% in 2007 to 1.4% in 2014 ($p<0.001$ for trend) whilst a significant increase in a radial approach for the PCI in the same period was observed (14.3% in 2007 to 43.9% 2014, $p<0.001$ for trend, $p<0.001$ for interaction between the VC temporal trend and the radial/femoral temporal trend). The independent predictors of a VC were ST-elevation MI (odds ratio (OR) 4.2, 95% confidence intervals [1.2:14.5], $p=0.022$), female sex (OR 2.3 [1.6:3.4], $p<0.001$), previous CABG (OR 2.0 [1.1:3.7], $p=0.038$), use of a glycoprotein inhibitor (OR 1.7 [1.1:2.5], $p=0.009$), and use of embolic protection (OR 3.8 [1.4:10.9], $p=0.0120$) with a lower likelihood of a VC occurring when radial access for used for PCI (OR 0.5 [0.3:0.8], $p=0.013$). Following adjustment, a femoral VC was associated with a higher likelihood of transfusion (OR 5.7 [3.5:9.2], $p<0.0001$), acute kidney injury (OR 2.6 [1.2:6.1], $p=0.027$) and periprocedural MI (OR 3.2 [1.5:6.7], $p=0.002$). However, survival was poor regardless of VC status with unadjusted in-hospital mortality (28.7% for the VC cohort vs 28.4% for the no VC cohort, $p=0.997$) and 12-month mortality (36.8% vs 41.1% respectively, $p=0.259$) similar between both groups. Adjusted mortality at discharge (OR 1.2 [0.8:1.7], $p=0.394$) and at 12 months (OR 1.1 [0.76:1.56], $p=0.639$) was not independently affected by the occurrence of a VC. In subgroup sensitivity analyses, a VC was not associated with adverse survival in patients by shock, sex, age, ejection fraction or left main status although there was a trend was higher mortality in patients undergoing PCI for stable angina who exeperienced a VC (OR 4.1 [1.0:16.4], $p=0.069$ for interaction). Adjusted Kaplan-Meier curves demonstrated similar 12-month survival between the two cohorts.

Conclusions: Vascular complications associated with IABP use have declined in frequency as radial access use for PCI increased. Although increases in several in-hospital non-fatal outcomes were observed with the occurrence of a vascular complication, in-hospital and 1-year survival was not affected.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Two-year results of the RESTORE ISR China in-stent restenosis trial: a head-to-head, multicentre, randomised trial for comparing the efficacy and safety of two DEB in Chinese patients with coronary in-stent restenosis

CHEN Yundai [(1)], CHEN Yundai [(1)], ZHOU Shanshan [(1)]

(1) The General Hospital of Chinese People's Liberation Internal Medical Building, Beijing, China

Aims: The head-to-head, multicentre, randomised trial investigated the safety and efficacy of RESTORE drug-coated balloon (DCB) angioplasty in a Chinese patient population with coronary in-stent restenosis (ISR). The present study aimed to evaluate the long-term clinical safety and effectiveness of the RESTORE DCB by the 2-year follow-up.

Methods and results: A total of 240 patients with coronary ISR were treated with RESTORE DCB or with SeQuent Please DCB. This randomised (1:1), head-to-head, multicentre trial in a Chinese population used 9-month in-segment late lumen loss (LLL) as the primary endpoint. Angiographic and clinical follow-ups were done at 9 months and 1 year, respectively. Furthermore, clinical follow-up extended to 2 years. Both DCB groups were similar in terms of patient, lesion, or procedural characteristics. Nine-month in-segment late loss was 0.38±0.50 mm with RESTORE versus 0.35±0.47 mm with SeQuent Please; achieving non-inferiority of RESTORE compared with SeQuent Please (p for non-inferiority = 0.02). The 2-year follow-up rates were 95.8% (115/120) in the RESTORE group and 94.2% (113/120) in the SeQuent Please group. Both groups had similar 1-year and 2-year target lesion failure (13.3% vs 12.6%; p=0.87 at 1-year, 14.8% vs 15.0%; p=1.0 at 2-year). After a 2-year follow-up, the all-cause mortality and myocardial infarction (MI) were 0 and 3.5% (4/120) in the RESTORE group and 0.9 (1/120) and 3.5 (4/120) in the SeQuent Please group.

Conclusions: In this head-to-head randomised trial, the 2-year follow-up demonstrated sustained long-term clinical safety and efficacy for both devices; the RESTORE DCB had similar TLF and rates of adverse clinical events to the SeQuent Please DCB. (Compare the Efficacy and Safety of RESTORE DEB and SeQuent Please in Chinese Patient With Coronary In-stent Restenosis; NCT02944890).

STEMI - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

PCI in all-comer real-world ACS patients having bifurcation lesion

CHOUDHARY Rahul [(1)], KAUSHIK Atul [(1)], DEORA Surender [(1)], SHARMA Jai Bharat [(1)], GOEL Akhil [(1)]

(1) All India Institute of Medical Sciences, Jodhpur, Rajasthan, India

Aims: Percutaneous coronary intervention (PCI) for the treatment of coronary bifurcation lesions in the acute coronary syndrome (ACS) setting is a high-risk procedure and is associated with higher periprocedural complications, a lower procedural success rate, and a higher probability of in-stent restenosis. Provisional stenting is the preferred strategy in stable patients, but there are limited data regarding outcomes of the provisional approach in ACS patients. So, we present real-world experience of all-comer bifurcation lesions in ACS settings at a tertiary care centre in India.

Methods and results: Out of 986 patients who underwent PCI for ACS at our centre, 144 (14.6%) patients having bifurcation lesion (main vessel diameter ≥2.5 mm and the SB ≥2.25 mm) were included in our study. Provisional stenting was favoured whenever feasible, elective stenting was reserved for significant long segment side branch involvement. Single-stent strategy was used in 125 (86.80%) patients and a double-stent strategy in 19 (13.19%) patients. The primary outcome was major adverse cardiovascular events (MACE), a composite of cardiac death, myocardial infarction, target lesion revascularisation, and stent thrombosis. The median length of follow-up was 14 months. Mean age of patients was 58.34±9.94 and 85.40 % were male. 56.94% had multivessel disease, left anterior descending (LAD-diagonal was the most common, 49.30%) target bifurcation lesion and most common Medina class was 1, 1, 1 (52.08%). There was no significant difference regarding risk factors (age, hypertension, diabetes mellitus, dyslipidaemia and smoking history) between 1-stent and 2-stent groups. Median SYNTAX score was 14 (IQR 10-20) in the 1-stent group and 22 (IQR 17-25) in the 2-stent group. The 2-stent group had higher proportion of left main coronary involvement as compared to the 1-stent group (47.40% vs 24.8%). Crush technique was the preferred 2-stent approach (73.68%) where as TAP was used in 62.5% patients whenever a second stent was required as bail-out in 1-stent strategy. Final kissing balloon inflation (FKBI) was used in 48 (38.40%) patients in the 1-stent group, while it was utilised in all patients with the 2-stent approach. Most of the procedures were done transradially (70.83%). Post-procedural side branch diameter stenosis differed significantly between the 2 groups (1-stent vs 2-stent, 34.86% vs 6.37%). The rate of MACE was similar in both groups but radiation dose and contrast volume utilisation were significantly more in the 2-stent group. On 14-month follow up, total MACE events were 6 (4.86 %); most were contributed by target lesion revascularisation.

Conclusions: PCI for bifurcation lesions, even during ACS, had acceptable success and periprocedural complication rates. If possible, the 1-stent strategy should initially be considered the preferred approach for the treatment of coronary bifurcation culprit lesions in the setting of PCI for ACS patients. Despite successful treatment of side branch, MACE was similar in two approaches.

Stable CAD - Invasive imaging and functional assessment, Stents and scaffolds - Invasive imaging and functional assessment

Comparison of diagnostic performance of intracoronary OCT-based and angiography-based FFR for evaluation of coronary stenosis

HUANG Jiayue [1,2], TU Shengxian [1], HUANG Jiayue [1,2], EMORI Hiroki [3], DING Daixin [1], KUBO Takashi [3], YU Wei [1], HUANG Peng [1], ZHANG Su [1], GUTIÉRREZ-CHICO Juan Luis [4], AKASAKA Takashi [3], WIJNS William [2]

(1) Med-X Institute, Shanghai, China; (2) Lambe Institute for Translational Research, Galway, Ireland; (3) Department of Cardiovascular Medicine, Wakayama, Japan; (4) Department of Interventional Cardiology, Campo de Gibraltar Health Trust, Algeciras, Spain

Aims: To evaluate the diagnostic performance of OCT-based optical flow ratio (OFR) in unselected patients and compare it with angiography-based quantitative flow ratio (QFR), OCT-derived minimum lumen area (MLA) and three-dimensional quantitative coronary angiography (3D QCA)-derived percent diameter stenosis (DS%), using wire-based FFR as the reference standard.

Methods and results: All patients with OCT and FFR assessment prior to revascularisation were analysed. OFR and QFR were computed in blinded fashion and compared with FFR, all applying the same cut-off value of ≤0.80 to define ischaemia. Comparison between OFR, QFR, OCT-derived MLA and 3D QCA-derived DS% was performed in 212 vessels from 181 patients. Average FFR was 0.82±0.10 and 40.1% vessels had FFR≤0.80. Diagnostic accuracy, sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio for OFR to identify FFR≤0.80 was 92%, 86%, 95%, 92%, 91%, 18.2 and 0.2, respectively. OFR showed higher diagnostic accuracy in identifying FFR ≤0.80 than QFR (92% versus 87%, p=0.207), and significantly higher diagnostic accuracy than OCT-derived MLA (92% versus 76%, p<0.001) and 3D QCA-derived DS% (92% versus 75%, p<0.001). The area under curve was 0.97 for OFR, higher than QFR (difference=0.05, p=0.017), and significantly higher than OCT-derived MLA (difference=0.15, p<0.001) and 3D QCA-derived DS% (difference=0.17, p<0.001). OFR showed significantly better correlation and agreement with FFR than QFR (r=0.87 versus 0.77, p<0.001; intraclass correlation=0.87 versus 0.76, p<0.001; SD of the difference=0.05 versus 0.07, p<0.001). Diagnostic accuracy of OFR was not significantly different in myocardial infarction (MI)-related vessels (95% versus 90%, p=0.456), nor in vessels with and without previously implanted stents (90% versus 93%, p=0.669). Better intraclass correlation with FFR was found for OFR than QFR regardless of the presence of myocardial infarction or prior PCI (MI-related vessels: 0.80 versus 0.69, p=0.178; non-MI-related vessels: 0.88 versus 0.77, p=0.004; stented vessels: 0.84 versus 0.71, p=0.005; non-stented vessels: 0.86 versus 0.77, p<0.001).

Conclusions: OFR had an excellent agreement with FFR in consecutive patients with *a priori* high likelihood of PCI. OFR was superior to QFR, and much better than conventional morphological parameters in determining the physiological significance of coronary stenosis. The diagnostic performance of OFR is not significantly different in patients with or without prior MI, nor in native vessels or in vessels with in-stent restenosis.

Stents and scaffolds - Tools, devices and techniques

FANTOM II long lesion study: safety and performance study of a Tyrocore sirolimus-eluting bioresorbable coronary scaffold in long lesions – first report: one-year outcomes

LUTZ Matthias [1], LUTZ Matthias [1], FREY Norbert [1], WEBER-ALBERS Joachim [3], JEFFREY Anderson [2], KISCHE Stephan [4], PYXARAS Stylianos [6], ACHENBACH Stephen [4], NORDBECK Peter [7]

(1) Universitätsklinikum Schleswig-Holstein, Campus Kiel Notaufnahme, Kiel, Germany; (2) Reva Medical, CA, USA; (3) St.-Johannes-Hospital Dortmund, Dortmund, Germany; (4) Vivantes Klinikum im Friedrichshain, Berlin, Germany; (5) Universitätsklinikum Erlangen, Erlangen, Germany; (6) LAKUMED Kliniken – Krankenhaus Landshut-Achdorf, Landshut, Germany; (7) Universitätsklinikum Würzburg, Würzburg, Germany

Aims: The primary objective of the FANTOM II long lesion study was to evaluate the safety and performance of native coronary artery stenting of lesions ≥ 20mm in length using one or more Fantom sirolimus-eluting bioresorbable coronary scaffolds. Fantom is a fully resorbable scaffold, manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque enabling multiple scaffolds to be placed in a precise edge-to-edge configuration allowing for complete coverage of longer target lesions.

Methods and results: The FANTOM II long lesion study is a prospective, multicentre trial which enrolled 33 patients with *de novo* coronary stenosis with reference vessel diameters between 2.5 to 3.5 mm in diameter and lesion lengths ≥ 20 mm. In this study all lesions were predilated using a 1:1 NC balloon and then subsequently assessed to determine vessel diameter and lesion length. Once sizing was complete, either one or two scaffolds were selected to enable complete target lesion coverage. Post-implantation results were analysed by OCT in all cases. In this study acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol were 100% (33/33) in all cases. Angiographic imaging results from for all patients through 6 months of follow-up as well as MACE, TLF and scaffold thrombosis through 12 months of follow-up will be made available.

Conclusions: The Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favourable initial acute safety in this first cohort of patients with more complex lesions. Longer-term follow-up through 5 years is ongoing to examine the late outcomes with this novel device.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Shockwave intravascular lithotripsy in calcified coronary lesions: a retrospective, observational, international multicentre analysis

AZIZ Amir [1], AZIZ Amir [1], LELASI Alfonso [2], CORTESE Bernardo [3], TESTA Luca [4], VIGANO Elena [3], MOKDAD Rami [3], WATKIN Richard [1], BHATIA Gabir [1], PITT Michael [1], BASAVARAJAIAH Sandeep [1]

(1) Birmingham Heartlands Hospital, Birmingham, United Kingdom; (2) Sant'Ambrogio, Metropolitan City of Milan, Italy; (3) Clinica San Carlo, Metropolitan City of Milan, Italy; (4) Policlinico san donato, Metropolitan City of Milan, Italy

Aims: Sub-optimal stent expansion due to coronary calcification augments the risk of restenosis and stent thrombosis. Calcium modification is generally achieved by rotational atherectomy or specialised balloons (scoring and cutting balloons), which carries risk of complications. Intravascular lithotripsy (IVL) appears safe and also aids in cracking deep seated adventitial calcium. Although there are reported studies on this novel technology, there is a lack of real-world data. In this study, we report the experience from 4 centres that undertake high-volume complex coronary interventions.

Methods and results: We enrolled all patients treated with IVL between September 2018 and October 2019 at 4 centres (1 in UK and 3 in Italy). Procedural success and complications were assessed. The clinical outcomes evaluated were; cardiovascular death, target vessel MI (TVMI), target lesion revascularisation (TLR) and MACE (composite of cardiovascular death, TVMI and TLR). During the study period, 100 lesions (in 94 patients) with a mean age of 71±9.7 years (range;30-88) were treated using IVL. 70% (n=70) were male, 85% (n=80) had hypertension, 51% (n=48) had diabetes and 20% (n=19) had chronic kidney disease. Acute coronary syndromes accounted for 40% of patients (n=38). *de novo* lesions accounted for 66% of cases (n=66) and the remaining 34% (n=34) were restenotic lesions. Left anterior descending artery (56%) accounted for most cases followed by right coronary artery (22%), left circumflex artery (21%), left main (17%) and saphenous vein grafts (3%) procedures. Upfront use of IVL occurred in 18% of cases whilst the rest were bail-out procedures due to inadequate predilatation with conventional balloons. Adjuvant rotational atherectomy (Rota-tripsy) was used in 10 cases (10%) prior to the use of IVL. The mean diameter of IVL balloon was 3.3±0.5 mm. Intravascular imaging (IVUS) was used in 19% of cases. Procedural success was achieved in 100% of cases with a complication rate of 2% (2-cases of coronary perforation and one of them resulted in in-hospital mortality). During the median follow-up of 150 days, there were no clinical events including cardiac death, TVMI and TLR.

Conclusions: Initial experience and short-term clinical follow-up from IVL use appears safe and is an effective PCI strategy for dealing with calcified coronary lesions. A high success rate was observed with low event rates and procedural complications.

Other Coronary interventions - Other

Immediate versus staged revascularisation of non-culprit arteries in patients presenting with an ACS: a systematic review and meta-analysis

DEN DEKKER Wijnand [(1)], DEN DEKKER Wijnand [(1)], WILSCHUT Jeroen [(1)], DAEMEN Joost [(1)], DILETTI Roberto [(1)], ZIJLSTRA Felix [(1)], DE JAEGERE Peter [(1)], VRIESENDORP Pieter [(1)], VAN MIEGHEM Nicolas [(1)]

(1) Erasmus MC, Rotterdam, the Netherlands

Aims: Although there is consensus that revascularisation of non-culprit vessels should be pursued in patients presenting with an acute coronary syndrome (ACS) and multivessel coronary artery disease, the optimal timing of complete revascularisation remains unclear. This study aims to determine if immediate complete revascularisation (ICR) improves outcomes compared with staged complete revascularisation (SCR).

Methods and results: A systematic review and meta-analysis comprising 20 studies (5 randomised controlled trials and 15 retrospective cohorts) and 10,853 patients was performed. The protocol for this systematic review and meta-analysis is registered in the PROSPERO database (CRD42019124604). Studies were identified in PubMed, Embase, Cochrane Central and MEDLINE databases, and manual reference search of relevant literature was performed to ensure completeness. Studies comparing ICR with SCR in patients with ST-elevation myocardial infarction (STEMI) or non ST-elevation myocardial infarction acute coronary syndrome (NSTE-ACS) and multivessel disease were included if reported in English literature, as full text report (no conference abstracts), up until 1 December, 2019. Primary endpoints were 30-day and 1-year all-cause mortality. Pair-wise meta-analysis showed that ICR, compared with SCR, increased 30-day mortality risk (OR 3.7 95% CI: 2.5-5.6) and increased 1-year mortality risk (OR 2.1 95% CI: 1.3-3.2). Sensitivity analyses showed that 1-year mortality was increased in patients with STEMI (OR 2.8 95% CI: 1.9-3.9), compared with NSTE-ACS (OR 0.65 95% CI: 0.4-1.1); and increased in non-randomised studies (OR 2.6 95% CI: 1.8-3.9) compared with randomised trials (OR 0.7 95% CI: 0.4-1.2).

Conclusions: This systematic review and meta-analysis showed that in patients with an ACS and multivessel coronary artery disease, there was an increased risk of periprocedural and 1-year mortality if ICR was performed, compared with SCR. However, these findings are mainly driven by non-randomised studies and cautious interpretation of this finding is recommended.

Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

A comparison of concordance between diastolic pressure ratio to FFR in the right vs left coronary arteries

BALFE Christopher [1], BALFE Christopher [1], MOLONEY Conor [1], GORECKA Miroslawa [1], LOO Bryan [1]

(1) Tallaght University Hospital, Dublin 24, Ireland

Aims: Diastolic to systolic flow often differs between the right and left coronary arteries. Diastolic to systolic flow is normally >2.0 in the left versus <1.5 in the right coronary artery. The accuracy of resting pressure ratios for predicting positive FFR might differ between the left and right arteries. While no difference for diagnostic accuracy of the resting pressure ratios between the arteries are reported, few studies have directly assessed this question. We aim to assess the difference in discordance rates between FFR and our resting pressure ratio (DPR) for left versus right arteries.

Methods and results: We carried out diastolic pressure ratio (DPR) assessment and FFR testing in intermediate severity coronary stenoses in a single centre between March and December 2019 using the Opsens pressure wire. DPR was measured three times and an average taken. FFR was carried out with intravenous infusion of adenosine at 140mcg/kg/minute. In keeping with major trials showing non-inferiority for iFR to FFR for clinical outcomes, treatment thresholds were a DPR of 0.89 and an FFR of 0.80 2,3. Provisional data for forty patients is available at time of submission. 44 DPR to FFR comparisons were carried out for 40 patients. The average age was 62.6±8.5 years. 85% of patients were male. 27.5% patients had diabetes. 56.8% had testing of an LAD lesion, compared to 15.9% LCx and 27.3% RCA. Discordant DPR to FFR results were found in 5 out of 44 tests. All discordant tests occurred in LAD lesions, representing 20% of all LAD lesions tested. 4 discordant tests had a positive DPR and negative FFR (DPR of 0.88, 0.88, 0.89 and 0.89), while one showed a positive FFR (0.79) and negative DPR. 10 of the 25 LAD lesions had a positive DPR, with 6 of these lesions being positive by FFR. Only 1 RCA lesion was positive by DPR; this also had a positive FFR.

Conclusions: All diastolic resting indexes, including DPR, have been demonstrated to correspond perfectly to iFR5. This allows cut-off values and clinical recommendations for iFR to be extended to these other indexes. The iFR cut-off of 0.89 has been shown to correctly classify 83 percent of stenoses when compared to FFR (<0.8). Thus, discordant FFR to resting index is not an uncommon occurrence in clinical practice. The approach to discordant results remains controversial. Two studies have suggested possible superiority of iFR-guided deferral of revascularisation compared to FFR guidance. However, a more recent study has shown similarly low rates of coronary events in patients with discordant results compared to those with normal FFR and resting index. In this small, single centre analysis, we found that 20% of LAD lesions tested had discordant resting pressure ratio to FFR ratio. No discordance was identified in the LCx or RCA. This analysis is ongoing and full results including p values will be published as an update to the data.

Stents and scaffolds - Tools, devices and techniques

DEB-only angioplasty in de novo large vessel versus small vessel coronary disease

WICKRAMARACHCHI Upul [1,2], WICKRAMARACHCHI Upul [1,2], CORBALLIS Natasha [1,2], MAART Clint [1], SULFI Sreekumar [1], WISTOW Trevor [1], RYDING Alisdair [1], SAREV Toomas [1], GILBERT Timothy [1], SKINNER Jane [2], FLATHER Marcus [1,2], ECCLESHALL Simon [1]

(1) Norfolk & Norwich University Hospital NHS Foundation Trust, Norwich, United Kingdom; (2) University of East Anglia, Norwich, United Kingdom

Aims: Drug-coated balloon (DCB)-only angioplasty has shown to be effective and safe in *de novo* small vessel coronary disease (SVD). Data for its efficacy in large vessel coronaries (LVD) are limited. This retrospective, observational study was carried out to compare the clinical outcomes of DCB-only angioplasty in small versus large vessel coronaries. This is the largest DCB-treated large vessel coronary cohort reported thus far.

Methods and results: 520 consecutive patients who had percutaneous coronary intervention (PCI) with a drug-coated balloon of a diameter of 3 mm or more and 292 patients with a DCB diameter of less than 3 mm were included in this comparison. All patients were treated at the Norfolk and Norwich University Hospital, UK from 1 January 2009 to 31 December 2015. Patient demographics, indication and lesion characteristics were obtained from the hospital data base (prospectively filled) and by reviewing angiograms. No patients were excluded. Clinical (MI and vascular) outcomes were obtained from the National Institute for Clinical Outcomes Research (NICOR), UK for all (100%) patients for 12 months. Up-to-date mortality data were obtained from the spine portal of the NHS Digital, UK. Mortality data were available for 99.9% patients up to three years. A major adverse cardiac event (MACE) was defined as a composite of all-cause death, MI and target lesion revascularisation. There were 603 lesions (520 patients) in the LVD cohort and 333 lesions (292 patients) in the SVD cohort. There was no difference in age, previous MI, CABG, dyslipidaemia, diabetes, family history and presence of cardiogenic shock between the two groups. There were more patients with history of previous PCI (22 vs 32%, p 0.001), hypertension (48 vs 56%, p 0.02) and of female gender (19 vs 35%, p<0.001) in the SVD group. The LVD group had more acute coronary syndromes (NSTEMI/UA 35% vs 29%, STEMI 29% vs 22%, p<0.001). The mean length of the treated section was 24.6 mm for both groups. The mean device diameter was 3.30 mm vs 2.35 mm (p<0.001). There was no difference in number of bifurcation lesions, chronic total occlusions, severe calcific lesions or tortuous lesions between the groups. 27% of LVD lesions and 12% of SVD lesions had thrombus present (p<0.001). In both groups, 6% had additional stents deployed (94% treated with DCB-only strategy).Bail-out stents during the index PCI were used in 5.3% of large vessel lesions and in 2.4% of the small vessel lesions (p 0.035). 3 LVD lesions (0.5%) and 1 SVD lesion (0.3%) required intervention during the index admission due to ongoing chest pains/ECG changes (0.4% of the total number of lesions). All-cause death at one year was 2.7% in the LVD and 5.1% in the SVD group (p 0.07). The three-year death was 6.5% vs 9.2% (p 0.15). MI at 12 months was 3.1% for both groups. Target lesion revascularisation at 12 months was 2.5% vs 1.2% (p 0.18). MACE (death, MI, TLR) at 12 months was 8.1% vs 7.9% (p 0.89). No definite treated lesion thrombosis reported for either group at 12 months.

Conclusions: In this comparison, 94% of lesions from both groups had DCB-only PCI indicating that it is feasible to treat coronary artery disease without the ubiquitous use of stents. The clinical outcomes show that DCB-only angioplasty in large vessel coronaries is as safe and effective as in small vessel coronaries. There was no significant difference in the individual or composite MACE outcome between the groups.

Stents and scaffolds - Invasive imaging and functional assessment

Intimal coverage and apposition among DESs with persistent, absorbable or without polymer at one- and six-month OCT follow-up

CALVO-FERNANDEZ Alicia [1], CALVO-FERNANDEZ Alicia [1], NEGRETE Alejandro [1], TIZON-MARCOS Helena [1], MILLAN Raul [1], SALVATELLA Neus [1], DE LA TORRE Jose Maria [2], DIEZ Jose Luis [3], IVERN Consol [1], GOMEZ-LARA Josep [4], VAQUERIZO Beatriz [1]

(1) Hospital del Mar, Barcelona, Spain; (2) Hospital Universitario Marqués de Valdecilla, Santander, Spain; (3) Hospital Universitario y Politécnico La Fe, Valencia, Spain; (4) Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Spain

Aims: Despite technological advances in DES design, delayed vascular healing is still a problem, triggered by the polymers, among others. This may induce restenosis and thrombosis. The development of biodegradable polymers and DES without polymer is thought to improve the vascular response and enhance earlier neointimal healing. OCT is the best intracoronary imaging tool to evaluate endothelial coverage after stent implantation. We aimed to quantitatively assess the differences on intimal coverage between biodegradable-polymer, durable-polymer and without-polymer DES at 1- and 6-month follow-up OCT.

Methods and results: A total of 94 patients with *de novo* coronary lesions were treated with DES: 26% were treated with biolimus A9 (BA9) stent without polymer, 30% were treated with everolimus DES with biodegradable polymer (EESb) and 44% with everolimus DES with persistent polymer (EESp). OCT analysis was performed blindly at an independent core lab at three stages: implantation, after one month and after six months. The primary endpoint was to compare neointimal coverage and apposition of these three different types of DES with OCT at one and six months after implantation. A total of 16,034 struts were analysed (24% BA9, 29% EESb and 47% EESp). No significant differences were found among the groups regarding baseline clinical characteristics. When studying the strut coverage, it is remarkable the relatively low percentage of early neointimal coverage with no significant differences among stents one month after implantation (84-87%). After six months, there was better coverage in the three stent groups compared with one month ($p<0.001$). The stents without polymer had better neointimal coverage at six months compared with the stents with persistent polymer (99% vs 92%, $p=0.0002$). No significant differences were found in the strut apposition after one or six months among the three stent types. However, the rate of apposition was higher after six months compared with one month in all stent groups ($p=0,001$). No significant differences were found in the neointimal hyperplasia at one month among the three stent groups. At six months there was a higher hyperplasia in the stent without polymer compared to the stent with persistent polymer (164µm vs 92µm, $p=0,003$). The degree of hyperplasia after six months was higher compared to one month in all groups ($p=0,001$).

Conclusions: The new-generation DES with biodegradable-polymer or without polymer showed relatively poor early neointimal coverage and similar to the last generation durable-polymer EES. According to these results, DAPT may not be shortened in any of the three DES types studied.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Six months and one year after ACS, 8/10 of the patients are treated in accordance with international guidelines in the Middle East and North Africa: the TOURACO study

SOBHY Mohamed [1], SOBHY Mohamed [1], ARAFAH Mohammed [4], ALSAYED Mohamed [3], AL SUWAIDI Jassim [2], BASLAIB Fahad [5], MALVOLTI Elmas [6], NIBOUCHE Djamaleddine [7], RAGY Hany [8], RHOUATI Adel [9], GUINDY Ramez [10]

(1) International Cardiac Center, Qesm, Egypt; (2) Hamad Medical Corporation, Doha, QATAR; (3) AstraZeneca FZ LLC, Dubai, United Arab Emirates; (4) King Saud University, Riyadh, SAUDI ARABIA; (5) Rashid Hospital, Dubai, United Arab Emirates; (6) Astrazeneca, Luton, United Kingdom; (7) CHU Nefissa Hamoud EX: Hopital PARNET, Hussein Dey, Algeria; (8) National Heart Institute, Agouza, Egypt; (9) CHU Benbadis, Constantine, Algeria; (10) Ain Shams University, Al Waili, Egypt

Aims: The TOURACO (Treatment patterns of acute coronary syndrome at One month of follow-Up in a Real life setting for patients hospitalised with an Acute COronary syndrome) study aimed at evaluating ACS quality of care in the Middle East and North Africa by assessing the treatment patterns compared to the 2012 European Society of Cardiology (ESC) and 2000 American College of Cardiology (ACC) guidelines, in a real-life setting.

Methods and results: TOURACO is an ongoing, observational, prospective and longitudinal cohort study conducted in Algeria, Bahrain, Egypt, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates, in 45 centres. Ongoing antiplatelet drugs, cholesterol- and glucose-lowering agents and antihypertensive drugs at 6-month and 1-year follow-up visits after hospital discharge, were compared to guidelines. Eligible patients were adults hospitalised within 24 hours of ACS onset and having given written informed consent. Factors associated with good compliance with guidelines, were analysed at 6 months, using mixed logistic regression models with adjustment on the site as random effect. Mean±standard deviation or median (interquartile) for non-normal values and odds ratio and 2-sided 95% confidence interval (CI) are displayed. Risk factors are those diagnosed during hospitalisation of the index event. Between December 2015 and February 2017, 1,124 eligible patients (mean age: 56±11 years; 912 [82.1%] males; median body mass index: 27.1 [24.0; 30.4] kg/m^2) were included. Overall, 603 (53.6%) patients had a STEMI, 300 (26.7%) patients a NSTEMI and 222 (19.8%) patients an unstable angina. A total of 1,111 patients were included in the follow-up population. A 6-month visit was documented in 911 (82.0%) patients. At 1 year, 26 (2.5%) patients (missing data: 63) had died and information was available for 972 (87.5%) patients including a hospital visit for 321 (33.1%) patients among which detailed ongoing treatment was recorded in 312 patients. At 6 months, 862 (77.6%) patients were receiving an antithrombotic treatment, 804 (72.4%) patients ≥2 antiplatelets, 835 (75.2%) patients a cholesterol-lowering treatment, 241 (21.7%) patients glucose lowering agents and 834 (75.1%) patients an antihypertensive drug treatment. At 1 year, 940 (96.7%) patients continued treatments prescribed at discharge. Treatments complied with ESC and with ACC guidelines in 622/817 (76.1%) patients at 6 months and in 261/312 (83.7%) patients at 1 year. Compliance with guidelines at 6 months and 1 year were respectively: among the diabetic patients, 181 (52.3%) and 104 (68.4%); among the hypertensive patients, 290 (71.3%) and 137 (80.1%) and among the hypercholesterolaemic patients, 207 (80.5%) and 91 (82.0%). Compliance with guidelines was inversely associated with diabetes (odds ratio [OR] at 6 months=0.12; 95% CI: [0.08-0.18]).

Conclusions: One year after discharge, 29% of the patients are still followed in the same hospital. Six months and 1 year after ACS, 8/10 of patients were treated in compliance with ESC and ACC guidelines. However, compliance with guidelines was poor in the subgroup of patients with diabetes. The ongoing follow-up will track the 2- and 3-year evolution in the management of those patients.

Stents and scaffolds - Tools, devices and techniques

Clinical and imaging outcomes of thin-strut sirolimus-eluting BRS in patients with de novo coronary artery lesions: the MeRes-1 Extend trial

ABIZAID Alexandre [1], ABIZAID Alexandre [1], SASKO Kedev [2], ROSLI Bin Mohd Ali [3], TEGUH Santoso [4], ANGEL Cequier [5], RJM van Geuns [6], BERNARD Chevalier [7], FARREL Hellig [8], ONUMA Yoshinobu [9], SERRUYS Patrick [10]

(1) Instituto Dante Pazzanese de Cardiologia, State of São Paulo, Brazil; (2) University Clinic of Cardiology, Skopje, The former Yugoslav Republic of Macedonia; (3) National Heart Institute, Federal Territory of Kuala Lumpur, Malaysia; (4) Medistra Hospital, Jakarta, Indonesia; (5) Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Spain; (6) Erasmus MC, Rotterdam, the Netherlands; (7) Institut Cardiovasculaire Paris Sud (ICPS), Massy, France; (8) Sunninghill Medical Centre, Johannesburg, South Africa; (9) Cardialysis B.V., Rotterdam, the Netherlands; (10) Imperial College London, London, United Kingdom

Aims: The MeRes-1 Extend study sought to assess the safety and efficacy of the novel thin-strut BRS in diverse patient populations in Europe, Brazil, South Africa, and Asia Pacific.

Methods and results: The MeRes-1 Extend was a prospective, multicentre, single-arm study that enrolled 64 patients from Macedonia, Spain, South Africa, Brazil, Indonesia and Malaysia. The major adverse cardiac event, consisting of cardiac death, myocardial infarction, and ischaemia-driven target lesion revascularisation, was the safety endpoint. At baseline and 6-month follow-up, quantitative coronary angiography and OCT imaging were performed. A total of 64 patients were enrolled and mean age was 58.30±9.02 years. From 64 patients, 76.56% had hypertension, 26.56% had diabetes mellitus, 48.44% had dyslipidaemia, and 28.13% had previous myocardial infarction. Amongst 64 patients, 68.75% patients presented with stable angina, 9.38% patients with unstable angina and 21.88% with silent ischaemia. Total number of target lesions was 69; of which type B2/C were 71.01%; 14.37±5.89 mm was mean lesion length and 3.03±0.35 mm was mean reference vessel diameter. Device and procedural success was achieved in 62 and 64 patients, respectively. At 24-month follow-up, major adverse cardiac events in the form of ischaemia-driven target lesion revascularisation was reported in one patient (1.61%); there was no myocardial infarction, cardiac death or scaffold thrombosis. At six-month angiographic follow-up in a subset of 32 patients, mean in-scaffold late lumen loss was 0.18±0.31 mm. OCT analysis (21 patients) showed 97.95±3.69% strut coverage and mean scaffold area of 7.56±1.79 mm^2, with no evidence of strut malapposition.

Conclusions: Based on two-year clinical and six-month imaging outcomes, the MeRes-1 Extend trial established favourable safety and efficacy of novel thin-strut sirolimus-eluting BRS in patients with *de novo* coronary artery lesions.

Other Coronary interventions - Other

Buddying up for complex PCI: does having a co-operator improve in-patient outcomes?

KINNAIRD Tim [1], KINNAIRD Tim [1], ANDERSON Richard [1], FAROOQ Vasim [1], SHARP Andrew [1], GALLAGHER Sean [1]

(1) University Hospital of Wales, Cardiff, United Kingdom

Aims: Little is known about the outcomes of complex and indicated high risk PCI (CHIP-PCI) procedures in which there are two consultant operators (buddied procedures, BP) compared to CHIP-PCI procedures in which there is a single consultant operator (NBP). Potential benefits include preprocedural discussion and planning, use of optimal PCI strategies, improved trouble-shooting and complication management, and reducing operator stress. Whether these potential benefits improve patient outcomes is unknown.

Methods and results: PCI data were derived from a large regional teaching hospital with a regional and supra-regional PCI network. All PCI procedures between 2008 and 2018 were included. CHIP criteria were defined as one or more of the following: previous CABG, history of chronic renal failure, ejection fraction <30%, use of LV support, CTO-PCI, left main-PCI, or use of rotational/laser atherectomy. In-hospital MACE was defined as a composite of death, MI and stroke. To test for trends between different cohorts we fitted a linear regression model with CHIP number and buddy status with an interaction term between these. We tested for associations between each categorical variable and access site using a Chi-squared test, and for continuous variables we used one-way analysis of variance. Of 17,531 total PCI procedures, 323 (1.8%) of cases were buddied-up. For all PCI, compared to NBP, patient comorbid burden including age (67.7±11.6 vs, 64.6±11.7years, p<0.0001), previous MI (45.7 vs 30.2%, p<0.0001), EF (44.2±7.9 vs 46.1±7.4, p=0.0001), peripheral/cerebrovascular disease (8.4 vs 4.6%, p=0.002), severe valve disease (2.2 vs 0.8%, p=0.016) and chronic renal failure (7.1 vs 2.8%, p<0.0001) was greater in the BP cohort. Procedural complexity was also greater in the BP cohort with left main PCI (19.4 vs 4.5%, p<0.0001), CTO-PCI (33.4 vs 7.1%, p<0.0001), number of vessels treated (1.43±0.72 vs1.29±0.55, p<0.0001) and use of rotablation (13.4 vs 1.3%, p<0.0001) all more frequent. Despite a significant imbalance in patient and procedural complexity between the BP and NBP groups, survival to discharge was similar between cohorts (1.6 vs 1.0% respectively, p=0.33). When outcomes were examined by the number of CHIP criteria, there was a significant reduction in in-hospital MACE as the number of criteria increased - no CHIP criteria 0.2% (NBP) vs 0.4% (BP), one CHIP criterion 0.8% vs 2.1% (p<0.05), two CHIP criteria (1.8% vs 4.6% (p<0.01), three or more CHIP criteria 4.3% vs 9.5% (p<0.001), p=0.002 for comparative trend.

Conclusions: These data demonstrate reduced in-hospital MACE following CHIP-PCI procedures with buddying-up, and thus support this concept on a more routine basis for complex PCI procedures to optimise patient outcomes. This hypothesis generating data supports the on-going national UK buddying-up study.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Quantitative flow ratio comparison to FFR for estimation of functional significance of intermediate coronary artery stenosis

ZIUBRYTE Greta [(1)], ZIUBRYTE Greta [(1)], UNIKAS Ramunas [(1)], JARUSEVICIUS Gediminas [(1,2)]

(1) Department of Cardiology, Hospital of Lithuanian University of Health Sciences Kaunas Clinics, Kaunas, Lithuania; (2) Institute of Cardiology, Lithuanian University of Health Sciences, Kaunas, Lithuania

Aims: The primary aim of this study was to prove excellent agreement between quantitative flow ratio (QFR), a minimally invasive method used for FFR value computation from ordinary coronary angiograms, in comparison to FFR, a gold standard method for assessment of functional significance of coronary artery (CA) stenosis. The secondary aim was to evaluate the difference between QFR and FFR on making a treatment decision.

Methods and results: One-hundred-twenty-nine patients who underwent coronary angiography revealing intermediate stenosis (lumen stenosis of 35-75%) by visual evaluation and for whom FFR measurements were performed or planned to be performed between 1 January 2018 and 31 December 2019 have been prospectively included into our single centre study. Online QFR analyses were performed at inclusion and repeated offline twice after inclusion to identify inner agreement between repeated QFR analyses. FFR values were averaged from 3 independent measurements during the same procedure. The chosen level of significance was $p<0.01$. Excellent inner agreement of three QFR analyses were found, $r = 0.998$, $p<0.001$. Averaged QFR values were compared to averaged FFR values. In total, 144 lesions (89 left anterior aescending (LAD), 12 left circumflex (LCX) and 43 right coronary artery (RCA)) were analysed. In the analyses of all lesions, a strong significant correlation coefficient between QFR and FFR was found, $r = 0.869$, $p<0.001$. After dividing lesions according to CA, following results have been found: LAD $r = 0.940$, $p<0.001$; LCX $r = 0.609$, $p=0.032$ and RCA $r = 0.890$, $p<0.001$. The analyses of extracted LAD and RCA have shown strong significant correlation coefficients, while in LCX were found moderate significant correlation coefficients, due to low number of cases in LCX sub-group. The secondary outcome was the agreement of clinical decision-making between QFR and FFR which have shown strong significant correlations between QFR and FFR, $r = 0.938$, $p<0.001$. Compared to FFR as a reference, QFR had a sensitivity of 100%, specificity of 97.4% and accuracy of 97.9%.

Conclusions: A coronary intervention guided by functional evaluation of significance of CA stenosis is widely recommended and accepted. Great agreement between QFR and FFR has been repeatedly published by various researchers. QFR is a reliable method for CA stenosis functional significance evaluation, and acceptance in everyday clinical practice may improve PCI outcomes by identifying target lessons and avoid unnecessary coronary interventions. QFR is safe, fast and easy-to-use method with an excellent correlation with FFR in both CA stenosis functional significance assessment and clinical decision making with a great sensitivity, specificity and accuracy. The greatest agreement was found in LAD and RCA. The study is being continued.

Bifurcation lesion - Tools, devices and techniques

Contemporary bifurcation treatment practice in patients treated with bioresorbable polymer sirolimus-eluting stent

CHEVALIER Bernard [(1)], CHEVALIER Bernard [(1)]

(1) Cardiovascular Institute Paris Sud (ICPS), Massy, France

Aims: Proximal optimisation technique (POT) in bifurcation stenting is highly recommended despite scarce clinical data. The aim of the present study is to describe the influence of stenting techniques on 1-year clinical outcome in patients with bifurcation lesions using the large all-comer data of the e-Ultimaster registry.

Methods and results: The present analysis was a sub-study of the e-Ultimaster registry, which was a prospective, single-arm, multicentre, worldwide, all-comers registry enrolling 36,916 patients, of which 34,538 (93.6%) had 1-year follow-up completed or had died. Of these, 4,199 patients underwent percutaneous coronary intervention (PCI) in at least one bifurcation lesion. All patients were treated with a cobalt-chromium, open-cell 2-link thin-strut design sirolimus-eluting Ultimaster stent with an abluminal bioresorbable polymer coating. The primary endpoint was target lesion failure (TLF) at 1 year, a composite of cardiac death, target-vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent clinical events committee adjudicated all endpoint-related adverse events. In 4,199 patients undergoing bifurcation PCI, the mean age was 65.7±11.1 and 76.6% of patients were male. At index procedure, 48.5% of patients presented with acute coronary syndrome. The rate of the true bifurcation (Medina classification 1,1,1, 1,0,1, or 0,1,1) was 53.2%. During procedure, kissing balloon inflation (KBI) and POT were performed in 37.0% and 34.3%, respectively. Intravascular imaging was used in 13.1%. At 1 year, TLF rate was 5.2%. To investigate the impact of true bifurcation and bifurcation techniques on clinical outcomes (POT and non-POT, KBI and non-KBI, 1-stent technique and 2-stent technique), propensity score matching was performed to adjust the difference of baseline and procedural characteristics. After the propensity score matching, 1-year TLF was comparable between patients with true bifurcations and those with non-true bifurcations (5.1% vs 5.0%, p=0.89). Patients treated with the POT technique had lower TLF rate (3.6% vs 6.3%, p<0.001), which was driven by lower TV-MI rate (0.6% vs 2.0%, p<0.001) and lower TLR rate (1.9% vs 3.8%, p=0.001). Definite/probable ST was also significantly lower in patients with POT (0.3% vs 1.3%, p<0.001). There was no significant difference in TLF between patients with and without KBI (5.2% vs 4.9%, p=0.68). Target-vessel MI was higher in patients treated with main branch stenting and side branch balloon compared to patients treated with main branch stenting and KBI (3.9% vs 0.7%; p=0.03, after propensity adjustment). There was no significant difference in TLF between the 1-stent technique and 2-stent technique for bifurcation lesions (4.7% vs 6.2%, p=0.07). However, the 1-stent technique was associated with a lower risk of any MI (1.4% vs 2.7%, p=0.008) and definite/probable ST (0.6% vs 1.5%, p=0.014) when compared to the 2-stent technique.

Conclusions: In this large all-comer registry, POT was associated with a significant benefit for ischaemic events up to 1 year, whereas KBI was not influencing the midterm outcome.

Stents and scaffolds - Invasive imaging and functional assessment

Clinical implications of post-stent OCT findings after DES implantation: severe malapposition and thrombotic events

KIM Byung Gyu [1], KIM Byung Gyu [1], KACHEL Mateusz [3], KIM Jung-Sun [2], HONG Sung-Jin [2], AHN Chul-Min [2], KIM Byeong-Keuk [2], KO Young-Guk [2], CHOI Donghoon [2], HONG Myeong-Ki [2], JANG Yangsoo [2]

(1) Paik Hospital, Inje University countervailing, Seoul, Republic of Korea; (2) Severance Hospital, Seoul, Republic of Korea; (3) American Heart of Poland, Katowice, Poland

Aims: The clinical implications of optical coherence tomography (OCT) assessment following percutaneous coronary intervention are controversial. We sought to evaluate the impact of post-stent OCT findings, including significant malapposition, on long-term clinical outcomes.

Methods and results: A total of 1,290 patients with 1,348 lesions, in which OCT was performed immediately post-stent, were consecutively enrolled in the prospective OCT registry. Post-stent OCT findings were assessed to identify predictors of device-oriented clinical endpoints, including cardiac death, target vessel-related myocardial infarction, stent thrombosis, and target lesion revascularisation. We also looked for significant malapposition criteria that may be associated with thrombotic events such as cardiac death, target vessel-related myocardial infarction, and stent thrombosis. Incidences of stent edge dissection (13.7%), tissue prolapse (58.3%), thrombus (52.1%), and malapposition (67.4%) after intervention were not associated with occurrence of adverse thrombotic events. However, patients with significant malapposition (total malapposed volume ≥ 7.0 mm^3, hazard ratio, 7.89 [2.44-25.58]; p=0.001 or total malapposed volume/stent volume ≥ 4.1%, hazard ratio 4.92 [1.51-16.02]; p=0.037) exhibited more frequent thrombotic events. In multivariate analysis, smaller minimal stent area was identified as an independent predictor for device-oriented clinical end points (hazard ratio, 1.21 [1.01-1.45]; p=0.037). Malapposition with total malapposed volume ≥ 7.0 mm^3 was found to be an independent predictor of thrombotic events (hazard ratio, 4.62 [1.29-16.47]; p=0.018).

Conclusions: Although most high-resolution OCT findings were not associated with clinical outcome, smaller minimal stent area was associated with device-oriented clinical end points, driven mainly by target lesion revascularisation, and significant malapposition with total malapposed volume ≥ 7.0 mm^3 was associated with more thrombotic events after drug-eluting stent implantation.

Stable CAD - Tools, devices and techniques

Accuracy of a fast non-invasive FFR from coronary CT angiography: Flash CT FFR

HUO Yunlong [(1)], FENG Yundi [(1)], LI Li [(1)]

(1) Pku-Hkust Shenzhen-Hongkong Planning And Design Institution, Guangdong, China

Aims: CT-derived fractional flow reserve (CTFFR) can be used to identify lesion-specific ischaemia. The aim of the study is to evaluate the diagnostic performance of a fast CTFFR software (FlashCT FFR) against invasive FFR.

Methods and results: In FlashCT FFR, myocardial volume and epicardial coronary arterial trees were reconstructed from patient CTA. The resting blood flow was obtained from myocardial volume and the hyperaemic flow was estimated by an empirical model similar to the FlashAngio FFR system. An automated plaque analysis was performed to improve the accuracy of the reconstructed lumen size in the FlashCT FFR. A total of 130 patients (>50% with calcified plaques, 63±9 years) and 185 vessels underwent CTA at two hospitals. CTFFR was computed by the FlashCT FFR and compared with the invasive FFR on per-vessel level. The total operation time of CTFFR is 5±3 minutes. The diagnostic performance of CTFFR versus FFR was diagnostic accuracy of 87%, sensitivity of 84% and specificity of 90%.

Conclusions: Using the wire-based FFR as the reference, the FlashCT FFR improved the performance of coronary CTA in diagnosing ischaemia, especially in lesions with calcified plaques.

Stable CAD - Invasive imaging and functional assessment

Use of coronary physiology in chronic coronary syndromes in Germany from 2007-2017

STACHON Peter [1], STACHON Peter [1], KAIER Klaus [1], ZEHENDER Manfred [1], BODE Christoph [1], VON ZUR MÜHLEN Constantin [1]

(1) University Heart Center, Cardiology and Angiology I, Freiburg, Germany

Aims: Coronary physiology is increasingly used in evaluating coronary stenosis, but the penetration of FFR (fractional flow reserve) or resting indices (e.g. iwFR or RFR) in daily clinical routine is not known.

Methods and results: The number of coronary angiographies and use of coronary physiology (CP) in patients with chronic coronary syndromes (CCS) in Germany was identified by ICD and OPS codes. From 2007 to 2017, there was a constant increase in CP usage, with an application rate of 9.19% in 2017. Patients with use of CP were younger (68.8 vs 70.8 years), had less often severe co-morbidities (peripheral or carotid disease, chronic obstructive pulmonary disease, pulmonary hypertension, renal disease, atrial fibrillation, diabetes), had milder symptoms (10.4 vs 14.4% in NYHA class III or IV), and a lower EuroSCORE (6.1 vs 8.3%). Fewer coronary stents were implanted in patients with use of CP (0.6 vs 0.8, 95% CI: -0.14-0.26; p<0.001), even after risk adjustment for co-morbidities. Concerning in-hospital outcomes, acute kidney injury occurred less in CP (1.8 vs 3.7%) with subsequently shorter hospital stays (4.3 vs 5.9 days). Also in-hospital morbidity was lower in CP (0.28 vs 1.5%), even after risk adjustment (OR 0.28, p<0.001, 95% CI: 0.23-0.36).

Conclusions: In 2017, coronary physiology was used in 9.19% of patients with CCS in Germany. CP resulted in better in-hospital outcomes and fewer stent implantations. The reasons for a reduced use of CP in patients with significant co-morbidities, and their impact on clinical outcomes require further attention and evaluation in the future.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Treatment of extremely small de novo vessel coronary artery disease with DEB – a single-centre experience

NURUDDIN Amin [(1)], NURUDDIN Amin [(1)], TEY Yee Sin [(1)], PALANIAPPAN Ganapathi [(1)], M. SUNDRAN Rhuban [(1)], STANISLAUS Rohith [(1)], MOHAMED NAZEEB Mohamed Nazrul [(1)], TEOH Chee Kiang [(1)], SABIAN Intan Safarinaz [(1)], RAMLI Mohd Faizal [(1)], MOHAMED YUSOF. Ahmad Khairuddin [(1)]

(1) Institut Jantung Negara, Federal Territory of Kuala Lumpur, Malaysia

Aims: To compare the outcomes of paclitaxel drug-eluting balloon (DEB) angioplasty in patients with ≤2.25 mm and >2.25 mm *de novo* small vessel coronary artery lesions.

Methods and results: All patients who underwent *de novo* coronary artery lesion angioplasty with DEB between January 2012 and December 2018 were included in the analysis. Patient baseline characteristics, angiographic data, post-procedural and 12-month follow-up outcomes, including cardiac death, myocardial infarction and major adverse coronary event (MACE) were compared. A total of 1,574 patients with 1,733 *de novo* small coronary artery lesions were included in the study. Mean age was 59±10 years with a predominance of males (n= 1,326, 84%). The majority were hypertensive (n=1,159, 74%) and diabetes mellitus accounted for 893 (57%) of cases. Fifteen percent presented with acute coronary syndrome (ACS), 5% had STEMI, 6% had NSTEMI and 4% unstable angina. Diffuse vessel disease were present in 868 cases (50%). The majority of stenotic lesions were in the left coronary artery; left anterior descending artery, n=676, (39%) and left circumflex artery, n=553 (32%). Four hundred and fifty-five (26%) lesions were in the right coronary artery and 30 were in bypass grafts (2%). The majority of the lesions were type B2 and C lesions (n=1043, 60%). Predilatation of the lesions was performed in the majority of cases (n=1721, 99%) with a pressure of 11±5 atmospheres. The mean DEB diameter and dilatation pressure were 2.5±0.4 mm and 8±4 atmospheres, respectively. The mean inflation time was 58±16 seconds. Flow-limiting lesions post DEB that were bailed-out with stents were 24 (1.4%). One-thousand and ninety-nine (70%) patients received both aspirin and clopidogrel on discharge. Clinical follow-up was available in 1,527 (98%) patients. There were no complications of acute or subacute vessel thrombosis following treatment. Out of 1,733 lesions, 615 (35%) cases treated with DEB had a diameter of ≤2.25 mm. Dissection in vessels ≤2.25 mm and >2.25 mm were in 36 (6%) and 78 (7%) cases, respectively (p=0.367). Flow limiting dissection was not significant in vessels ≤2.25 mm as compared to vessels >2.25 mm (p=0.836), which occurred in 9 (1.5%) and 15 (1.3%) cases, respectively. At follow-up, major adverse cardiac events (MACE) in vessels ≤2.25 mm and >2.25 mm were 14 (2.5%) and 23 (2.4%), respectively (p=0.868). Cardiac deaths were 5 (0.9%) in vessels ≤2.25 mm and 5 (0.5%) in vessels >2.25 mm (p=0.511). TLR in vessels ≤2.25 mm were 7 (1.3%) and 17 (1.8%) in vessels >2.25 mm (p=0.449). Freedom from MACE at 1 and 2 years in vessels ≤2.25 mm was 98% and 92%, respectively and in vessels >2.25 mm was 98% and 95%, respectively (p=0.304).

Conclusions: Our experience demonstrates that using DEB in the treatment of extremely small *de novo* vessels in coronary artery disease was favourable and safe with a low MACE rate at mid-term follow-up and offers an alternative treatment to stenting in *de novo* small vessel coronary artery disease.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Impact of coronary artery lesion calcification on clinical outcomes after implantation of newer-generation DES – a patient-level pooled analysis of the randomised BIOFLOW trials

HEMETSBERGER Rayyan [1], HEMETSBERGER Rayyan [1], ABDELGHANI Mohammad [2,3], TOELG Ralph [1], WINDECKER Stephan [4], LEFÈVRE Thierry [5], SAITO Shigeru [6], SLAGBOOM Ton [7], KOOLEN Jaques [8], KANDZARI David E. [9], RICHARDT Gert [1]

(1) Segeberger Kliniken GMBH / Herz- und Gefäßzentrum, Bad Segeberg, Germany; (2) Al Azhar University Hospital, Cairo Governorate, Egypt; (3) AMC, Amsterdam, the Netherlands; (4) Inselspital, Universitätsspital Bern, Bern, Switzerland; (5) Hôpital privé Jacques Cartier - Ramsay Santé, Massy, France; (6) Shonan Kamakura General Hospital, Kanagawa, Japan; (7) Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands; (8) Catharina Hospital, Eindhoven, the Netherlands; (9) Piedmont Heart Institute, GA, USA

Aims: Data on the clinical outcomes after percutaneous coronary intervention (PCI) of calcified lesions with newer-generation drug-eluting stents (DES) are scarce. The aim of this study was to investigate the impact of calcified coronary lesions in patients undergoing PCI with an ultrathin bioresorbable polymer sirolimus-eluting stent (BP-SES) or a thin durable polymer everolimus-eluting stent (DP-EES).

Methods and results: Individual patient data from the randomised BIOFLOW-II, -IV, and -V trials were pooled. Target lesion calcification was categorised into none/mild vs moderate/severe by a core laboratory. Endpoints were: 1) target lesion failure (TLF; a composite of cardiac death, target-vessel myocardial infarction [TV-MI] or target lesion revascularisation [TLR]) and 2) stent thrombosis at two years. Out of 2,285 patients, 389 (17%) had moderate/severe lesion calcification. They were older, more often hyperlipidaemic and had more often a history of PCI or CABG as compared to patients with none/mild calcification. The clinical presentation did not differ between the groups, but calcified lesions were more complex and resulted in worse residual diameter stenosis after PCI (8.9% [3.2-14.8] vs 7.1% [1.8-12.4], p<0.0001). At 2 years, the rate of TLF (10.5% vs 7.2%; p=0.0263), cardiac death (1.3% vs 0.6%, p=0.0001), TV-MI (7.5% vs 3.8%; p=0.0014), and definite/probable stent thrombosis (2.1% vs 0.2%; p<0.0001) were higher in patients with moderate/severe vs none/mild calcification. Nevertheless, calcification had no impact on TLR (3.9% vs 3.3%; p=0.5596). In moderate/severe calcified lesions, TLF did not differ after BP-SES or DP-EES implantation (10% vs 11.6%, p=0.6156); whereas in none/mild calcified lesions a lower rate of TLF was observed after BP-SES implantation as compared to DP-EES (6.4% vs 8.9%, p=0.0453).

Conclusions: Target lesion calcification resulted in higher TLF and stent thrombosis as compared with none/mild calcification after PCI with newer-generation DES.

CTO - Tools, devices and techniques, Other Coronary interventions - Other

Impact of vessel size on outcome after PCI of CTO; six-month angiographic and two-year clinical outcomes

AHN Jihun [1], AHN Jihun [1], RHA Seung-Woon [2]

(1) Soonchunhyang University Hospital Gumi, Gyeongsangbuk-do, Republic of Korea; (2) Korea University Guro Hospital, Seoul, Republic of Korea

Aims: Chronic total occlusion (CTO) intervention is still challenging because of the limited procedural success rate and higher target failure. Also, small vessel coronary artery disease is associated with risk of adverse outcome. The aim of this study was to investigate the angiographic and clinical outcomes between small vessel CTO and large vessel CTO.

Methods and results: A total of 291 consecutive patients who underwent CTO intervention were divided into two groups according the reference vessel diameter (large vessel group, ≥2.75 mm: n=168 patients, small vessel group, <2.75 mm: n=123 patients). 6-month angiographic and 24-month clinical outcomes were compared between the two groups. The baseline clinical characteristics were similar between the two groups except old age was more frequent in the small vessel group. In-hospital complications were similar between the two groups. Both groups had similar angiographic outcomes at 6 months and clinical outcomes up to 2 years including TLR (8.9% in small vessel group vs 10.1% in large vessel group, p=0.842), TVR (9.8% in small vessel group vs 19.0% in large vessel group, p=0.575) and MACE (17.9% in small vessel group vs 10.1% in large vessel group, p=0.879). In multivariate analysis, old age was a predictor for MACE for those undergoing PCI for CTO (OR;1.038, CI 1.006-1.072, p=0.019).

Conclusions: The safety profile, long-term angiographic and clinical outcomes were similar between small vessel and large vessel group in the CTO era. Long-term randomised clinical trials with larger study population will be necessary to elucidate the final conclusion.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Laser Quest: the determinants and outcomes of PCI cases utilising excimer laser coronary atherectomy – an analysis of 1,471 laser cases from the British Cardiovascular Intervention Society database

PROTTY Majd [1,2], PROTTY Majd [1,2], HUSSAIN Hussain [1], GALLAGHER Sean [1], AL-RAISI Sara [1], ALDALATI Omar [1], FAROOQ Vasim [1], SHARP Andrew [1], ANDERSON Richard [1], KINNAIRD Tim [1]

(1) University Hospital of Wales, Cardiff, United Kingdom; (2) Cardiff University, Cardiff, United Kingdom

Aims: Introduction: Excimer laser coronary atherectomy (ELCA) is an established adjunctive therapy utilised in the percutaneous management of complex coronary lesions. Despite this, studies examining its safety and utility have been limited by small sample sizes. Our study examines the 'real-world' determinants and outcomes of ELCA over a ten-year period in a national registry.

Methods and results: Using the British Cardiac Intervention Society database, data were analysed on all PCI procedures in the UK between 2006-2016. Descriptive statistics and multivariate logistic regressions were used to examine baseline, procedural and outcome associations with ELCA. We identified 1,471 (0.21%) ELCA cases out of 686,358 PCI procedures with complete outcome records. Baseline covariates associated with ELCA use were age, BMI, number of lesions, CTO or restenosis attempted and history of prior MI, CABG or PCI. Procedural co-variates associated with ELCA were the use of GPIIBIIIA inhibitors, imaging, rotational atherectomy, cutting balloons, microcatheters and intra-aortic balloon pumps. Adjusted rates of in-hospital major adverse cardiac/cerebrovascular events (MACCE) or its individual components (death, periprocedural MI, stroke and major bleed) were not significantly altered by the use of ELCA. However, there were higher odds of dissection (OR 1.52, 95% CI: 1.17-1.98), perforation (OR 2.18, 95% CI: 1.44-3.30), slow flow (OR: 1.67, 95% CI: 1.18-2.36), re-intervention (OR: 2.12, 95% CI: 1.14-3.93) and arterial complications (OR: 1.63, 95% CI: 1.21-2.21).

Conclusions: Excimer laser use is associated with higher risk baseline and procedural characteristics, but appears to have no effect on the likelihood of in-hospital MACCE or its individual components.

STEMI - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

The natural history of non-culprit lesions in STEMI: an FFR substudy of the COMPARE-ACUTE trial

PIROTH Zsolt [1], PIRÓTH Zsolt [1], BOXMA-DE KLERK Bianca M. [2], OMEROVIC Elmir [3], ABDEL-WAHAB Mohamed [4], NEUMANN Franz-Josef [5], RICHARDT Gert [6], ABDELGHANI Mohammad [6], SMITS Pieter C. [7]

(1) Gottsegen György Országos Kardiológiai Intézet, Haller Street, Hungary; (2) Maasstad Hospital, Rotterdam, the Netherlands; (3) Gothenburg University, Gothenburg, Sweden; (4) Universität Leipzig, Leipzig, Germany; (5) Universitäts-Herzzentrum Bad Krozingen, Bad Krozingen, Germany; (6) Segeberger Kliniken GMBH / Herz- und Gefäßzentrum, Bad Segeberg, Germany; (7) Maasstad Hospital, Rotterdam, the Netherlands

Aims: Patients with ST-segment elevation myocardial infarction (STEMI) often present with multivessel disease. The treatment of non-infarct related arteries (nIRA) continues to be debated. Fractional flow reserve (FFR) has emerged as one of the tools of assessing coronary lesion severity, but its applicability has not been widely proven in acute coronary syndrome. We aimed to study the role of FFR in the decision making concerning nIRA revascularisation in STEMI.

Methods and results: The present study analyses the outcome of all patients of the COMPARE-ACUTE trial in whom, after successful primary PCI of the culprit artery, the nIRA was interrogated by FFR and treated medically. The treating cardiologist was blinded to the FFR value. The primary endpoint of the study was the composite of cardiovascular mortality, target vessel (nIRA with FFR measurement at the primary PCI) related non-fatal myocardial infarction (MI) and target vessel repeat revascularisation (TVR): major adverse cardiac events (MACE) at 24 months. 751 patients (963 vessels) were included. Target nIRAs with MACE had a significantly lower FFR value measured compared to those without MACE (0.78 vs 0.84, respectively, $p<0.001$). The median FFR value of nIRAs that had TVR was statistically significantly lower than that of those without revascularisation during follow-up: 0.79 vs 0.85, respectively ($p<0.001$). The difference was significant in all the vessels: LAD 0.77 vs 0.82 ($p=0.002$), Cx 0.83 vs 0.89 ($p<0.001$), RCA 0.83 vs 0.87 ($p=0.021$). The median FFR value of target nIRAs that were related to MI during follow-up was significantly lower than that of those not related to MI during follow-up: 0.79 vs 0.84, respectively ($p=0.016$). When grouping the FFR values of target nIRA's in tertiles, the lowest tertile had FFR values <0.80, the middle 0.80-0.87, the highest 0.88 or more. The difference in MACE between the lowest vs the other two tertiles is statistically significant ($p<0.001$).

Conclusions: In a patient population of STEMI with multivessel disease, treated by primary PCI of the culprit and medical therapy of the non-culprit vessels, FFR measured in the nIRA immediately after successful primary PCI, shows a non-linear and inverse risk-continuum of MACE over the entire range of functional lesion severity. This finding extends the prognostic value of FFR to the acute setting (in non-culprit arteries) and reinforces the role of FFR in decision making in acute coronary syndrome. Importantly, the worsening of prognosis is demonstrated around the cut-off of 0.80.

CTO - Tools, devices and techniques

Coronary CTO: eight-year experience from a dedicated single-centre programme

BRÍZIDO Catarina [1], BRÍZIDO Catarina [1], MESQUITA GABRIEL Henrique [1], GONÇALVES Mariana [1], MADEIRA Sérgio [1], LEAL Sílvio [1], SANTOS Rita [1], RAPOSO Luís [1], GONÇALVES Pedro [1], CAMPANTE TELES Rui [1], ALMEIDA Manuel [1]

(1) Hospital de Santa Cruz, Carnaxide, Portugal

Aims: Coronary chronic total occlusion (CTOs) percutaneous coronary intervention (PCI) is a complex procedure that has been shown to be safe and effective in symptom relief when performed by experienced CTO-PCI operators. Our aim was to evaluate procedural and clinical outcomes of CTO-PCI in a high-volume centre.

Methods and results: This was a single-centre retrospective analysis of all patients included in a CTO-PCI dedicated program from January 2011 to November 2019. Baseline characteristics, procedural related features and clinical outcomes were analysed. Predictors of procedural success were assessed with uni- and multivariate analysis using binary logistic regression. A total of 183 patients were referred to our CTO-PCI dedicated program (mean age 65±9 years, 79% males). There were 169 patients with single vessel CTO and 14 patients with double occlusion (8 treated within the same procedure). Target vessel was RCA in 51%, LAD in 25% and circumflex artery in 24%. The median J-CTO score was 2 (IQR 1-3) and 70% of lesions had JCTO score ≥2. CTO-PCI attempt was made for 196 lesions throughout 210 procedures, with a success of 83% (n=163) per CTO and 81% (n=149) per patient. Most procedures where uneventful (96%), with 6 severe complications and 3 deaths. Higher J-CTO scores predicted procedural failure (HR 2.1, 95% CI: 1.2-3.7; p=0.006), as did using the retrograde approach (95% CI: 1.01-6.26; p=0.046). PCI success was independent of the target coronary artery, number of previous attempts and arterial access. Baseline characteristics and clinical cardiovascular background did not influence each patient's outcome. During a median follow-up of 41 months (IQR 20-68), all-cause mortality was 12% (n=22). Most patients who were alive at follow-up remained asymptomatic (69%) or in CCS class 1 (11.5%). 6.5% of patients (n=12) underwent at least one target lesion revascularisation since CTO-PCI.

Conclusions: We report good success rates without significant safety concerns in a cohort of patients with technically difficult lesions as classified by J-CTO score. Our dedicated CTO-PCI program resulted in long lasting symptom improvement with low rates of repeated revascularisation.

Other Coronary interventions - Other

Long-term clinical outcomes in patients with AMI treated with PCI according to daytime and night-time admission

JANUSZEK Rafal [1], JANUSZEK Rafal [1], SIUDAK Zbigniew [2], ZABOJSZCZ Michał [2], SADOWSKI Marcin [2], JEDRYCHOWSKA Magdalena [1], STASZCZAK Bartlomiej [4], BARTUS Jerzy [4], PLENS Krzysztof [3], BARTUS Jerzy [4], DUDEK Dariusz [4]

(1) SP ZOZ Szpital Uniwersytecki w Krakowie, Kraków, Poland; (2) Jan Kochanowski University of Kielce, Kielce, Poland; (3) KCRI, Kraków, Poland; (4) Collegium Medicum Uniwersytet Jagielloński, Kraków, Poland

Aims: It has been suggested that the time of the day or night may influence clinical outcomes in patients with acute myocardial infarction (AMI) treated with percutaneous coronary interventions (PCI). The aim of the current study was to assess the impact of day and night time on clinical outcomes.

Methods and results: This is a retrospective cohort study based on the prospectively assembled ORPKI registry which covers PCI procedures performed in Poland. Day hours were defined as the time from 7:00 a.m. until 10:59 p.m. Primary study endpoints included the overall mortality rate and main adverse cardiac and cerebrovascular events, with the follow-up time at 30 days, and 12 months as well as 36 months. The total number of patients included into the current study was 2,919 (2,462 patients treated during day hours, 84.3%). The main aetiology was STEMI (1,993 patients, 68.3%). The current study demonstrated that the 30-day mortality rate was significantly greater in patients treated during night hours in comparison to day hours (p=0.01) and was also among predictors of the increase in 30-day mortality (hazard ratio: 1.54, 95% confidence interval: 1.107-2.161; p=0.01). This relationship lost relevance at subsequent time points (12 and 36 months).

Conclusions: Patients treated with pPCI due to AMI and night hours are connected with increased 30-day mortality when compared to patients treated during day hours.

Other Coronary interventions - Other

Comparison of ticagrelor with clopidogrel on quality of life in patients with ACS

JO Yoon-Sung [(1)], PARK Kyungil [(1)], JO Yoon-Sung [(1)], HYEYEON Moon [(1)]

(1) Dong-a University Hospital, Busan, Republic of Korea

Aims: The recently available strong $P2Y_{12}$ inhibitor, ticagrelor, is a cornerstone drug in acute coronary syndrome (ACS). However, ticagrelor needs to be taken twice a day compared to clopidogrel, and adverse effects such as dyspnoea or bleeding are known to be more common than with clopidogrel. These characteristics of ticagrelor may affect quality of life (QOL). Therefore, the aim of this study is to evaluate the effect of ticagrelor on QOL in patients with ACS.

Methods and results: A subgroup analysis from a randomised clinical trial, PLEIO (comParison of ticagreLor and clopidogrEl on mIcrocirculation in patients with acute cOronary syndrome), was performed. Two study groups using ticagrelor and clopidogrel were evaluated for QOL for six months. The assessment of QOL was carried out with short-form 36 Health Survey (SF-36) questionnaire at discharge day after PCI and 6 months later. Of 120 subjects recruited in the PLEIO trial, 113 (94.2%) completed the health-related QOL assessment. Among 113 patients, 56 (49.6%) were in the ticagrelor group and 57 (50.4%) were in the clopidogrel group. At discharge, QOL measures were similar in the ticagrelor and clopidogrel groups with physical component summary (PCS) score (49.4±14.7 versus 51.7±6.9, p=0.14) and mental component summary (MCS) score (51.4±7.2 versus 49.5±8.2, p=0.09), respectively. Six-month follow-up QOL assessment showed that there were no differences in regard to PCS score (55.2±3.7 versus 56.1±3.6, p=0.24) and MCS score (52.3±3.8 versus 51.3±4.0, p=0.23) between the two study groups. In both groups, PCS scores increased significantly for 6 months treatment (both p<0.01), however, the MCS score did not differ significantly.

Conclusions: Ticagrelor did not significantly reduce QOL for 6 months after PCI in patients with ACS compared to clopidogrel.

Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

Hyperaemic haemodynamic characteristics of serial coronary lesions assessed by pressure pullback gradients (PPG) ndex

CANDREVA Alessandro [(1)], CANDREVA Alessandro [(1)], SONCK Jeroen [(1,2)], NAGUMO Sakura [(1,3)], MIZUKAMI Takuya [(1,3)], GALLINORO Emanuele [(1)], KODEBOINA Monika [(1)], BARTUNEK Jozef [(1)], SHINKE Toshiro [(3)], DE BRUYNE Bernard [(1,4)], COLLET Carlos [(1)]

(1) Cardiovascular Center Aalst, OLV Clinic, Aalst, Belgium; (2) Department of Advanced Biomedical Sciences, University of Naples, Federico II, Naples, Italy; (3) Showa University Fujigaoka Hospital, Kanagawa, Japan; (4) Lausanne University Hospital, Lausanne, Switzerland

Aims: To describe the functional characteristics of angiography-defined serial coronary lesions using fractional flow reserve (FFR)-derived motorised pullback tracings, and to describe the pullback pressure gradients (PPG) index in these lesions.

Methods and results: This was a prospective, multicentre study with independent core laboratory analysis. Patients undergoing coronary angiography due to stable angina were enrolled. Serial lesions were defined angiographically as the presence of 2 or more narrowings with visual diameter stenosis >50% separated at least by 3 times the reference vessel diameter in the same coronary vessel. Continuous IV adenosine-FFR measurements were obtained using a motorised-pullback device at a speed of 1 mm/s. Pullback curves were assessed to determine the presence of focal step-ups (FFR >0.05 units over 20 mm). In addition, the PPG index was computed for all vessels. PPG index values close to 0 define functional diffuse disease whereas values close to 1 define focal disease. From a total of 159 vessels (117 patients), 25 vessels were adjudicated as presenting serial lesions (mean PPG index 0.48±0.17, range 0.26 - 0.87). Two focal pressure step-ups were observed in 40% of the cases (n=10; mean PPG index 0.59±0.17), whereas 8% of the vessels presented a progressive pressure losses (n=2; mean PPG index 0.27±0.01). In the remaining 52% of the cases, a single pressure step-up was recorded (n=13; mean PPG index 0.44±0.12; ANOVA p-value = 0.01). The PPG index independently predicted the presence of two focal pressure step ups.

Conclusions: Hyperaemic FFR curves in tandem stenoses revealed high prevance of functional diffuse CAD. Two pressure step-ups occurred in less than half of the vessels. High PPG index identified vessels with two focal pressure drops. FFR tracings and the PPG index provide a more objective CAD evaluation, which can lead to changes in the therapeutic approach.

STEMI - Tools, devices and techniques, Other Coronary interventions - Other

SNOPI score (Score of NO-reflow in Primary angloplasty) as a predictor of no-reflow phenomena after primary angioplasty

BRÁS Diogo [1], BRÁS Diogo [1], ROCHA Ana Rita [1], CARRINGTON Mafalda [1], PAIS João [1], PIÇARRA Bruno [1], NEVES David [1], FERNANDES Renato [1], AGUIAR Jose [1], PATRICIO Lino [1], ACS Portuguese National Registry on [2]

(1) Hospital do Espírito Santo de Évora, EPE, Evora, Portugal; (2) Sociedade Portuguesa De Cardiologia, Lisbon, Portugal

Aims: No-reflow phenomenon is defined as a complex condition associated with inadequate myocardial reperfusion without angiographic evidence of epicardial vessel obstruction, spasm or dissection. Due to its consequences, it would be ideal to predict its occurrence. We sought to study the SNOPI score as a predictor of NR, intra-hospital mortality (IHM), reinfarction, complications and rehospitalisation/1-year mortality, in patients that underwent primary angioplasty.

Methods and results: This retrospective study gathers data from a national multicentre registry. We have included patients with ST-segment elevation myocardial infarction (STEMI) that underwent PPCI. NR was defined by a TIMI flow <3 after PCI. Regarding the creation of the score, in first place we tested 13 plausible variables using univariate analysis. Then we selected the statistically significant ones and performed a multivariate analysis reporting odds ratio (OR). The SNOPI score is defined as follows: Left ventricle ejection fraction (LVEF) <40%: 2 points (p); Killip class ≥2: 3p; Age ≥65 years: 2p; Occluded infarct-related artery (IRA): 3p; Multivessel disease: 1p. We tested the predicting quality of SNOPI score on 4 outcomes: No-reflow, IHM, reinfarction, complications and rehospitalisation/1-year mortality. The outcome "complications" is the combined endpoint of heart failure, sustained ventricular tachycardia, mechanical complication or cardiac arrest, during hospitalisation. We assessed the prediction quality through ROC curve and optimal cut-off point. We also studied the 1-year mortality and rehospitalisation between patients with SNOPI score higher and lower than the optimal cut-off point, using Kaplan-Meier and Log-rank analysis. The sample is composed of 5764 patients, with mean age is 63±14, which 77% are males. Eighty-six patients had NR. Regarding the patients with NR, their age was 69±15 years, 59% had abnormal LVEF, 39% presented with Killip class ≥2, 90% had occluded IRA and 62% had multivessel disease. The mean SNOPI score was 4.3±2.4 points for patients without NR and 6.4±2.9 points for patients with NR. The SNOPI score c-statistic for the outcome no-reflow performed fairly: 0.709 (0.644-0.774), as for complications: 0.758 (0.740-0.775). It performed very well for the outcome IHM: 0.861 (0.829-0.892). It performed poorly for reinfarction: 0.622 (0.538-0.707). The optimal cut-off point for no-reflow was 6 (sensibility 60%, specificity 70%, negative predictive value (NPV) 99%, positive predicting value (PPV) 3%); and for intra-hospital mortality was 7 (sensibility 72%, specificity 87%, NPV 99%, PPV 15%). The survival analysis showed a statistically significant log-rank analysis for the composed endpoint of rehospitalisation/1-year mortality for patients with SNOPI <6 versus ≥6 (10% vs 21%).

Conclusions: We conclude that SNOPI score is a very good test to acknowledge which patients will not suffer NR, as it is shown by its very high NPV (99%). It is a good test to predict intra-hospital mortality in patients that undergo PPCI. The SNOPI score also predicts rehospitalisation/1-year mortality, as it is shown by the survival analysis of the populations with scores higher and lower than the optimal cut-off point. This score, which encompasses clinical, echocardiographic and angiographic variables, may contribute to estimate the development of no-reflow in the pre-PCI period, risk stratification, complications and cardiovascular outcomes.

Stents and scaffolds - Tools, devices and techniques

Safety and performance of the resorbable magnesium scaffold, Magmaris in a real-world setting – NSTEMI, diabetes and B2/C lesion subgroup analyses of the first cohort subjects at 12-month follow-up of the BIOSOLVE-IV registry

WLODARCZAK Adrian [1], WLODARCZAK Adrian [1], STARMER Gregory [2], TORZEWSKI Jan [3], BENNETT Johan [4], WIEMER Marcus [5], NGUYEN Michael [6], SABATE Manel [7], VAN DER SCHAAF Rene J. [8], MONTORSI Piero [9], EECKHOUT Eric [10]

(1) Miedziowe Centrum Zdrowia SA, Lubin, Poland; (2) Cairns Hospital, Cairns, Australia; (3) Cardiovascular Center Oberallgaeu-Kempten, Oberallgaeu, Germany; (4) University Hospitals Leuven, Leuven, Belgium; (5) Johannes Wesling Hospital, Minden, Germany; (6) Fiona Stanley Hospital, Perth, Australia; (7) Hospital Clinic de Barcelona, Barcelona, Spain; (8) OLVG, Amsterdam, the Netherlands; (9) Centro Cardiologico Monzino, Milan, Italy; (10) Centre Hospitalier Universitaire Voudois, Lausanne, Switzerland

Aims: The aim of this registry is to investigate the clinical performance and long-term safety of the resorbable magnesium scaffold (Magmaris) in a real-world setting. Up to 2,054 subjects in up to 120 clinical sites in Europe, Asia and Asia-Pacific countries will be enrolled in this registry. This registry has two cohorts. The first cohort includes 1,075 subjects. These *post hoc* analyses include the subgroups of subjects with NSTEMI, diabetes and B2/C lesion of the first cohort. The 12-month target lesion failure (TLF) and its individual components were analysed in these subgroups analyses.

Methods and results: In this prospective, multicentre, controlled, global registry, the first 1,075 subjects with 1,121 *de novo* coronary artery lesions were enrolled between September 2016 and September 2018. Primary endpoint of the registry is TLF assessed at 12-month follow-up. Clinical follow-up visits are scheduled at 6, 12, 24, 36, 48 and 60 months. Out of 1075 subjects enrolled in the first cohort, 206 subjects presented with NSTEMI, 228 subjects had diabetes and 164 subjects possessed B2/C lesion types. At 12 month follow-up, 97.1% (200/206), 97.4% (222/228) and 92.7% (152/164) follow-up compliance was achieved in the NSTEMI, diabetes and B2/C lesion subgroups, respectively. NSTEMI subgroup: NSTEMI subgroup of the first cohort of BIOSOLVE-IV undergoing 12-month clinical follow-up had a TLF rate (6.1%) comparable to the remaining subjects of the first cohort (4.0%; p=0.19). Analysis of clinically driven target lesion revascularisation (CD-TLR) resulted in a rate of 5.6% versus 3.6% (p=0.20), in the NSTEMI subgroup versus the rest of the first cohort. Cardiac death was 0.0% in the NSTEMI subgroup and 0.2% in the rest of the first cohort (p=>0.999). Diabetes subgroup: At 12-months, TLF occurred in 4.7% of subjects in the diabetes subgroup versus 4.3% in the non-diabetic subjects (p=0.86). CD-TLR was 3.8% for the diabetes subgroup versus 4.0% for non-diabetic subgroup (p=0.79). The rate of cardiac death was similar at 12-month follow-up (0.4% versus 0.1%; p=0.32). B2/C lesion subgroup: 12-month TLF rate was 5.6% in the B2/C lesion subgroup and 4.1% in the remaining subjects (p=0.33). 5.6% of the B2/C lesion subgroup and 3.7% of the remaining subjects had CD-TLR (p=0.20). Cardiac death was 0.6% in the B2/C lesion subgroup and 0.1% in the rest of the first cohort (p=0.17).

Conclusions: The Magmaris scaffold showed an excellent safety profile up to 12 months in high risk subjects with NSTEMI, diabetes and B2/C lesions with results comparable to the rest of the first cohort subjects.

Other Coronary interventions - Other

Treatment of radial artery occlusion with low-molecular-weight heparin after transradial coronary catheterisation procedures: preliminary results

DIDAGELOS Matthaios [(1)], DIDAGELOS Matthaios [(1)], PAGIANTZA Areti [(1)], ZARRA Konstantina [(1)], ANGELOPOULOS Vasileios [(1)], KOUPARANIS Antonios [(1)], PETEINIDOU Emmanouela [(1)], KARVOUNIS Haralambos [(1)], ZIAKAS Antonios [(1)]

(1) AHEPA Hospital, Thessaloniki, Greece

Aims: There is no evidence-based treatment for radial artery occlusion (RAO) after transradial coronary catheterisation procedures. The aim of this study is to evaluate the efficacy and safety of low-molecular-weight heparin (LMWH) in the treatment of RAO.

Methods and results: We randomly assigned patients with RAO, after transradial coronary angiography and/or angioplasty, to a management strategy of either receiving LMWH for up to 4 weeks or nothing. RAO was diagnosed by radial artery ultrasound (2D, Doppler, colour) at 24 hours after haemostasis and re-evaluated at 1-, 2-, and 4-week intervals. The primary efficacy endpoint was radial artery patency between the two groups at 4 weeks. The secondary safety endpoint was bleeding between the two groups at 4 weeks. A total of 414 patients have been screened until now and 33 RAOs (female: 27.3%, male 72.7%, mean age: 66±13 years) have been diagnosed (RAO incidence: 7.9%). The primary endpoint occurred in 5 (1 female, 4 male) of the 16 patients (31.3%) in the LMWH group and in 2 (1 female, 1 male) of the 17 patients (11.8%) in the control group (p=0.134). The cumulative radial artery patency rates at 1-, 2- and 4-weeks were 12.5% vs 0%, 18.8% vs 0% and 31.3% vs 11.8% for the LMWH vs the control group. There were no bleeding or upper arm neurological adverse events.

Conclusions: These preliminary results show no advantage of LMWH in the treatment of RAO after transradial coronary procedures. However, LMWH may recanalise the occluded radial artery earlier. No safety issues appeared. The study is ongoing and the final results are anticipated.

Stable CAD - Invasive imaging and functional assessment

Validation of coronary angiographic FFR using angio FFR

OMORI Hiroyuki [1], OMORI Hiroyuki [1], YOSHIAKI Kawase [1], TORU Tanigaki [1], TETSUO Hirata [1], JUN Kikuchi [1], HIDEAKI Ota [1], MUNENORI Okubo [1], HIROKI Kamiya [1], MASAYASU Nakagawa [1], HITOSHI Matsuo [1]

(1) GIfu Heart Center, Gifu, Japan

Aims: Angiographic fractional flow reserve (angioFFR; Siemens Healthcare GmbH, Forchheim, Germany) is a novel non-invasive prototype enabling coronary artery disease (CAD) to determine physiological significance by using invasive coronary angiography. We validated agreement between angioFFR and invasive FFR to identify haemodynamically relevant CAD.

Methods and results: The present study was a prospective registry. We analysed 101 vessels in 87 patients with suspected CAD. We excluded ostial lesions, left main trunk lesions, in-stent restenosis and severe valve diseases. The primary endpoint was the diagnostic accuracy of angioFFR assessed using area under the curve (AUC) of receiver operating characteristics. The secondary endpoints included the accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of angioFFR ≤0.80 using invasive FFR ≤0.80 as the reference standard. The AUC of angioFFR was 0.89 (95% confidence intervals, 0.81–0.94). Accuracy, sensitivity, specificity, PPV, and NPV were 90.1, 76.9, 98.4, 96.8 and 87.1, respectively. Intra- and inter-rater agreements of angioFFR showed strong agreements; Kappa values were 0.83 and 0.75 (n=30), respectively.

Conclusions: The angioFFR showed a high concordance with invasive FFR for diagnosis of functional significance of CAD.

Stents and scaffolds - Tools, devices and techniques

Physician-directed complete revascularisation optimises patient outcomes in multivessel coronary artery disease: data from the global e-ULTIMASTER registry

HILDICK-SMITH David [(1)], HILDICK-SMITH David [(1)]

(1) Brighton & Sussex University Hospitals Nhs Trust, Brighton, United Kingdom

Aims: The value of complete revascularisation (CR) over incomplete revascularisation (IR) in patients with multivessel coronary artery disease (MVD) is not well established.

Methods and results: The e-Ultimaster Registry was a prospective, worldwide, multicentre study which enrolled patients with coronary artery disease who were treated with the thin-strut sirolimus-eluting Ultimaster stent (Ultimaster) with an abluminal bioresorbable polymer. e-Ultimaster recruited 34,538 patients aged 64.3±11.2 years; 76% of whom were male. Patient presentation included STEMI (20%), NSTEMI (23%) and stable angina (36%). 11,774 patients (34%) had MVD. Of these, 4,805 (41%) underwent complete revascularisation and 6,969 (59%) incomplete revascularisation. After propensity weighted analysis, 93% of CR patients were angina-free at 1 year compared to 89% of IR patients ($p<0.001$). All-cause mortality (2.2% vs 3.1%; $p=0.003$), TLF (3.3% vs 4.0%; $p=0.04$) and the patient-oriented composite endpoint of all-cause mortality, MI or revascularisation (6.0% vs 8.0%; $p<0.001$) were all lower in CR patients.

Conclusions: Our findings suggest that physician-directed use of complete revascularisation results in good clinical outcomes in MVD patients using contemporary drug-eluting stents.

STEMI - Tools, devices and techniques

Clinical outcomes of high-risk ACS patients treated with bioresorbable polymer sirolimus-eluting stent

LAANMETS Peep [1], LAANMETS Peep [1]

(1) North Estonia Medical Centre Foundation, Tallinn, ESTONIA

Aims: PCI in acute coronary syndrome (ACS) is in general associated with a high risk of adverse events and thrombosis. The aim of this study is to investigate the clinical outcomes of patients with high risk ACS (ST-segment evaluation and non-ST segment elevation myocardial infarction, STEMI and NSTEMI) who underwent PCI and were treated with bioresorbable polymer sirolimus-eluting stent.

Methods and results: The current analysis is using data from a large all-comer, prospective, worldwide, multicentre registry (e-Ultimaster), which enrolled 36,916 patients undergoing PCI with thin-strut (80 μm) bioresorbable polymer Ultimaster sirolimus-eluting stents. So far, 34,538 patients reaching one-year follow-up or who have died were included in this analysis. The primary endpoint of target lesion failure (TLF) at one year was defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent clinical event committee adjudicated all endpoint-related events. At the time of index PCI, there were in total 14,874 (43%) patients presenting with high risk (hr) ACS (6,863 STEMI and 8,011 NSTEMI). The mean age and body mass index of hr-ACS patients were similar as the rest of the patients. There are fewer patients with diabetes (24.2% vs 31.1%), hypertension (58.2% vs 70.6%), hyperlipidaemia (49.4% vs 61.1%) in hr-ACS group ($p<0.001$ for all) compared with the rest of the patients, while there are significantly more current smokers (31.8% vs 16.6%, $p<0.001$). Lesion characteristics were: complex (56.0% B2/C vs 51.4%, $p<0.01$); calcified (15.8% vs 20.2%, $p<0.01$); bifurcated (10.2% vs 13.8%, $p<0.01$) in hr-ACS vs the rest of the population, respectively. Thrombus aspiration was performed in 9.4% of the lesions in hr-ACS patients, and post-dilatation was performed in in 39.8% of the lesions in hr-ACS patients. The average number of successfully implanted Ultimaster stents was 1.43 in hr-ACS group and 1.46 in the rest of the population ($p=0.99$), while the total implanted stent length was also not different (31.5 mm vs 32.9 mm, $p=0.99$) between the two groups. At 1 year after index PCI, dual antiplatelet therapy was continued in 68.0% of patients with hr-ACS. As expected the rate of cardiac death (1.67% vs 0.92%, $p<0.001$) as well as stent thrombosis (0.85% vs 0.44%, $p<0.001$) in hr-ACS group were higher than in the rest of the population, while the occurrence of 1-year target vessel MI (0.91% vs 0.83%, $p=0.45$) and clinically driven target vessel revascularisation (2.1% vs 2.2%, $p=0.71$) were similar. The rates of TLF (3.3% vs 2.9%, $p=0.028$) and target vessel failure (3.7% vs 3.3%, $p=0.054$) at one year were also higher in hr-ACS group.

Conclusions: The one-year results of 14,874 STEMI or NSTEMI patients treated with the bioresorbable polymer sirolimus-eluting stent showed higher risk of cardiac death and stent thrombosis in this hr-ACS group, however numerically the clinical outcomes in both, hr-ACS and rest of the patients group, were very good.

Stable CAD - Invasive imaging and functional assessment, Stents and scaffolds - Tools, devices and techniques

BRS and optimised implantation technique: single-centre, long-term outcome

ALBANI Stefano [1], ALBANI Stefano [1], GIANNINI Francesco [2], KHOKHAR Arif A [2], LARICCHIA Alessandra [2], GALLO Francesco [2], PONTICELLI Francesco [2], MANGIERI Antonio [2], MITOMO Satoru [3], LATIB Azeem [4], COLOMBO Antonio [2]

(1) University of Trieste, Trieste, Italy; (2) Maria Cecilia Hospital, Province of Ravenna, Italy; (3) New Tokyo Hospital, Chiba, Japan; (4) Montefiore Medical Center Moses Division, NY, USA

Aims: Recent studies suggest favourable outcomes following bioresorbable vascular scaffold (BVS) implantation if an optimised implantation technique (OIT) was utilised. However, longer-term data are lacking, and our aim was to study the long-term clinical outcomes following BVS implantation with an OIT in an all-comers cohort with stable coronary artery disease (CAD).

Methods and results: We prospectively enrolled all patients undergoing BVS implantation at our single centre from 2012 to 2015. An OIT was utilised at the time of implantation with IVUS when possible. Long-term clinical follow-up was obtained and the primary and secondary endpoints were target lesion revascularisation (TLR) and scaffold thrombosis (ScT). 156 patients (median age 66±10 years, 90% male) underwent implantation of 347 BVS in 435 lesions. 120 (77%) patients had multivessel disease, 66.2% were B2/C lesions, 8.3% had significant calcification and 8% were bifurcation lesions. IVUS or OCT guidance was utilised in 303 (87.3%) implants and detected stent under-expansion/malapposition in 53 (28.7%) of the implants requiring further post-dilatation in 36 (67.9%) of these cases. At median follow-up of 60 months (IQR 45-73 months) TLR and ScT occurred respectively in 16 (10.3%) and 1 (0.6%) patients. At univariable analysis an IVUS guided procedure was a protective factor against TLR (OR 0.24, IC 95% 0.09-0.62, p=0.003).

Conclusions: Low rates of TLR and ScT were observed in patients undergoing BVS implantation on long-term follow-up. This highlights the potential benefit of utilising an IVUS-guided optimised implantation technique. This benefit was observed across the spectrum of complex stable CAD lesions encountered in everyday practice.

Other Coronary interventions - Calcified lesions

Rotational atherectomy complicated by coronary perforation is associated with poor outcomes: analysis of 10,980 cases from the British Cardiovascular Intervention Society database

PROTTY Majd [2], PROTTY Majd [2], HUSSAIN Hussain [1], GALLAGHER Sean [1], AL-RAISI Sara [1], ALDALATI Omar [1], FAROOQ Vasim [1], SHARP Andrew [1], ANDERSON Richard [1], KINNAIRD Tim [1]

(1) University Hospital of Wales, Cardiff, United Kingdom; (2) Cardiff University, Cardiff, United Kingdom

Aims: Rotational atherectomy (RA) during PCI is linked to a higher likelihood coronary perforations (CP). However, the evidence base on incidence, predictors and outcomes of this complication in RA-PCI remains limited. The aim of this study was to examine the incidence, predictors and outcomes of CP complicating RA-PCI.

Methods and results: Using the British Cardiac Intervention Society database, data were analysed on all RA-PCI procedures in UK 2007-2014. Descriptive statistics and multivariate logistic regressions were used to examine baseline, procedural and outcome associations. During 10,980 RA-PCI procedures, 167 CPs were recorded (1.52%) with a stable annual incidence. Baseline and procedural covariates associated with higher rates of RA perforation were number of stents used, female gender, smoking, and left-main stenosis. CP was significantly associated with shock, DC cardioversion, heart block, transfusion, emergency surgery, periprocedural MI, in-hospital major bleed, acute kidney injury, dissection, side branch loss and in-hospital death. CP was also associated with higher rates of in-hospital MACCE (OR 12.22, 95% CI: 7.67-19.47), 30-day mortality (OR 10.02, 95% CI: 5.87-17.09) and 12-month mortality (OR 3.90, 95% CI: 2.53-6.02).

Conclusions: CP is more frequent in RA-PCI than in all-comer PCI and is associated with a significant burden of morbidity and mortality. There are a limited number of baseline and procedural co-variates associated with CP in RA-PCI, making it difficult to predict.

Left main and multivessel disease - Tools, devices and techniques

The impact of coronary perforation in PCI involving the left main stem coronary artery in the United Kingdom 2007-2014: insights from the British Cardiovascular Intervention Society database

HUSSAIN Hussain [1], HUSSAIN Hussain [1], PROTTY Majd [2], GALLAGHER Sean [1], AL-RAISI Sara [1], ALDALATI Omar [1], FAROOQ Vasim [1], SHARP Andrew [1], ANDERSON Richard [1], KINNAIRD Tim [1]

(1) University Hospital of Wales, Cardiff, United Kingdom; (2) Cardiff University, Cardiff, United Kingdom

Aims: Percutaneous intervention (PCI) is increasingly utilised for treatment of coronary disease involving the unprotected left main stem (ULMS). However, no studies to date have examined the outcomes of such interventions when complicated by coronary perforation (CP). The aim of our study is to examine the predictors and outcomes of CP complicating ULMS PCI.

Methods and results: Using the British Cardiovascular Intervention society (BCIS) database, data were analysed on all ULMS-PCI procedures complicated by CP in England and Wales between 2007 and 2014. Multivariate logistic regressions were used to identify predictors of ULMS CP and to evaluate the association between this complication and outcomes. During 10,373 ULMS-PCI procedures, CP occurred more frequently than in non-ULMS-PCI (0.9% vs 0.4%, p<0.001) with a stable annual incidence. Covariates associated with CP included number of stents used, female gender, use of rotational atherectomy and chronic total occlusion (CTO) intervention. Adjusted odds of adverse outcomes for ULMS-PCI complicated by CP were higher for periprocedural complications including cardiogenic shock, tamponade, side-branch loss, DC cardioversion, in-hospital major bleeding, transfusion requirement, and periprocedural myocardial infarction. There were also significantly increased odds for in-hospital major adverse cardiac events (MACCE, OR: 8.779, 95% CI: 4.798-16.04) and 30-day mortality (OR 5.181, 95% CI: 2.681-10.016).

Conclusions: CP is an infrequent event during ULMS-PCI and is predicted by female gender, rotational atherectomy, CTO interventions or number of stents used. CP was associated with significantly higher odds of mortality and morbidity, but at rates similar to previously published all-comer PCI complicated by CP.

Stable CAD - Invasive imaging and functional assessment

Impact of lesion location on the diagnostic performance of resting full-cycle ratio as non-hyperaemic physiological assessment

TAKASHIMA Hiroaki [(1)], TAKASHIMA Hiroaki [(1)], OHASHI Hirofumi [(1)], ANDO Hirohiko [(1)], NAKANO Yusuke [(1)], SAKURAI Shinichiro [(1)], SUZUKI Akihiro [(1)], FUJIMOTO Masanobu [(1)], WASEDA Katsuhisa [(1)], AMANO Tetsuya [(1)]

(1) Aichi Medical University, Ngakute, Japan

Aims: Recently, wire-based resting indices have been recognised as the gold standard for evaluating physiological lesion assessment. The resting full-cycle ratio (RFR) is a unique resting index which is calculated as the point of absolutely lowest distal pressure to aortic pressure during entire cardiac cycle. It is unclear whether the diagnostic accuracy of RFR for detecting functional coronary artery stenosis is similar in each coronary artery. The aim of this study is to compare the diagnostic performance of RFR based on lesion location.

Methods and results: This study was a prospectively enrolled observational study. A total of 156 consecutive patients with 220 intermediate lesions were enrolled in this study. The RFR was measured after adequately waiting for stable condition, while FFR was measured after intravenous administration of ATP (180mcg/kg/min). Lesions with FFR ≤0.80 were considered functionally significant coronary artery stenosis. In all lesions, reference diameter, diameter stenosis, lesion length, RFR, and FFR were 3.0±0.7 mm, 45±13%, 13.0±8.8 mm, 0.90±0.09, and 0.82±0.10, respectively. Functional significance was observed in 88 lesions (40%) of all lesions. RFR showed a significant correlation with FFR in overall lesions ($r = 0.774$, $p<0.001$). The ROC curve analysis of RFR showed good accuracy for predicting functional significance (AUC 0.87, diagnostic accuracy 81%). Regarding each target vessel, there was similar and significant positive correlation between RFR and FFR (LAD; $r = 0.733$, $p<0.001$, LCX; $r = 0.771$, $p<0.001$, RCA; $r = 0.769$, $p<0.001$, respectively). The prevalence of discordance between RFR and FFR was significantly different among 3 vessels (LAD 26%, LCX 12%, RCA 13%, respectively, $p=0.04$ for among the 3 groups). Regarding the comparison of ROC curves according to lesion location, AUC was significantly lower in LAD than in LCX and RCA (LAD 0.780, LCX 0.947, RCA 0.926, $p<0.01$ for LAD compared to LCX, $p<0.01$ for LAD compared to RCA, respectively). Furthermore, the diagnostic accuracy was significantly different according to lesion location (LAD 74%, LCX 88%, RCA 87%, respectively, $p=0.04$ for among 3 vessels).

Conclusions: RFR demonstrated better diagnostic accuracy for evaluating functional lesion severity. The diagnostic performance of RFR was different based on lesion location. RFR is a unique and useful resting index, and it may detect functionally significant coronary stenoses that cannot be detected with other resting indices in daily practice.

Stents and scaffolds - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

Outcomes of the DESolve novolimus-eluting BRS in real-world clinical practice

ÇAKAL Beytullah [(1)], ÇAKAL Beytullah [(1)], BOZTOSUN Bilal [(1)], CAKAL Sinem [(1)], KARACA Oğuz [(1)], OMAYGENC Onur [(1)], GUNES Murat [(1)], KIZILIRMAK Filiz [(1)], OZCAN Ozgur Ulas [(1)], YILDIRIM Aydin [(1)], BARUTÇU Irfan [(1)]

(1) Medipol Mega Üniversite Hastanesi, Istanbul, Turkey

Aims: Clinical evidence for the most intensively investigated member of BRS group, Absorb bioresorbable vascular scaffold (BVS) were promising; nevertheless several meta-analyses encompassing the data beyond 1 year reported higher event rates of myocardial infarction, target lesion revascularisation and scaffold thrombosis. So far, there are limited real-life data searching mid- and long-term clinical results of PCI with the DESolve which is another (PLLA)-based polymer scaffold. In the present study, we analysed mid-term clinical outcomes of DESolve BRSs treated at a single centre.

Methods and results: One hundred and forty four patients (mean age 57.5±9.7 years, 78.5% male) treated with 206 scaffolds between October 2015 and December 2017 were enrolled. A device-oriented composite endpoint (DOCE) comprising cardiac death, target vessel myocardial infarction (TV-MI), clinically driven target lesion revascularisation (TLR) and the rate of scaffold thrombosis were investigated. Mean age was 57.5±9.7. The majority of the patients were male (78.5%), hypertensive (65.3 %) and hyperlipidemic (66.7%). Mean left ventricular ejection fraction (LVEF) of the patients was 56.5±7.1%. Seven patients had history of heart failure, 25 % had prior myocardial infarction, 3.5 % had prior CABG surgery. Clinical indication for PCI was stable angina in the majority of the patients (119 patients, 82.6%). Acetylsalicylic acid combined with new $P2Y_{12}$ inhibitors (prasugrel, ticagrelor) were given to 100 patients (66 %) while the rest received ASA plus clopidogrel. Average lesion length as assessed by QCA was 23.5±9.6 mm. Minimum lumen diameter was 0.88±0.44 mm and reference vessel diameter was 3.15±0.45 mm. Mean diameter stenosis was 72.7±12.9%. Mean scaffold size was 3.10±0.44 mm and length was 25.7±4.35 mm. The number of type A, type B1, type B2, and type C lesions were 59 (28.6 %), 88 (42.7%), 24 (11.7%), and 35 (17.0 %), respectively. Device success was 97.6% and procedural success was 99.3%. Four devices failed to cross the lesion due to severe calcification and/or tortuosity, however residual >30% stenosis despite deployment and post-dilatation of the device at the lesion site was observed in one patient. The clinical follow-up was available in 144 of 148 (97.3%) patients. During a mean follow-up of 33±9 months, 99% of patients achieved 1-year follow-up, 90% of patients achieved 2-year follow-up. DOCE occured in 9 patients (6.2%) of which cardiac death occured in 2 patients (1.4%), and clinically-driven TLR in 7 patients (4.9%), TV-MI in one patient and TVR in nine patients. None of our patients experienced definite or probable scaffold thrombosis.

Conclusions: DESolve scaffolds have favourable mid-term safety and success rates in treatment for coronary lesions. Possible explanation for our results was the strict interventional approach for lesion preparation and post-dilation, both performed routinely and more frequent use of off-label newer $P2Y_{12}$ inhibitors. Also the unique structural properties of the DESolve scaffold, such as quicker biodegradation and resorption, self-correction and greater elasticity, might have contributed to lower DOCEs reported in our study. Despite, these promising mid-term outcomes, long-term randomised trials will be necessary to investigate benefits of DESolve over DES and other BRS.

STEMI - Tools, devices and techniques

A simple score to select patients for manual thrombectomy in emergent PCI: the DDTA score

CORDERO Alberto [1], CORDERO Alberto [1,3], FREITES Alfonso [1], ESCRIBANO David [1], ZUAZOLA Pilar [1], FLORES Emilio [1], BADIMON Lina [2,3]

(1) Hospital Universitario San Juan de Alicante, Sant Joan d'Alacant, Spain; (2) Institut Català de Ciències Cardiovasculars (ICCC), Barcelona, Spain; (3) Centro de Investigación Biomédica en Red de Enfermedades Cardiovasculares, Madrid, Spain

Aims: We analysed the use of manual thrombectomy (MT) in patients referred for primary percutaneous angioplasty (PPA) with the objective of identifying variables associated to success with this technique and designing a score that could identify patients that benefit most from this procedure.

Methods and results: Observational study of all consecutive patients admitted for emergent PPA in a single centre. MT was considered successful when TIMI-flow 3 was achieved after using the device. The score was designed according to the results of a logistic multivariate analysis. The primary endpoint for the score and MT assessment was TIMI 3 flow after MT and secondary endpoints were in-hospital mortality or major cardiovascular event (MACE) which included death, unplanned revascularisation, stroke or major bleeding. We included 618 patients, 65.1% treated with MT. No significant differences in clinical features or time delays were observed between patients treated with vs without MT but MT-treated patients more often received dual antiplatelet treatment (DAPT) before PPA. Final TIMI-flow 3 was achieved in most patients and more frequently in MT-treated patients (94.8% vs 86.6%; p<0.01). Successful MT rate was 81.3% and it was higher in patients pre-treated with DAPT (84.1% vs 64.3%; p<0.01). Time delay to first medical contact was not related to final TIMI 3 but it was significantly and negatively related to successful MT. According to the multivariate analysis we designed the DDTA score: DATP pre-treatment (yes=2); delay to PPA: <2h =3; or 2-4h =2; TIMI flow improvement after wiring the lesion: yes=2; Age <55: yes=3). The model was well calibrated (p=0.63) with a significant diagnostic accuracy (AUC 0.73 95% CI: 0.65-0.80; p<0.01). Individual score ranged from 0 to 10 and patients with DDTA score ≥4 had higher incidence of TIMI 3 after MT (89.6% vs 61.7; p<0.01) and final TIMI 3 flow (94.2% vs 90.2%; p=0.06); patients with DDTA score ≥4 also had lower incidence of mortality (6.0% vs 13.1%; p=0.004), MACE (22.8% vs 41.2%; p<0.001) and no-reflow (3.8% vs 9.6%; p=0.03). Four strokes were codified during hospital stay which represented a rate of 0.65% (95% CI: 0.45-0.83%); 2 cases occurred in MT-treated patients and 2 in non-MT-treated patients (0.9% vs 0.5%; p=0.58). None of the strokes occurred during the primary PCI or the following 6 hours.

Conclusions: The DDTA score (DAPT pre-treatment, time delays, TIMI flow improvement after wiring the lesion and age) identifies patients that benefit most from MT. Patients with a DDTA score ≥4 obtained the most benefit from MT and have better in-hospital outcomes.

STEMI - Adjunctive pharmacotherapy

Outcome of transferring STEMI patients from non-PCI to PCI-capable hospital

AL MATROOSHI Nadya [(1)], EL YAZORI Yara [(1)], AL NAQBI Aisha [(1)], AYAD Adel [(2)], KHAN Zafar [(1)], ALZUBAIDI Abdul Majeed [(1)]

(1) Sheikh Shakhbout Medical City, Abu Dhabi, United Arab Emirates; (2) Al Rahba Hospital, Abu Dhabi, United Arab Emirates

Aims: ST-segment elevation myocardial infarction (STEMI) patients frequently present to non-PCI hospitals.The number of PCI facilities is increasing in the UAE, but they are nevertheless still lacking in relation to the areas needing to be covered, which makes transferring STEMI patients to PCI-capable hospitals a part of a well-established network transfer system.Transfer systems for STEMI patients are well-established worldwide, however they are relatively still primitive in the Gulf region. In this study, we aim to evaluate the outcomes of transferring STEMI patients from non-PCI to PCI-capable hospitals in the UAE.

Methods and results: Between February 2014 and November 2019, 238 patients with the diagnosis of STEMI underwent inter-hospital transfer from non-PCI hospital to PCI-capable hospital for primary PCI. Data were collected from a non-PCI hospital registry, and more detailed information was obtained from the patient's medical charts. The mean age was found to be 58, with expected male predominance representing 93.7 %. Transfer distance from the studied non-PCI-capable hospital to PCI-capable hospital is 34 km. Mean door in-to door-out was 50 minutes. Median transfer time was found to be 60 minutes. The first door-to-balloon time of ≤120 minutes was established in 71%, in 29% door-to-balloon time was ≤90 minutes. Documented complications are cardiac shock 3.4%, 5.5% had arrhythmias, and only one patient had reinfarction. Mortality was 3.4%. 3.8% were false STEMI who did not require a transfer.

Conclusions: More than two-thirds of patients transferred have reached the door-to-balloon time of ≤120 minutes. The busy facility, complicated patients and those reluctant to transfer mainly compose the remaining one-third exceeding120 minutes time period of the door-to-balloon.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Multicentric retrospective registry on coronary lithotripsy: the French shock initiative

HONTON Benjamin [1], HONTON Benjamin [1], MONSEGU Jacques [2], LIPIECKI Janusz [3], LEROY Fabrice [4], COMMEAU Philippe [5], MOTREFF Pascal [6], CAYLA Guillaume [7], SOUTEYRAND Geraud [6], LEFEVRE Thierry [8], SAUGUET Antoine [1], LAPERCHE Clemence [1], FAURIE Benjamin [2], FARAH Bruno [1], FAJADET Jean [1]

(1) Clinic Pasteur, Toulouse, France; (2) Groupe Hospit. Mutualiste De Grenoble, Grenoble, France; (3) Centre Republique, Clermont Ferrand, France; (4) Hopital Prive La Louviere, Lille, France; (5) Polyclinique Les Fleurs, Ollioules, France; (6) CHU G. Montpied, Clermont Ferrand, France; (7) CHU Nimes Caremeau, Nimes, France; (8) Cardiovascular Institute Paris Sud (Icps), Massy, France

Aims: Coronary calcifications are associated with a worse procedural and clinical prognosis. Incidence and prevalence of coronary calcifications will be increased regarding their epidemiological factors. Intravascular lithotripsy (IVL) is a promising new technology for lesion preparation in disrupting coronary calcifications but with a level of evidence which remains low. We aim to evaluate outcomes of patients who underwent coronary intervention requiring intravascular lithotripsy with the Shockwave lithotripsy system in all-comer patients.

Methods and results: We conducted a retrospective multicentre study in 7 high-volume French centres since IVL CE market approval. Follow-up was performed for all patients enrolled at 31 December 2019 by phone call or consultation. 99 patients were included with 107 procedures. Mean age was 73.5. Distribution of lesion was: left main lesion in 9.3%, LAD in 37,8%, CX in 7% and RCA in 32.7%. In-stent restenosis was treated in 17 patients (1.,2%). Mean lesion length was 19.4 mm and most were complex lesions (type B2-C lesions: 67.2%). Interestingly, 42% of lesions were eccentric. Device success was achieved in 97.2% of patients and procedural success in 90.7%. In-hospital MACE was low (9.1%) with one acute stent thrombosis. One-month, 6-month and 12-month follow-up MACE were respectively 9.9%, 6.7% and 5%. We noted one cardiac death at 30 days with one sub-acute stent thrombosis.

Conclusions: To our knowledge, we report the largest multicentric cohort of all-comer patients who underwent coronary intravascular lithotripsy. IVL treatment for in-stent restenosis was achieved in 15% of patients with all procedure success in this subgroup. Moreover, more than 40% of patient presented eccentric lesions suggesting efficacy of IVL in this pattern of lesions, usually excluded from CAD studies. This study confirmed a good safety with comforting in-hospital, 1-month, 6-month and 12-month outcomes in this complex patient group.

NSTEMI - Vascular access and bleeding

Distal radial artery access cardiac catheterisation; single-centre initial experience in the United Kingdom

UPADHYAYA Subramanya GN [(1)], ELHOSIENY Adel [(1)]

(1) Birmingham City Hospital, Birmingham, United Kingdom

Aims: We describe our initial real-world experience with distal transradial access (DRA) for invasive catheterisation at a large non-surgical teaching hospital in the United Kingdom.

Methods and results: All patients assigned to only one-operator program underwent diagnostic or percutaneous interventions (PCI) via DRA. Retrospective analysis of all DRA cases between February 2019 and June 2019 was performed. Case and procedure note data were obtained using electronic patient records at Birmingham City Hospital and the British Cardiac Interventional Society database. A total of 95 patients underwent cardiac catheterisation procedures via DRA in the study period. The majority of them had both diagnostic angiogram followed by PCI at the same time. The mean age of patients was 63 years, with 71% males. Eighty-eight percent of patients had hypercholesterolaemia, 81 % hypertension, 65 % diabetes mellitus, 7.4% previous bypass grafting, 27% with previous PCI via other access. The indications for procedure were acute coronary syndrome (n=37/95, 39%), stable angina (n=48/95, 50.5%), staged procedures (n=10/95, 10.5%). Diagnostic angiograms were only performed in n=43/95 (45.3%) whereas the PCI in n=52/95 (54.7%). The case mix of PCIs as follows: emergency PCI cases (n=11/52, 21.15%), complex coronary PCIs requiring bifurcation strategy, left main stem PCI, calcium modification and chronic total occlusion (CTO) PCI (n=12/52, 23%), single vessel PCI (n=26/52, 50%) and diagnostic interventions (n=13/52, 25%). The same site DRA was reused for second procedure in (n=6/95, 6.3%) cases. The laterality of the access site was predominantly right DRA (n=76/95, 80%) followed by left DRA (n=18/95, 18.9%) and bilateral DRA (1/95, 1.1%). All cases were completed successfully using DRA and there was no crossover of access in this cohort. There were zero observed or reported vascular or systemic complications. The majority of the patients gave positive feedback about the comfort level experienced during the procedure.

Conclusions: DRA is a safe and patient-friendly access for cardiac catheterisation. Utilisation of DRA gives more access route options to the operator. Complex PCIs can be performed using DRA with added patient comfort. Bilateral DRA is feasible and safe. DRA site can be reused safely for the second time which is novel and unique to our practice.

STEMI - Invasive imaging and functional assessment

Coronary flow reserve calculation by simple equations using intracoronary pressure measurements and 3D coronary reconstruction – validation by detailed computational fluid dynamic simulations

KOSZEGI Zsolt [1,2], KOSZEGI Zsolt [1,2]

(1) University of Debrecen, Dept. of Cardiology, Debrecen, Hungary; (2) András Jósa Teaching Hospital,, Nyíregyháza, Hungary

Aims: Measurements of fractional flow reserve (FFR) and/or coronary flow reserve (CFR) are widely used for haemodynamic characterisation of coronary lesions. The frequent combination of epicardial and microvascular disease may indicate a need for complex haemodynamic evaluation of coronary lesions. This study aims at validating the calculation of CFR based on a simple haemodynamic model to detailed CFD analysis by finite volume method, solving the Navier-Stokes equations.

Methods and results: 3D morphological data and pressure values in the hyperaemic and resting state were used for the calculations in the target vessel. 3D angiographic reconstructions were performed from two angiographic recordings using dedicated software. 9 patients with one intermediate stenosis measured by pressure wire were included in this study. Significant correlations between the CFR values calculated according to transient and steady flow simulations were found ($r=0.93$; $p<0.001$), and even stronger relationship between the determined CFR from simple equations and from the steady flow simulation was estabilised ($r=0.993$; $p<0.00001$). The Bland-Altman analysis did not show systematic skewing between the values in the investigated range.

Conclusions: A simple haemodynamic calculation of CFR, based on 3D-angiography and intracoronary pressure measurement was demostrated. This method can be suitable for clinical applications offering a more comprehensive evaluation than from the FFR measurement alone.

STEMI - Invasive imaging and functional assessment

The impact of hyperaemic contrast velocity assessment on image-based FFR calculation

KOSZEGI Zsolt [1,2]

(1) University of Debrecen, Dept. of Cardiology, Debrecen, Hungary; (2) András Jósa Teaching Hospital,, Nyíregyháza, Hungary

Aims: Image-based fractional flow reserve (FFR) calculations reported good agreement with FFR measured invasively. The purpose of this study was to perform a retrospective analysis of the cases of a previous study on less invasive FFR calculation (simple FFR: FFRsim) as a simple calculation from hyperaemic contrast flow data and three-dimensional coronary parameters.

Methods and results: We aimed to analyse the relations between the pressure wire-based FFR (FFRmeas) and fixed FFRsim: calculated from the fixed hyperaemic velocity, rest FFRsim: calculated using the non-hyperaemic frame count data to extrapolate the hyperaemic velocity (based on the database used in the FAVOR1 study) hyp FFRsim: the hyperaemic velocity derived from the frame count assessment during vasodilation.To calculate the frame count reserve (CFRFC) the resting frame count was divided by the hyperaemic frame count; this value was then used to determine the CFRFC/FFRmeas ratio as an indicator of microvascular function in the corresponding myocardial area of the measured coronary vessel. A total of 50 lesions with intermediate stenosis were investigated. Correlation between rest FFRsim (from the resting frame count extrapolated to the hyperaemic velocity) and FFRmeas was lower than the correlation between hyp FFRsim and FFRmeas (r = 0.761 vs 0.824). Based on ROC curve analysis for predicting abnormal FFR of ≤0.80, the AUC were significantly higher for the hyperaemia-based parameter than those calculated from resting frame counts. Significantly higher AUC were detected by the hyp FFRsim than by the rest FFRsim: 0.936 (95% CI: 0.828 to 0.985) vs 0.862 (CI: 0.734 to 0.943); p=0.011. Linear regression analyses between the FFRsim (either by fixed FFRsim or by rest FFRsim or by hyp FFRsim methods) and the FFRmeas showed higher intercepts and less steep slopes in the subgroups with presence of microvascular disease defined as CFRFC/FFRmeas <2 than in those without microvascular disease (CFRFC/FFRmeas >2); the difference reached significant level (p=0.019) when calculated by rest FFRsim.

Conclusions: Hyperaemic challenge either by adenosine or regadenoson is required for exact image-based FFR calculation especially in cases of suspicion of microvascular coronary disease.

STEMI - Tools, devices and techniques, NSTEMI - Adjunctive pharmacotherapy

Coronary angioplasty and stenting in ACS with very low contrast volume (inferior to 30ml) using Cordis diagnostic catheters and improved cardiovascular and renal outcomes

AROKIARAJ Mark Christopher [1],

(1) Pondicherry institute of medical sciences, Puducherry, India

Aims: To safely perform angioplasties in acute coronary syndromes with very low contrast volume using Cordis diagnostic catheters and thereby improve the cardiovascular and renal outcomes.

Methods and results: In 1,109 patients (1,437 lesions/ 1,605 stents) with acute coronary syndromes, angioplasty was performed with Cordis 6F diagnostic catheters. Primary angioplasty was performed in 345 cases. In 76% of cases, iodixanol was used. All contrast injections were given by hand. A regular follow-up of the patients was performed 30 days after the procedure. All the procedures were performed through the femoral route. Tirofiban was used in 99% cases with adjusted dosages based on the creatinine values. The mean contrast volume used per patient was 27 ml (±6 ml) including the angiogram prior to the angioplasty. Sixty-five patients had creatinine more than 2mg/dl before the angioplasty procedures. Left main angioplasty was performed in 30 patients. Forty-seven patients had cardiogenic shock at presentation. 76% of the cases had diabetes. IVUS was used in only two patients. A variety of coronary stents from various companies were used. Buddy wires were used in 34 cases. Ticagrelor was used in 38 cases, and in other cases clopidogrel was used. Mild reversible nephropathy (CIN) was observed in five patients. Three patients were already on dialysis, and dialysis was continued thereafter. Switch-over of angioplasty to the radial route was performed in four cases due to associated aortic/iliac obstructive lesions. Nineteen deaths in total were observed in this series; 12 of these patients had cardiogenic shock (4 late presenters), and two patients expired after discharge due to possible acute stent thrombosis. Groin haematoma was seen in three cases requiring one unit of blood transfusion. Proximal mild edge dissection in the deployed stent was seen in 2 cases. Wire breakages were not seen. Acute in-hospital stent thrombosis was seen in 4 cases, which were managed with balloon dilatations and stents.

Conclusions: Angioplasty and stenting can be performed safely in patients with acute coronary syndromes using Cordis diagnostic catheters and a very low volume of contrast with improved clinical outcomes.

Other Coronary interventions - Other

Type 1 spontaneous coronary artery dissection: incidence, clinical characteristics, management and follow-up results

KASTRATOVIC Dragana [(1)], BABIC Rade [(1)], KASTRATOVIC Dragana [(1)]

(1) Institute for Cardiovascular Diseases Dedinje, Belgrade, Serbia

Aims: Spontaneous coronary artery dissection (SCAD) is rare but increasingly recognised non-atherogenic cause of acute coronary syndromes. Type 1 SCAD is characterised by longitudinal filling defect on angiography, representing radiolucent intimal flap, with double lumen appearance often followed by contrast staining of arterial wall. The aim of the study was to assess incidence of typeb1 SCAD in patients admitted for coronary angiography, their clinical characteristics, modalities of treatment and 6-month follow-up results.

Methods and results: We retrospectively analysed all consecutive diagnostic coronary angiographies from January to December 2018 looking for SCAD. Angiographic diagnosis of type 1 SCAD was confirmed by consensus of two experienced interventional cardiologists with meticulous attention to exclude iatrogenic or traumatic dissections. Type 1 SCAD was found in 7 out of 4,026 diagnostic angiographies (0.2%, 95% confidence interval 0.1 - 0.4%). Mean patient age was 47 years, with 4 female (57.1%) and 3 male (42.9%). LAD was involved in 2 (28.6%), LCX in 1 (14.3%) and RCA (57.1%) in 4 patients. Recognised predisposing factors or potential stressors (including childbirth, extreme physical exertion, intense emotional stress, hypertensive crisis, energy drinks or sympathomimetic drug abuse) were present in 6 of 7 cases (85.7%). Six coronary angiographies were performed in ACS patients (85.7%) and one was elective (14.3%). Following elective coronarography one patient presenting with stable coronary disease was treated by medical therapy alone. One patient formerly treated by fibrinolytic therapy for STEMI in a non-PCI hospital before transfer to our institute was treated by rescue PCI. Five remaining ACS patients were treated by *ad hoc*k stenting: four with angiographic success and 1 with suboptimal result necessiating urgent surgical revascularisation (LIMA graft to LAD and SVG to diagonal branch). In order to completely cover intimal flap and to prevent dissection propagation, patients treated with stents only received in average 1.8 stents per patient. Following stenting of SCAD, irrespectively of clinical presentation, all patients were put on dual antiplatelet therapy for 12 months. The patient treated by medical therapy alone had uneventful clinical course during 6-month follow-up. He underwent control coronary angiography 2 months after the index procedure revealing complete healing of the dissected RCA. Patients with ACS successfully treated by stenting alone had prompt recovery and uneventful clinical course during 6-month follow-up. The patient sent to surgery had prolonged hospitalisation and decline of ejection fraction at hospital discharge necessitating comprehensive treatment of heart failure. Follow-up angiography at 3 months demonstrated mild residual stenosis at stented area with patent LIMA graft and total occlusion of SVG for diagonal.

Conclusions: By increased awareness and earlier use of coronary angiography, type 1 SCAD can be easily diagnosed. It is commonly associated with well recognised predisposing factors and potential provoking stressors. Conservative management is the preferred option in elective patients with stable and uncomplicated presentation. If feasible, stenting with full coverage of the dissected segment followed by dual antiplatelet therapy provides favourable results. CABG is a viable option for patients unsuitable for PCI, however final results, particularly in ACS, are related to the clinical presentation and residual left ventricular function.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Distal transradial access in the cathlab – are the "times a-changing"?

MOTA Teresa [(1)], MOTA Teresa [(1)], FERNANDES Raquel [(1)], COSTA Hugo [(1)], BISPO João [(1)], AZEVEDO Pedro [(1)], GUEDES João [(1)], VINHAS Hugo [(1)], MIMOSO Jorge [(1)], JESUS Ilídio [(1)]

(1) Centro Hospitalar Universitário do Algarve - Hospital de Faro, Faro, Portugal

Aims: Transition from femoral to radial arterial accesses in the cath lab has been long established. However, in recent years, forearm radial techniques have evolved, and innovative distal radial accesses are being proposed as a more comfortable and potentially safer alternative. The authors aimed to compare the time spent for access obtention (time-to-access) in forearm transradial access (RA) and distal transradial access (d-RA).

Methods and results: The authors present a 5-month retrospective, observational and analytical study. All patients admitted at our centre's cath lab for cardiac catheterisation between 1 August and 4 December 2019 were included. Demographic and cardiovascular risk factors data were collected, as well as procedural information. Statistical analysis was performed using SPSS 24.0 software. For analytical inferences, a significance level of 0.05 was used. A total of 475 patients were included in the analysis, of whom 27.6% were female, with a mean age of 65.8±12.1 years. Regarding previously known cardiovascular risk factors, 26.3% had diabetes mellitus, 63.2% had dyslipidaemia, 65.3% had arterial hypertension, and 7.8% had a family history of coronary events. Some patients had a record of previous acute myocardial infarction (19,4%), and coronary interventions, either percutaneous (30.5%) or surgical (4.2%). When considering the type of arterial access used, right d-RA was the most commonly chosen (51.8%), followed by right RA (37.5%), right femoral (4%), left d-RA and left RA (2.3%). Unsuccesful access varied between techiques, with 1 case in each left radial accesses (9.1%), 21 cases in right d-RA (8.5%) and 3 cases in right RA (1.7%). These differences only showed statistical significance between right d-RA and right RA (p=0.003). When comparing the most used accesses, left RA took significantly longer time to catheterise, when compared to right RA (p=0.036), d-RA (p=0.043) and left d-RA (p=0.001). Regarding right RA vs d-RA, no statistically significant differences were found in time-to-access (2'54''±0'16'' vs 3'09''± 0'09'', p =0,429). However, when comparing two different operators (experienced vs inexperienced), although right RA time-to-access was similar (3'41'' vs 3'27'', p =0,792), the same was not true for right d-RA (2'47'' vs 3'51'', p =0,001). Yet, when analysing the evolution of time-to-access through time, statistically significant differences between operators were only seen in the first month, disappearing in the subsequent period.

Conclusions: Between August and December 2019, right d-RA was the most used arterial access at our cath lab. Globally, this type of access didn't show to take longer than the right RA access type. When comparing d-RA time-to-access between experienced and inexperienced operators, the significant difference detected in the 1st month didn't sustain throughout the study, suggesting a short learning curve for this technique.

Stable CAD - Invasive imaging and functional assessment

Serial near-infrared spectroscopy assessment of change in coronary atherosclerotic plaque

SHIN Sanghoon [1]

(1) Ewha Woman's University Seoul Hospital, Seoul, Republic of Korea

Aims: The purpose of this study was to evaluate changes in lipid content and plaque morphology in patients with coronary artery atherosclerotic plaque according to statin dose during one-year follow-up.

Methods and results: This study is a prospective single-centre randomised study. A total of 84 patients who underwent percutaneous coronary intervention on target vessels, and used high-dose statins (atorvastatin 80mg, n=41) or medium-dose statins (atorvastatin 10 mg, n=43) for one year were enrolled, and serial near-infrared spectroscopy evaluation was performed on non-target vessels. The maxLCBI4 mm of non-target vessels was significantly reduced from 302±185 to 242±165 (p=0.038). This change was similar in both atorvastatin 10 mg group (from 255 [119, 413] to 222 [2.5, 412], p=0.016] vs 80 mg group (from 265 [181, 459] to 253 [169, 360]), and the decrease in LCBI was not seen in the atorvastatin 10 mg group (from 87 [19,188] to 66 [1,202], p=0.099]) but only in the atorvastatin 80 mg group. (from 124 [53,252] to 86 [54,178], p=0.024]

Conclusions: The use of statins reduced maxLCBI4 mm and LCBI, but not as much as previous studies. The difference between the medium dose and the high dose statin was small for plaque changes.

Stable CAD - Diabetes

The five-year prognosis in patients with contrast-induced acute kidney injury and stable coronary artery disease

LAKOTKA Polina [1], MIRONOVA Olga [1], PEREKOSOVA Olga [1], USHANOVA Aline [1], ISAEV Georgy [1], ERMOLAEV Alexander [1], LAKOTKA Polina [1], MIRONOV Vsevolod [2], FOMIN Victor [1]

(1) Sechenov University, Moscow, Russian Federation; (2) Russian Cardiology Research and Production Complex, Moscow, Russian Federation

Aims: The aim of the study was to assess the incidence and influence of contrast-induced acute kidney injury (CI-AKI) and different risk factors on 5-year prognosis in patients with stable coronary artery disease undergoing PCI.

Methods and results: The prospective, cohort, observational study (ClinicalTrials.gov ID: NCT04014153) included 2 groups assessing 1-year and 5-year prognosis in patients with stable coronary artery disease (CAD) receiving optimal medical treatment and requiring PCI with iodinated contrast media. All the patients randomly received iodixanol (iso-osmolar contrast) or iopromide (low-osmolar contrast). CI-AKI was defined as an increase of 25% or more, or an absolute increase of 0.5 mg/dl or more in serum creatinine from baseline value, assessed at 48 hours following PCI (according to the 2012 KDIGO Clinical Practice Guideline for Acute Kidney Injury). The 5-year prognosis bundle included 561 patients aged 18-89. The prevalence of male patients developing CI-AKI was higher than female 72 (69%) vs 32 (31%), but the difference was statistically insignificant ($p<0.05$). 24 patients (23%) who met the criteria of CI-AKI suffered from diabetes mellitus and only 9 (37.5% of all the patients with diabetes) received metformin. Only 1 female patient died during the hospitalisation due to myocardial infarction. 10 patients (42% of all the patients with diabetes and CI-AKI) had repeat revascularisation (repeat PCI) mostly in the first 1-2 years after the date of inclusion compared to 43 (41%) of all the patients with CI-AKI. So the rate of repeat revascularisations was almost the same in patients with and without diabetes. 29 patients (28%) suffered from myocardial infarction. The overall rate of myocardial infarction during follow-up period of 5 years was 13% (73 cases), so two times lower than in CI-AKI group. 5 patients (4.8%) suffered a stroke after the episode of CI-AKI. 11 patients with CI-AKI (10.6%) had episodes of decompensation of chronic heart failure during the follow-up period. Anaemia was diagnosed in 7 patients with CI-AKI (6.7%) and did influence the 5-year prognosis statistically significantly ($p=0.0013$), as did chronic heart failure diagnosed in 8 patients on admission (7.7%) ($p=0.0001$).

Conclusions: The incidence of CI-AKI was 104 cases (18.5%). Gender and diabetes did not statistically significantly influence the 5-year prognosis in our study. Anaemia and heart failure on admission were associated with statistically significantly worse prognosis in our group of patients with CI-AKI. Larger groups are needed to define the importance of potential risk factors influencing the outcomes in patients who develop CI-AKI during planned PCI procedures in patients with stable coronary artery disease.

Stable CAD - CT / MRI imaging

Temporal trends in referral patterns for invasive coronary angiography – a multicentre 10-year analysis

FERREIRA António Miguel [1], GONÇALVES Mariana [1], ROQUE David [2], DE ARAÚJO GONÇALVES Pedro [1], BORGES SANTOS Miguel [2], FAUSTINO Mariana [2], CAMPANTE TELES Rui [1], FARTO E ABREU Pedro [2], DE SOUSA ALMEIDA Manuel [1], BRAVO BATISTA Sérgio [2], FERREIRA António Miguel [1]

(1) Santa Cruz Hospital, Carnaxide, Portugal; (2) Hospital Fernando Fonseca, Amadora, Portugal

Aims: The evaluation of patients with suspected stable coronary artery disease (CAD) is based on clinical assessment and non-invasive testing serving as "gatekeeper" for invasive coronary angiography (ICA). The purpose of this study was to assess the temporal trends in the usage pattern of non-invasive testing before ICA and its diagnostic yield in patients with suspected CAD.

Methods and results: Cross-sectional observational multicentre study of 4,805 consecutive patients (60% male, mean age 66±10 years) without known CAD, undergoing elective ICA due to stable chest pain symptoms in two centres between January 2008 and December 2017. The use of non-invasive testing and the proportion of patients with obstructive CAD (defined as the presence of at least one ≥50% stenosis on ICA) were assessed. From an initial cohort of 11,102 patients undergoing ICA, 4,805 patients were identified with initial suspicion of stable angina. Overall, 4,038 (84%) had a positive non-invasive test: SPECT (38%, n=1,828), exercise ECG (36%, n=1,731), coronary CT angiography (6%, n=302), stress echocardiogram (3%, n=157), or stress cardiac magnetic resonance (0.4%, n=20). Obstructive CAD was found in 53% (n=2,543) of the patients, with 46% (n=2,209) having at least one stenosis >70%. Only 38% (n=1997) underwent revascularisation either by percutaneous coronary intervention or surgery. Overall, only 12% of the patients with obstructive CAD underwent invasive functional assessment. This proportion did not increase significantly over the years (p for trend 0.405). The prevalence of obstructive CAD was higher in patients with vs without previous non-invasive testing (54% vs 46%, respectively, p<0.001) and tended to decrease during the study period (p for trend <0.001). Over this 10-year period, there were small but statistically significant decreases in the proportion of patients referred after exercise testing and SPECT (p for trend 0.005 and 0.006, respectively), and increases in referral after coronary CT angiography and stress CMR (both p for trend <0.001). The proportion of patients referred without previous testing remained stable (p for trend 0.251).

Conclusions: Half of the patients undergoing ICA for suspected CAD did not present obstructive coronary lesion. This proportion tended to increase over the 10-year span of this study. Better clinical assessment tools and diagnostic pathways for stable CAD seem to be needed.

STEMI - Invasive imaging and functional assessment

Clinical, angiographic and procedural predictors of increased microcirculatory resistance in patients with STEMI treated with primary PCI

ORLIC Dejan [1], ZOBENICA Vladimir [1], TESIC Milorad [1], ALEKSANDRIC Srdjan [1], DOBRIC Milan [1], ORLIC Dejan [1], ASANIN Milika [1], STOJKOVIC Sinisa [1], STANKOVIC Goran [1], BELESLIN Branko [1], OSTOJIC Miodrag [1]

(1) Klinicki Centar Srbije, Belgrade, Serbia

Aims: Clinical outcome of patients with ST segment elevation myocardial infarction (STEMI) is related to myocardial perfusion and microcirculatory resistance. Coronary microcirculation is assessed by index of microcirculatory resistance (IMR). Objective was to determine clinical, angiographic and procedural parameters that have impact on IMR value.

Methods and results: IMR was assessed in infarct-related artery (IRA) in 128 consecutive patients with STEMI. Increased values of IMR were defined as those over 24 U. IMR was >24 U in 80 (51.0±29.4U, 24.3-162.1 U) patients and ≤24 U in 48 (16.4±4.53 U, 7.4-23.9 U) patients. Patients with increased IMR were older (62.0±10.88 vs 54.9±9.94 years, p=0.00035), had anterior STEMI more frequently (48.8% vs 29.2%, p=0.029), lower MBG (MBG 0/1 34.2 vs 8.3%), rarely complete resolution of ST-segment elevation (48.8% vs 66.7%, p=0.048), and higher values of CK max (2432.7±1784.3U vs 1473.1±1158.3U, p=0.0035). Univariate analysis of 40 variables showed association of age, smoking, glycaemia at presentation and MBG at the end of pPCI with value of IMR. Multivariate regression analysis showed age as independent predictor of increased IMR.

Conclusions: Although advanced age, anterior STEMI, incomplete resolution of ST-segment elevation and enzymatically assessed larger infarct size were more frequent in patients with increased IMR, only age was an independent predictor of increased microcirculatory resistance in STEMI patients treated with pPCI.

Other Coronary interventions - Calcified lesions

A real-world UK tertiary centre experience of advanced coronary calcium modification techniques with intravascular lithotripsy and rotational atherectomy: patient, lesion and procedural characteristics

DOOLUB Gemina [(1)], MAHADEVAN Kalaivani [(1)], DASTIDAR Amardeep [(1)], DOOLUB Gemina [(1)], YEAROO Ibrahim [(1)], RICHARDS Gavin [(1)], DORMAN Stephen [(1)], JOSHI Nikhil [(1)], DE SILVA Kalpa [(1)], JOHNSON Tom [(1)], STRANGE Julian [(1)]

(1) Bristol Royal Infirmary, Bristol, United Kingdom

Aims: Presence of coronary calcification increases procedural complexity in PCI, with a higher risk of complication and major adverse cardiac events (MACE). We describe the characteristics of all patients undergoing advanced calcium modification techniques (ACMT) – intravascular lithotripsy(IVL) or rotational atherectomy(RA) over a 12-month period at our centre.

Methods and results: We included all PCI procedures utilising ACMT-IVL and RA at our institution. Demographic, procedural and post-procedural outcomes were recorded and characteristics compared between the IVL and RA groups. The indication for ACMT-IVL or RA was based on presence of an undilatable lesion, under-expanded stent and severe calcification on angiography/intravascular imaging. 86 patients were included (4% of total PCIs undertaken annually), 44 in the IVL arm (mean 75.1 years, 84% male), and 42 in the RA arm (mean 76.1 years, 81% male). All clinical presentations were included: 9% STEMI, 51% ACS, 8% with cardiogenic shock and 5% with cardiac arrest; 37% underwent elective PCI. The following patient characteristics were balanced across IVL and RA cohorts respectively to include diabetes (34% vs 29%), renal impairment with eGFRr<60 (34% vs 31%), previous MI (23% vs 24%), previous CABG (20% vs 21%). There were differences in a number of characteristics including hypertension (73% vs 60%) though the only statistically significant difference was presence of moderate or severe LV impairment (36% vs 12%, p=0.01). Lesion characteristics were similar with LMS/LAD as the treated vessel in 67% (n=34) and 64% (n=34) in IVL and RA cohorts respectively. 98% (n=84) were deemed significantly calcified on angiography alone and 11% were undilatable. There was a significant difference in use of IVL vs RA for stent failure which accounted 15% of all cases (n=11 IVL, n=2 RA, p=0.049). Intracoronary imaging was utilised in 77% (n=66) of all cases, OCT more frequently in the IVL group (27%, n=12) and IVUS equally across cohorts (59% vs 57% IVL and RA respectively). The use of adjunctive cutting/scoring techniques was also similar across cohorts, 35% IVL vs 29% RA. In the RA group upsizing to a second burr was undertaken in 26% (n=11) whilst a single device was utilised in 100% of IVL cases. Mean number of stents deployed and largest stent diameter was similar (1.9 and 3.5 mm vs 1.66 and 3.4 mm) in RA and IVL groups respectively. Total complication rates were 14% (type A-C dissection n =7, perforation n=4, slow flow n=1). Contrast volumes, radiation dose and procedural duration were all equal across cohorts. Device cross-over occurred in 7 cases (5 from RA to IVL, 2 from IVL to RA) where a role for both adjuncts was identified on intracoronary imaging and single device modification had failed. Outcomes were assessed at 30 days. TVR, TLR (n=1) and stroke (n=0) were equal across cohorts. There was a single stent thrombosis event with MI occurring in the IVL group at day 6 with no recurrent MI in the RA cohort. There was no difference in 30-day (n=1 both groups) or 3-month (n=1 IVL, n=3 RA, p=0.35) mortality.

Conclusions: IVL and RA are both safe and feasible advanced calcium modification techniques. Whilst use of IVL therapy is higher in patients presenting with STEMI and in those with stent failure, RA use was driven primarily by balloon uncrossable lesions. Given the differential modification of calcium with each adjunct, intracoronary imaging is advised for appropriate device selection, though sometimes both maybe required.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Other

Results of PCI in restenotic lesions with second-generation DEB at long-term follow-up

ABELLÁN-HUERTA José [1], ABELLÁN-HUERTA José [1], SÁNCHEZ-PÉREZ Ignacio [1], LÓPEZ-LLUVA María Thiscal [1], LOZANO-RUIZ-POVEDA Fernando [1], PÉREZ-DÍAZ Pedro [1], FRÍAS-GARCÍA Raquel [1], PIQUERAS-FLORES Jesús [1], MASEDA-URIZA Ramón [1]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Drug-coated balloons (DCB) currently constitute one of the therapeutic tools used in percutaneous coronary interventions (PCI) of in-stent restenotic lesions. Nowadays, their results at a long-term follow-up are unclear. Our objective was to evaluate the efficacy and safety of second-generation drug-coated balloons (DCB) for in-stent restenosis at a long-term follow-up.

Methods and results: We prospectively included 240 lesions in 185 patients (66.5±12.5 years, 76.1% male) with restenotic lesions treated with DCB between March 2009 and January 2018. We evaluated the presence of major cardiac events (MACE) after a clinical follow up (median 32 months): death, non-fatal myocardial infarction (MI), target lesion revascularisation (TLR) and thrombosis. The 48.6% of the patients had stable coronary artery disease, and 51.4% acute coronary syndromes (47.8% non-STEMI and 3.6% STEMI). 53.4% of the patients were diabetic, 84.8% had hypertension and 66.8% had dyslipidaemia. 12.4% of the lesions were bifurcations. 49.7% were focal restenosis (type IA or IC of Mehran classification) and 50.3% were diffuse restenosis (type II or IV). 73% were bare-metal stent (BMS) restenosis and 26.5% were drug-eluting stent (DES) restenosis. Predilation at high atmospheres was performed in 87.4% of patients with a balloon/stent diameter ratio of 1-1.5. DCB inflation was performed at a mean pressure of 17.2±2.3 atm for at least 45 seconds. The coated drug was paclitaxel in 91.1% of the lesions, and sirolimus in the remaining 9.9%. An additional stent was implanted after the DCB in the 11.2% of the restenoses. When comparing BMS vs DES restenotic lesions, there were no significant differences regarding baseline characteristics nor in the MACE rate after the follow-up (p=0.08). The rate of death was 9% (3.6% cardiovascular death, 5.4% non-cardiovascular death), the rate of non-fatal MI was 3.6% and the TLR rate was 6.7% during follow-up. No cases of thrombosis were observed immediately after the procedure or during follow up. We did not observe a higher incidence or MACE (p=0.07) or need for additional stent after PCI in BMS vs DES restenosis (p=0.5). 18.2% of patients had an angiographic follow-up.

Conclusions: Despite the presence of both unfavourable clinical and angiographic risk factors, the PCI with second-generation drug-eluting balloon in BMS and DES in-stent restenotic lesions provides very good results at long-term follow-up.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Gender difference in response to new antiplatelet agents in ACS patients undergoing PCI: analysis from the RENAMI registry

AL RAISI Sara [1], AL RAISI Sara [1], PROTTY Majd [1], CORTESE Martina [2], RAPOSEIRAS-ROUBIN Sergio [3], ABU-ASSI Emad [3], IÑIGUEZ-ROMO Andrès [3], ARIZA-SOLÉ Albert [4], GROSSO Alberto [2], TEMPLIN Christian [5], KINNAIRD Tim [1]

(1) University Hospital of Wales, Cardiff, United Kingdom; (2) University of Turin, Metropolitan City of Turin, Italy; (3) Álvaro Cunqueiro Hospital, Vigo, Spain; (4) Bellvitge University Hospital, L'Hospitalet de Llobregat, Spain; (5) University Hospital of Zürich, Zürich, Switzerland

Aims: The use of new antiplatelet agents (prasugrel & ticagrelor) in acute coronary syndrome (ACS) patients undergoing PCI is a class Ia recommendation. We sought to assess the impact of gender on clinical outcomes in real-world ACS patients treated with PCI and dual antiplatelet therapy with either prasugrel or ticagrelor.

Methods and results: Data from the multicentre REgistry of New Antiplatelets in patients with Myocardial Infarction (RENAMI) for ACS patients (n=4,424) who underwent PCI and were treated with prasugrel or ticagrelor between January 2012 to January 2016 was analysed using multivariate logistic regression model. After adjustment for baseline and procedural variables, the variables that remained independently associated with female gender included older age, hypertension, lower body weight, lower creatinine, less smoking history and less likelihood of multivessel disease. Females were more likely to be on ticagrelor compared to males (OR 1.25, 95% CI: 1.02-1.53, p=0.03). Adjusted outcomes by female gender demonstrated no difference in the likelihood of occurrence of net adverse clinical events (NACE: OR 0.92, 95% CI: 0.74-1.13, p=0.42), major adverse cardiac events (MACE: OR 0.95, 95% CI: 0.77-1.17, p=0.62), all-cause death (OR 0.93, 95% CI: 0.75-1.15, p=0.51), reinfarction (OR 0.94, 95% CI: 0.76-1.17, p=0.59), BARC major bleeding (OR 0.90, 95% CI: 0.73-1.11, p=0.33), stent thrombosis (OR 0.88, 95% CI: 0.44-1.76, p=0.72) or any bleeding (OR 1.31, 95% CI: 0.56-3.07, p=0.46) in females compared to males. Additional subgroup analysis for those age > 75 years, weight < 60 kg, and creatinine > 1.5 mg/dL also demonstrated no significant difference in rates of NACE, MACE, all-cause death, reinfarction, BARC major bleeding, stent thrombosis or any bleeding between males and females.

Conclusions: In this real-world ACS population, there was no difference in response to new antiplatelet agents between males and females despite some features of higher bleeding risk (older age, lower body weight) in females.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Other

Results of PCI in de novo lesions with second-generation DEB at long-term follow-up

ABELLÁN-HUERTA José [(1)], SÁNCHEZ-PÉREZ Ignacio [(1)], ABELLÁN-HUERTA José [(1)], LÓPEZ-LLUVA María Thiscal [(1)], LOZANO-RUIZ-POVEDA Fernando [(1)], PÉREZ-DÍAZ Pedro [(1)], PIQUERAS FLORES Jesús [(1)], MASEDA-URIZA Ramón [(1)]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Drug-coated balloons currently constitute one of the therapeutic tools used in percutaneous coronary interventions (PCI) of *de novo* coronary lesions, mainly in bifurcations and small vessels. Currently, their results at long-term follow up are unclear. Our purpose was to evaluate the efficacy and safety of second-generation drug-coated balloons (PCB) in *de novo* coronary lesions at long term follow-up.

Methods and results: We prospectively included 191 lesions in 166 patients (67.5±12 years, 74.9% male) with *de novo* lesions treated with DCB between March 2009 and January 2019. Additional bare-metal stents (BMS) or drug-eluting stents (DES) were implanted after DCB if the result was not satisfactory because of dissection, recoil or significant residual stenosis. We evaluated the presence of major cardiac events (MACE) after clinical follow-up (median 33 months): death, non-fatal myocardial infarction (MI), target lesion revascularisation (TLR) and thrombosis. The 43.3% of the patients had stable coronary artery disease, and 56.7% acute coronary syndromes (43.3% non-STEMI and 13.4% STEMI). 44.4% of the patients were diabetic, 75.3% had hypertension and 52.2% had dyslipidaemia. 31.8% of the lesions were bifurcations, 25.2% diffuse and 46.7% type B2/C. Mean vessel diameter and length were 2.5±0.7 mm and 19.1±8 mm, respectively. The coated drug was paclitaxel in the 91.2% of the lesions, and sirolimus in the remaining 8.8%. 72.6% of the lesions were treated with DCB, 13.3% with DCB and BMS and 14.1% with DCB and DES. The angiographic success rate was 99.5%. There were no significant differences regarding baseline characteristics nor in the MACE rate after follow-up (p=0.5) of these three groups. The rate of death was 6.1% (1.7% cardiovascular death, 4.4% non-cardiovascular death), the rate of non-fatal MI was 4.4% and the TLR rate was 2.8% during follow-up. No cases of thrombosis were observed immediately after the procedure or during follow-up. We did not observe a higher need for additional stents after DCB in complex lesions (p=0.7) such as diffuse lesions (p=0.8), bifurcation lesions (p=0.7) or in vessel whose diameter was 2.5 mm or less (p=0.5). 15% of patients had an angiographic follow-up.

Conclusions: Percutaneous coronary intervention of *de novo* coronary lesions with second-generation drug-eluting balloon offers very favourable results at long-term follow up. There was not a greater need for additional stents in cases of small vessel or diffuse and bifurcated lesions.

Stable CAD - CT / MRI imaging, Other Coronary interventions - Calcified lesions

CT is a useful modality to evaluate coronary calcium thickness

OKUTSU Masaaki [(1)], OKUTSU Masaaki [(1)], NAKAMURA Sunao [(1)], NAKAMURA Shotaro [(1)], KURITA Naoyuki [(1)], ISHIGURO Hisamasa [(1)], TAHARA Satoko [(1)], MITOMO Satoru [(1)], TANAKA Kentaro [(1)], TANI Kenjiro [(1)], OUCHI Toru [(1)]

(1) New Tokyo Hospital, Chiba, Japan

Aims: Coronary calcium evaluation for PCI is a very important issue but there is no established method to measure its size. CT scan can detect its presence exactly regardless of its size or position, but the size measurement is considered to be impossible because of own blooming artifact. In this study we investigated a new algorithm of calcium size measurement by CT scan.

Methods and results: CT density of calcium borderline is different for each calcium, and this is the reason that it is impossible to decide calcium size. We hypothesised that CT density of calcium is depend on calcium volume, and calcium volume can be replaced by its peak CT density. 59 consecutive calcified segments from 48 patients who underwent CT scan and OCT before PCI procedure between January 2017 and April 2019 were enrolled in this study. Calcium thickness was measured by OCT and this was defined as the gold standard value. CT density profile was measured at same point in the same CT cross-sectional slice as the OCT. Peak CT density and calcium borderline CT density were measured with reference to OCT data. Peak CT density had good correlation with calcium thickness ($r=0.684$, $p<0.001$). Borderline CT density was quite different from lesion to lesion but had very good correlation with peak CT density ($r=0.895$, $p<0.001$) and there was a correlation of "estimated calcium borderline CT density = 0.6x(peak – baseline CT density) +209 HU". In the validation group (42 lesions of 15 patients), calculated calcium thickness by this estimated calcium borderline CT density formula and actual measured thickness by OCT are highly consistent ($r=0.855$, $p<0.001$).

Conclusions: Calcium thickness can be well evaluated by CT regardless of its size or position.

Euro2OA-POS148
Posters

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Analysis of coronary angiography in survivors of cardiac arrest – a retrospective observational study

DA SILVA Roberto Leo [(1)], FILIPPINI Filippe Barcellos [(1)], DA SILVA Roberto Leo [(1)], WALDRICH Leandro [(1)], STURMER Janine Daiana [(2)]

(1) Instituto de Cardiologia de Santa Catarina, State of Santa Catarina, Brazil; (2) Instituto de Cardiologia, RS, Brazil

Aims: Emergency coronary angiography in survivors of cardiac arrest (CA) is a matter of debate in the setting of non-ST segment elevation (STE). This matter encompasses a broad spectrum of causes and after the return of spontaneous circulation (ROSC) its prognosis is dismal. Identifying the cause and which patients are likely to survive is always challenging.

Methods and results: Patients were eligible if they had been successfully resuscitated after cardiac arrest (CA) without an EKG previous to the event and had received emergency coronary angiography (CoA). We retrospectively analysed, from 2016 to 2019, a total of 52 patients; 73% were male, 19% had previous diagnosis of coronary arterial disease (CAD), 90% with shockable rhythm, 75% with out-of-hospital cardiac arrest (OHCA) and 58% had typical ischaemic chest pain described previous to the CA. In the post-ROSC EKG, 69% had an STE, the mean age of these patients was 63 years, 80% had acute thrombotic occlusion (ATO) in the CoA, the culprit vessel was the left anterior descending (LAD) in 56% and a total of 28% died. In the non-STE patients, the mean age was 59 years, 25% had ATO in the CoA and 37% died. In the bivariate analysis, we found the prevalence of CAD was statistically higher in the STE group (p 0.035).

Conclusions: In accordance with recent data published, this study had similar rates of acute thrombotic occlusion in the STE patients post ROSC. We found higher rates of death in the non-STE patients, a fact that may be involved with more complex comorbidities, misdiagnosed and delayed angiography.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Intravascular lithotripsy in under-expanded stents in calcified lesions: 12-month clinical outcome of patients from a prospective, observational register study

AKSOY Adem [(1)], NICKENIG Georg [(1)], SINNING Jan-Malte [(1)], ZIMMER Sebastian [(1)]

(1) Heart Center Bonn, Department of Medicine II, University Hospital, Bonn, Germany

Aims: Percutaneous coronary intervention (PCI) of calcified lesions is associated with a higher prevalence of target vessel revascularisation and myocardial infarction. Intravascular lithotripsy (IVL) has been recently proposed for the treatment of underexpanded stents in calcified coronary lesions. This study sought to report 12-month clinical outcomes of IVL on calcified lesions in patients with underexpanded stents.

Methods and results: We treated 22 patients with in-stent stenosis due to stent underexpansion after previous stenting in calcified lesions with IVL. The primary endpoint of the current analysis was the occurrence of major adverse cardiac events (MACE) at 12-month follow-up, defined as the composite of death, myocardial infarction, and target lesion revascularisation (TVR). Average diameter of in-stent stenosis was 87.9±9.4 % at baseline and decreased significantly to 15.7±19.53 % (p-value: 0.01) after PCI. Minimal lumen diameter was 0.97±0.6 mm at baseline and significantly increased after IVL (2.49±0.7 mm, p-value < 0.01). At 12 months, MACE occurred in 9 patients (46.9%). The rates of death (12.3%), myocardial infarction (66%), target lesion revascularisation (72.8%).

Conclusions: Despite high rates of initial strategy success, nearly half of patients enrolled in the register experienced MACE.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Other

Results of PCI with second-generation DEB in elderly patients at a long-term follow-up

ABELLÁN-HUERTA José [(1)], SÁNCHEZ-PÉREZ Ignacio [(1)], ABELLÁN-HUERTA José [(1)], LÓPEZ-LLUVA María Thiscal [(1)], LOZANO-RUIZ-POVEDA Fernando [(1)], PIQUERAS FLORES Jesús [(1)], PÉREZ-DÍAZ Pedro [(1)], MASEDA-URIZA Ramón [(1)], FRÍAS-GARCÍA Raquel [(1)]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Drug-coated balloons (DCB) constitute one of the therapeutic tools used in percutaneous coronary interventions (PCI) of both stent restenosis and *de novo* coronary lesions, mainly in bifurcations and small vessels. Elderly patients represent an unfavourable prognosis subgroup, in which this technique could be of great value. Nevertheless, the results of PCI with DCB at a long-term follow up are unclear in this subset of patients. Our purpose was to evaluate the efficacy and safety of PCI with second-generation drug-coated balloons (DCB) in patients older than 75 years at a long-term follow-up.

Methods and results: We prospectively included 130 lesions in 114 patients (80.9±4.1 years, 61.2% male) treated with DCB between March 2009 and January 2019. We evaluated the presence of major cardiac events (MACE) after a clinical follow up (median 36 months): death, non-fatal myocardial infarction, target lesion revascularisation (TLR) and thrombosis. 43.4% of the patients had stable coronary artery disease, and 56.6% acute coronary syndromes (49.6% non-STEMI and 7% STEMI). 87.7% of the patients had hypertension, 60% had diabetes, 58.5% had dyslipidaemia and 19.2% were active smokers. 20.8% of the lesions were bifurcations. The target lesion diameter was 2.5 mm or less in 50.8% of the cases. The coated drug was paclitaxel in 90.7% of the lesions, and sirolimus in the remaining 9.3%. Of the 130 lesions, 48% were *de novo* lesions and 52% were restenotic (33.9% restenosis of bare-metal stent [BMS] and 18.1% of drug-eluting stent [DES]). 84.2% of the lesions were treated with DCB, 6.5% with DCB and BMS and 9.3% with DCB and DES. The angiographic success rate was 99%. There were no significant differences regarding baseline characteristics of these three groups nor in the MACE rate after the non-cardiovascular death). The rate of non-fatal MI was 2.3% and the TLR rate was 1.5% during follow-up. No cases of thrombosis were observed immediately after the procedure or during follow up. 13.5% of patients had an angiographic follow-up.

Conclusions: In the elderly patient, percutaneous coronary intervention of *de novo* coronary lesions and in-stent restenosis (both BMS and DES) with second-generation drug-eluting balloons provides very favourable outcomes at a long term follow-up, constituting an alternative to the PCI with stent implantation.

NSTEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Comparison of long-term outcomes of PCI with Sequent Please versus In-Pact Falcon paclitaxel-eluting balloon catheter

ABELLÁN-HUERTA José [(1)], SÁNCHEZ-PEREZ Ignacio [(1)], ABELLÁN-HUERTA José [(1)], LOZANO-RUIZ-POVEDA Fernando [(1)], LÓPEZ-LLUVA María Thiscal [(1)], PÉREZ-DÍAZ Pedro [(1)], PIQUERAS-FLORES Jesús [(1)], MASEDA-URIZA Ramón [(1)], MARTÍNEZ-DEL-RÍO Jorge [(1)]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Drug-coated balloons (DCB) currently constitute one of the therapeutic tools used in percutaneous coronary interventions (PCI). The widely used Sequent Please® and In-Pact Falcon® are paclitaxel DCB that differ in several features such as the drug carrier. Their results at a long-term follow up have never been compared. Our objective was to compare the efficacy and safety of second-generation DCB Sequent Please® and In-Pact Falcon® at a long-term follow-up.

Methods and results: We prospectively included 368 lesions in 307 patients (67.2±12.3 years, 75.3% male) treated with Sequent Please (242 lesions; 65.8 %) and In-Pact Falcon (126 lesions; 34.2%) DCB between March 2009 and January 2019. We evaluated and compared the presence of major cardiac events (MACE) after a clinical follow up (median 35 months): death, non-fatal myocardial infarction (MI), target lesion revascularisation (TLR) and thrombosis. 45.3% of the patients had stable coronary artery disease, and 54.7% acute coronary syndromes (46.6% non-STEMI and 8.1% STEMI). 51.5% of the patients were diabetic, 81.8% had hypertension and 60.2% had dyslipidaemia. 22% of the lesions were bifurcations, 42.6% diffuse and 56.3% type B2/C. The target lesion diameter was 2.5 mm or less in 53.8% of the cases and the mean length treated lesion was 20.6±11 mm. Of the 368 lesions, 45.1% were *de novo* lesions and 54.9% were restenotic (38.9% restenosis of bare-metal stent [BMS] and 16% of drug-eluting stent [DES]). 85% of the lesions were treated with DCB, 6.8% with DCB and BMS and 8.2% with DCB and DES. The rate of death was 7.7% (2.5% cardiovascular death, 5.2% non-cardiovascular death), the rate of non-fatal MI was 3.3% and the TLR rate was 4.4% during follow-up. No cases of thrombosis were observed, immediately after the procedure nor during follow up. Basal characteristic showed no statistical differences when comparing both types of DCB. The rates of MACE were similar between groups at the end of the follow-up, as follows: cardiovascular death (Sequent 2.5% vs Falcon 2.4%; p=0.9), non-cardiovascular death (Sequent 5.4% vs Falcon 4.8%; p=0.8), non-fatal MI (Sequent 2.5% vs Falcon 4.8%; p=0.2), TLR (Sequent 4.6% vs Falcon 4%; p=0.8). 16.7% of patients had an angiographic follow-up.

Conclusions: Percutaneous coronary intervention of *de novo* and restenotic coronary lesions with Sequent Please and In-Pact Falcon paclitaxel drug-eluting balloons provide very favourable and comparable outcomes at a long-term follow-up.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Other

Results of PCI with second-generation DEB at long-term follow-up

ABELLÁN-HUERTA José [(1)], ABELLÁN-HUERTA José [(1)], SÁNCHEZ-PÉREZ Ignacio [(1)], LOZANO-RUIZ-POVEDA Fernando [(1)], LÓPEZ-LLUVA María Thiscal [(1)], PÉREZ-DÍAZ Pedro [(1)], PIQUERAS-FLORES Jesús [(1)], REQUENA-IBÁÑEZ Juan Antonio [(1)], MASEDA-URIZA Ramón [(1)]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Drug-coated balloons (DCB) currently constitute one of the therapeutic tools used in percutaneous coronary interventions (PCI) of both stent restenosis and *de novo* coronary lesions, mainly in bifurcations and small vessels. Currently, their results at a long-term follow up are unclear. Our objective was to evaluate the efficacy and safety of second-generation drug-coated balloons (DCB) at a long-term follow-up.

Methods and results: We prospectively included 426 lesions in 346 patients (66.9±12 years, 75.5% male) treated with DCB between March 2009 and February 2019. We evaluated the presence of major cardiac events (MACE) after a clinical follow up (median 32 months): death, non-fatal myocardial infarction, target lesion revascularisation (TLR) and thrombosis. 46.1% of the patients had stable coronary artery disease, and 53.9% acute coronary syndromes (45.9% non-STEMI and 8% STEMI). 49.9% of the patients were diabetic, 80.5% had hypertension, 60.8% had dyslipidaemia and 20.8% of the lesions were bifurcations. The target lesion diameter was 2.5 mm or less in 52.3% of the cases. Of the 426 lesions, 44.7% were *de novo* lesions and 55.3% were restenotic (40.4% restenosis of bare-metal stent [BMS] and 14.9% of drug-eluting stent [DES]). 82.3% of the lesions were treated with DCB, 6.2% with DCB and BMS and 11.5% with DCB and DES. The rate of death was 8.1% (2.9% cardiovascular death, 5.2% non-cardiovascular death), the rate of non-fatal MI was 4% and the TLR rate was 4.5% during follow-up. Diabetic patients showed a higher incidence of MACE after one year of follow-up (9.8% vs 2.9%; p=0.05) and a higher incidence of cardiovascular death (5.4% vs 0.5%; p=0.03). No cases of thrombosis were observed immediately after the procedure or during follow up. 16.6% of patients had an angiographic follow-up.

Conclusions: Percutaneous coronary intervention of *de novo* coronary lesions and in-stent restenosis (both BMS and DES) with second-generation drug-eluting balloons provide very favourable outcomes at a long-term follow-up. However, diabetic patients presented a higher incidence of MACE and cardiovascular death during follow-up.

Bifurcation lesion - CT / MRI imaging

Comparison of fractional myocardial mass, a vessel-specific myocardial mass-at-risk, with coronary angiographic scoring systems for predicting myocardial ischaemia

CHOI Jin-Ho [1], CHOI Jin-Ho [1], KIM Hyung Yoon [2], NAM Chang-Wook [3], SHIN Eun-Seok [5], LIM Hong-Seok [6], KOO Bon-Kwon [7], KIM Sung Mok [1]

(1) Samsung Medical Center, Seoul, Republic of Korea; (2) Chonnam National University Hospital, Gwangju, Republic of Korea; (3) Keimyung University Dongsan Hospital, Daegu, Republic of Korea; (4) Inje University Ilsan-Paik Hospital, Goyang, Republic of Korea; (5) Ulsan Hospital, Ulsan, Republic of Korea; (6) Ajou University Hospital, Gyeonggi-do, Republic of Korea; (7) Seoul National University, Seoul, Republic of Korea

Aims: The burden of coronary artery disease has been assessed by various semi-quantitative angiographic scores, which are frequently different each other. A non-invasive and quantitative modality may substitute angiographic sores for prognostic implication and decision of revascularisation strategy. We compared fractional myocardial mass (FMM) with angiographic scores for predicting myocardial ischaemia.

Methods and results: In this multicentre registry, 411 patients who underwent coronary computed tomography angiography (CCTA) were followed by invasive coronary angiography and fractional flow reserve (FFR) measurement. CCTA–derived %FMM with diameter stenosis≥70% (%FMM-70) or ≥50% (%FMM-50) were compared with 9 angiographic scores (APPROACH, Duke Jeopardy, BARI, CASS, SYNTAX, Jenkins, BCIS-1, Leaman, Modified Duke) and were tested regarding their performance for predicting FFR≤0.80. The performance of %FMM-70 and %FMM-50 were similar to most angiographic scores (%FMM-70, c-statistics=0.74; %FMM-50, 0.73; angiographic scores, 0.68 – 0.77). The frequency of FFR≤0.80 increased consistently according to %FMM-70, %FMM-50, and all angiographic scores (p<0.001, all). The optimal cutoff of %FMM-50 and %FMM-70 for FFR≤0.80 were ≥36.3% and ≥8.7%, respectively. Using these cutoffs, the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of %FMM-50 were 81%, 55%, 3%, 67%, 71%, and of %FMM-70 were 67%, 78%, 82%, 61%, 71%.

Conclusions: %FMM was comparable to angiographic scores for prediction of functional stenosis defined by FFR≤0.80. The integration of the severity of stenosis and the amount of subtended myocardium may improve the detection of the functional significance of vessel.

Bifurcation lesion - Invasive imaging and functional assessment

Allometric scaling patterns in human myocardial mass to morphology and coronary artery flow

CHOI Jin-Ho [1], CHOI Jin-Ho [1], EUNSOO Kim [1], HYUNG YOON Kim [2], KIM Sung Mok [1]

(1) Samsung Medical Center, Seoul, Republic of Korea; (2) Chonnam National University Hospital, Gwangju, Republic of Korea

Aims: Allometric scaling is ubiquitously observed in living organisms, and may elucidate a key design principle among size and pattern in human coronary circulation. We investigated whether allometric scaling coronary artery tree supplies blood flow to myocardium in heterogenous sizes and branching patterns.

Methods and results: We enrolled patients who underwent coronary computed tomography angiography without obstructive lesion. The cumulative arterial length (L), volume (V), diameter (D) in relation to the artery-specific myocardial mass (M) were assessed. Flow rate (Q) was also assessed using quantitative flow ratio (QFR) measurement in patients undergoing invasive angiography. A total of 638 arteries from 43 patients (mean age 61 years, male gender 65%) were analysed. A significant power-law relationship was found among the following parameters ($p<0.001$, all). The scaling exponents among L–M, V–M, D–M, V–L, D–L, and V–D were 0.750±0.150, 1.031±0.023, 0.215±0.008, 1.318±0.020, 0.274±0.009, and 3.387±0.088, respectively. In 106 arteries interrogated with QFR, the scaling exponents among Q–M, Q–L, Q–V, and Q–D were 0.429±0.069, 0.598±0.084, 0.455±0.058, and 2.012±0.224, respectively.

Conclusions: These allometric scaling patterns among myocardial mass, coronary artery morphology and flow provides insight into the fundamental design principle of human coronary circulation. It may facilitate the scientific definition of pathophysiology such as diffuse coronary artery disease or ventricular hypertrophy.

STEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Prognosis associated with the use of very long stents and overlapping stents in STEMI

ABELLÁN-HUERTA José [1], ABELLÁN-HUERTA José [1], NEGREIRA-CAAMAÑO Martín [1], JURADO-ROMÁN Alfonso [2], SÁNCHEZ-PEREZ Ignacio [1], LOZANO-RUIZ-POVEDA Fernando [1], LÓPEZ-LLUVA María Thiscal [1], PIQUERAS-FLORES Jesús [1], MASEDA-URIZA Ramón [1]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain; (2) University Hospital La Paz, Madrid, Spain

Aims: Both the stent length and the stent overlap have been considered predictors of adverse events in percutaneous coronary intervention (PCI). However, there are no comparative data on the use of very long stents (VLS) or overlapping stents (OS) in the context of STEMI and primary angioplasty. Our objective was to compare the results of the VLS (≥40 mm) or OS during primary PCI.

Methods and results: A total of 167 PCI of 159 consecutive patients were included (81.4% male, 64.2±12.3 years). 63 lesions were treated with VLS and 104 with OS between March 2014 and January 2019. We analysed the procedural characteristics and the rate of the combined endpoint (cardiovascular death [CD], non-fatal myocardial infarction [MI], need for target lesion revascularisation [TLR] or stent thrombosis [ST]) after a median follow-up of 18.8 months (11-28). 27.6% of patients were diabetics. Drug-eluting stents were implanted in 78.4% of lesions and bare-metal stents in 21%. The SYNTAX-score was 22.2±12.6 and 18.6% of lesions were bifurcations. The minimum diameter was 3.2±2.4 mm and the number OS was 1.7±0.7. The most frequent treated vessel was the right coronary artery (52.7%) followed by the left anterior descending artery (40.1%). Procedures with OS required a longer stent length (56.1±19.9 vs 45.4±5.1 mm; p<0.01), a longer procedure time (41±24.7 vs 34.1±14.4 min; p=0.05) and greater number of stents 2.5±0.8 vs 1.4±0.7; p<0.01). The combined endpoint at the end of the follow-up was 17.8%, being similar between groups (OS:20 vs VLS:14,5%; p=0.38). The independent event rate was: CD 13.9%; MI: 1.9%; TLR: 3.8%; ST: 1.3%. No differences were observed in the rate of the events between both groups [CD (OS:14.6 vs VLS:12.9%; p=0.5); MI (OS:3.2 vs VLS:0%; p=0.28); TLR (OS:6.8 vs VLS:0%; p=0.08); ST (OS:2.2 vs VLS:0%; p=0.51).

Conclusions: The use of VLS allows the treatment of increasingly complex lesions in the context of primary angioplasty, simplifying the procedure and decreasing the number of stents implanted with results similar to those obtained with stent overlapping.

Stable CAD - Adjunctive pharmacotherapy

Development and validation of a prediction rule for transfusion in patients undergoing PCI using administrative clinical parameters

CHOI Jin-Ho [(1)], CHOI Jin-Ho [(1)], CHOI Jung-Min [(1)], LEE Seung-Hwa [(1)]

(1) Samsung Medical Center, Seoul, Republic of Korea

Aims: Patients undergoing percutaneous coronary intervention (PCI) are treated with antiplatelet agents that carry a bleeding risk for many years. However, there is no standardised tool predicting long-term bleeding risk.

Methods and results: From the retrospective nationwide RealPCI PCI registry (N=48,726), a bleeding prediction score was established in a derivation cohort using LASSO regression. DAPT was defined by proportion of days covered ≥80% per 6-month basis. RealPCI bleeding score was compared with absolute risk difference (ARD) between the benefit (reducing major adverse clinical events (MACE) including cardiovascular death, revascularisation, critically ill cardiovascular status, or stroke) and the harm (bleeding) of DAPT per 6 months up to 4 years. The RealPCI bleeding score consisted of 23 clinical parameters, and had moderate accuracy for both bleeding (c-statistics=0.668) and MACE (c-statistics=0.732). In the derivation cohort (N=251,191, mean age=64.9, male=68%), DAPT resulted in positive ARD from 6 to 12 months. ARD increased according to score quartiles from 5.0 to 37.3% ($p<0.001$). From 6 to 48 months, ARD was negative but diminished according to score quartiles from -12.4 to -1.0% ($p<0.01$). The validation cohort (N=23595) replicated these results with good calibration.

Conclusions: The RealPCI bleeding score predicted long-term risk of bleeding and MACE, and discerned patients who might most benefit from DAPT per 6 month period up to 4 years. The discriminative performance of this novel score for optimal DAPT duration needs further prospective evaluations and validations in other cohorts.

Other Coronary interventions - Other

Gender difference in long-term clinical outcomes after PCI

CHOI Jin-Ho [(1)], CHOI Jin-Ho [(1)], CHOI Jung Min [(1)], LEE Seung-Hwa [(1)]

(1) Samsung Medical Center, Seoul, Republic of Korea

Aims: The comparative gender-specific outcome after PCI in real-world practice is limited. We investigated the gender difference in the 5-year outcome after percutaneous coronary intervention (PCI).

Methods and results: All PCI performed in Korea in year 2011 (N=48,783). Outcomes adjusted with age and propensity for clinical characteristics were compared. Primary outcome was 5-year cumulative incidence of major adverse clinical event (MACE) consisting of all-cause death, revascularisation, shock, or stroke. In unadjusted analysis, women (N=15,710) were older (69.7±9.7 versus 62.0±11.1 year) and had higher frequency of comorbidities including hypertension, hyperlipidaemia, and diabetes compared to men (N=33,073) ($p<0.001$, all). Women had higher 5-year cumulative incidence of MACE than men (41.9% versus 37.2%; hazard ratio [HR] 1.16, 95% confidential interval [CI] 1.12 – 1.19; $p<0.001$). In propensity score-matched 14,462 pairs, women had lower 5-year mortality risk (40.7% versus 46.0%, HR 0.85, 95% CI: 0.82-0.88, $p<0.001$). The lower 5-year MACE risk in women was consistent in subgroup analyses of age, risk factors, and clinical diagnosis including angina or acute myocardial infarction ($p<0.05$, all). The risk of all-cause death, revascularisation, and shock were also lower in women than men ($p<0.05$, all) but the risk of stroke was not different between women and men.

Conclusions: The apparent worse outcome in women can be explained by older age and more common comorbidities in women. After adjusting these disadvantages, women had better outcome after PCI than men. Our result suggests presence of the reversal paradox in the gender-specific outcome following PCI.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Comparison between the use of overlapping stents and very long stents in patients with chronic kidney disease and diffuse coronary artery disease

ABELLÁN-HUERTA José [1], NEGREIRA-CAAMAÑO Martín [1], ABELLÁN-HUERTA José [1], JURADO-ROMÁN Alfonso [2], LÓPEZ-LLUVA María Thiscal [1], LOANO-RUIZ-POVEDA Fernando [1], PÉREZ-DÍAZ Pedro [1], PIQUERAS-FLORES Jesús [1], MASEDA-URIZA Ramón [1], SÁNCHEZ-PÉREZ Ignacio [1]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain; (2) University Hospital La Paz, Madrid, Spain

Aims: Both the stent length and the need of stent overlap have been considered predictors of adverse events in the percutaneous treatment (PCI) of diffuse coronary artery disease. However, there is no evidence about the prognosis associated to the use of very long stents (VLS, ≥40 mm) and overlapping stents (OS) in patients with chronic kidney disease (CKD), which itself is associated with a worse prognosis after PCI. Our objective was to compare the clinical results of the use of VLS or OS in a cohort of patients with CKD.

Methods and results: A total of 104 lesions in 103 consecutive patients were analysed between April 2014 and February 2019 (73.3% male, 73.6±10.6 years). We included patients with prior CKD diagnosis or a glomerular filtration rate <60 ml/kg/min. We analysed the procedural characteristics and the incidence of the combined endpoint (cardiovascular death [CD], non-fatal myocardial infarction [M]), need for target lesion revascularisation [TLR] or stent thrombosis [ST]) after a median follow-up of 19.8 months (11.2-19.7). 61.2% of patients were diabetic and 88.3% had hypertension. The median creatinine was 1.5 mg/dL (1.3–2.1). The clinical presentation was acute coronary syndrome in the 58.3% and stable coronary artery disease in the 41.7%. 88.8% of the interventions used drug-eluting stents. 27% of lesions were bifurcations and SYNTAX-score was 27.4±15.3. The most frequent treated vessel was the right coronary artery (36.9%). Procedures with OS reported a higher total stent length (58.7±20.7 vs 46.8±5.7 mm; p<0.01), needed more fluoroscopy time (21.4±11.5 vs 15.2±6.9 min; p<0.01) and more contrast volume (309±120 vs 242±98 cc; p=0.01) in comparison with the VLS group. The combined endpoint at the end of the follow-up was 18.6%. It was similar in both groups (p=0.07). Independent event rate was: CD 1.3%; MI: 1.1%; TLR: 2.1%; ST: 0%. There were no differences between OS and VLS in the independent event rate analysis [CD (9.1% vs 12.9%; p=0.3), MI (0% vs 3.6%; p=0.3), TLR (3.1% vs 0%; p>0.99 and ST (NA).

Conclusions: The use of VLS in patients with CKD is a safe alternative, with similar outcomes to the use of OS. In our study, VLS procedures required less fluoroscopy time and a lower contrast volume administration.

Stable CAD - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Efficacy and safety of directional coronary atherectomy followed by DEB without stent strategy

OKUTSU Masaaki [1], OKUTSU Masaaki [1], NAKAMURA Sunao [1], NAKAMURA Shotaro [1], KURITA Naoyuki [1], ISHIGURO Hisamasa [1], TAHARA Satoko [1], MITOMO Satoru [1], TANAKA Kentaro [1], TANI Kenjiro [1], OUCHI Toru [1]

(1) New Tokyo Hospital, Chiba, Japan

Aims: To verify the safety of directional coronary atherectomy (DCA) followed by drug-coated balloon (DCB) by OCT.

Methods and results: 18 lesions from 15 cases received DCA followed by DCB without stent in our hospital in 2019. Of these, 9 lesions from 8 patients underwent follow-up angiography and OCT 3 months later and these are evaluated in this study. Major adverse cardiac events (MACE) are cardiac death, myocardial infarction, definite or probable thrombosis and ischaemic driven target vessel revascularisation. DCA catheter size was 8 of large and 5 of medium. Debulking was performed with 40±22 cuts at 4.7±2.4 atm as max pressure. Paclitaxel-coated balloon was used as DCB and balloon size was 3.6±0.4 mm and length was 18.6±3.8 mm. Minimum lumen area (MLA) of pre- and post DCA was 3.0±1.8 and 11.6±2.0 mm^2, % plaque area (%PA) was 81.9±9.4 and 41.7±8.1%. Deep cuts extended to adventitia in two lesions at initial procedure without coronary perforation. Follow-up period was 116±19 days. No lesions had MACE in clinical follow-up. And there was no angiographical restenosis and no thrombotic event. From OCT findings, MLA post DCA and follow-up was 10.5±3.3 and 8.7±4.2 mm^2. Vessel walls had many irregularities post DCA in all lesions but there was mild irregularity in 2 lesions at follow-up. 9.6±6.1 flaps were observed after DCA and 0.4±0.7 at follow-up. 2 deep cut segments after DCA were well healed and no aneurysmal formation at follow-up. Low reflective neointima was observed in 3 lesions.

Conclusions: DCA followed by DCB without stent strategy had excellent patency and good vessel endothelialisation at 3-month follow-up. DCB might be safe for deep cut segment by DCA.

Other Coronary interventions - Other

The long-term patterns of red blood cell transfusion and outcome in patients undergoing PCI

CHOI Jin-Ho [1], CHOI Jin-Ho [1], CHOI Jung Min [1], LEE Seung-Hwa [1], LEE Joo Myung [1], PARK Taek Kyu [1], YANG Jeong Hoon [1], SONG Young Bin [1], HAHN Joo-Yong [1], CHOI Seung-Hyuk [1], GWON Hyeon-Cheol [1], LEE Sang-Hoon [1]

(1) Samsung Medical Center, Seoul, Republic of Korea

Aims: We investigated the long-term patterns and impact of transfusion on the clinical outcome of patients undergoing percutaneous coronary intervention (PCI) using a retrospective nationwide registry.

Methods and results: Five-year clinical outcomes of all Koreans undergoing PCI using stent in year 2011 (n=48786) were investigated. Primary outcome was the incidence density of transfusion. The association of transfusion with major adverse clinical event (MACE) consisting of all-cause death, revascularisation, critically ill cardiovascular status, or stroke was assessed after reflecting the propensity of each patient for transfusion. The 5-year incidence density of transfusion was 4.74 (95% confidence interval [CI]=4.70–4.79) per 100 person-years. Patients who received transfusion were older and had higher frequency of clinical risk factors ($p<0.001$, all). Transfusion was associated with MACE (hazard ratio [HR]=3.2, 95% CI=3.2–3.3, $p<0.001$) and all other clinical events (HR 1.5 to 6.9, $p<0.001$, all). The period of transfusion coincided with the period of highest MACE incidence density. Subgroup analyses showed consistent results.

Conclusions: A total of 22.9% of patients received transfusion during a mean follow-up period of 4.8 years, and had 3.2-fold higher risk of MACE compared to patients without transfusion. These observational findings may warrant the establishment of transfusion strategies for patients undergoing PCI.

Left main and multivessel disease - Invasive imaging and functional assessment

Assessment of left main coronary artery stenosis severity comparing CT coronary angiography to intravascular ultrasound

NOGIC Jason [1], NOGIC Jason [1,3], THAKUR Udit [1], MICHAIL Michael [1], NERLEKAR Nitesh [1], IHDAYHJID Abdul [1], KO Brian [1], SENEVITATNE Sene [1], DEY Damini [2], BROWN Adam [1]

(1) MonashHeart, VIC, Australia; (2) Cedars-Sinai Medical Center, CA, USA; (3) Eastern Health, VIC, Australia

Aims: Angiographic assessment of stenosis severity with the left main coronary artery (LMCA) can be unreliable. In cases of ambiguity, intravascular ultrasound (IVUS) can be utilised with a minimal lumen area (MLA) of ≥6 mm^2 an accepted threshold for safe deferral of revascularisation. With the emergence of computed tomography coronary angiography (CTCA) as a first line investigation for patients with chest pain, we sought to assess which quantitative CTCA measures could assist clinicians in making LMCA revascularisation decisions when compared with IVUS as gold standard.

Methods and results: Consecutive patients undergoing IVUS assessment of angiographically intermediate LMCA stenosis were included. All patients underwent 320-slice CTCA <90 days prior to IVUS imaging. Offline quantitative assessment of IVUS- and CT-derived measures were undertaken. The cohort was then divided into those with significant (S-LMCA) versus non-significant (NS-LMCA) disease using the accepted IVUS thresholds. A total of 48 patients were included in the final analysis. The mean age (60.3±12.4 vs 59.9±11.9 yrs, p=0.91), percentage of males (57.7% vs 54.6%, p=0.83) and other baseline demographics were similar between groups. The mean time from CTCA to IVUS assessment was 17.4±19.8 days, with angiographic stenosis severity being 46±18.6%. Patients with NS-LMCA had larger CT luminal area (8.3±3.8 vs 5.2±1.6 mm^2, p=0.005), larger minimal lumen diameter (MLD) (3.2±0.7 vs 2.5±0.4 mm, p<0.001) but similar luminal volumes (99.9±50.5 vs 113.5±73.9 mm^3, p=0.47). There was a significant positive correlation between CTCA and IVUS MLA (r=0.77, p<0.001) and MLD (r=0.73, p<0.001). ROC analysis demonstrated CTCA MLA <8.29 mm^2 had the best diagnostic accuracy for predicting IVUS MLA <6 mm^2 (area under the curve = 0.76, sensitivity = 100%, specificity = 54% p=0.002).

Conclusions: CTCA derived MLA and MLD have a high correlation with IVUS, with a CTCA MLA cut-off >8.29 mm^2 most predictive of the IVUS deferral threshold. These results suggest that CTCA can provide a reliable tool for the assessment of the LMCA stenosis severity.

Stents and scaffolds - Adjunctive pharmacotherapy

Adherence to DAPT and long-term outcome of drug-eluting or bare-metal stents: a Korean nationwide longitudinal real-world cohort study

CHOI Jin-Ho [1], CHOI Jin-Ho [1], CHOI Jung Min [1], LEE Seung-Hwa [1], JANG Yu Jeong [1], LEE Joo Myung [1], PARK Taek Kyu [1], YANG Jeong Hoon [1], SONG Young Bin [1], HAHN Joo-Yong [1], CHOI Seung-Hyuk [1], GWON Hyeon-Cheol [1], LEE Sang-Hoon [1]

(1) Samsung Medical Center, Seoul, Republic of Korea

Aims: The clinical benefit of drug-eluting stents (DES) compared to bare-metal stents (BMS) in percutaneous coronary intervention (PCI) needs to be investigated with the real-world usage pattern of dual antiplatelet therapy (DAPT).

Methods and results: We retrospectively enrolled all Korean PCI patients from January 1, 2011 to December 31, 2011 (n=47,291). The usage pattern of DAPT was estimated using the proportion of days covered (PDC) of DAPT per 6 months. Analysis adjusted with the clinical propensity for receiving DES or BMS and DAPT PDC of the first 6 months was performed. Primary outcome was the 5-year major adverse clinical event (MACE) rate consisting of all-cause death, revascularisation, critically ill cardiovascular status, or stroke. Patients with DES (n=46,356) were younger and had lower frequency of clinical risk factors compared to patients with BMS (n=935). Patients with DES showed higher PDC (78% versus 60%, p<0.001) and lower MACE rate (39% versus 56%, p<0.001) compared to patients with BMS. In the propensity-matched 1,868 patients reflecting the clinical propensity and PDC of DAPT, MACE rate was lower with DES than BMS (46% versus 54%, HR=0.80, 95% CI: 0.70–0.91, p<0.001). Good compliant patients with PDC ≥80% showed a much lower MACE rate compared to patients with PDC <80% regardless of DES or BMS (HR=0.36, 95% CI: 0.30-0.44; HR=0.40, 95% CI: 0.33-0.48, p<0.001, all).

Conclusions: The clinical outcome of DES was better than BMS even after reflecting baseline clinical profiles and medication adherence to DAPT. In both DES and BMS, good medication adherence to DAPT was associated with better clinical outcome.

Stable CAD - Diabetes, Stents and scaffolds - Tools, devices and techniques

Prognosis associated with the use of overlapping stents and very long stents in the diabetic population with diffuse coronary artery disease. A real-life study

ABELLÁN-HUERTA José [(1)], NEGREIRA-CAAMAÑO Martín [(1)], ABELLÁN-HUERTA José [(1)], JURADO-ROMÁN Alfonso [(2)], SÁNCHEZ-PEREZ Ignacio [(1)], LOZANO-RUIZ-POVEDA Fernando [(1)], LÓPEZ-LLUVA María Thiscal [(1)], PÉREZ-DÍAZ Pedro [(1)], MORÓN-ALGUACIL Alfonso [(1)]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain; (2) University Hospital La Paz, Madrid, Spain

Aims: Both the stent length and the need for stent overlap have been considered predictors of adverse events in the percutaneous treatment (PCI) of diffuse coronary artery disease. However, there is no evidence about the prognosis associated to the use of very long stents (VLS, ≥40 mm) and overlapping stents (OS) in the diabetic group with a recognised worse prognosis after PCI. Our objective was to compare the clinical results of the use of VLS and OS in a cohort of diabetic patients.

Methods and results: A total of 327 lesions in 292 consecutive diabetic patients were included (73.5% male, 68.6±11 years), treated with the implantation of VLS (112) or ≥2 OS (215) between March 2014 and March 2019. We analysed the procedural characteristics and the incidence of the combined endpoint (cardiovascular death [CD], non-fatal myocardial infarction [M]), need for target lesion revascularisation [TLR] or stent thrombosis [ST]) after a mean follow-up of 21.6 months. 19.3% of the patients reported chronic kidney disease and 35.5% were smokers. Clinical presentation was acute coronary syndrome in the 56.6% of cases and stable coronary artery disease in the 43.4%. 80.3% of the stents were drug-eluting type. 27% of lesions were bifurcations and the SYNTAX-score was 24.23±14.3. Minimum diameter was 2.9±1.8 mm. The most frequent treated vessel was the left anterior descending artery (45%). Procedures with OS showed a longer total stent length (59±20.8 vs 45.8±5.1 mm; p<0.01), needed a longer fluoroscopy time (21±11 vs 16±8 min; p<0.01) and higher contrast volume (311 vs 285 cc; p=0.02) than those with VLS. The combined endpoint rate was 11.5%, being similar between groups (p=0.11). Independent event rate was: CD 7%; MI: 4.3%; TLR: 4%; ST: 0,9%. The TLR rate was inferior in patients treated with VLS (0.1% vs 6.2%; p=0.03), whereas no differences were observed in the rate of CD (7.2% vs 7.2%; p=0.98), MI (5.3% vs 2.7%; p=0.39) and ST (0.1% vs 0.1%; p>0.99) between groups.

Conclusions: The use of very long stents simplified the PCI of the diffuse coronary disease usually seen in diabetic patients, reducing the fluoroscopy time and the number of implanted stents, with very favourable results in comparison with the use of overlapping stents.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Comparison between the use of very long stents and overlapping stents for the treatment of diffuse coronary artery disease. A real-life registry

ABELLÁN-HUERTA José [1], ABELLÁN-HUERTA José [1], JURADO-ROMÁN Alfonso [1,2], NEGREIRA-CAAMAÑO Martín [1], LÓPEZ-LLUVA María Thiscal [1], LOZANO-RUIZ-POVEDA Fernando [1], SÁNCHEZ-PÉREZ Ignacio [1], PÉREZ-DÍAZ Pedro [1], MARTÍNEZ-DEL-RÍO Jorge [1], PIQUERAS-FLORES Jesús [1]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain; (2) University Hospital La Paz, Madrid, Spain

Aims: Both the stent length and the need for stent overlap have been considered predictors of adverse events in the percutaneous treatment of diffuse coronary artery disease. The evidence about the prognosis associated with the use of very long stents (VLS, ≥40 mm) versus overlapping stents (OS) is limited. Our objective was to compare the clinical outcomes of the use of VLS and OS in the real clinical practice.

Methods and results: A total of 846 consecutive percutaneous coronary interventions (PCI) were included between March 2014 and March 2019 (78% males, 66.8±12 years), treated with VLS (307 cases) or ≥2 OS (539 cases). We analysed the procedural characteristics and the incidence of the combined endpoint (cardiovascular death [CD], non-fatal myocardial infarction [M]), need for target lesion revascularisation [TLR] or stent thrombosis [ST]) after a mean follow-up of 21 months. The clinical scenario was acute coronary syndrome in 59.9% of the cases and stable coronary artery disease in 40.1%. 42.1% were smokers and 39.7% diabetics. Drug-eluting stents were used in 75.6% and bare-metal stents in 13.8%. Total stent length was 54.3±18.8 mm. The most frequent treated vessel was the left anterior descending artery (41.9%) followed by the right coronary artery (37%). Procedures with VLS needed less contrast volume (280±128 vs 315±122 cc; p<0.01) and shorter fluoroscopy time (16±9 vs 22±14 min; p<0.01) than those with OS. The combined endpoint rate was 11.5%, being comparable between groups (p=0.11). Independent event rate was: CD 5.7%; MI: 2.7%; TLR: 3.9%; ST: 0.9%. There was no difference between groups in the rate of CD (4.3 vs 6.5%; p=0.21), MI (1.9 vs 3.2%; p=0.32), and ST (0.9 vs 0.9%; p=0.99), whereas the TLR rate was inferior in the VLS cohort (1% vs 5.8%; p<0.01). After adjusting the variables unequally distributed between both groups, no significant differences were found in the rate of any adverse event.

Conclusions: In our sample, the use of VLS was associated with shorter procedure times and the need for less contrast volume, reporting favourable outcomes during the follow-up, constituting an effective and safe alternative to OS.

Other Coronary interventions - Other

Comparison of the age, creatinine, and ejection fraction (ACEF) with PARIS score to predict cardiovascular events in patients presenting with ACS: insights from the START-Antiplatelet registry

SCALAMOGNA Maria [1], SCALAMOGNA Maria [1], DI SERAFINO Luigi [1], CALABRÒ Paolo [2], GRESELE Paolo [2,3], PALARETI Gualtiero [3,4], PATTI Giuseppe [5], PENGO Vittorio [6], PIGNATELLI Pasquale [7], CIRILLO Plinio [1], MARCUCCI Rossella [8]

(1) Division of Cardiology, Department of Advanced Biomedical Sciences, University of Naples Federico II, Naples, Italy, Naples, Italy; (2) Department of Cardio-Thoracic and Respiratory Sciences, Universita` degli Studi della Campania "Luigi Vanvitelli", Caserta, Italy, Caserta, Italy; (3) Section of Internal and Cardiovascular Medicine, Department of Medicine, University of Perugia, Perugia, Italy; (4) Arianna Anticoagulazione Foundation, Bologna, Rome, Italy, Bologna, Italy; (5) University of Eastern Piedmont, Novara, Italy., Rome, Italy; (6) Department of Cardiac, Thoracic, and Vascular Sciences, Padua University Hospital, Padua, Italy, Padua, Italy; (7) Department of Internal Medicine and Medical Specialities, University of Rome "La Sapienza", Roma, Italy, Rome, Italy; (8) Department of Experimental and Clinical Medicine, Center for Atherothrombotic Disease, University of Florence, Florence, Florence, Italy

Aims: A wide variety of risk scores (RS) have been developed to predict long-term clinical outcome after the acute coronary syndrome (ACS). However, some of these RS are difficult to calculate and others need many items such as the DAPT of the PARIS score. ACEF score is a simple-to-calculate RS composed of only three items: age, creatinine and ejection fraction. Thus, the aim of the present study was to compare the ACEF and PARIS scores to stratify the risk of developing future events in ACS patients treated with coronary revascularisation or medical therapy and enrolled in the START-Antiplatelet registry.

Methods and results: From January 2014 to December 2016, a total of 1,171 consecutive patients presenting with ACS who completed 1-year follow-up were enrolled. In a stratified approach, patients were divided into tertiles according to the ACEF score and into three risk categories according to the PARIS score (low, intermediate or high). The primary end point was major adverse cardiac and cerebrovascular events (MACCEs), a composite of death, myocardial infarction, stroke or target vessel revascularisation. The coprimary end point was net adverse cardiac and cerebrovascular events (NACEs), based on MACCE plus major bleeding. At Cox analysis, the incidence of MACCE at 1-year follow-up was significantly higher in patients with the highest ACEF score value (respectively, 14 [3%] vs 26 [7%] vs 58 [15%], HR:2.20 [1.68-2.90], p<0.001) and in the high-risk patients according to the PARIS score (respectively, 3 [3%] vs 44 [6%] vs 51 [16%], HR:4.58 [2.78-7.52], p<0.001). This difference remained even after the adjustment of the Cox analysis for confounding variables (ACEF score: HR:1.75 [1.25-2.43], p=0.001, PARIS score: 2.58 [3.75-5.54], p=0.001). Equally, the incidence of NACE was significantly higher in patients with the highest ACEF score value (respectively, 16 [6%] vs 28 [10%] vs 63 [21%], HR: 1.68[1.35-2.09], p<0.001) and in the high-risk patients according to the PARIS score (respectively, 3 (5%] vs 49 (9%] vs 55[24%], HR:1.86 [1.14-3.02], p=0.01). This difference remained even after the adjustment of the Cox analysis for confounding variables (ACEF score: HR:1.61 [1.16-2.24], p=0.005, PARIS score: 2.25 [1.56-3.23], p<0.001). A moderate accuracy to predict both MACCE and NACE was found for both the ACEF (respectively, AUC:0.71[0.65-0.76], p<0.001 and AUC: 0.70[0.64-0.75], p<0.001) and the PARIS scores (respectively, AUC:0.65[0.59-0.71], p<0.001 and AUC: 0.65[0.59-0.71], p<0.001).

Conclusions: The "simple to calculate" ACEF score was equally able as the PARIS score to predict both MACCE and NACE at one-year follow-up in a real-world scenario of all-comerspatients presenting with ACS.

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Stents and scaffolds - Invasive imaging and functional assessment

Comparison of malapposed struts by means of OCT between the index PCI and six-month follow-up among three different DES

GIGLIOLI Cristina [(1)], GIGLIOLI Cristina [(1)], FORMENTINI Chiara [(1)], ROMANO Salvatore Mario [(1)], CHIOSTRI Marco [(1)], MARCHIONNI Niccolò [(1)], CECCHI Emanuele [(1)]

(1) Azienda Ospedaliero-Universitaria Careggi, Metropolitan City of Florence, Italy

Aims: In the CREBX-OCT study we compared uncovered, protruding or malapposed struts among 3 DES: Cre8, BioMatrix and XIENCE, using OCT at 6 months in 60 patients and found no uncovered struts in the 3 groups with Cre8 and BioMatrix showing a greater proportion of protruding and malapposed struts. Aims of this study were to identify the presence of malapposed struts at OCT performed at the index procedure to evaluate if malapposition observed at 6 months was late and acquired or it was pre-existing and to analyse the difference in lumen areas between the index procedure and 6 months among the 3 groups.

Methods and results: In the present sub-analysis of CREBX-OCT study, we analysed OCT data recorded after the index procedure and compared them with those recorded at 6-month follow-up in 37/60 enrolled patients. OCT analysis was performed in the 3 groups of patients (Cre8: 14; BioMatrix: 11; XIENCE: 12) evaluating 524 cross-section areas (Cre8: 191; BioMatrix: 156; XIENCE: 177) and 5,514 struts (Cre8: 2079; BioMatrix: 1615; XIENCE: 1820). No significant difference was observed in OCT qualitative analysis (plaque type, homogeneous struts distribution) and in the number of malapposed struts among the 3 groups. Comparing acute with 6-month OCT data we found any uncovered strut and no significant difference in lumen areas in all 3 groups. A significant difference was observed between the percentage of malapposed struts at the index procedure vs 6-month follow-up in BioMatrix (0.6±1.8 vs 1.7±2.3; p=0.024) and Cre8 (0.6±1.5 vs 3.5±5.5; p=0.023) but not in XIENCE group (0.6±1.5 vs 0.3±0.9; p=0.166).

Conclusions: The 3 DES were similarly effective in permitting struts coverage without a significant late lumen loss, but their behaviour was different in relation to malapposition that increased in BioMatrix and Cre8 but not in XIENCE group probably for biomechanical reasons due to the structural differences among the three stents. Therefore, in our study population, malapposition observed at 6-month follow-up was mainly acquired.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Clinical prognosis associated with the use of overlapping stents with homogenous vs heterogeneous pharmacological characteristics for the treatment of diffuse coronary artery disease

ABELLÁN HUERTA José [1], ABELLÁN-HUERTA José [1], JURADO-ROMÁN Alfonso [2], LOZANO-RUIZ-POVEDA Fernando [1], SÁNCHEZ-PÉREZ Ignacio [1], LÓPEZ-LLUVA María Thiscal [1], NEGREIRA-CAAMAÑO Martín [1], PÉREZ-DÍAZ Pedro [1], FRÍAS-GARCÍA Raquel [1]

(1) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain; (2) University Hospital La Paz, Madrid, Spain

Aims: Overlapping stents (OS) are a common technique in percutaneous coronary intervention (PCI). There are insufficient data on the prognostic impact of overlapping multiple platforms with different pharmacological characteristics. Our objective was to compare the outcomes of the PCI with OS according to their pharmacological characteristics.

Methods and results: All PCI with OS performed from May 2014 to March 2019 were included. Two groups were created according to whether the stents release the same or no drug (homogeneous: (HO]) or different (heterogeneous: [HE]). We compared the incidence of the combined endpoint (cardiac death, non-fatal myocardial infarction, need for target lesion revascularisation [TLR] or stent thrombosis) after a median follow-up of 21 months. A total of 502 lesions with OS (HO: 275; HE: 227) were included (77.6% male, 67.6±11.8 years). Clinical presentation was stable coronary artery disease in 46.8%. 88.4% of the lesions received drug-eluting stents. The SYNTAX score was 23.5±13.3 (p=0.62). The number OS was 2.2±0.5 (HE:2.4±0.7 vs HO:2.1±0.4; p<0.01) and the overlapping length was 59.2±21.9 mm (HE:64.7±25 vs HO:55.9±17.8 mm; p<0.01). The combined endpoint was 11.2% and similar between groups (HE:8.4% vs HO: 13.5%; p=0.07). TLR was inferior in the HE group (HE: 2.7%; HO: 7%; p=0.03). In the multivariate analysis, the OS with homogeneous-drug devices proved to be an independent predictor of a higher rate of TLR.

Conclusions: In our study, PCI with OS with homogeneous pharmacological characteristics was associated with a higher rate of TLR in comparison with the PCI with OS with heterogeneous pharmacological characteristics.

Stable CAD - Vascular access and bleeding, Other Coronary interventions - Other

Coronary angiography using 4Fr catheters: a randomised comparison with 5Fr catheters

KINTIS Konstantinos [1], KINTIS Konstantinos [1], MANTIS Christos [1], SOUSONIS Vasilis [1], KATSAROS Lampros [1], PAPADAKIS EMMANOUEL [1], ANTONATOS Dionisis [1], KOUTOUZIS Michael [2], POULIANITOU Areti [1], KIRIAKOPOULOS Vasilis [1], PATSILINAKOS Sotiris [1]

(1) Konstantopoulio General Hospital, Nea Ionia, Greece; (2) Erythros Stavros HOSPITAL, Athens, Greece

Aims: The use of small catheters for coronary angiography can reduce the risk of vascular complications, but data on radiation exposure comparing the use of 4 French (Fr) diagnostic catheters with larger sized catheters are lacking. The aim of the present study was to evaluate the safety, feasibility, and radiation exposure using 4 Fr diagnostic catheters through radial approach.

Methods and results: 120 consecutive patients without previous history of CABG (70 males, aged 66 years) underwent transradial coronary angiography. 60 were performed using 4 Fr diagnostic catheters and 60 were performed using 5 Fr diagnostic catheters. The primary endpoints of the study were procedural success, fluoroscopy time (FT), dose-area product (DAP), air kerma (AK), number of catheters, and amount of contrast agent. Independent-samples t-test indicated that the group of 5 Fr, compared to the group of 4 Fr was characterised by increased FT (3.36±1.10 versus 2.27±0.89 minutes, $p<0.001$), DAP (30205±9423 versus 22367±5761 mGycm^2, $p<0.001$), AK (443±63 versus 329±51 mGy, $p<0.001$), and amount of contrast agent (25±3 versus 20±2 ml, $p<0.05$). There were no significant differences in procedural success and number of catheters between the groups. Multiple regression analysis revealed that the size of diagnostic catheter and weight were independently associated with DAP ($R2 = 0.44$, $p<0.001$) and AK ($R2 = 0.53$, $p<0.001$).

Conclusions: 4 Fr diagnostic catheters are associated with decreased radiation exposure in patients undergoing transradial diagnostic coronary angiography, as reflected by decreased DAP, AK, and FT values. These findings imply that catheter size should be taken into account to help minimise radiation dose.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Clinical outcomes of guide extension catheter use in proximal vs distal coronary lesions

SIMPSON Brian [1], THORP Andrew [1], DESAI Chirag [1], WILSON Jeffrey [1], GEDELA Maheedhar [1], SINGH Aditya [1], VARGA Zoltan [1], PETRASKO Phillip [1], KREMER Andrew [1], STYS Adam [1], STYS Tom [1]

(1) Sanford USD Medical Center and Hospital, SD, USA

Aims: Guide extension catheter devices allow for increased support, distal delivery of intracoronary devices, and selective delivery of contrast. This study aims to evaluate the difference in clinical outcomes when using guide extension catheters in proximal and ostial as compared with distal epicardial coronary lesions.

Methods and results: Data were retrospectively analysed for all percutaneous coronary interventions (PCI) performed at a single high-volume academic institution between January 2011 and June 2019. Guide extension catheters were used according to provider preference. Cases were selected that involved a single-segment lesion of an ostial, proximal, or distal epicardial artery. Procedural data regarding total contrast use, radiation exposure, and procedure duration were collected. Adverse cardiac events were defined as the occurrence of myocardial infarction (MI), coronary artery bypass grafting (CABG), or death at 30 and 365 days post-PCI. Cases were performed using automated contrast delivery systems and either single or bi-plane fluoroscopic systems, according to provider judgement. Comparisons were made by linear regression, and a p-value of <0.05 was considered significant. A total of 3,153 single lesion PCIs were identified, 914 of which used a guide extension catheter. 536 ostial or proximal and 378 distal epicardial artery lesions were intervened on. Cases that utilised guide extension catheters had longer procedural duration, higher radiation, and more contrast as compared to cases that did not. Compared to guide catheter assisted distal lesions, ostial and proximal lesion cases utilised more contrast (105.84 mL SD [76.67] vs 95.66 mL SD [67.10], p=0.018), more radiation (1842.85 mGy SD [1947.56] vs 1504.19 mGy SD [1451.29], p=0.004), and had longer procedure duration (51.66 min SD [32.88] vs 44.84 [25.87], p<0.001). For cases that utilised guide extension catheters, there were no statistically significant differences in the rate of CABG, death, or the composite of CABG, death, and MI at 30 days or 1 year, between distal and proximal cases. However, among patients undergoing guide extension catheter procedure, there was a higher rate of MI at 1 year among ostial or proximal lesions than for distal (5.0% vs 2.4%, p=0.044). There was also a higher rate of MI at 1 year for proximal and ostial cases that used guide extension catheters than those cases that did not (5% vs 1.9%, p<0.001).

Conclusions: In this retrospective cohort analysis, we found that patients undergoing PCI with guide extension catheter for a single lesion were exposed to higher radiation, contrast, and procedural duration, with a higher rate of MI at 1 year. Proximal and ostial lesions that received guide extension catheters also had a surprisingly higher rate of MI at 1 year. These findings likely reflect the high complexity of the patients for which guide extension catheters are used in proximal lesions, and further investigation is warranted.

Other Coronary interventions - Other

Radial artery compression device for patent haemostasis to reduce the incidence of radial artery occlusion after transradial PCI: a comparison between TR Band and RadiStop

GRANATA Riccardo [(1)], DI SERAFINO Luigi [(1)], GRANATA Riccardo [(1)], PETITTO Marta [(1)], SERINO Federica [(1)], CAMMAROTA Fabiola [(1)], GARIFALOS Dimitri [(1)], FERRARA Barbara [(1)], CIRILLO Plinio [(1)], ESPOSITO Giovanni [(1)]

(1) University of Naples Federico II, Metropolitan City of Naples, Italy

Aims: Although usually asymptomatic, radial artery occlusion (RAO) is an infrequent but discouraging complication of transradial access. Although a "patent haemostasis" (PH) has been shown to significantly reduce the incidence of RAO, it is not always possible to achieve. The preprocedural reverse Barbeau test (RBT) has been shown to facilitate a PH during compression with the TR Band (TB). Thus, the aim of the present study was to compare the RBT-guided TB-mediated radial artery compression with RadiStop (RS) to perform a PH; in addition, the incidence of RAO was also evaluated at 24 hours.

Methods and results: Two hundred and four consecutive patients undergoing transradial catheterisation were prospectively enrolled and randomised to group A (RBT-guided TB-mediated compression, n=114) or group B (RadiStop-mediated compression, n=90). Randomisation was performed only at the end of the procedure. However, a preprocedural RBT was performed in all patients in order to evaluate the exact amount of air to be eventually inflated in the TB after the procedure in order to obtain a PH. No differences were noted between the two groups of patients in terms of both clinical and procedural characteristics. During radial compression, a PH was significantly more often possible in patients enrolled in the group A as compared with group B (respectively, 89 (78%) vs 49 (54%), p<0.001). No difference in bleedings was observed (respectively, 5 (4%) vs 3 (3%), p=1.00). At 24 hours, RAO occurred significantly more often in patients enrolled in the group B as compared with group A (respectively, 16 (18%) vs 7 (6%), p=0.01).

Conclusions: RBT-guided TB-mediated radial artery compression was more effective in performing a correct patent haemostasis as compared with RadiStop, thereby significantly reducing the incidence of RAO at 24 hours.

Stable CAD - Invasive imaging and functional assessment

Comparison of morphological characteristics of stable coronary atherosclerotic plaques leading to revascularisation compared to those that remained quiescent

RAMASAMY Anantharaman [1], RAMASAMY Anantharaman [1], BAJAJ Retesh [1], JAIN Ajay [1], OZKOR Muhiddin [1], KOH Tat [1], SAFI Hannah [1], TORII Ryo [2], KILIC Yakup [1], MOON James [1], AMERSEY Rajiv [1], PUGLIESE Francesca [1], MATHUR Anthony [1], BAUMBACH Andreas [1], BOURANTAS Christos [1]

(1) St Bartholomew's Hospital, London, United Kingdom; (2) University College London, London, United Kingdom

Aims: The morphological characteristics of culprit lesions and non-culprit lesions in ACS have been well described. However, the differences between symptom-producing and asymptomatic lesions in chronic coronary syndrome have not been studied. We aim to describe the morphological characteristics of coronary atherosclerotic plaques that led to revascularisation compared to those that remained quiescent.

Methods and results: Forty-nine patients (138 vessels) participating in the "Evaluation of CTCA in assessing plaque pathology and physiology study" (NCT03556644) who had NIRS-IVUS imaging of all the epicardial coronary arteries and their major side branches before revascularisation were included in the present analysis. NIRS-IVUS analysis was performed at every end-diastolic frame (0.4 mm) detected using a previously described automated methodology. The lumen and external elastic membrane were manually detected and the plaque burden (PB) was estimated. A lesion was defined as a segment of 3 consecutive frames with PB >40%. Fibroatheromas (FA) were defined as plaques with PB>67% and a maximum 2 mm-lipid core burden index (maxLBCI2mm) >178. Revascularisation was performed in lesions with severe stenosis (diameter stenosis >90%) or moderate stenosis with evidence of ischaemia on invasive or non-invasive imaging tests. Thirty-six patients (53 plaques) underwent PCI - none of the patients were referred for surgical revascularisation. There were no differences in the baseline demographics between the patients who underwent revascularisation compared to those who did not have revascularisation (age: 61.61±7.98 vs 62.39±7.75 years, p=0.719; incidence of diabetes mellitus: 31.4% vs 31.9%, p=0.786, hypertension: 62.9% vs 51.1%, p=0.413, hyperlipidaemia: 71.4% vs 70.2%, p=0.535, previous ACS 20.0% vs 12.8%, p=0.183 and previous PCI 34.3% vs 23.4%, p=0.263). Revascularised plaques were more often located in the right coronary artery (RCA) compared to the left anterior descending artery (LAD) and left circumflex artery (LCx) – [RCA: 0.93 vs LAD: 0.53 vs LCx:0.13 plaques per vessel, p<0.001]. Sub-analysis of the revascularised plaques at the coronary segment level showed that these plaques were located more frequently in the proximal and mid segment of the epicardial vessels compared to the distal segment or the major side branches (proximal segment: 41.9%, mid segment: 43.0%, distal segment: 10.5% and major side branches: 4.7%, p=0.035). Lesions that were revascularised had a smaller minimum lumen area (2.93±1.72 vs 5.18±3.17 mm^2, p<0.001) longer lesion length (24.21±18.09 vs 13.13± 13.14 mm, p<0.001) and increased PB compared to non-revascularised plaques (66.54 vs 55.87%, p<0.001). Moreover, the revascularised plaques had a higher maxLCBI2mm (263.5 vs 142.8, p<0.001) and were more likely to have an FA phenotype than those that remained quiescent (54.7% vs 14.0%, p<0.001). Conversely, there were no differences in the reference lumen area (9.97±3.54 vs 9.48± 3.82 mm^2, p=0.412), external elastic membrane area (14.03± 4.86 vs 13.19±5.44 mm^2, p=0.307) and remodelling index (1.03±0.50 vs 0.95±0.27, p=0.593) between the two groups.

Conclusions: Similar to reports in patients with ACS, significant lesions (symptom-producing or ischaemic lesions) in patients with chronic coronary syndrome are frequently located in the proximal and mid segment of the coronary arteries. These lesions often have an FA phenotype, a smaller lumen area and increased PB compared to those that remained quiescent.

Stable CAD - Invasive imaging and functional assessment

Coronary plaque distribution in chronic coronary syndrome patients: a comprehensive three-vessel near-infrared spectroscopy–intravascular imaging (NIRS-IVUS) study

RAMASAMY Anantharaman [(1)], RAMASAMY Anantharaman [(1)], BAJAJ Retesh [(1)], KILIC Yakup [(1)], OZKOR Muhiddin [(1)], JAIN Ajay [(1)], TUFARO Vincenzo [(1)], TORII Ryo [(1)], AMERSEY Rajiv [(1)], PUGLIESE Francesca [(1)], DEANER Andrew [(1)], WESTWOOD Mark [(1)], MOON James [(1)], MATHUR Anthony [(1)], BAUMBACH Andreas [(1)], BOURANTAS Christos [(1)]

(1) St Bartholomew's Hospital, London, United Kingdom

Aims: The longitudinal distribution of atherosclerotic plaques and the morphological characteristics of culprit and non-culprit lesions in acute coronary syndrome have been widely described. However, little information is available regarding the distribution and plaque composition in chronic coronary syndrome patients. We aim to prospectively characterise plaque distribution and morphology at a vessel and coronary segment level in patients with chronic coronary syndrome undergoing 3-vessel near-infrared spectroscopy-IVUS (NIRS-IVUS) imaging.

Methods and results: Patients with chronic coronary syndrome participating in the "Evaluation of CTCA in assessing plaque pathology and physiology study" (NCT03556644) who had NIRS-IVUS imaging of the epicardial coronary arteries and their major side branches were included in the present analysis. In total, 138 vessels (588,135 frames with a length of studied segments of 9,802 mm) from 49 patients were included in this analysis. NIRS-IVUS segmentation was performed at every end-diastolic frame (0.4 mm interval) that was identified using an automated methodology. In each frame, the lumen and external elastic membrane borders were annotated and the plaque burden (PB) was estimated. A lesion was defined as a segment with a minimum PB >40% over 3 consecutive frames. Stented segments within a vessel were excluded from the analysis. Fibroatheromas (FA) were characterised as lesions with a PB >67% and a maximum 2 mm-lipid core burden index (maxLBCI2mm) >178. Segment level analysis was performed according to the American Heart Association classification. The mean age of the studied patients was 62.41±7.81 years old, 34.7% of the patients were diabetic, 53.1% had hypertension, 71.4% suffered from hyperlipidaemia, 14.3% of them suffered previous acute coronary syndrome and 24.5% of them had a previous PCI. There were 224 plaques identified (4.6 plaques per patient), of which 53 plaques (23.6%) were classified as FA. There was no significant difference in the distribution of the plaques in the major epicardial vessels (2.03, 1.79 and 2.14 plaques per vessel in the left anterior descending [LAD], left circumflex [LCx] and right coronary artery [RCA], respectively, p=0.327). Similarly, the distribution of FA was statistically insignificant between vessels (0.51, 0.34 and 0.57 FA in the LAD, LCx and RCA respectively, p=0.193). At a segment level analysis, there were more plaques seen in the mid segment rather than the proximal or distal segments (left main stem [LMS]: 0.45, proximal segment: 0.54, mid segment: 0.83 and distal segment: 0.55 plaques per vessel, p<0.001). However, the incidence of FA was similar in the proximal and mid segments but significantly lower in the distal segments (LMS: 0.28, proximal segment: 0.28, mid segment: 0.28 and distal segment: 0.08, p=0.011).

Conclusions: Chronic coronary syndrome patients have multiple atherosclerotic lesions that are equally distributed in the major epicardial coronary arteries. A heterogeneous lesion distribution was noted with an increased number of lesions in the mid vessel. However, FA are more often seen in the proximal and mid vessel – similar to the previous reports in patients with ACS.

Stable CAD - Vascular access and bleeding

Distal left radial access – only good alternative in limited group of patients

BAKRACHESKI Nikola [1], BAKRACHESKI Nikola [1], MOJSOVSKA Violeta [1], KOVACESKA-BASHUROSKA Elena [1], MANCHEVSKI Dejan [1], ZIMBOVA Marija [1], VASILEVA-KOLEVSKI Katerina [1]

(1) Cardiology Center St. Stephen, Sveti Stefan, The former Yugoslav Republic of Macedonia

Aims: To evaluate the potential benefits and difficulties of distal left radial access compared to standard right radial artery access in patients undergoing coronary angiography.

Methods and results: We enrolled 174 patients undergoing coronary angiography in two groups: group A with right radial artery access (N=87 patients) and group B with distal left radial artery access (N= 87 patients). Both groups were evaluated on: puncture success rate, puncture time, fluoroscopy time, total radiation dose, contrast medium used and radial patency rate confirmed by ultrasound after 30 days. Puncture success rate was significantly higher in standard right radial artery access compared to distal left radial artery access (97% vs 60% $p<0.01$), and right radial artery access group has significantly shorter puncture time (2±2 min vs 4±2min $p<0.01$) and total procedural time (25.5± 10 min vs 36± 10 min $p<0.01$). The total radiation dose was significantly lower in the right radial artery access group (33±37 µSv vs 44±32 µSv $p<0.01$) and no significant differences in fluoroscopy time (349±231s vs 370±246 $p<0.01$) and contrast medium used (92.5±35.3 ml vs 93.2±32.5 ml $p<0.01$) were observed. Radial patency rate followed by ultrasound at day 30 was insignificantly higher in the distal left radial artery access group (1.9% vs 3.6% $p<0.05$). Most of the patients with right radial access occlusion were with repeated PCI. We also conducted a questionnaire among four senior interventional cardiologist with similar right radial artery access experience and distal left radial artery access experience in terms of ergonomic comfort, procedural difficulties (radial artery puncture, cannulation of left coronary artery in tall patients) and assessment of image quality in LAO/CAU view. All four operators confirmed that distal left radial artery access is ergonomically uncomfortable. Using distal left radial artery access they experienced some technical difficulties cannulating left coronary artery in tall patients and puncture difficulties as well, and all of them were agreed that image quality at LAO/CAU view has poor quality due to the position of the left forearm in case of distal left radial artery access. Operators noted that distal left radial artery access of choice in LIMA-LAD graft cannulation, anatomical deviation of innominate artery and right radial artery occlusion.

Conclusions: Distal left radial artery access takes more time, fails more often, has left coronary artery cannulation difficulties in tall patients, and it is less comfortable for the operator. It may be good access alternative for the group of patients with occluded right radial artery, anatomical anomaly of innominate artery and angiography of coronary bypass grafts.

Euro2OA-POS193
Posters

Stents and scaffolds - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Single-centre experience with STENTYS Xposition S – angiographic and clinical results

PEREZ GUERRERO Ainhoa [1], PEREZ GUERRERO Ainhoa [1], FUERTES FERRE Georgina [1], GALACHE OSUNA Gabriel [1], SANCHEZ-RUBIO Juan [1], CABALLERO JAMBRINA Isabel [1], FERRER GRACIA Maria Cruz [1], ORTAS NADAL Maria del Rosario [1], DIARTE DE MIGUEL Jose Antonio [1]

(1) Hospital Universitario Miguel Servet, Zaragoza, Spain

Aims: The STENTYS Xposition S Self-Apposing ® stent (STENTYS S.A, Paris, France) is the only self-apposing sirolimus-eluting stent in the market. The characteristics of this stent make it useful for the treatment of challenging lesions with vessel diameter variance, ectasia, high thrombus burden, bifurcations including left main or vein grafts. Our objective was to evaluate the efficacy and safety of this stent in our daily clinical practice.

Methods and results: From January 2018 to September 2019, a total of 62 lesions in 50 patients were treated in our tertiary care centre. All coronary lesions were quantified by quantitative coronary angiography (QCA). In addition, intracoronary ultrasound (IVUS) was performed in 15 patients (30%) and in one patient optical coherence tomography (OCT). The median age of the patients was 66 years (49-92). Eighty eight per cent of patients were male. Most frequent clinical presentation was non-ST-elevation acute coronary syndrome (NSTEMI) in 23 patients (46%), followed by STEMI in 24 patients (46%) and stable angina in 5 patients (10%). Ectasia and significant vessel diameter variance was the most common scenario in 72.6% of cases and bifurcation in the remaining 27.4% (two of them in left main coronary). Most frequent type of lesion treated according to the ACC/AHA classification was B1 (38.7%), there was high thrombus load in eight lesions and the right coronary was the most treated vessel, in 33 patients (53.2%). Predilatation was performed in 32 lesions (51.6%) and post-dilatation in 37 (59.7%). Angiographic success was achieved in all patients except one; in which there was a failure of implantation in a severely calcified left main coronary bifurcation. In 48 patients (96%), dual antiplatelet therapy was prescribed for 12 months. With a median follow-up of 83.5 days (31-189), one patient presented non-infarct-related lesion three months after PCI. An old patient with low ejection fraction died due to cardiac failure, two patients died of non-cardiac cause, one of them at five days due to septic shock, and another at four months due to lung carcinoma. There were no cases of definitive stent thrombosis (ST) or target lesion revascularisation (TLR). No bleeding was observed during the follow-up.

Conclusions: In conclusion, the Self-Apposing STENTYS Xposition S showed good angiographic and clinical outcomes in a real life experience.

CTO - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Cornwall CTO angioplasty hybrid approach (CHAP) programme: transradial approach for CTO PCI

MENGI Siddhartha [(1)], MENGI Siddhartha [(1)], UNGVARI Tamas [(1)], LIVINGSTONE William [(1)]

(1) Royal Cornwall Hospital, Truro, United Kingdom

Aims: We sought to evaluate the safety, efficacy, procedural success and mortality of performing percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) with hybrid approach predominantly via transradial access over 2 years.

Methods and results: Retrospective study. Data were collected from individual case note review and e-records tracking for 70 patients who underwent CTO PCI between January 2017 and January 2019 at a non-surgical centre in U.K. Multiple variables were recorded including access site, lesion complexity using J-CTO (Japanese multicentre CTO Registry) score, successful outcome defined by first or overall attempt with TIMI 3 flow across the lesion, periprocedural/in-hospital complications and endpoints including 30-day major adverse cardiovascular events (stroke/myocardial infarction(MI)/unplanned target vessel revascularisation (TVR)/vascular complications /death). Mean age was 69.2 years, and 83% were men, 20% had prior coronary artery bypass grafting (CABG) and 31% prior PCI. The average J-CTO score was 1.92. Transradial access used in 85.7%, transradio-femoral in 11.4%, transfemoral and transbrachial in 1.4% each. 100% of cases were performed using dual catheter angiography. The final successful strategy to cross the lesion was antegrade wire escalation (71.45%), followed by antegrade dissection re-entry (15.7%), retrograde wire escalation (8.5%) and retrograde dissection re-entry (4.35%). The overall success rate and first attempt success rate was 92.4% and 84.2%, respectively. 4% of cases had periprocedural mechanical circulatory support. Complication of coronary perforation in 1 case (1.4%) and in-hospital mortality in 1 case (1.4%). No acute vascular complications. 30 days MACE of 2.8% as 2 patients required unplanned TVR in the form of CABG. At 30 days, no late vascular complications at the access site, no MI/stroke. 97% of patients were angina free post CTO-PCI at 30 days.

Conclusions: Overall, transradial approach is safe and efficient to perform CTO PCI with high success rate, low procedural complications and acceptable MACE.

STEMI - Adjunctive pharmacotherapy

Importance of organised STEMI network for the improvement of contact-to-wire time and 30-day mortality rate in STEMI patients

BAKRACHESKI Nikola [(1)], BAKRACHESKI Nikola [(1)], MOJSOVSKA Violeta [(1)], KOVACESKA-BASHUROSKA Elena [(1)]

(1) Cardiology Center St. Stephen, Sveti Stefan, The former Yugoslav Republic of Macedonia

Aims: To demonstrate the benefit of systematically organised STEMI network in the management of patients with ST-elevation myocardial infarction by shortening pre-hospital delay and inter-hospital transfer time.

Methods and results: We conducted a registry for evaluation of the contact-to-wire time and mortality rate in STEMI patients treated in our centre within the regional STEMI network that involve: one 24/7 PCI centre, six non-PCI centres and six separate emergency medical services in the Southwestern part of the country with the total population of 350,000 inhabitants. We compare contact-to-wire time and 30-day mortality rate in two separate periods of time: first, before the regional STEMI network was organised and second, after the systematically organised STEMI network was established. In the first period of time we evaluated two groups of patients: Group 1A included 322 STEMI patients (37.88%) treated with PPCI with contact-to-wire time <90 minutes, and Group 1B included 528 STEMI patients (62.12%) with contact-to-wire time >90 minutes. The mortality rate was significantly lower in patients with contact-to-wire time <90minute (2.5% vs 7.4% p<0.05). In the second followed period of time after we established systematically organised STEMI network, we also evaluated two groups of patients: Group 2A included 873 patients (48.99%) with contact-to-wire time <90 min, and Group 2B included 909 patients (51.01%) with contact-to-wire time >90 min. Improving the quality of service, communication and cooperation among the centres in the network, resulted in an increased percentage of patients with contact-to-wire <90 min and further improvement in clinical outcomes as well. The mortality rate decreased in both evaluated groups in favour of group 2A with contact-to-wire <90 min (1.9% vs 7.1%, p<0.05).

Conclusions: Contact-to-wire time is still the most powerful predictor of mortality in patients with STEMI. Management of STEMI treatment into the system of regional STEMI network, by improving the communication and cooperation between all network participants, additional improvement in the contact-to-wire time and the mortality rate can be achieved.

Stable CAD - Adjunctive pharmacotherapy

Cardiac ischaemic event safety of direct oral anticoagulants versus warfarin after PCI in patients with atrial fibrillation

CORDERO Alberto [1,6], FERREIRO JL [2,6], BERTOMEU-GONZÁLEZ Vicente [1,6], RODRIGUEZ-MANERO Moisés [3,6], FACILA Lorenzo [4], ESCRIBANO David [1], PILAR Zuazola [1], RUIZ-NODAR Juan Miguel [5,6], GONZALEZ-JUANATEY José Ramón [3,6]

(1) Hospital Universitario San Juan de Alicante, Sant Joan d'Alacant, Spain; (2) Bellvitge University Hospital, L'Hospitalet de Llobregat, Spain; (3) Complejo Hospital Universitario de Santiago, Santiago de Compostela, Spain; (4) Consorci Hospital General Universitari de València, Valencia, Spain; (5) Hospital general universitari d'Alacant, Alicante, Spain; (6) CIBER - Centro de Investigación Biomédica en Red, Madrid, Spain

Aims: Recent clinical trials assessed the effect of direct oral antagonists (DOACs) in patients with atrial fibrillation (AF) after percutaneous coronary interventions (PCI) with positive results in bleeding incidence, as compared to vitamin-K antagonist, but safety on cardiac ischaemic events is still controversial.

Methods and results: We performed a meta-analysis with currently available studies involving DOACs vs Vitamin-K antagonist in patient AF after PCI. The primary endpoint was the incidence of cardiac ischaemic events, including myocardial infarction and stent thrombosis. Secondary endpoints were the incidence of stroke, all-cause mortality and major bleeding. 11,023 patients were included in the analysis: 5,510 receiving DOACs and 5,513 vitamin-K antagonists. A total of 190 cases of myocardial infarction were registered in patients treated with DOACs and 177 in patients on vitamin-K antagonist and statistical difference was noted (RR: 1.07 95% CI: 0.88-1.31). The incidence of stent thrombosis was very low with no differences between the treatment strategies (RR: 1.14 95% CI: 0.76-1.71). As result the incidence of cardiac ischaemic events was the same in patients receiving DOACs or warfarin (HR 1.09 95% CI: 0.91-1.30). No differences were observed in the incidence of stroke (RR: 0.86 95% CI: 0.61-1.23) or mortality (RR: 1.09, 95% CI: 0.90-1.31). Treatment with DOACs was associated with 34% reduction in major bleeding (RR: 0.66, 95% CI: 0.54-0.81).

Conclusions: Treatment with DOACs in patients with AF after a PCI does not increase the risk of cardiac ischaemic events, stroke or death, and reduced the incidence of major bleeding by 34%.

Stents and scaffolds - Tools, devices and techniques, CTO - Tools, devices and techniques

Assessment of silent cerebral infarcts in CTO patients with PCI

SOYLU Korhan [(1)], UYANIK Muhammet [(1)], YILDIRIM Ufuk [(1)], AVCI Bahattin [(1)], SOYLU Korhan [(1)]

(1) Ondokuz Mayıs Üniversitesi Tıp Fakültesi, Samsun, Turkey

Aims: Neuron-specific enolase is a cytoplasmic enzyme and sensitive neuronal ischaemia marker found in nerve cells. Elevation of neuron-specific enolase (NSE) in the absence of any clinically apparent stroke or transient ischaemic attack, so-called silent cerebral infarcts (SCIs). SCI may be associated with neurological deficits. In this study, we aimed to evaluate the incidence of silent cerebral infarcts, defined as elevated neuron-specific enzyme after coronary chronic total occlusion (CTO) intervention and elective coronary stenting, and procedural factors affecting silent cerebral infarcts.

Methods and results: Study population consisted of 2 groups of patients. Group 1 included consecutive patients with elective coronary chronic total occlusion stenting; group 2 consisted of patients who underwent elective coronary stenting. NSE blood levels were measured before and 12-18 hours after the procedure. Elevation of >20 ng/ml was considered as SCI. Exclusion criteria were baseline NSE elevation, acute coronary syndromes or cardiac surgery within 4 weeks, planned use of glycoprotein IIb/IIIa receptor inhibitors, patients with recent cerebrovascular accident, intracranial haemorrhage, and head trauma, central nervous system tumor, degenerative central nervous system disorders, neuroendocrine tumors. After pre-evalution, 120 patients met the study criteria and 12 of them were excluded for following reasons: 1 patient had myocardial infarction from another coronary artery within 24 hours, 1 patient had acute stent thrombosis, 1 patient had ventricular fibrillation, 1 patients had stroke during intervention, 1 patient had transient ischaemic attack after PCI, 2 patients underwent unplanned left main coronary artery (LMCA) stenting, 1 patient had hypotension requiring inotropic agent, 4 patients had elevated baseline NSE. Finally, 108 patients were included in the study. Fifty-five of 108 study patients (50.9%) had SCI after the procedure. The rate of silent brain infarction was 59.7% in the CTO group and 39.1% in the elective coronary stenting group. Patients with SCI were more likely to have diabetes mellitus, hyperlipidaemia, higher HbA1c, total stent length, longer procedural time. Multivariate logistic regression analysis demonstrated CTO procedure (odds ratio [OR] 3.129; 95% confidence interval [CI] 1.246 to 7.858; $p<0.015$), and presence of diabetes mellitus (odds ratio [OR] 2.93; 95% confidence interval [CI] 1.185 to 7.291; $p<0.020$) as independent predictors of SCI.

Conclusions: Increased catheter manipulations, procedure time, and number of equipment used may lead to an increase in the frequency of silent brain damage in complex procedures such as CTO. It can occur even in patients with elective coronary interventions. This may lead to decreased cerebral function in the long term. SCI's should be considered in the treatment of CTOs and similar complicated procedures, especially in diabetic patients.

Other Coronary interventions - Other

Predictive value of high-sensitivity cardiac troponin T for significant coronary artery disease in patients with newly diagnosed atrial fibrillation

RATTKA Manuel [1], ULRICH Luca [1], GUNDLACH Jule [1], POTT Alexander [1], WEINMANN Karolina [1], BOTHNER Carlo [1], DAHME Tillman [1], ROTTBAUER Wolfgang [1], MARKOVIC Sinisa [1], STEPHAN Tilman [1]

(1) University Hospital Of Ulm, Ulm, Germany

Aims: Clinically it is often difficult to separate atrial fibrillation (AF) from coronary artery disease (CAD), as both diseases can be accompanied by similar symptoms, display ST depression in the electrocardiogram and show elevated cardiac biomarkers. We set out to investigate the predictive value of high-sensitivity cardiac troponin T (hs cTnT) for significant coronary artery disease (sCAD) in patients with newly diagnosed AF and unknown coronary artery status for the first time.

Methods and results: We conducted a study of retrospective character of consecutive patients who were treated at our hospital emergency care unit between January 2013 and October 2019 for AF. Patients were eligible for inclusion if they were ≥18 years old, had no history of coronary catheterisation and had hs cTnT testing at admission. Additionally, they had to be at risk for sCAD, subsequently undergoing percutaneous coronary angiography. For identification of independent predictors of hs cTnT elevation and sCAD we performed a univariate logistic regression analysis. Due to the retrospective nature of our study we performed propensity score matching and adjusted for predictors of hs cTnT elevation other than CAD prior to the evaluation of the predictive value of hs cTnT for sCAD by receiver operating curve analysis and calculation of Youden Indices. Out of 2,535 AF patients we identified 144 patients with the initial diagnosis of AF and unknown coronary artery status who underwent coronary catheterisation. At baseline 104 out of 144 patients (72%) had an elevated hs cTnT above the 99th percentile and 40 out of 144 patients (28%) had a normal hs cTnT. By univariate logistic regression analysis we identified "reduced left ventricular systolic function" as the only independent predictor of hs cTnT elevation (HR: 1.99; 95%-CI: 1.04-3,78, p=0.036). 77 out of the included 144 patients undergoing cardiac catheter examination had diagnosis of sCAD (54%) requiring revascularisation, while in 67 patients (46%) sCAD could be excluded. Patients with sCAD were significantly older, had more frequent diagnosis of arterial hypertension and chronic kidney disease, a higher CHA2DS2-VASc score and higher 0 hour-, 1 hour- and delta hs cTnT levels. Univariate logistic regression analysis identified concomitant diagnosis of arterial hypertension (HR: 4.33; 95%-CI: 1.05-17.80, p=0.042), the CHA2DS2-VASc score (HR: 1.50; 95%-CI: 1.01-2.24, p=0.046), 0 hour hs cTnT (HR: 1.01; 95%-CI: 1.00-1.03, p=0.045) and delta hs cTnT (HR: 1.20; 95%-CI: 1.09-1.33, p<0.001) as independent predictors of sCAD. After propensity score matching for possible confounders of hs cTnT elevation, only higher hs cTnT levels retained significant differences between the matched "sCAD" (53 patients) - and "no sCAD" (53 patients) – group. Receiver operating characteristic curve analysis of the matched groups showed an area under the curve of 0.65 (95%-CI: 0.54-0.75, p=0.01) for 0 hour hs cTnT and 0.77 (95%-CI: 0.67-0.87, p<0.001) for delta hs cTnT. The Youden Index for 0 hour hs cTnT was 0.25 with a corresponding cut-off of 20.5 ng/pl and 0.52 for delta hs cTnT with a corresponding cut-off of 4.5 ng/pl.

Conclusions: Our study revealed that changes in high sensitive troponin T (delta hs cTnT) might display an efficient approach to identify patients with sCAD in patients with newly diagnosed symptomatic AF. As a consequence, excessive and unnecessary cardiac catheter examinations could be avoided.

Stents and scaffolds - Tools, devices and techniques

Outcomes of DEB PCI in a South Asian population: ten-year experience from a tertiary care centre in Pakistan

AHMED Syed Waqar [(1)], AHMED Syed Waqar [(1)], FAHEEM Osman [(1)], HUSSAIN Bilal [(1)], RAHMAN Nasir [(1)]

(1) Aga Khan University Hospital, Pakistan, Karachi, Pakistan

Aims: Emerging evidence suggests that South Asian (SA) population have an increased rate of in-stent stenosis (ISR) after PCI when compared to other ethnicities.The European Society of Cardiology has endorsed DEB as a class I indication for the treatment of ISR. However, there is a lack of data describing the outcomes of DEB PCI in the SA populations. Since the magnitude of the problem is larger in the SA ethnicity, it's essential to evaluate the efficacy of DEB PCI for ISR.Hence the aim of this study was to report DEB PCI outcomes and its predictors in a cohort of Pakistani patients treated for ISR.

Methods and results: In this retrospective study we primarily investigated the incidence and predictors of target lesion revascularisation (TLR) after DEB PCI for ISR at 1-year follow up and long-term follow-up, in a cohort of Pakistani population. In addition we also studied the major adverse cardiac events (MACE), i.e. a composite of myocardial infarction, TLR and cardiac death at long-term follow-up. Between January 2010 to January 2019, a total of 147 ISR lesions in 112 patients were treated with DEB PCI in our centre. The incidence of clinically driven TLR after long-term follow-up was 15.2% for the total number of patients (112) and 15.6% for the total number of lesions (147). TLR at mean follow up of 2.73±2.14 years was 26.8% for total patients and 25.9% for total lesions. The major predictors for TLR were diffuse and occlusive ISR types, the presence of 3 or more traditional risk factors at the time of DEB PCI and DEB PCI as a part of multivessel PCI strategy. The incidence of MACE after DEB PCI was 16.1 % at long-term follow-up and 35.7% at mean follow-up for the total number of patients.

Conclusions: Our study is an effort to bridge the gap in literature regarding DEB outcomes from South Asian countries. We report a higher rates of TLR at 1 year and mean follow-up in our study compared to other registry data. However the rate of MACE from our data was found to be similar to other studies. We also report predictors of TLR that have not been previously described. This may suggest that the DEB PCI in ISR may be effective in a tailored group of south Asian population.

STEMI - Tools, devices and techniques, Stable CAD - Diabetes

Subgroup analysis comparing ultrathin sirolimus-eluting stents versus newer-generation DES, report from the SWEDEHEART registry

YNDIGEGN Troels [1], YNDIGEGN Troels [1], BUCCHERI Sergio [2], SARNO Giovanna [2], LAGERQVIST Bo [2], GRIMFJÄRD Per [3], FRÖBERT Ole [5], PERSSON Jonas [6], BÖHM Felix [7], JAMES Stefan [2], ERLINGE David [1]

(1) Department of Cardiology, Clinical Sciences, Lund University, Lund, Sweden; (2) Department of Medical Sciences and Uppsala Clinical Research, Uppsala, Sweden; (3) Department of Cardiology, Västerås Hospital, Västerås, Sweden; (4) Department of Clinical Science and Education, Karolinska Institutet, Unit of Cardiology, Södersjukhuset, Stockholm, Sweden; (5) Örebro University, Faculty of Health, Department of Cardiology, Örebro, Sweden; (6) Department of Cardiology, Danderyd University Hospital, Stockholm, Sweden; (7) Coronary Artery Disease Area, Heart and Vascular Theme, Karolinska Institutet and Karolinska University Hospital, Stockholm, Sweden

Aims: Recent randomised clinical trials and real-world data suggest beneficial effect of ultrathin sirolimus-eluting stents (Orsiro) vs newer-generation drug-eluting stents (n-DES). We report real-world outcomes in multiple subgroups of patients implanted with the Orsiro stent versus frequently used n-DES.

Methods and results: Between October 2011 (date of the first Orsiro implantation in Sweden) up to June 2017 patients were identified using the SWEDEHEART (Swedish Web-System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies) registry. In 13 different subgroups, Cox proportional hazards were used in 5 different models to compare the outcome between Orsiro and n-DES: (1) unadjusted; (2) adjusted for age, gender; (3) adjusted for age, gender, index, year; (4) adjusted for age gender, index, year, indication; (5) unadjusted in propensity score matched and weighted data. The analyses were carried out on stent level and on individual level. 65,532 patients were identified (4,192 Orsiro group, 61,340 n-DES group) with a total of 171,032 stents implanted (11,005 Orsiro, 160,027 n-DES). The number of individuals in the Orsiro vs control in the subgroups were as follows: bifurcation (817 vs 11,585), chronic occlusion (164 vs 2,773), diabetes (800 vs 11,493), insulin-treated diabetes (329 vs 5,073), small (≤ 2.5 mm) vessels (719 vs 9,971), STEMI (1,384 vs 18,764), age 65 or older (2,498 vs 38,237), complex lesion (2,904 vs 40,246), female (1,155 vs 16,888), left main (104 vs 2,978), male (3,037 vs 44,452), STEMI/NSTEMI (3,052 vs 43,812), stent above 26 mm (2,823 vs 38,542). Across all statistical models (1-5), on stent level, the performance of the Orsiro stent vs n-DES was associated with significantly lower incidence of restenosis in the following subgroups: bifurcations (Model 5: hazard ratio 0.27, 95% confidence interval 0.12-0.61); diabetes (Model 5: hazard ratio 0.73, 95% confidence interval 0.54-0.98); complex lesions (Model 5: hazard ratio 0.77, 95% confidence interval 0.61-0.95); and STEMI/NSTEMI (Model 5: hazard ratio 0.66, 95% confidence interval 0.49-0.89). However, on individual level analysis, we found no increased risk in these subgroups with respect to repeat revascularisation, MI or all-cause mortality. Orsiro implanted in small (≤ 2.5 mm) vessels was associated with increased incidence of stent thrombosis (Model 5: hazard ratio 1.71, 95%-confidence interval 1.11-2.67).

Conclusions: In a large real-world population, the Orsiro stent was associated with a reduction of restenosis in subgroups of STEMI/NSTEMI, diabetes, complex lesions and bifurcations and an increased incidence of stent thrombosis in small (≤ 2.5 mm) vessels.

Bifurcation lesion - Tools, devices and techniques

Temporal trends treating coronary bifurcation lesions in a large tertiary centre

GREENBERG Gabriel [1,2], PERL Leor [1,2], BENTAL Tamir [1,2], VAKNIN-ASSA Hana [2], SAMARA Abid [1,2], CODNER Pablo [2], LEV Eli [3], KORNOWSKI Ran [1,2], ASSALI Abid [2,4]

(1) Rabin Medical Center Golda Hasharon Campus, Petah Tikva, Israel; (2) Beilinson, Petah Tikva, Israel; (3) Assuta Kalaniot Ashdod, Ashdod, Israel; (4) Meir Medical Center, Kefar Sava, Israel

Aims: We sought to evaluate the demographic and anatomic characteristics and outcomes of patients with bifurcation disease over a period of 12 years, in real-world clinical practice.

Methods and results: We analysed 965 consecutive patients who underwent PCI for bifurcation lesions during the years 2006-2018. 483 patients were included in period 1 (2006-2012) and 482 patients in period 2 (2012-2018). COX regression model was used to adjust for comorbidities. Patients with bifurcation lesions treated in the two time periods were comparable regarding age, gender, and known comorbidities. Lesions with true bifurcations (i.e., Medina 1,1,1; 0,1,1; 1,0,1) tend to be more frequent in period 2 (66% vs 74.2%, p=0.24), and side branch stenting was only modestly increased (39.3% vs 45.2%, p=0.22). Fluoroscopic time had decreased in period 2 (23.6±14 vs 21.4±11minutes), and so did total contrast volume (241.5±100 vs 222±75). After correcting for confounding factors, the second period is associated with reduced risk of major adverse cardiovascular events (MACE) [HR-0.47; 95% CI-0.23-0.92, p=0.037], but not with mortality (HR-0.64; 95% CI-0. 34-1.18, p=0.148).

Conclusions: Despite the more complex coronary artery anatomy and the need for more side-branch stenting, outcomes have improved over the years.

Stents and scaffolds - Invasive imaging and functional assessment, Other Coronary interventions - Other

StEnt coverage and neointimal tissue characterisation after eXtra long evErolimus-eluting stent imPlantation: prospective sTudy using optIcal cOhereNce tomography

PROKHORIKHIN Aleksei [(1)], PROKHORIKHIN Aleksei [(1)], KRETOV Evgeny [(1)], MERKULOV Evgeny [(2)], ARUTYUNYAN Goar [(2)], BOYKOV Andrei [(1)]

(1) Natsional'nyy Meditsinskiy Issledovatel'skiy Tsentr Imeni Akademika Ye.n. Meshalkina, Novosibirsk, Russian Federation; (2) Russian Cardiology Research and Production Complex, Moscow, Russian Federation

Aims: The 48 mm long biodegradable polymer everolimus-eluting SYNERGY stent (BP-EES) is a novel very thin strut device, designed to overcome necessity of stent overlapping while stenting long coronary lesions or CTOs. However, stent length is known to be an independent predictor of restenosis. We sought to study the stent coverage and neointima progression within 3 and 6 month follow-up in CAD patients who underwent PCI.

Methods and results: Exeption study (Clinicaltrials.gov NCT03401216) is a multicentre randomised trial aimed to evaluate the short-term neointimal proliferation of BP-EES Synergy 48 mm. A total of 80 patients, after stent implantation, were randomised 1:1 to 3-month (group 1) or 6-month (group 2) OCT follow-up. Raw data of OCT image acquisitions were collected at two recruiting centres and analysed at a centralised core laboratory. Morphometric analysis of contiguous cross-sections was performed at 1 mm longitudinal intervals within the stented segment using Cardiology: E.0.2 software. The primary effectiveness endpoints were neointimal healing score (NIH) and neointimal thickness. We present the analysis of OCT imaging data at post-stenting follow-up on a total of 80 patients (40 - 3 month FU and 40-6 month FU). There were no significant differences between groups regarding clinical, angiographic measurements, and procedural data. Stent implantation was followed by NC-balloon post-dilation in all cases. The analysed average stent length was 43.03±0.86 mm and diameter 3.53±0.3 mm. Total number of 3,441 frames were assessed, with a total of 32,230 visible struts. Overall strut coverage per stent was 82.96%±5.23 and 94.25%±3.4 (p=0.0001) in 3mFU and 6mFU groups, incidence of malapposed and uncovered struts was 0.3%±0.04 and 17.04%±5.23 versus 0.25%±0.03 (p=0.005)and 5.75%±3.4 (p=0.0001) in study groups, consequently. Cross-section level analysis revealed mean lumen area 9.64±2.01 and 8.73±1.46 mm^2 (p=0.0001), stent area 10.34±2.05 and 10.2±1.39 mm^2 (p=0.219) and neointimal area 0.7±0.05 and 1.47±0.17 mm^2 (p=0.0001). The NIH score per stent was 34.86±9.8 and 10.23±3.76 (p=0.0001), while neointimal thickness per strut was 60±53 µm and 108±84 µm (p=0.0001) in study groups. Safety analysis demonstrated no signs of stent thrombosis or restenosis in both groups.

Conclusions: The 48 mm long everolimus-eluting stent is associated to a good intimal coverage at 3 months after implantation with significant increase at 6 months. Incidence of strut malapposition was extremely low, due to adequate post-dilation. Synergy 48 mm, despite the stent length, showed favourable healing profile.

Other Coronary interventions - Other

Gender in the Italian cathlab: the GENDER-CATH study

BERNELLI Chiara [1], BERNELLI Chiara [1], CERRATO Enrico [2], ORTEGA Rebecca [3], PICCALUGA Emanuela [4], RICOTTINI Elisabetta [5], CHIEFFO Alaide [6], MASIERO Giulia [7], MATTESINI Alessio [8], LA MANNA Alessio [9], TARANTINI Giuseppe [7], MUSUMECI Giuseppe [10], MEHRAN Roxana [3]

(1) Santa Corona Hospital: First Aid, Province of Savona, Italy; (2) Ospedale San Luigi Gonzaga, Metropolitan City of Turin, Italy; (3) Mount Sinai Medical Center, NY, USA; (4) ASST Great Metropolitan Niguarda, Metropolitan City of Milan, Italy; (5) Campus Biomedico, Metropolitan City of Rome, Italy; (6) San Raffaele Hospital, Metropolitan City of Milan, Italy; (7) Padova Ospedale, Province of Padua, Italy; (8) Careggi University Hospital, Metropolitan City of Florence, Italy; (9) Presidio Ospedaliero Ferrarotto, Province of Catania, Italy; (10) Ospedale Mauriziano Torino, Metropolitan City of Turin, Italy

Aims: Women represent an increasing percentage of interventional cardiologists in Italy, however, gaps exist in understanding and adapting to the impact of these changing demographics. We sought to investigate the demographics of Italian interventional cardiologists and gender-based professional differences in Italian cath lab settings. Specifically, cath lab abstention and radiation safety issues were evaluated.

Methods and results: A survey supported by the Italian Society of Interventional Cardiology (SICI-GISE) was mailed to all SICI-GISE members. Categorical data were compared using the chi-square test. P-values <0.05 were considered significant. There were 326 respondents: 20.2% were <35-years-old, and 64.4% had > 10-years of cath lab experience. Notably, 26.4% were female. Workload wasn't gender influenced (females performed "on call" duty 69.8% vs males 68.3%, p=0.97). Females were more frequently unmarried (22.1% females vs 8.7% males, p=0.002) and childless (58.1% vs 26.7%, p<0.001). Regarding cath lab abstention, 38.9% and 69.6% of respondents considered it useful to perform PCI-robotic-simulations and "refresh-skill" sessions while they were absent or on return to work, respectively, without gender-differences. Interestingly, 69.8% of females vs 44.6% of males (p<0.001) argued that pregnancy/breastfeeding negatively impacts professional skill-development and career advancement. Overall, 80% of respondents described current radioprotection counseling efforts as inadequate and not gender specific. Finally, 26.7% faced some type of job-discrimination; a significantly higher proportion of whom were females.

Conclusions: Several gender-based differences exist or are perceived to exist among interventional cardiologists in Italian cath labs. Strategies addressing cath lab abstention and radiation exposure education should be developed in order to meet an increasingly diverse workforce.

Stents and scaffolds - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

Local stent delivery technique with mother-and-child guiding catheter extension systems for complex PCI (LSD-TELESCOPE registry)

PELLICANO Mariano [1,2], XAPLANTERIS Panagiotis [1], DI GIOIA Giuseppe [1,2], CICCARELLI Giovanni [1], COLAIORI Iginio [1], TOTH Gabor G [3], FERRARA Angela [1], ADJEDJ Julien [4], KODEBOINA Monika [1], BARBATO Emanuele [2], DE BRUYNE Bernard [1,5]

(1) Olv Ziekenhuis, Aalst, Belgium; (2) University of Naples Federico II, Metropolitan City of Naples, Italy; (3) University of Graz, Graz, Austria; (4) Arnault Institute Tzanck, Saint-Laurent-du-Var, France; (5) CHUV Centre hospitalier universitaire vaudois, Lausanne, Switzerland

Aims: To assess feasibility and safety of "local stent delivery" (LSD) technique with mother-and-child catheter for complex PCI, in a prospective single-center registry.

Methods and results: LSD technique requires the following steps: 1) advancement of the mother-and-child catheter as close to the target lesion as possible, with balloon-assisted tracking; 2) inflation of the balloon in the stenosis; 3) while slowly deflating the balloon, the mother-and-child catheter is placed across and distal to the stenosis (telescope manoeuver); 4) placement of the stent distally to the stenosis; 5) pull-back of the mother-and-child catheter; 6) positioning and deployment of the stent in the target segment. 421 PCI with mother-and-child catheter were prospectively performed in 396 consecutive patients with complex coronary anatomies and/or PCI settings (extreme tortuosities and calcifications, CTO, anomalous or angulated take-off of the coronaries, proximal previous stent, distal location of target stenosis, calcified SVG lesions). 96 PCI were excluded because the mother-and-child catheter was not used according to LSD technique. Finally LSD technique was performed in 325 complex PCI (44% Ad-hoc PCI) out of 300 patients with stable angina (55%), silent ischaemia (11%), unstable angina (5%), STEMI (10%) and NSTEMI (19%). Primary endpoints were feasibility and safety of LSD technique. Feasibility criteria were: 1) "device success", defined as successful wire crossing, balloon angioplasty and stent delivery only with LSD technique; 2) "target lesion procedural success", defined as successful wire crossing, balloon angioplasty and stent delivery with or without LSD technique 3) "device-related procedural success", defined as achievement of post-PCI diameter stenosis <20% with TIMI 3 flow only with LSD technique and 4) number of stents implanted in the target vessel with LSD technique. Safety criteria were divided in: major intra-procedural and periprocedural complications (death, acute or subacute stent thrombosis, stroke, acute myocardial infarction requiring emergency CABG, coronary artery perforation, limiting flow coronary artery dissection and abrupt closure–type F, stent dislodgement, major bleeding BARC type 3–5) and minor intra-procedural and periprocedural complications (air embolism, not limiting flow coronary dissection – type A to E, minor bleeding BARC type 0-2). 39% of the procedures were performed by radial access and only in 1.7% of them the shift to femoral approach for poor backup was needed. Thanks to LSD technique a single stent delivery and implantation was possible in half of the procedures (51%), while 2 stents and 3 or more stents were implanted in 27% and 18% respectively. In 4% of the cases, because of LSD technique failure, no stent was implanted with final POBA, in all of them. "Device success", "target lesion procedural success" and "device-related procedural success" were 97%, 96% and 88.3% respectively. Regarding the safety, there was a low rate of major complications: one case of bleeding BARC 3B (0.3%) and one case of stent dislodgment (0.3%). As minor complications we observed a low rate of: air embolism (0.6%), stent underexpansion (0.9%), no-reflow phenomenon (0.9%), side branch occlusion (1.2%) and coronary dissection type A to E (5%).

Conclusions: LSD technique with mother-and-child catheter is a valuable option for a fast and safe single stent delivery in the context of complex PCI and challenging coronary anatomies.

NSTEMI - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Intravascular imaging-guided intracoronary shockwave lithotripsy: first real-world experience

FAN Lampson [1], FAN Lampson [1], SINCLAIR Hannah [1], EOIN Fahy [2], RATIB Karim [2], NOLAN Jim [2], MAMAS Mamas [2], AHMED Javed [1]

(1) Freeman Hospital, Newcastle upon Tyne, United Kingdom; (2) University Hospital North Staffordshire, Stoke-on-Trent, United Kingdom; (3) Royal Stoke University Hospital, Stoke-on-Trent, United Kingdom

Aims: Coronary calcification remains a significant challenge for the contemporary interventional cardiologist. Shockwave intravascular lithotripsy (S-IVL, Shockwave Medical), is a recently approved device for the treatment of calcific coronary lesions. However, real-world data are still limited and the only case series published to date (Wong et al, 2019) included only 26 patients and did not utilise any intracoronary imaging. In this study, we present our experience of imaging guided S-IVL in contemporary real-world patients.

Methods and results: In the 18 months between June 2018 and November 2019, 65 patients underwent S-IVL during PCI. 80% of patients were male and the mean age was 70.1±12.0 years. The majority of patients (54%) presented with ACS. 53 patients underwent S-IVL to *de novo* coronary lesions, with 12 requiring S-IVL within pre-existing stents. 70% of patients had intra-coronary imaging. 12% of treated lesions were in the left main. All balloons were successfully delivered to the lesion with 98.5% procedural success. In patients with intra-coronary imaging, there was significant gain in MLA post-PCI, 277.0±98.6%. There were two procedural complications (a distal wire perforation in the s-IVL treated artery, and a VF arrest during an S-IVL treatment). There was one death in our cohort due to the previously mentioned distal wire perforation. One patient required procedure due to stent under-expansion, and one was readmitted with a troponin-negative acute coronary syndrome and underwent coronary artery bypass grafting (CABG) to a non-target vessel.

Conclusions: In this largest real-world case series of imaging guided S-IVL for calcified lesions to date, we demonstrate that S-IVL is deliverable, safe and effective at calcium modification especially when intracoronary imaging is used. S-IVL is therefore a useful adjunct for calcium modification and should be considered in appropriately selected cases.

Left main and multivessel disease - Tools, devices and techniques

The outcome of left main PCI: a single-centre experience of first 50 cases without use of IVUS

AREFIN Md Minhaj [(1)], AREFIN Md [(1)], AZAM M G [(1)]

(1) National Institute of Cardiovascular Diseases, Dhaka, Bangladesh

Aims: The aim of this study was to evaluate the clinical outcomes, including unstable angina, myocardial infarction, heart failure, target vessel revascularisation, and death in patients undergoing LM stenting without the use of IVUS.

Methods and results: Cross-sectional study done in NICVD from March 2014 to June 2019. Included 50 patients who underwent PCI for LM stenosis without the use of IVUS. Patients were followed up for 1 year & 2 years, one patient was lost to follow-up. Outcomes included in major adverse cardiac events (MACE) were cardiac death, death due to other causes, MI, UA, HF, stroke and TLR. 50 patients (mean age 58.4±4.1 years, 44 male, 06 female) were treated with a mean SYNTAX score of 29.2±8.6. 32 (64%) patients had stable angina, 17 (34%) had UA/NSTEMI, and 1 (02%) had STEMI. Among the risk factors, HTN (66%) is predominant followed by smoking (44%) & DM (42%). Preprocedural LVEF was 49.92± 6.60% and post-procedural LVEF was 54.84±4.55%, which showed significance (p=0.003). Most of the patients presented with LM with SVD (82%). Among all patients, 39(78%) underwent complete revascularisation in comparison to 11 (22%) incomplete revascularisations. 41 (82%) patients received single-stent DES, 8 (16%) received two-stent DES & one patient (02%) underwent POBA without any stenting. Among the double stent strategy, the majority underwent mini-crush (52.94%). One patient was lost to follow-up. After 1-year follow-up period, 1 (02%) patient had non-fatal MI, 7 (14%) had UA and 3 (06%) had HF. After 2 years there was no new MI but 9 (18%) had UA & 4 (08%) had HF. TLR was 2 (04%) in 1st year and 4 (08%) in 2nd year along with total mortality 1(02%) vs 3(06%). The multivariable analysis showed a good prognosis in patients receiving LM PCI with a total event rate of 28% & mortality 6%. A multivariate regression analysis showed that high SYNTAX score (p=0.013), incomplete revascularisation (p=0.002) and low post-procedural LVEF (p=0.002) were independent predictors of MACE.

Conclusions: PCI to LM coronary artery stenosis without the use of IVUS showed good prognosis after 1-year and 2-year follow-up. It would not only save a huge amount of time for physicians during procedures but also prevent a financial burden on patients if they cannot afford intravascular imaging.

STEMI - Tools, devices and techniques

Vulnerable myocardial microvasculature: microvascular obstruction in STEMI is preordained and predicted by controlled flow infusion in a porcine model

SCHWARTZ Robert [1], SCHWARTZ Robert [1], HOEM Jon [2], CESAROVIC Nikola [3], LIPISKI Miriam [4], KOZERKE Sebastian [5], BLUDAU Oliver [2], GERTEIS Esther [2], SCHWARTZ Jonathan [6], ROTHMAN Martin [2]

(1) Minneapolis Heart Institute and Foundation, Minneapolis, USA; (2) CorFlow Therapeutics AG, Baar, Switzerland; (3) Translational Cardiovascular Technologies, ETH Zürich and German Heart Center, Berlin, Zürich, Switzerland; (4) Division of Surgical Research, University Hospital Zurich, Zurich, Switzerland; (5) Institute for Biomedical Engineering, University and ETH Zurich, Zurich, Switzerland; (6) Sanger Clinic, Charlotte, Charlotte, USA

Aims: Coronary microvascular integrity is key in maintaining myocardial function and viability. Acute coronary syndromes disrupt normal microvascular function and create conditions of low pressure and low flow, resulting in microvascular obstruction. Associated with profoundly and dangerously progressively lower pressure, lower blood flow and severe ischaemia cause infarction. The key microvascular dysfunction manifests as complete intraluminal collapse, cellular obstruction and oedema resulting in high microvascular resistance.

Methods and results: This preclinical study used epicardial coronary artery resistance to determine microvascular obstruction risk factors in a porcine STEMI model. We characterised microvascular instability in a porcine STEMI model using controlled flow infusion (CoFI), a novel method for precise microvascular resistance measurement in real time, and across a wide range of normal and low-flow states. STEMI was induced in 7 healthy pigs by 90-minute LAD balloon occlusion followed by reperfusion. Pre-STEMI, controlled flow infusion assessed microvascular resistance pre- and post-reperfusion using standard techniques with LAD balloon occlusion and distal crystalloid infusion via precision pump. Coronary back pressure (P) resulting from the controlled flow (Q) was measured during stepped flow sequencing (15 sec infusion steps each at 5, 10, 20, 30 and 40 ml/min). The resulting processed P-Q relationship yielded absolute dynamic microvascular resistance (dMVR). CoFI measurements were repeated post-reperfusion, after which MRI was performed. Microvascular pressure and flow were highly linear across physiologic values. Microvascular instability developed at low intracoronary pressure (<30 mmHg), and at these pressures microvascular resistance rose rapidly by nearly 30% pre-infarct to post reperfusion. Microvascular obstruction presence and severity was determined by cardiac MRI scan performed 6 hours post-reperfusion after the CoFI resistance determination. Post-STEMI CoFI-derived parameters showed statistically significant univariate correlate with MVO presence and severity. Interestingly, pre-STEMI CoFI measurement predicted MVO presence and size (grams) as well as post-STEMI measurements.

Conclusions: These surprising data suggest that wide individual variability may exist in myocardial microvasculature, predisposing these hearts to more severe microvascular dysfunction during STEMI. If these findings of 'vulnerable microvasculature' extend to human clinical trials, we may be able to predict individual patient risk, prognosis, and response to STEMI by simple cath lab based microvascular assessment and will be able to treat patients during PPCI individually according to their 'vulnerability for MVO'.

Other Coronary interventions - Other

Radial vs femoral artery access for coronary catheterisation in patients with history of coronary bypass surgery

STEPHAN Tilman [(1)], STEPHAN Tilman [(1)], GIERL Marie-Therese [(1)], FELBEL Dominik [(1)], RATTKA Manuel [(1)], ROTTBAUER Wolfgang [(1)], MARKOVIC Sinisa [(1)]

(1) Universitätsklinikum Ulm, Ulm, Germany

Aims: Coronary catheterisation through the radial access site has been shown to be superior compared with the femoral access in various clinical settings. Nevertheless, especially in challenging and vulnerable subgroups with high procedural complexity, such as patients with history of coronary artery bypass grafting (CABG), procedures are still frequently undertaken using the femoral artery. The aim of the present study was to analyse the influence of vascular access site on procedural and clinical outcomes in patients with history of CABG undergoing coronary catheterisation.

Methods and results: A total of 1,206 post-CABG patients who had undergone diagnostic coronary angiography or intervention in our centre between April 2010 and May 2018 were included in this study. 12 patients (1.0%) with ulnar or brachial artery access were excluded from the analysis. The entire study population was dichotomised into 441 patients (36.9%) with femoral and 753 patients (63.1%) with radial access. The primary outcome was one-year mortality after coronary catheterisation. Further outcome measures were 30-day-mortality, length of hospital stay, periprocedural complications as well as relevant procedural data including amount of contrast media used, procedure time, fluoroscopy time and dose. Multivariate logistic regression analysis was performed to identify predictors of access site choice and radial access site failure. Short stature (OR=1.62; p=0.004), peripheral artery disease (OR=1.42; p=0.039), cardiopulmonary resuscitation (OR=4.17; p<0.001) and ST-elevation myocardial infarction (OR=2.56; p=0.012) were independent correlates of femoral approach. Radial access was significantly associated with shorter procedure time (72.8±1.2 vs 88.5±1.9 min; p<0.001), fluoroscopy time (1301.2±31.8 vs 1481.4±52.2 sec; p=0.001), as well as lower amount of contrast media used (196.8±3.7 vs 210.5±5.0 ml, p=0.012) compared to the femoral access. In contrast, periprocedural complications such as acute kidney injury (5.3% vs 2.4%; p=0.009) and access site complications (4.3% vs 1.6%; p=0.004) occurred significantly more often in the femoral cohort. This resulted in shorter length of hospital stay when the radial artery was used (5.4±7.2 days vs 7.2±9.3 days; p=0.008). All in all, femoral access was significantly associated with an increased one-year mortality compared to the radial approach (Kaplan-Meier estimates 10.8% vs 6.3%; HR=1.89 [0.62-5.76]; p=0.002). Rate of access site crossover was 10.1% (N=121 patients; 116 patients [95.9%] were switched from a radial to femoral access). Predictors of radial access site failure were short stature (OR=2.21; p<0.001) and acute coronary syndrome (OR=1.54; p=0.038). Except for fluoroscopy time (1732.7±1021.2 sec vs 1301.2±31.8 sec) and procedure time (102.9±43.6 min vs 72.8±1.2 min) all other procedural and clinical study outcomes were similar between patients with access site crossover and patients with initial successful radial approach.

Conclusions: Coronary catheterisation through the radial access remains favourable even in the setting of complex patients with history of CABG. The radial access was significantly associated with lower rates of mortality and procedural complications compared to the femoral approach. Access site crossover seems not to be associated with a significant worse outcome.

Stable CAD - Invasive imaging and functional assessment

In silico real-time coronary velocity deficiency ratio from coronary angiography predicts FFR in intermediate lesions

LIN Po-Lin [1], LIU Lawrence Yu-Min [1], LIN Po-Lin [1]

(1) Mackay Memorial Hospital Hsinchu Branch, Hsinchu City, Taiwan

Aims: Fractional flow reserve (FFR) measured by pressure wire during hyperaemia provides functional assessment of stenosis severity and guides coronary intervention for improved outcomes. However, the need for pressure wire lowers FFR use. We developed a novel approach using the contrast medium flow distance before and after the stenosis to assess the functional significance.

Methods and results: Real-time coronary velocity deficiency (RTCVD) with and without adenosine-induced hyperaemia was calculated on 14 vessels (12 left anterior descending arteries and 2 right coronary arteries) in 14 patients. Average diameter stenosis was 52.5±9.2%. The average pre- and post-hyperaemia RTCVD were 0.958±0.039 and 0.895±0.076, respectively. The corresponding wire-based FFR of the coronary stenosis were 0.953±0.036, 0.896±0.069, respectively. The correlations between RTCVD and FFR were good in both pre- and post-hyperaemia measurements ($r=0.836$, $p<0.001$ and $r=0.894$, $p<0.001$, respectively).

Conclusions: Our method provides a novel and rapid tool to assess the functional significance of intermediate stenosis during diagnostic angiography.

NSTEMI - Vascular access and bleeding, Stable CAD - Vascular access and bleeding

Use of long radial sheath in coronary procedures through left radial access: a single-centre experience

DAHAL Khagendra [(1)], DAHAL Khagendra [(1)], LEE Juyong [(1)], AZRIN Michael [(1)]

(1) UCONN farm, CT, USA

Aims: Left radial artery access (RAA) is an alternative in patients with right radial artery (RA) occlusion, LIMA graft or tortuous innominate artery. Working through left RA can be cumbersome for the providers while standing on the right side of the patient, and uncomfortable for the patients. Various techniques have been used for left RAA including snuffbox access. Long 25 cm sheath gives additional length to perform procedures through left RAA. Therefore, we designed a quality initiative project for feasibility of left RAA using a long sheath.

Methods and results: This project was performed at a university hospital. We obtained data on patient and procedural characteristics including success rate, cross-over and immediate complications. Standing on the left side of the patient, a 25 cm long radial sheath is placed with half of its length free outside in the skin. After it is sewn within the skin, the left arm is brought to the right side and the procedure can be performed. It provides an additional 10-15cm free length to work upon. If additional length is needed for certain patients, the sheath can be pushed inside during the procedure. We report the results in consecutive patients from July to Dec 2019. There were a total of 20 procedures (6 diagnostic [30%] and 14 intervention [70%]) through left RAA. 20% were female with mean age of 69.85±13.1 years. The indications for using left RAA were LIMA graft (55%), weak right RA pulse (35%), right hand dependence (5%), cross-over from right (5%) and recently used right (5%). Long radial sheath was utilised in a total of 16 patients (80%), short radial sheath was used in 3 patients (15%) and sheath-less guide was used in one patient (5%). 100% procedures were completed through left RAA without need for cross-over. There was one small haematoma that was managed conservatively. The providers and patients were satisfied with the technique.

Conclusions: Long radial sheath allows successful completion of procedures through left RAA with improvement in the comfort of patients and providers. Further research is needed to compare this technique vs other approaches.

CTO - Tools, devices and techniques

Possible sex-related bias when choosing the treatment strategy for patients with CTO

BAJORAS Vilhelmas [2], BAJORAS Vilhelmas [1,2], CERLINSKAITE Kamile [1,2], SAULE Ieva Marija [2], DAVIDAVICIUS Giedrius [1,2], BARANAUSKAS Arvydas [1,2]

(1) Vilnius university hospital Santaros klinikos, Vilnius, Lithuania; (2) Faculty of Medicine of Vilnius University, Vilnius, Lithuania

Aims: Female sex is considered to be a factor leading to under-treatment of cardiovascular disease. We aim to evaluate whether there is any sex-related difference in choosing surgery over other strategies in patients with coronary artery disease (CAD) and CTO.

Methods and results: We retrospectively analysed 825 consecutive patients with chronic coronary syndrome or NSTE-ACS from a single university centre registry who had a coronary CTO by angiography in the single university centre from June 2014 to December 2017. For the purpose of this analysis, treatment strategies were divided into two groups: CABG and other (PCI or optimal medical therapy alone). The differences between sexes were compared using Student's t-test for continuous variables and $\chi 2$ test for the categorical variables. Univariate and multivariate logistic regression was used to examine the differences in treatment strategy between the sexes. For adjustment we used the criteria considered significant for choosing treatment strategy: age≥65 years, diabetes and three-vessel disease. Data was analysed using SPSS v23 statistical package. P value of <0.05 was considered statistically significant. There were 75% men with CTO in our cohort; 16% of patients were referred to surgery. Women were older (73±9 vs 67±11 years), had more diabetes (30% vs 22%) and less previous MI (53% vs 62%, p<0.05 for all). 86% of women were 65 years or older vs 59% of men (p<0.001). There were no differences in diagnosis of NSTE-ACS (46% in women vs 42% in men) and three-vessel disease (37% vs 38%, respectively) between the sexes (p>0.05). Despite that, women were significantly less likely to be referred to surgery (10% vs 18% respectively, unadjusted odds ratio [OR] 0.48, 95% confidence interval [CI] 0.29-0.79, p=0.004). Female sex remained an independent predictor for less CABG as a treatment strategy for CTO after adjustment (adjusted OR 0.55, 95% CI: 0.32-0.94, p=0.029).

Conclusions: Even though female patients had a higher frequency of diabetes and the same rate of three-vessel disease compared to men, they were significantly less likely to receive CABG as a treatment option for CAD with CTO. This reveals a potential bias related to sex when chossing a treatment strategy for patients with CTO.

Stable CAD - Vascular access and bleeding

Barbeau's test for radial artery occlusion evaluation after transradial procedures: is it good enough?

DA SILVA Roberto Léo [1,2,3], DA SILVA Roberto Léo [1,2,3], DE ANDRADE Pedro Beraldo [4], ABIZAID Alexandre [1], BRITTO Paulo [2], FILIPPINI Filippe [2], VIANA Renata [1], SOUSA Amanda [1], FERES Fausto [1], COSTA JÚNIOR José de Ribamar [1]

(1) Instituto Dante Pazzanese de Cardiologia, State of São Paulo, Brazil; (2) Instituto de Cardiologia de Santa Catarina, State of Santa Catarina, Brazil; (3) Hospital Universitário Polydoro Ernani de São Thiago, State of Santa Catarina, Brazil; (4) Hospital Santa Casa de Misericórdia de Marília, State of São Paulo, Brazil

Aims: Background: Radial artery occlusion is an infrequent complication of transradial procedures (3-10%). Assessment of radial artery occlusion after procedure is an important aspect of clinical assistance and it could be done clinically (by verifying radial pulse) or using tests. Usually, the maintenance of radial artery patency is verified by a plethysmographic test (Barbeau's test) or using ultrasound. We sought to evaluate whether Barbeau's test has the same efficacy in detecting radial artery occlusion compared to duplex Doppler scans.

Methods and results: This is a dual centre observational study encompassing patients submitted to diagnostic and therapeutic percutaneous coronary procedure by radial access. All patients received at least 5,000 UI of heparin, sheaths were immediately removed after procedure, and a radial pneumatic wristband was applied to the access site, aiming patent haemostasis. A short compression time was applied (1 to 2 hours). Patency of radial artery was verified by Barbeau's test and duplex Doppler evaluation within the first 24 hours after removal of haemostatic band. A total of 316 patients were enrolled between January 2019 and December 2019, with mean age of 61.8 (±9.6) years. The majority was male (58.5%), 36.7% had diabetes and 79.1% had hypertension. Radial artery occlusion was verified after procedure in 16 (5.1%) patients, using duplex Doppler scan. Application of Barbeau's test had the follow results: 69.6% type A curve, 12.3% type B, 7.3% type C and 10.8% type D (the former suggesting occlusion). With Barbeau's test, patients with confirmed occlusion by ultrasound evaluation, 18.8% would be missed by a false-negative test and in the ones without radial artery occlusion, and 7.0% would be misdiagnosed as having radial artery occlusion (sensibility 81.2%; specificity 93.0%; accuracy 92.4%). Remarkably, pulse was absent in only 2.5% of patients.

Conclusions: In the present study, the use of Barbeau's test resulted in a good accuracy in detecting radial artery occlusion, as compared to duplex Doppler scan. Although Barbeau's test is still a good option for daily clinical use, given its widespread availability and low costs, using Barbeau's test results in overestimation of occlusion cases, detecting twice the actual incidence. Therefore, duplex Doppler scan should be considered the standard method in future studies on radial artery occlusion.

Stents and scaffolds - Tools, devices and techniques

Safety and performance of the Orsiro sirolimus-eluting stent in the treatment of all-comer patient population in daily clinical practice. Results from the BIOFLOW-III Canada registry

MANSOUR Samer [(1)], BOUKHRIS Marouane [(1)], POTTER Brian [(1)], FAM Neil [(2)], MATTEAU Alexis [(1)], GRAHAM John [(2)], GOBEIL Francois [(1)], HILLANI Ali [(1)], KUTRYK Michael [(2)], MANSOUR Samer [(1)]

(1) CHUM, QC, Canada; (2) St. Michael's Hospital, ON, Canada

Aims: BIOFLOW-III Canada registry aimed to evaluate the safety and efficacy of Orsiro sirolimus-eluting stent (SES) with biodegradable polymer, in an all-comer patient population.

Methods and results: We conducted a prospective, non-randomised, multi-centre, observational all-comer registry in a real-life patient population, undergoing percutaneous coronary intervention (PCI) with Orsiro SES, at two high-volume Canadian centres. The primary endpoint was one-year target lesion failure (TLF) defined as a composite of cardiac death, target vessel myocardial infarction (MI), coronary artery bypass grafting and clinically driven target lesion revascularisation. Four subgroups were pre-defined: i) diabetic patients; ii) small vessels (≤2.75 mm); iii) chronic total occlusion (CTO) and iv) acute MI. From May 2014 to July 2016, 250 patients (mean age 66.2±10.8 years, 75.6% males, 30% diabetes) underwent PCI with Orsiro SES for 385 coronary lesions. The mean stent diameter was 2.98±0.50 mm and the mean stent length was 22±8 mm. Clinical device and procedural success rates were as high as 99.5% and 97.6%, respectively. The overall one-year TLF estimates rate was 2.8% (95% confidence interval [CI] 1.4-5.8%). Whereas TLF rates were 4.1% (95% CI: 1.3-12.2%), 3.2% (95% CI: 1.2-8.4%), 8.3% (95% CI: 2.2-29.4%), and 2.6% (95% CI: 0.7-9.9%) in the pre-defined risk groups of patients with diabetes, small vessels ≤2.75 mm, CTO, and acute MI, respectively. One possible ST was reported (0.4% [95% CI: 0.1-2.8%]), while no case of definite/probable ST was observed at one year.

Conclusions: Our data provide further evidence on the safety and clinical performance of Orsiro SES in an unselected complex patient population in daily clinical practice.

Other Coronary interventions - Calcified lesions

Coronary lithotripsy followed by DEB angioplasty – first experiences

KLEBER Franz [1], KLEBER Franz [1], TÖPPER Agnieszka [1], AFAN Samuel [1]

(1) Evangelisches Krankenhaus Paul Gerhardt Stift, Wittenberg, Germany

Aims: PCI of severe calcified coronary artery lesions is associated with a lower success rate and a higher complication and restenosis rate, partly due to maladaptation of stents. On the other hand, there is concern about tissue penetration of drugs, especially with drug-coated balloons (DEBs). We therefore studied feasibility of application and follow-up results after using DEBs after lithotripsy.

Methods and results: We treated 16 coronary vessels in 14 patients (3 female, 78±5 yrs old) with severe, mostly double rail calcifications with lithotripsy followed by application of drug-coated balloon angioplasty. 2 lesions were in stent restenosis lesions, 1 was a saphenous vein graft lesion and 13 were *de novo* lesions. Introduction of the lithotripsy catheter was always preceded by predilatation, which happened to be difficult in some cases, and was unsuccessful in one patient. This patient was successfully switched to rotablation. Lithotripsy was successful in all other patients, though in two cases a balloon rupture of the lithotripsy catheter occurred and the catheter had to be replaced. Lithotripsy catheter (Shockwave Medical U.S.) application was followed by drug-coated balloon (SeQuent Please, BBraun, Germany) dilatation in all cases. No major dissection was seen that needed a stent, applying the criteria of the German drug-coated balloon consensus group recommendations. All DEBs could easily be placed into the severely calcified vessels despite the sticky surface of the DEB, which is known to be troublesome in calcified lesions. Follow-up was angiographic in 6 patients and so far clinical in the others. One patient developed a restenosis and was again treated with a DEB. The saphenous vein graft was found to be occluded at follow up. All other lesions were without angiographic or clinical restenosis.

Conclusions: We conclude that in our early experience lithotripsy was an excellent partner for lesion preparation before coronary DEB angioplasty, allowing treatment of lesions that otherwise cannot be reached with the DEB catheter, and providing a high success rate.

NSTEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Correlation between high-volume operator experience with GuideLiner and procedural efficiency in complex coronary interventions

WILSON Jeffrey [1,2], WILSON Jeffrey [1,2], STYS Adam [1,2], STYS Tomasz [1,2], PETRASKO Marian [1,2], DESAI Chirag [1], GEDELA Maheedhar [1], WILLIAMS Vanessa [2], BARES Valerie [2]

(1) Sanford School of Medicine, SD, USA; (2) Sanford Cardiovascular Institute, SD, USA

Aims: Prompt and liberal utilisation of guide extension catheters in complex coronary interventions reduces procedural duration, contrast dye load, and radiation exposure when used in experienced hands. Lessions learned from analysing the world's largest database of guide extension catheter-facilitated PCI.

Methods and results: Data were analysed for all PCIs performed at a single tertiary centre from January 2011 to June 2019. Procedural characteristics included contrast volume used, total radiation exposure, and procedure time. Data were studied by comparing procedural metrics in guide extension catheter vs non-guide extension catheter (99% GuideLiner) cases as well as in cases performed by the higher volume operator vs the lower volume operators. Mixed effects regression was used to analyse the association between contrast volume, total radiation, and procedure time with operator experience and guide extension catheter use. Operator experience and guide extension catheter use were considered in the regression model simultaneously to account for any confounding effects between them. During the study period, there were a total of 9,526 procedures, of which 3,113 required GuideLiner use. Although contrast volume was not significantly different in GuideLiner vs non-Guideliner cases (102±72 mL vs 105±61 mL, p=0.098), there was greater radiation use (1672±1790 mGy vs 1478±1805 mGy, p<0.001) and longer procedure duration (52±31 min vs 45±25 min, p<0.001) for GuideLiner cases. Of all PCIs performed, proceduralist experience data were available for 3,843 higher-volume operator cases and 5,681 lower-volume operator cases. In this analysis, higher-volume operator cases required less contrast volume (92±57 mL vs 112±69 mL), radiation (1317±1790 mGy vs 1705±1799 mGy), and shorter procedure time (37±19 min vs 54±30 min) (p<0.001 for all).

Conclusions: Radiation dose and procedure times were longer in GuideLiner cases, likely reflecting the device's utility in complex PCIs without increasing contrast volume exposure when considering all operators. When used by higher volume operators, GuideLiner use is associated with a reduction in contrast volume, radiation dose, and procedure time, reflecting increased procedural efficiency.

Left main and multivessel disease - Bypass surgery

Impact of smoking on ten-year all-cause death in stable patients with complex coronary artery disease: insights from the SYNTAXES study

TAKAHASHI Kuniaki [1], THUIJS Daniel J.F.M. [2], HOLMES David R. [3], MORICE Marie-Claude [4], MOHR Friedrich-Wilhelm [5], MACK Michael J. [6], ONUMA Yoshinobu [7], KAPPETEIN Arie Pieter [2], HEAD Stuart J. [2], SERRUYS Patrick W. [7]

(1) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (2) Erasmus MC, Rotterdam, the Netherlands; (3) Mayo Clinic, MN, USA; (4) Hôpital Privé Jacques Cartier, Massy, France; (5) Heart Centre Leipzig, Leipzig, Germany; (6) Baylor University Medical Center, Dallas, USA; (7) National University of Ireland Galway, Galway, Ireland

Aims: Data on a relative treatment benefit of coronary artery bypass grafting (CABG) versus percutaneous coronary intervention (PCI) in relation to various smoking habits are limited to date.

Methods and results: The SYNTAX Extended Survival (SYNTAXES) study evaluated survival status up to 10 years in 1,800 patients with *de novo* three-vessel disease and/or left main coronary artery disease who were originally randomised to CABG or PCI in the SYNTAX trial. In the present analysis, patients were divided into three groups (current, previous, and never smokers at the time of randomisation), and the pre-specified primary endpoint of 10-year all-cause death was assessed according to smoking status. Smoking status was available in 1,793 (99.6%) patients at the time of randomisation, of whom 363 (20.2%) were current smokers, 798 (44.5%) were previous smokers, and 632 (35.2%) were never smokers. Compared with previous smokers or never smokers, current smokers were on average nearly 10 years younger and had a lower prevalence of medically treated diabetes and lower SYNTAX score, although other comorbidities such as peripheral vascular disease, chronic obstructive pulmonary disease, and low left ventricular ejection fraction, were more frequently observed among current smokers. The crude rates of all-cause death at 10 years were 29.7% in current smokers, 25.3% in previous smokers, and 25.9% in never smokers (Log-lank p=0.342). After adjustment for imbalances in baseline characteristics, current smokers had a significantly higher risk of 10-year all-cause death than never smokers (adjusted hazard ratio [aHR]: 2.26; 95% confidence interval [CI]: 1.59 to 3.23; p<0.001), whereas previous smokers did not. PCI was associated with a higher risk of all-cause death than CABG among current smokers (aHR: 1.74; 95% CI: 1.04 to 2.91; p=0.035), but not among previous smokers or never smokers, showing no significant smoking-by-treatment interaction (Pinteraction=0.288).

Conclusions: Current smokers at randomisation had a higher adjusted risk of all-cause death at 10 years, whereas previous and never smokers did not. The relative treatment benefit of CABG vs PCI did not differ significantly according to smoking status.

Left main and multivessel disease - Tools, devices and techniques

Left main PCI with second-generation DES: a single-centre experience

OLIVEIRA Cátia [1], OLIVEIRA Cátia [1], CAMPOS Isabel [1], MEDEIROS Paulo [1], RODRIGUES Carla [1], FLORES Rui [1], MANÉ Fernando [1], QUINA Rodrigues [1], COSTA João [1], BRAGA Carlos [1], MARQUES Jorge [1]

(1) Hospital de Braga, Braga, Portugal

Aims: To characterise patients and procedures with left main (LM) percutaneous coronary intervention (PCI) and to evaluate their outcomes.

Methods and results: Single-centre, retrospective study performed from January 2015 to December 2017 in patients with LM PCI with second-generation drug-eluting stents (n=67). Patients with LM PCI were mainly male (68.7%) with median age of 70.1 years. 57.1% of patients were diabetic and 52% had reduced ejection fraction. Previous CABG was presented in 20.9% (only patient had unprotected LM). The SYNTAX score was low (22 or less) in 56.6%, intermediate (22 to 32) in 30.2% and high (33 or higher) in 13.2%. Distal LM bifurcation PCI was performed in 79.1%, and 73% of patients had two-vessel or three-vessel disease. 13.2% of patients with distal disease were treated with a two-stent technique (1 with T-stent, 2 with TAP, and 4 with culotte technique), in which proximal optimisation technique (POT) and kissing balloon were always performed. When one-stent technique was used in distal LM, POT was performed in 66.0% and kissing balloon in 25%. Pre- and post-dilatation were performed in 91.0 and 82.1% of all cases, respectively. Indications for PCI were elective PCI for stable angina (n=18), stabilised NSTEMI(n=20), NSTEMI with ongoing instability (n=10), STEMI (n= 16), and non-culprit lesion treatment after primary PCI for STEMI(n=3). 22.4% of patients were in cardiogenic shock. After our first LM PCI guided with intracoronary imaging, 38.6% of the procedures were performed with it. 14.6% of patients died during the hospitalisation (1 with stent thrombosis; 9 were in cardiogenic shock). All patients had at least 1 year of follow-up. At follow-up, 13.2% of patients died. 85% of deaths were non-cardiovascular; cardiovascular deaths were due to heart failure. Non-fatal myocardial infarction occurred in 7.5% patients with 2 patients undergoing unplanned PCI (one with LM PCI). Target lesion failure occurred in 4 patients (1 had fatal stent thrombosis; 3 had stent restenosis; 2 were sent to CABG and 1 was treated with PCI). One patient had a stroke during hospitalisation and another during follow-up.

Conclusions: LM PCI can be considered as an alternative revascularisation in urgent situations when surgery cannot be considered. Though it can be a high-risk subset, the results in our population are encouraging.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Two-year readmission rates, timing and causes after PCI: insights from a European database

WANG Rutao [1,2,3], WANG Rutao [1,2,3], TAKAHASHI Kuniaki [5], GAO Chao [1,2,3], ONO Masafumi [3,5], KAWASHIMA Hideyuki [3,5], HARA Hironori [3,5], VAN GEUNS Robert Jan [2], WIJNS William [3], ONUMA Yoshinobu [3], SERRUYS Patrick W. [3,4]

(1) Xijing Hospital, Shaanxi, China; (2) Radboud University Medical Center, Nijmegen, the Netherlands; (3) National University of Ireland Galway, Galway, Ireland; (4) Imperial College London, London, United Kingdom; (5) University of Amsterdam, Amsterdam, the Netherlands

Aims: The incidence and causes of hospital readmission following PCI have not been fully investigated. To identify the causes and predictors of readmission is crucial in order to develop interventions to reduce that specific outcome. The aim of the study was to investigate the rates and causes of readmission at different time points within 2 years after percutaneous coronary intervention (PCI).

Methods and results: In patients undergoing PCI in the Global Leaders trial we investigated the incidences, causes and predictors for readmission between 0-30 days, 31-365 days and 366-730 days after index discharge. A total of 15,195 patients undergoing PCI were included in our analysis, 5.1% with readmission between 0-30 days, 16.2% between 31-365 days, and 9.1% between 366-730 days (cumulative rates 5.1%, 21.3%, and 30.3%, respectively). Cardiac disorder was the most common cause of readmission at all time points studied, ranging from 43.6% at 0 to 30 days, 44.2% at 31-365 days to 41.9% at 366 and 730 days. Unstable angina was the most common cardiac reason for readmission at 0 to 30 days (19.7%) and 31-365 days (20.7%), ischaemic heart disease (other than myocardial infarction or unstable angina) was the most common cardiac reason at 366 and 730 days (26.9%). Respiratory disorder was the main non-cardiac cause for readmission at 0 to 30 days (16.4%), gastrointestinal disorder was the most common non-cardiac cause at 31-365 days (11.3%), while musculoskeletal disorder was the most common non-cardiac reason for readmission at 366 and 730 days (15.9%). COPD was the strongest predictor for readmission across all the time points studied: 0-30 days (1.66 [1.26-2.19], p<0.001), 31-365 days (1.41 [1.18-1.69], p<0.001) and (1.28 [1.01-1.61], p=0.037) at 366-730 days. No interaction was found between COPD and antiplatelet strategy in the present analysis (p-inter=0.219).

Conclusions: Approximately 30% of patients were readmitted to hospital after PCI within 2 years; most readmissions occurred in the first month. More than half of the patients were readmitted due to non-cardiac causes. The most common cause of readmission varied at different time points. Interventions to prevent readmissions should consider the timing.

STEMI - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

Mortality after left main stenting – results from a real-life registry

ZHELEVA Ivaila [(1)], ZHELEVA Ivaila [(1)], GELEV Valeri [(1)]

(1) Acibadem City Clinic Tokuda Hospital, Sofia, Bulgaria

Aims: Outcomes of PCI with DES are comparable with CABG, especially in selected patients. All patients undergoing PCI for significant left main (LM) disease from March 2013 to November 2019 were included in a prospective registry. We analysed preprocedural characteristics, mortality rate and time-to-first-death during follow up.

Methods and results: The cohort included 295 patients, mean age 67.20±10.97 years, 209 (70.8%) were males, and the majority −242 (82%) were with unprotected LM stenosis. The decision for LM revascularisation was based on patients' clinical and angiographic characteristics assessed by risk score calculators – Logistic EuroSCORE II and SYNTAX score. Every patient was discussed with the Heart Team taking into account patients' and their family's preferences. Patients with ACS, including ST-elevation myocardial infarction were not excluded from the study. During follow up all patients were assessed for major adverse cardio-vascular events (MACE) defined as death, ischaemia driven TLR and stroke at hospital discharge, 1st, 6th and 12th month and yearly after, with mean follow-up for 31.44±21.92 (0.20-85.17) months. For the aim of this study in addition to pre-and periprocedural characteristics we assessed overall mortality (in-hospital and out of hospital) and time-to-first-death between three groups of patients: ACS with ST-elevation, non-ST-elevation ACS and stable angina patients. The distribution between different groups was as follows: STEMI 25 (8.5%), NSTEMI or unstable angina 155 (52.5%) and 115 (39%) had stable chronic angina. The majority of patients (242 (82%) had unprotected LMS. The overall mortality rate was 15.6% and, as expected, it was higher in STEMI PCI than for other indications −44.0% vs 14.8% for ACS without ST-elevation and 10.4% for stable patients (p<0.001). These results were mainly due to in-hospital mortality – 3.7% (respectively 28.0% vs 1.9% vs 0.9%, p<0.001). During follow-up despite the trend of higher mortality in STEMI patients (22.2%), it does not reach significance between groups (respectively 13.2% for ACS w/o ST-elevation and 9.6% for the stable patients, p=0.289). Event-free survival analysis presented that after acute phase mean time-to-first-death in STEMI group is 1,586.13 days (95% CI: 1,987.66-2,262.99) and no significant difference was found between different clinical presentations (log rank test, p=0.121). There was no difference in the clinical presentation between protected and ULMS (p=0.278) or in the in-hospital and overall mortality rate (p=0.120 and p=0.813).

Conclusions: Clinical presentation has important prognostic significance in patients with LMCAD, with worse outcome in those presenting with STEMI as compared to other clinical scenarios. Our study showed that in-hospital mortality for LM STEMI treated with PCI is high, but survivors had similar mortality risk over follow-up, regardless of their index clinical presentation.

STEMI - Tools, devices and techniques

Outcomes after mechanical thrombectomy in combination with deferred stent implantation in patients presenting with STEMI and high thrombus burden: a three-year follow-up study

KINTIS Konstantinos [1], KINTIS Konstantinos [1], MANTIS Christos [1], SOUSONIS Vasilis [1], KATSAROS Lampros [1], PAPADAKIS EMMANOUEL [1], ANTONATOS Dionisis [1], KOUTOUZIS Michael [2], POULIANITOU Areti [1], KIRIAKOPOULOS Vasilis [1], PATSILINAKOS Sotiris [1]

(1) Konstantopoulio General Hospital, Nea Ionia, Greece; (2) Erythros Stavros HOSPITAL, Athens, Greece

Aims: High thrombus burden is an independent risk factor for death and complications, including no reflow, impairing the prognosis of patients with ST-segment elevation myocardial infarction (STEMI). The aim was to assess the outcomes of mechanical thrombectomy in combination with deferred stent implantation versus standard percutaneous coronary intervention (PCI) in patients with STEMI and high thrombus burden. We aimed to clarify the longer-term benefits, to help guide clinical practice.

Methods and results: It was a prospective and randomised study of mechanical thrombectomy in combination with deferred stent implantation versus standard PCI in 215 patients with STEMI and high thrombus burden. Eligible patients (aged >18 years) had acute onset symptoms lasting 12 hours or less, and ST-segment elevation of 0.1 mV or more in at least two or more contiguous electrocardiographic leads, or newly developed left bundle branch block. Patients were randomly assigned (1:1) to receive either standard primary PCI with immediate stent implantation (n=109) or mechanical thrombectomy in combination with deferred stent implantation (n=106) 48 hours after the index procedure if a stabilised flow could be obtained in the infarct-related artery. The endpoints of interest were cardiovascular mortality, long-term left ventricular ejection fraction, recurrent infarction, and any unplanned revascularisation of the target vessel within 3-year follow-up. Median follow-up time was 2.8 years. Reduced left ventricular ejection fraction occurred in 20 (18%) patients who had standard PCI and in 13 (12%) patients who had mechanical thrombectomy in combination with deferred stent implantation (HR 1.77, 95% CI: 1.09–2.04; p=0.03). Target vessel revascularisation occurred in 4 (4%) of patients in the deferred stent implantation group compared with 8 (7%) of conventional PCI (HR 1.70, 95% CI: 1.04–2.42; p=0.034). Cardiovascular mortality and recurrent infarction were similar between the groups.

Conclusions: In patients with STEMI and high thrombus burden, mechanical thrombectomy in combination with deferred stent implantation reduces the occurrence of heart failure and repeat revascularisation compared with conventional PCI. Results from ongoing randomised trials might shed further light on the concept of mechanical thrombectomy and deferred stenting in this patient population.

Other Coronary interventions - Other

Spontaneous coronary artery dissection: a single-centre experience

OLIVEIRA Cátia [(1)], OLIVEIRA Cátia [(1)], CAMPOS Isabel [(1)], MEDEIROS Paulo [(1)], RODRIGUES Carla [(1)], FLORES Rui [(1)], MANÉ Fernando [(1)], QUINA Catarina [(1)], BRAGA Carlos [(1)], COSTA João [(1)], MARQUES Jorge [(1)]

(1) Hospital de Braga, Braga, Portugal

Aims: To investigate the characteristics and prognosis of patients with sponteaous coronary artery dissection (SCAD).

Methods and results: Single-centre, retrospective study performed in patients hospitalised from January 2010 to December 2018 with diagnosis of SCAD (n= 52), regarding patient characteristics and outcomes (death, myocardial infarction, SCAD recurrence and stroke at discharge and during follow-up). Patients with SCAD were mainly female (78.8%) with median age of 55.6 years. Predisposing factors were identified in 36.5% of patients and precipitating factors in 23.1%. Non-ST-elevation myocardial infarction (NSTEMI) was the main form of presentation (65.4%). The left anterior descending artery (LAD) was the most commonly involved (34.5%) and 5 patients had compromise of 2 or more non-contiguous arteries. Type 2 dissection was the most prevalent angiographic pattern (73.1%). Ejection fraction was reduced in 30.8%. The majority of patients (69.2%) were managed medically and the remaining patients underwent percutaneous coronary intervention (PCI) with second-generation drug-eluting stents. PCI were mainly due to re-infarction during hospitalisation (n=4) or due to the nature of the territories involved (left main or proximal LAD, n=4). Eight patients re-infarcted while in the hospital and 5 during follow-up (SCAD was present in 4 patients: in 3 patients the event occurred in a coronary territory other than that of the index case, and in 1 patient it occurred in the previously affected territory). At discharge, 75% of patients were medicated with dual antithrombotic therapy. Over the period of follow-up, 3 patients develop heart failure and there was no record of death or stroke. Fibromuscular dysplasia and inflammatory/connective tissue diseases were not investigated in our population. We are currently implementing a protocol with rheumatology to rule-out these predisposing factors for SCAD. Ten patients were already involved and, in at least 1 patient, an inflammatory disease was diagnosed.

Conclusions: SCAD is mostly associated with young women with low cardiovascular risk. It is important to investigate predisposing factors since SCAD recurrence was not rare. Nevertheless, the prognosis of the disease in our population was good.

Left main and multivessel disease - Diabetes

In-stent restenosis after left main stenting: rarity or daily routine – single-centre analysis

CHILINGIROV Nihtyan [1], ZHELEVA Ivaila [1], CHILINGIROV Nihtyan [1], GELEV Valeri [1]

(1) Acibadem City Clinic Tokuda Hospital, Sofia, Bulgaria

Aims: Percutaneous coronary interventions (PCI) can be the standard of care for left main (LM) coronary artery disease. In-stent restenosis (ISR) is a rare complication and is associated with patient- and procedure-specific aspects. The aim of our analysis is to evaluate the incidence and the predictors of ISR after left main PCI.

Methods and results: From March 2013 till September 2019 278 LM procedures were performed in our centre with second-generation drug-eluting stents (DES). Our registry includes a wide spectrum of patients, with stable coronary artery disease and with acute coronary syndrome, including STEMI, unprotected and protected LM, high and low SYNTAX scores, with or without true bifurcation disease (engagement). Prior percutaneous or surgical revascularisation was found in 18.6% of patients. Preferred treatment technique was provisional stenting used in 64% of the cases and IVUS guidance was used in 41%. Patients were followed up prospectively for MACE (defined as death, stroke, symptom driven repeat revascularisation) on hospital discharge, the 1st, 6th, 12th month, and each year thereafter. The rate of major adverse cardiac events (MACE) was 17.5%. ISR was found in 7.9% (22 patients) with mean time of occurrence of 491 days, with most common location at the ostium of left circumflex artery in 54.5% (12 patients) and the distal LM in 22.7% (5 patients). According to our data, the only predictor of ISR at multivariate analysis turned out to be insulin-dependent diabetes (OR=3.64; 95% CI: 1.16-11.45, p=0.027), while sex, age, prior revascularisation and the clinical presentation at admission (stable or acute), stent technique and complex anatomy were not. All patients with ISR were retreated successfully; 19 (86%) of them interventionally and in 3 (14%) of the cases, surgically.

Conclusions: According to the results from our registry, composed of all-comer patients, restenosis after PCI of LM with second-generation DES is an infrequent event. The most common location of IRS is at the ostium of circumflex artery and distal left main. Insulin-dependent diabetes is the only predictor of ISR at multivariate analysis.

STEMI - Adjunctive pharmacotherapy

Pre-treatment with ARNI gives better frame count in the culprit artery after primary PCI for AMI in patients with reduced left ventricular function

KADRO Waleed [1,2], KADRO Waleed [1,2], NAIR Sarath [1], MATHEW Suja Achu [1], KADRO Khaled [2], KADRO Mohammad Y [2]

(1) Zulekha Hospital, Sharjah, United Arab Emirates; (2) The Golden Center for Academic Cardiovascular Teaching and Research, Damascus, THAILAND

Aims: Primary PCI has been established as the best treatment for acute MI when it is used appropriately. It is known to give better TIMI 3 flow and better frame count when compared with thrombolytics. Adjunctive therapies with primary PCI are still controversial. We report the effect of pre-treatment with angiotensin receptor-neprilysin inhibitor (ARNI) on the TIMI frame count in the culprit artery after successful primary PCI in patients with reduced left ventricular (LV) function.

Methods and results: We calculated the TIMI frame count in the culprit artery after successful primary PCI in 42 patients who has a history of reduced LV function and presented to our centre with acute MI. The mean door-to-balloon time was 98±12 minutes. All patients received 325 mg of aspirin and 150mg loading dose of ticagelor. GP IIb/IIIa inhibitors were not used in any of those cases. UFH was used in all cases. Stent usage was 100%. No thrombectomy device was used in any of these cases. TIMI 3 flow after stenting was achieved in all culprit arteries. 21 patients (group 1) were receiving ARNI therapy (a combination of sacubitril and valsartan) before admission. The other 21 patients (group 2) were not receiving ARNI but they were either on ACE (angiotensin converting enzyme) inhibitors or on ARBs (angiotensin receptor blockesr). The mean corrected TIMI frame count in the culprit artery post-PCI was 18.34±3.16 frames in group 1 and 29.73±3.92 in group 2 (p=0.02).

Conclusions: Pre-treatment with ARNI gives faster flow after successful primary PCI in acute MI when compared with traditional RAS inhibitors. This is because ARNI therapy can cause: improvement in endothelial dysfunction, improvement in coronary microcirculation, and also reduction in LVEDP, which facilitate coronary flow to the subendocardial areas. Since this is a retrospective observation a larger prospective randomised study can be done.

Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

Discrepant FFR/iFR/CFR measurements in the left versus right coronary artery – findings from the FiGARO registry

JERABEK Stepan [1], JERABEK Stepan [1], KRAL ALES [1], KOPRIVA Karel [2], MATSUO Hitoshi [3], VODZINSKA Alexandra [4], MENDIZ Oscar [5], KOVARNIK Tomas [1]

(1) Department of Cardiovascular Medicine, General University Hospital in Prague, Prague, Czech Republic; (2) Na Homolce Hospital, Prague, Czech Republic; (3) Gifu Heart Center, Gifu, Japan; (4) Cardiological Department, Hospital Trinec Podlesi, Trinec, Czech Republic; (5) Fundacion Favaloro Hospital Universitario, Buenos Aires, Argentina

Aims: The FiGARO registry collected data from fractional flow reserve (FFR), instantaneous wave-free ratio (iFR) and coronary flow reserve (CFR) measurements in five Czech, one Japanese and one Argentinian cath labs. The main objective was to analyse possible predictors of FFR and iFR discrepancy. In this sub-analysis we focused on differences between the right (RCA) and left coronary (LCA) arteries.

Methods and results: Data were prospectively collected from 2016 to 2019, 1,953 combined FFR and iFR measurements in 1,626 patients were analysed (371 measurements in the RCA), CFR was performed in 320 patients (70 in the RCA). The median FFR/iFR/CFR was markedly higher in the RCA (0.81 vs 0.78; 0.92 vs 0.86; 2.06 vs 1.56; $p<0.0001$). Both types of FFR/iFR discrepancy (FFRpos/iFRneg and FFRneg/iFRpos) occurred more frequently in the RCA compared to LCA (24.8% vs 18.5%, $p=0.006$). Correlation between FFR a CFR was low in both coronary territories ($r=0.35$ in RCA vs $r=0.36$ in LCA; $p<0.0001$), while iFR correlated with CFR more closely and correlation coefficient was higher in RCA (0.62, $p<0.0001$) compared to LCA (0.53, $p<0.0001$).

Conclusions: FFR/iFR/CFR characteristics clearly differ between the right and left coronary circulations. The right coronary artery has less diastolic dominant flow-velocity pattern. iFR targets wave-free period of the diastole, therefore its outcome in right coronary territory may not be optimal compared to FFR (considering FFR as the gold standard). This is consistent with our results, where we found significantly higher number of FFR/iFR discrepancies in the RCA. As proposed by number of works, flow in the RCA during the cardiac cycle remains more constant than in the LCA. FFR should theoretically correlate more closely with coronary flow than iFR in the RCA. In our study iFR correlated markedly better with CFR, both in left and right coronary arteries, with higher correlation coefficient in the RCA.

Left main and multivessel disease - Adjunctive pharmacotherapy, Other Coronary interventions - Other

Three-year outcomes of patients with left main stenosis treated by PCI

BAJORAS Vilhelmas [1], BAJORAS Vilhelmas [1,2], ŠUKYTE Emilija [2], DAINIUTE Gabriele [2], ABRAITIS Vytautas [1], SAMALAVICIUS Robertas [1], BARANAUSKAS Arvydas [1], BUDRYS povilas [1], DAVIDAVICIUS Giedrius [1,2]

(1) Vilnius university hospital Santaros klinikos, Vilnius, Lithuania; (2) Vilnius University, Vilnius, Lithuania

Aims: The NOBLE and EXCEL clinical trials showed that all-cause mortality rates at five years are 9.4%-13% in selected patients treated by PCI for left main (LM) stenosis. We present mortality analysis of all the patients treated by PCI for the unprotected LM disease in our centre.

Methods and results: Clinical notes of all patients (n=257; age 71±11.9 yrs.; 68% male gender; 18% diabetes mellitus, mean time of observation 3.7 years) who were admitted to Vilnius University Hospital from January 2015 to January 2017 and received PCI of left main were reviewed and analysed. Three patients (1.2%) died in the cath lab, twenty-four (9.3%) died in the hospital, and ninety patients (35%) died at follow-up. Mortality in hospital and at follow-up differed in various clinical situations: chronic coronary syndrome: 1.3% (1 patient out of 75) and 18.7% (14/75). All stable angina patients were treated electively after discussion in Heart Team meeting. Unstable angina: none has died in hospital, but 25.6% (10/39) died at follow up. Non-STEMI: 12.2% (9/74) and 43.2% (32/74); STEMI: 20% (12/60) and 46.7% (28/60); Other (cardiogenic shock; out of hospital cardiac arrest) 22.2% (2/9) and 66.7% (6/9).

Conclusions: Mortality rates at 3.7 years of follow-up remain high despite successful treatment of the LM stenosis by PCI. All-cause mortality rate remains high (18.7%) even in patients with stable angina pectoris in whom PCI was performed electively after discussion in the Heart Team. In patients with non-ST-segment elevation and ST-segment elevation myocardial infarction mortality rates are very high indicating the difference between all-comers and patients

Other Coronary interventions - Other

Initially elevated troponin I in rapid atrial fibrillation should lead to coronary angiography

ESTEVES Ana [1], ESTEVES Ana [1], PARREIRA Leonor [1], MARINHEIRO Rita [1], FONSECA Marta [1], FARINHA José [1], PINHEIRO António [1], FONSECA Nuno [1], SANTOS Ricardo [1], CARIA Rui [1]

(1) Hospital São Bernardo, Setúbal Municipality, Portugal

Aims: In patients admitted to the emergency department (ED) with rapid atrial fibrillation (AF), the decision to undertake coronary angiography is usually due to elevated cardiac biomarkers. However, a study evaluating the effectiveness of this approach has never been done. Our aim is to evaluate the predictors of a positive coronary angiography performed in patients with rapid AF and elevated cardiac biomarkers.

Methods and results: We retrospectively studied patients admitted to the ED between January 2016 and December 2018 with rapid AF who have undergone coronary angiography. We analysed symptoms, risk factors, initial value, peak value and curve of troponin I (TnI) and ST-T segment abnormalities. We evaluated the presence of significant coronary artery stenosis with the need of revascularisation at coronary angiography and we used logistic regression to assess the predictors of a positive result. From 2,265 patients admitted to the ED with rapid AF, 46 patients, 60.9% (28) male, median age 73 (IQR 14.75) years, were submitted to coronary angiography. Significant coronary artery stenosis was present in 24 (52.2%) patients. Regarding cardiovascular risk factors, 39 (85.6%) patients had hypertension, 15 (32.6%) had type 2 diabetes mellitus, 36 (78.3%) had dyslipidaemia, 25 (54.3%) were obese or overweight and 12 (26.1%) had a previous history of CAD. Twenty-eight (60.9%) patients presented with chest pain and 27 (58.7%) had ST-T segment abnormalities. Of note, in 17 (37.0%) cases high-sensitivity TnI was measured. In univariable analysis, ST-T segment abnormalities (OR 6.650, 95% CI: 1.788-24.730, p-value 0.005), the presence of typical TnI curve (OR 9.000, 95% CI: 1.628-49.756, p-value 0.012) and an elevated initial TnI (OR 3.600, 95% CI: 1.033-12.542, p-value 0.044), but not peak TnI value elevation, predicted the presence of significant CAD in coronary angiography. In multivariable analysis, an initial TnI value above the upper reference limit was the only independent predictor of significant CAD in coronary angiography (OR 15.167, 95% CI: 1.363-168.778, p-value 0.027).

Conclusions: In this group of patients with rapid AF an initial elevated TnI was the only independent predictor of the presence of significant CAD. Therefore, maybe it would be advisable to perform coronary angiography in these patients.

Other Coronary interventions - Other

Gender disparities of Chilean patients undergoing urgent percutaneous intervention

GIACAMAN ARTURO [1], GIACAMAN Arturo [1], PEREZ Osvaldo [2], EISEN Daniela [1], ANTEZANA Gonzalo [1], GUTIERREZ Marcos [1], LINDH Marcelo [1], MALUENDA Gabriel [1]

(1) San Borja Arriarán Clinic Hospital, Santiago, Chile; (2) Hospital las Higueras, Concepcion, Chile

Aims: ST-segment elevation myocardial infarction (STEMI) remains one of the leading causes of mortality in the Chilean population. It is well documented that women have a worse prognosis than their male peers, but the underlying causes remain unclear. Limited information is available on this matter in the Latin American and Chilean populations. We aimed to characterise Chilean patients presenting with STEMI undergoing urgent percutaneous coronary intervention (PCI) in terms of gender, clinical presentation, and mid-term survival.

Methods and results: Patients undergoing urgent PCI from January 2017 to August 2019 at two Chilean clinical centres, San Borja Arriaran Hospital and Las Higueras Hospital, from a prospectively collected database were analysed. The primary endpoint was defined as 12-month follow-up overall mortality. 1,226 patients entered the registry, more frequently male, n= 915 (74.6%). Women were older, the mean age of 65.2±12.3 years-old vs 60.1±12.0 years-old compared to men (p<0.01), and had a higher prevalence of hypertension (75.8% vs 58.7%, p<0.01), diabetes mellitus (36.4% vs 23.6%, p<0.01). On the other hand, men were more frequently hyperlipidaemic (12.2% vs 10.0, p=0.23) and active tobacco smokers (42.7% vs 23.4%, p<0.01) than women. Women presented more commonly with cardiogenic shock (n=15, 4.82%) as compared to men (n= 20, 2.18%), p=0.16. Radial access was predominantly used, overall in 90.0% of the cases (n=1,103), but it was less likely used in women (n= 259, 83.2%), p<0.01. The overall 30-day survival rate was 93.8% (88.9% in women vs 95.4% in men). At 12-month follow-up, the overall survival was 88.5%, which was significantly lower in women than men (82.2% vs 90.6%, p<0.01).

Conclusions: In a real-life registry, Chilean women presenting with STEMI and undergoing urgent PCI were older and sicker than men, presented more commonly with cardiogenic shock, and were less likely to be treated by the radial approach. All this accounts for a worse survival after a STEMI in women. Larger and longer clinical follow-up of Chilean patients undergoing urgent PCI is required to confirm this gender disparity.

Other Coronary interventions - Other

The relationship between endothelial dysfunction and late in-stent restenosis in patients with DES implantation

YIN Jiasheng [1,2], YIN Jiasheng [1,2], CHEN Zhangwei [1,2], YANG Zhuoran [1,2], CHEN Ao [1,2], JIANG Jieyu [1,2], GE Junbo [1,2]

(1) Zhongshan Hospital Fudan University, Shanghai, China; (2) Shanghai Institute Of Cardiovascular Diseases, Shanghai, China

Aims: Stent neoatherosclerosis is one of the most common causes of late in-stent restenosis. Endothelial function plays a crucial role in the pathogenesis of atherosclerosis. This study aims to evaluate the relationship between endothelial dysfunction and late in-stent restenosis.

Methods and results: Reactive hyperaemia index (RHI), which was detected by EndoPAT 2000, showed good correlation with coronary endothelial function by invasive evaluation. We enrolled 180 patients who underwent angiography follow-up beyond one year after DES implantation in our centre. Patients were divided into three groups (ISR, n=75, non-target lesion revascularisation [non-TLR] and control group) according to the findings at follow-up angiography. RHI was measured using EndoPAT 2000 according to the standard procedure before angiography. The demographic and laboratory characteristics were similar among the three groups. RHI was significantly lower in ISR (1.733±0.05, p=0.0009) and non-TLR group (1.78±0.08, p=0.04) compared with the control group (2.03±0.07). There was no difference between ISR and non-TLR group. Multivariate regression revealed that RHI, LDL-C were independent risk factors for late ISR formation. Patients in the ISR group were further divided according to Mehran classification. We found that RHI was significantly different among four pattens (1.86±0.41, 1.68±0.54, 1.50±0.34, 1.82±0.52, for class I to IV, respectively, p=0.03).

Conclusions: RHI was significantly lower in patients with late ISR. Besides, it seemed that RHI was even lower in diffuse ISR lesions than focal ISR lesions. Endothelial dysfunction is associated with late DES restenosis.

Stable CAD - Invasive imaging and functional assessment

Analysis of coronary pathophysiology in patients with previous ischaemic heart disease, complete revascularisation and persistence of angina

SIGISMONDI Andrea [1], SIGISMONDI Andrea [1], ROA GARRIDO Jessica [1], ORTIZ CRUCES Samuel [1], GOMEZ MENCHERO Antonio Enrique [1], LOPEZ ROJAS Luis Marco [1], CARDENAL PIRIS Rosa [1], CAMACHO FREIRE Santiago Jesus [1], DIAZ FERNANDEZ Jose Fransisco [1]

(1) Hospital Universitario Juan Ramón Jiménez, Huelva, Spain

Aims: The existence of significant stenosis at the level of the coronary arteries was considered necessary to generate myocardial ischaemia. Recent findings suggest that this entity is more complex, and there may be ischaemia without epicardial coronary obstruction. Invasive methods such as the coronary artery pressure flow measurement have allowed a better knowledge of coronary pathophysiology. We analysed the microcirculation and coronary flows as causes of chest pain in patients with previous complete percutaneous revascularisation and persistent angina.

Methods and results: We recruited 42 patients, from January 2018 until April 2019, with angina and/or positive invasive functional testing for ischaemia and angiographic coronary stenosis <70%. Clinical characteristics were analysed and measurement of FFR (by coronary pressure), coronary flow reserve (by coronary thermodilution) and microvascular resistance index were performed. Baseline parameters and in maximum hyperaemia were collected. Mean age 64.88±10,015 years, 47.6% diabetics and 23.5% with active smoking. Reduced flow was found in 40.5% of patients, of which 64.70% with high microvascular resistance (> 25) and 35.29% with severe epicardial stenosis (FFR <0.80). Reduced flow pattern was found with normal resistances in 14.28% and normal flow with high resistances in 9.5%. It should be noted that 11.90% of the patients presented FFR>0.80 of a segment to be treated and 21.4% had significant diffuse epicardial stenosis (mean FFR of 0.83±0.8).

Conclusions: In patients with prior revascularised ischaemic heart disease, all the pathophysiological patterns described are found. The presence of coronary microvascular stenosis is a possible cause of persistent angina in almost half of patients with previous ischaemic heart disease and complete epicardial revascularisation. Diffuse epicardial involvement is present in a significant percentage of patients.

Stable CAD - Invasive imaging and functional assessment

Assessing the accuracy of simultaneous measurements of two coronary pressure wires with two different types of sensors (ACCURACY trial)

MANSOUR Samer [1], HADDAD Kevin [1], POTTER Brian [1], ALEXIS Matteau [1], POTVIN Jeannot [1], MASSON Jean-Bernard [1], QUAN Vu [1], PILON Claude [1], SAMER Mansour [1]

(1) CHUM, QC, Canada

Aims: Issues with pressure drift in today's practice increase uncertainty about the correct FFR value. Incorporating an optical pressure sensor is expected to be less prone to pressure drift seen with the piezo-electric coronary pressure wires; the aim of this study is to test this hypothesis.

Methods and results: This is a single centre, prospective, non-blinded clinical investigation enrolling 45 consecutive patients with coronary lesion candidate for FFR assessment between April and December 2019. Lesions of the first 30 patients (n=34 lesions) were assessed with two OptoWire DEUX guidewires (Group O-O), and the remaining 15 lesions obtained from 15 patients were evaluated with one OptoWire DEUX and one Verrata guidewire simultaneously (Group O-V). Significant drift was defined as a pressure ratio deviation of >0.03 in the PCI FFR recording. The average age of the study population was 68±9 years, 82.2% were males, 40% had diabetes and 77.8% had hypertension and dyslipidaemia. Indications for FFR measurements were stable angina in 82.2% of cases and ACS (unstable angina + non-culprit lesion NSTEMI) for 17.8% of patients. Lesions were located in the left anterior descending arter in 57.1% of cases. Stenosis length, reference vessel diameter and degree of stenosis were 13.2±7.5 mm, 3.7±0.7 mm and 52.1±11.8 % respectively. Mean FFR measurements in group O-O were 0.84±0.10 for both wires (p=0.52). On the other side, the mean FFR measurement was numerically lower with Verrata (0.85±0.09) compared to OptoWire DEUX (0.88±0.08) in group O-V (p=0.09). The rate of drift was significantly lower in group O-O compared to group O-V (8.8% vs 33.3% respectively, p=0.03). OptoWire DEUX showed a trend towards a lower degree of drift compared to Verrata (0.01 IQR [0.0,0.02] vs 0.02 IQR [0.0,0.04] respectively, p=0.06).

Conclusions: The magnitude of drift with OptoWire DEUX tends to be lower compared to Verrata, and there were significantly less drifts when using simultaneously 2 OptoWire guidewires. A larger randomised clinical trial is warranted to assess the efficacy of incorporating an optical pressure sensor for reducing issues of pressure drift and increasing the accuracy of FFR measurements.

Left main and multivessel disease - Bypass surgery

Long and short-term outcomes after percutaneous treatment of left main coronary artery in patients disqualified from CABG surgery

SKORUPSKI Wojciech [(1)], SKORUPSKI Wojciech [(1)], GRYGIER Marek [(1)], GRAJEK Stefan [(1)], PYDA Malgorzata [(1)], MITKOWSKI Przemyslaw [(1)], ARASZKIEWICZ Aleksander [(1)], SKORUPSKI Wlodzimierz [(1)], SINIAWSKI Andrzej [(1)], JANKIEWICZ Stanislaw [(1)], LESIAK Maciej [(1)], KALUZNA-OLEKSY Marta [(1)]

(1) I Department of Cardiology, Poznan University of Medical Sciences, Poznan, Poland, Poznan, Poland

Aims: Current ESC guidelines still favor coronary artery bypass graft (CABG) as the only method for left main (LM) disease with diffuse coronary artery disease (CAD). However, in less advanced CAD, percutaneous coronary intervention (PCI) of LM disease is a method of choice. Moreover, in some patients disqualified from the CABG, LM PCI should be considered. The aim of the study was to evaluate short and long-term outcomes of LM PCI in patients disqualified from CABG surgery.

Methods and results: Four hundred and fifty-nine consecutive patients (mean age: 68.4±9.4) in whom PCI of LM was performed (between January 2015 and June 2018) were included in the study. The study group consisted of 396 patients in whom PCI was offered as an alternative to CABG (Group 1) and 63 patients who were disqualified from CABG by heart team (Group 2). The clinical and angiographic data of these patients, including short and long-term outcomes, has been analysed. The whole LM PCI group consisted of 75.6% men and 24.4% women. In Group 2 , women were more frequent (34.9% vs 22.7%; p=0.036) and chronic kidney disease was found more often (54% vs 31.6%; p<0.01). SYNTAX score (29.1±9.5 vs 23.2±9.7; p<0.01) and EuroSCORE II (2.71 vs 2.15; p<0.01) were significantly higher and ejection fraction was lower (46% vs 51%; p<0.01) in Group 2. That group of patients more often required complex stenting techniques (33.3% vs 16.2%; p<0.01). Procedure success rate was very high (99%) and did not differ between two study groups. All periprocedural complications (12.7% vs 7.8%; p=0.198) did not differ among the groups. We observed higher mortality probability in Group 2 (27.5% vs 22%; p=0.024) at a median follow-up of 808 days (range 367 to 1,616 days).

Conclusions: LM PCI in patients disqualified from bypass surgery is effective and safe procedure with low in-hospital complication rate. Long-term results in this group of patients are satisfactory. This life saving treatment, remains the only option for such patients.

Stents and scaffolds - Adjunctive pharmacotherapy, Other Coronary interventions - Other

The association of body mass index with clinical outcomes after ticagrelor monotherapy following abbreviated DAPT in patients undergoing PCI: insights from the GLOBAL LEADERS trial

ONO Masafumi [1,5], ONO Masafumi [1,5], TOMANIAK Mariusz [2], KAWASHIMA Hideyuki [1,5], HARA Hironori [1,5], TAKAHASHI Kuniaki [1], WANG Rutao [3,5], GAO Chao [3,5], WINDECKER Stephan [4], ONUMA Yoshinobu [5], SERRUYS Patrick [5,6]

(1) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (2) Erasmus MC, Rotterdam, the Netherlands; (3) Radboud Universitair Medisch Centrum, Nijmegen, the Netherlands; (4) University of Bern, Bern, Switzerland; (5) National University of Ireland Galway, Galway, Ireland; (6) Imperial College London, London, United Kingdom

Aims: The efficacy of antiplatelet therapies following percutaneous coronary intervention (PCI) may be affected by body mass index (BMI). The present study aims to investigate the clinical impact of BMI on the novel antiplatelet strategy with ticagrelor monotherapy in patients undergoing PCI.

Methods and results: This is a subgroup analysis of the GLOBAL LEADERS trial, a prospective, multicentre, open-label, randomised controlled trial in an all-comer population undergoing PCI, comparing the experimental strategy (23-month ticagrelor monotherapy following 1-month dual antiplatelet therapy [DAPT]) with a reference regimen (12-month aspirin monotherapy following 12-month DAPT). Patients were stratified according to baseline BMI with a prespecified threshold of 27 kg/m^2. Baseline BMI was available in 15,968 patients, in which 6,973 (43.7%) patients had BMI <27 kg/m^2. After adjustment for potential confounding factors, patients with BMI <27 kg/m^2 had a higher risk of all-cause mortality (3.4% vs 2.7%, adjusted HR: 1.24, 95% CI: 1.02-1.49, p=0.029) than those with a BMI ≥27 kg/m^2. At 2 years, the rates of the primary endpoint (all-cause mortality or new Q-wave myocardial infarction) were similar between treatment strategies in either BMI group (p for interaction=0.51). In acute coronary syndrome, however, the experimental strategy was associated with significant reduction of the primary endpoint compared to the reference strategy in patients with BMI <27 kg/m^2 (HR: 0.69, 95% CI: 0.51-0.94, p=0.019), but not in the ones with BMI ≥27 kg/m^2 (p for interaction=0.047). In chronic coronary syndrome, there was no between-group difference in the efficacy and safety of the two antiplatelet strategies.

Conclusions: There was no overall treatment effect of experimental ticagrelor monotherapy versus standard DAPT strategy between the groups with high or low baseline BMI. However, a beneficial treatment effect on all-cause mortality or new Q-wave MI of the experimental treatment with ticagrelor monotherapy was observed in ACS patients presenting with BMI <27 kg/m^2, which was not seen in those with BMI ≥27 kg/m^2. Our results suggest the potential benefit of a novel antiplatelet monotherapy regimen in targeting non-obese ACS patients.

Stable CAD - Tools, devices and techniques

Patient specific, wall-less poly(vinyl alcohol) gel intravascular imaging phantoms using 3D printing methods

MACKLE Eleanor [1,6], MACKLE Eleanor [1,6], LITTLE Callum [1,3,6], MANEAS Efthymios [1,6], CARR Elizabeth [1,6], XIA Wenfeng [1,2], RAKHIT Roby [3], FINLAY Malcolm [1,4,5,6], DESJARDINS Adrien [1,6]

(1) University College London, London, United Kingdom; (2) King's College London, London, United Kingdom; (3) Royal Free Hospital, London, United Kingdom; (4) Queen Mary University of London, London, United Kingdom; (5) St Bartholomew's Hospital, London, United Kingdom; (6) Wellcome EPSRC Centre for Interventional and Surgical Sciences, London, United Kingdom

Aims: Vascular phantoms are useful clinical training tools for percutaneous cardiovascular interventions (PCI). Wall-less vascular phantoms are attractive for intravascular imaging involving intravascular ultrasound (IVUS), as they can allow for realistic acoustic matching at the luminal vessel surface and simulate realistic flow conditions. Using current techniques, it is challenging to fabricate wall-less vascular phantoms with patient-derived vessel geometries and realistic ultrasonic properties. We present a new method for fabricating wall-less ultrasound phantoms with CTCA-derived vasculature.

Methods and results: Poly(vinyl alcohol) (PVA) in two different forms was used to create the ultrasound phantoms. The first form is a solid, water soluble PVA material that is 3D printed. The second is a hydrogel material, known as PVA-cryogel, or PVA-c, which is insoluble and used as the tissue-mimicking material. To create patient specific vasculature, patient CTCA scans were obtained and segmented to extract vessels of interest. The required vessels were then 3D printed in PVA, using a commercial printer, and embedded in PVA-c, the tissue-mimicking material. The phantoms underwent several freeze-thaw cycles, changing both the mechanical and acoustic properties. As printed PVA is water soluble, it could then be dissolved out of the PVA-c to create wall-less vessel structures. Two patient specific phantoms with different geometries were created; a carotid artery and a branching coronary vessel, approximately 2.5 mm in diameter. The PVA-c was shown to have ultrasonic properties comparable to that those of human tissues, both with IVUS and external ultrasound imaging. Pulsatile flow, which was created with a peristaltic pump, was readily visualised using Doppler imaging with an external imaging probe.

Conclusions: We have demonstrated a method for fabricating wall-less, patient specific vascular phantoms that have realistic ultrasound appearances using IVUS and external imaging probes and allow for realistic flow conditions. The 3D printed vessel structures and fabrication method can readily be shared and modified to accommodate different clinical applications.

Bifurcation lesion - Tools, devices and techniques

One-year outcome of provisional versus double stent strategy for true bifurcation lesion using transradial approach: a single-centre study in Bangladesh

KABIR C.M. Shaheen [1]

(1) Ibrahim Cardiac Hospital & Research Institute, Dhaka, Bangladesh

Aims: Coronary bifurcation lesions are frequent in everyday practice and account for up to 20% of all PCIs. The question relating to a one- or two-stent strategy for bifurcation lesions has been a subject of many debates over recent years. Double stent technique is associated with a lower procedural success rates & a higher rate of long-term adverse cardiac events such as stent restenosis and thrombosis.

Methods and results: 80 patients with true bifurcation lesions according to Medina classification were included in this single-centre study and randomly assigned to one (n=40) or two (n=40) stent strategy group. The lesion type of 1,1,1 was the most common type seen in both groups (p=0.94). Both the groups were similar in terms of patient and lesion characteristics. PCIs were performed (90% via TAP technique & the rest via DK crush or minicrush) according to standard routine through transradial approach using 6F guiding catheter. The most common site of treated bifurcation lesions in both groups was the junction of LAD/DG branches followed by LCX/OM branches. There was no crossover from one-stent to two-stent strategy. The endpoints were cardiac death, MI, stent thrombosis & TLR over 6 months. For the bifurcation lesions, comparing routine two-stent strategy with a provisional strategy have shown comparable efficacy outcomes (TVR rates) between the two treatment strategies at 1-year follow-up. The provisional strategy resulted in lower rates of periprocedural MI, less contrast use, lower X-ray doses & shorter procedural times.

Conclusions: Though limited due to low number of participants, this study gave results that in case of true bifurcation lesion, double stent strategy was non-inferior to provisional stent strategy.

Bifurcation lesion - Tools, devices and techniques

Angiographic comparison of DEB and DES implantation after directional coronary atherectomy

YAMAZAKI Seiji [(1)], YAMAZAKI Seiji [(1)], KATAGIRI Yuki [(1)]

(1) Sapporo Higashi Tokushukai Hospital, Hokkaido, Japan

Aims: Directional coronary atherectomy (DCA) is a unique technique used in percutaneous coronary intervention (PCI) which involves the removal of plaque from the coronary artery. Treatment with a drug-coated balloon (DCB) appears to be effective, especially after appropriate predilation. However, the efficacy and safety of the PCI with DCA followed DCB dilatation (DCA-B) has not been investigated as compared to the PCI with DCA followed by drug-eluting stent (DES) implantation (DCA-S). The aim of this study is to compare angiographic and clinical results between DCA-B and DCA-S.

Methods and results: We retrospectively enrolled 25 and 32 patients treated in our centre from September 2016 to April 2019 by DCA-B and DCA-S, respectively. All DCA procedures were performed under the guidance of intravascular ultrasound findings. Routine angiographic follow-up was scheduled at 3 to 6 months. QCA preprocedure, post procedure, and at follow-up was performed. Mean age was 72.3 and 73.2 years old (p=0.752); 88.0% and 78.1% were male (p=0.487) in DCA-B and DCA-S, respectively. All procedures were successfully performed without incurring major complications such as a coronary perforation. QCA showed minimum lumen diameter (MLD) preprocedure was 1.66±0.52 and 1.80±0.44 mm (p=0.258) in DCA-B and DCA-S, respectively. MLD post-procedure and follow-up was smaller in DCA-B than in DCA-S (2.74±0.65 vs 3.26±0.63 [p=0.004] post-procedure; 2.30±0.66 vs 2.78±0.58 [p=0.017]). Acute gain in DCA-B was smaller than in DCA-S (1.08±0.66 vs 1.45±0.64; p=0.037), whereas late loss was not different (0.43±0.89 vs 0.47±0.59 mm; p=0.858). The Kaplan-Meier survival analysis (median follow-up: 358 days) showed that target lesion failure (a composite of cardiac death, target-vessel myocardial infarction, ischaemia-driven target lesion revascularisation [TLR]) was not different between groups (19.4% vs 13.8%; p=0.923). However, all TLR (regardless of whether ischaemia-driven or not) tended to higher in DCA-B (32.9% vs 10.5%; p=0.590) than in DCA-S.

Conclusions: This study suggests that DCA-B is less effective as compared to DCA-S, especially in terms of angiographic outcome. The small sample size in the study did not allow us to draw conclusions in clinical outcomes; however, higher TLR rate in DCA-B would be a reflection of lower acute gain in DCA-B. Further prospective investigation would be necessary.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Influence of bleeding risk on outcomes of radial and femoral access for PCI: an analysis from the GLOBAL LEADERS trial

GAO Chao [1,2,3], GAO Chao [1,2,3], BUSZMAN Piotr [4,5], TAKAHASHI Kuniaki [3], KAWASHIMA Hideyuki [3], WANG Rutao [3], ONO Masafumi [3], HARA Hironori [3], ONUMA Yoshinobu [3], SERRUYS Patrick [3], ZURAKOWSKI Aleksander [6]

(1) Xijing Hospital, Shaanxi, China; (2) Radboudumc, Nijmegen, the Netherlands; (3) National University of Ireland Galway, Galway, Ireland; (4) American Heart of Poland, Katowice, Poland; (5) Andrzeja Frycza Modrzewski Krakow Univeristy, Kraków, Poland; (6) American Heart of Poland, Chrzanow, Chrzanow, Poland

Aims: Experienced femoral artery access interventionists still prefer this route for percutaneous coronary intervention. However, radial access has shown to reduce mortality and bleeding events, especially in patients with acute coronary syndromes. Little is known regarding the merits of each vascular access in patients stratified by their bleeding risk.

Methods and results: A total of 14,629 participants from the GLOBAL LEADERS trial were dichotomized into low or high bleeding risk by the median of the PRECISE-DAPT score. There were 7,447 patients with a PRECISE-DAPT score<16 categorised in the low bleeding score group (mean±SD of PRECISE-DAPT: 9.8±3.7) and 7,182 patients with a score≥16 categorised in the high bleeding score group (mean±SD of PRECISE-DAPT: 23.4±7.0). Clinical outcomes were compared at 30 days. In the overall population, there were no statistical differences between radial and femoral access in the rate of primary endpoint, all-cause mortality or new Q-wave MI (HR: 0.70, 95% CI: 0.42-1.15). However, the radial access was associated with a significantly lower rate of secondary endpoint, BARC 3 or 5 bleeding (HR: 0.55, 95% CI: 0.36-0.84). Compared respectively by bleeding risk strata, adjusted Cox proportional-hazards models showed that in the high bleeding score population, primary (HR: 0.47, 95% CI: 0.26-0.85, p=0.012, pinteraction=0.019) and secondary safety endpoint (HR: 0.57, 95% CI: 0.35-0.95, p=0.030, pinteraction=0.631) favored radial access. In the low bleeding score population however, the differences in the primary (HR: 3.51, 95% CI: 0.80-15.35, p=0.095) and secondary (HR: 0.69, 95% CI: 0.29-1.60, p=0.381) endpoints between vascular access were no longer statistically significant.

Conclusions: Our findings suggest the outcomes favour radial access in patients with high but not those with low bleeding risk. Since this was not a primary analysis, it should be considered hypothesis-generating that in patients with high bleeding risk, radial access should be always adopted whenever considered feasible.

Bifurcation lesion - Tools, devices and techniques

The efficacy and safety of modified jailed balloon technique for complex true bifurcation lesions

SHISHIDO Koki [1], SHISHIDO Koki [1], MORIYAMA Noriaki [1], HAYASHI Takahiro [1], OCHIAI Tomoki [1], TOBITA Kazuki [1], YAMANAKA Futoshi [1], MIZUNO Shingo [1], TANAKA Yutaka [1], TAKAHASHI Saeko [1], SAITO Shigeru [1]

(1) Shonan Kamakura General Hospital, Kanagawa, Japan

Aims: Percutaneous coronary intervention (PCI) for true bifurcation lesions has high risk for adverse events. Side branch (SB) occlusion is one of the most serious complications. The aim of this study is to evaluate the short- and long-term clinical outcomes after treatment of true bifurcation lesions using a modified jailed balloon technique (MJBT).

Methods and results: The method of MJBT was that a jailed balloon was introduced into SB after crossing guidewires into both branches, while a stent was placed in MB as crossing over side branch. The position of jailed balloon is carefully adjusted as its proximal end is attaching to MB stent, then both stent and jailed balloon were simultaneously inflated. After that, the proximal optimisation technique, guidewire exchange, kissing balloon inflation and provisional stenting were applied at the operators' discretion. Between February 2015 and February 2018, 328 patients with 349 true bifurcation lesions underwent PCI using MJBT. True bifurcation lesions were defined as Medina classifications (1,1,1), (1,0,1) or (0,1,1) lesions. We investigated the procedural and long-term clinical outcomes. Furthermore, angiographic outcomes were assessed at follow-up diagnostic angiography. The mean age of patients was 71.6±9.9 years. Procedural success was achieved in all patients; postoperative SB occlusion was noted in only one patient (0.3%). The cumulative incidence of all-cause death was 23 patients (7.0 %) in the follow-up period (median 717 days). Target lesion revascularisation was performed in 19 patients (5.8%) with 23 lesions (6.6%), and 0.6% of myocardial infarction and 0% of definite stent thrombosis were observed. No jailed balloon was trapped. Angiographic follow-up was performed in 243 patients (74.1%); the percent diameter stenosis in SB was not significantly different between after the index procedure and follow-up angiography.

Conclusions: This MJBT is safe and effective in preserving SB patency for true bifurcation lesions. Furthermore, long-term clinical outcomes after MJBT are feasible. If the operators consider provisional approach for true bifurcation lesions, this technique can help to avoid SB occlusions at the time of stent implantation in main vessel.

Stable CAD - Invasive imaging and functional assessment

Endothelial dysfunction in patients with ischaemic cardiomyopathy

SIGISMONDI Andrea [1], SIGISMONDI Andrea [1], ROA GARRIDO Jessica [1], ORTIZ CRUCES Samuel [1], LANDERO GARCIA Fransisco Javier [1], GRACIA HIRALDO MARIA Eugenia [1], BOBO MASSO Esteban [1], GOMEZ FERNANDEZ Prudencia [1], SANCHEZ FERNANDEZ Irene [1], GOMEZ MENCHERO Antonio Enrique [1], DIAZ FERNANDEZ Jose Francisco [1]

(1) Hospital Universitario Juan Ramón Jiménez, Huelva, Spain

Aims: Endothelial dysfunction is described as a mechanism contributing to angina and atherosclerosis. The acetylcholine test with a moderate vasoconstrictor response reflects the existence of endothelial dysfunction that may contribute to myocardial ischaemia. Our objective was to analyse the type of response in the acetylcholine test in patients with previous complete percutaneous revascularisation and persistence of angina.

Methods and results: We recruited 42 patients, from January 2018 until April 2019, with angina and/or positive invasive functional testing for ischaemia and angiographic coronary stenosis <70%. Acetylcholine test was performed according to study protocol (prior signed informed consent). Mean age 64.88±10.01 years, 47.6% diabetics and 23.5% with active smoking. Acetylcholine test was positive in 69% of the patients. In most of the cases we documented changes in the ST segment in the electrocardiogram and negative T (43.47%), and distal and diffuse ischaemia in the angiography (81.48%). The minimum dose of 2 micrograms of acetylcholine was sufficient for a positive test result in one third of the patients (33.33%). In relation to treatment for symptoms, 85.7% were under treatment with beta blockers and 38% with calcium antagonists. Diabetes was the most related factor to a positive.

Conclusions: Endothelial dysfunction can justify two thirds of patients with ischaemic cardiomyopathy and persistent angina, diffusely and in most cases with minimal doses of acetylcholine there is a diffuse vasospasm. These patients are mostly treated with BB and may benefit from a modification of the treatment with calcium antagonists.

Other Coronary interventions - Calcified lesions

Investigation of fracturing capability of coronary lesion modification devices against calcification using a tubular calcified model

ITO Ryota [(1)], ISHIZUNA Yumi [(1)], ZHU Xiodong [(1)], CHEN Zeyu [(1)], UMEZU Mitsuo [(1)], IWASAKI Kiyotaka [(1)]

(1) Waseda University, Tokyo, Japan

Aims: Fracturing calcification before stenting is desired to reduce stent underexpansion. Although several lesion modification devices are available, differences in fracturing capability are not well understood yet due to lesion variations in the clinical situation. The aim of this study was to investigate fracturing capability of currently available balloon-type lesion modification devices using a stenotic tubular calcified coronary artery model. In addition, the fracturing capability of the devices against thicker calcification models was compared.

Methods and results: 50% stenotic tubular calcification models with reference diameter of 3.0 mm were developed. The calcification model with internal diameter and longitudinal length of 1.5 mm and 5 mm, respectively, was prepared. As to the calcification thickness, 400 µm, 450 µm, and 500 µm were prepared by changing the outer diameter. The calcification was fabricated by the mixture of calcium-sulphate-hemihydrate powder, cement powder, and polyurethane resin. The artery model was fabricated with silicone. Based on the clinical report that the threshold of calcification thickness which could be fractured using lesion preparation devices was approximately 450 µm, the mechanical strength of the calcification was adjusted so that non-compliant balloon (NCB) (NC Emerge, Boston Scientific) with 3.0 mm diameter and 10 mm length could fracture the calcification model with the thickness of 400 µm and could not fracture the 450 µm thick calcification. We investigated fracturing capability of the cutting balloon (CB) (Wolverine, Boston Scientific) with 3.0 mm diameter and 12 mm length, the scoring balloon (SB) (Scoreflex, OrubusNeich) with 3.0 mm diameter and 15 mm length, and the non-slip element balloon (NSEB) (NSE Alpha, Aesculap) with 3.0 mm diameter and 13 mm length against the calcification models. The CB, SB, and NSEB respectively equipped with blades made of stainless steel, wires made of nitinol, and non-slip elements made of nylon. In addition, balloon inflation pressure of each device for fracturing the calcification models was compared. Fracturing capabilities of the CB, SB, and NSEB against the 450 µm and 500 µm thick calcification models were investigated. The results showed that the 450 µm thick calcification models could be fractured by the CB at 13.0±1.2 atm (n=6), by the SB at 16.5±1.2 atm (n=6), and by the NSEB at 19.2±1.7 atm (n=6). The CB could fracture the 450 µm thick calcification models at lower inflation pressure than the SB ($p<0.001$) and the NSEB ($p<0.001$). As for the 500 µm thick calcification model, the CB and the SB could fracture calcification while the NSEB could. The fracture of calcification occurred at the locations where the blade or wire came into contact with the calcification. The locations were consistent with portions of the mechanical stress concentration elucidated by finite element analysis. These data suggested that the CB could fracture calcification safely at the lowest pressure.

Conclusions: Our study elucidated that the CB is effective for fracturing completely tubular 450-µm thick calcification model with lower inflation pressure as compared with the SB and NSEB. The CB and the SB could fracture 500-µm thick calcification model, while NSEB could not. Finite element analysis confirmed that the fracture locations of the calcification were coincident with the portions of mechanical stress concentration.

Left main and multivessel disease - Tools, devices and techniques

Long-term clinical outcomes after PCI of unprotected or protected left main coronary artery with second-generation DES

PAPAFAKLIS Michail [1], RAMMOS Aidonis [1], PAPAFAKLIS Michail [1], MPAMPALI Theodora [1], NAKA Katerina [1], KATSOURAS Christos [1], MICHALIS Lampros [1]

(1) University Hospital of Ioannina, Ioannina, Greece

Aims: Percutaneous coronary intervention (PCI) is increasingly used for treating left main coronary artery (LMCA) lesions. We aimed to (1) evaluate the long-term clinical outcome for PCI LMCA with second-generation drug-eluting stents (DES), and (2) compare the results between protected (left coronary artery grafted) and unprotected LMCA PCI.

Methods and results: We retrospectively reviewed outcomes in 90 consecutive patients who underwent protected or unprotected LMCA PCI with second-generation DES (zotarolimus- and everolimus-eluting stents) from 2015 to 2017. All-cause and cardiac mortality, non-fatal myocardial infarction (MI), repeat revascularisation, and the combined major adverse clinical event (MACE: all-cause mortality plus MI plus repeat revascularisation) rates up to four years were assessed by Kaplan-Meier (log-rank test for comparison between groups) and Cox regression statistical analysis. The SYNTAX II score and the respective predicted 4-year mortality rates for PCI or coronary artery bypass grafting (CABG) were computed for all cases with protected PCI LMCA as a measure of comparison against the observed 4-year mortality. EuroSCORE I and II were computed for all cases. Clinical follow-up was completed in 86 patients (96%). Sixty patients (70%) underwent unprotected and 26 patients (30%) underwent protected LMCA PCI. All patients with protected PCI LMCA had a left internal mammary graft in the left anterior descending artery. Thirty-five patients (41%) presented with acute myocardial infarction (ST-segment elevation MI [STEMI]or nonSTE-MI) and 51 (59%) with stable or unstable angina. Ten out of the 11 STEMI cases (91%) were in the protected LMCA group. Median EuroSCORE I (14.11% [8.74-38%] vs 9.6% [IQR 3.03-18.6%]; p=0.006) and EuroSCORE II (5.99% [4.3-11.2%] vs 2.1% [IQR 1.03-5.8%]; p<0.001) were higher in the protected LMCA group, respectively. Cumulative 4-year all-cause mortality (29.5 vs 7.7%, p=0.14), cardiac mortality (17.6 vs 7.7%, p=0.42), MI rate (8.6 vs 5.9%, p=0.49) and repeat revascularisation rate (27.5 vs 10.3%, p=0.165) were all higher in the unprotected LMCA group without reaching statistical significance. The cumulative 4-year MACE rate (48.9 vs 17.2%, p=0.038) was significantly higher in unprotected LMCA. Multivariable Cox regression analysis showed that the independent predictors of 4-year (1) all-cause mortality were acute MI presentation (HR 5.97 [95% CI: 1.15-31.13]) and EuroSCORE II (HR 1.07 [95% CI: 1.01-1.14]); (2) MACE were acute MI presentation (HR 3.07 [95% CI: 1.34-7.02]). In the unprotected LMCA patients without acute MI (n=35), median SYNTAX I score was 22 (IQR 15-28) and median SYNTAX-II predicted 4-year mortality for PCI was 8.9% (IQR 4.4-17.1%) and for CABG 10.6% (IQR 6.4-29.9%), while the cumulative 4-year Kaplan-Meier mortality (i.e. observed mortality) was 6.1%.

Conclusions: In the current era of routine PCI with second-generation DES for LMCA lesions, there is higher long-term mortality and MACE rate in patients with unprotected LMCA. This difference seems to be explained by a higher rate of acute MI in the unprotected LMCA group. Acute MI presentation was the most powerful independent predictor for the long-term outcomes. In patients with unprotected LMCA PCI without acute MI, long-term mortality was much lower and similar to the SYNTAX-II predicted mortality. Larger studies are needed to evaluate the long-term outcomes after PCI for unprotected or protected LMCA lesions.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Radiation exposure reduction and patient outcome by using low-frame-rate fluoroscopy protocol during PCI

GUPTA Ankush [(1)], GUPTA Ankush [(1)], MAHESH Nalin Kumar [(1,2)], DATTA Rajat [(3)], CHHIKARA Sanya [(1)], VIJAYVERGIYA Rajesh [(4)], MAURYA Preetika [(1)]

(1) Base Hospital Delhi Cantt, Delhi, India; (2) INHS Asvini, Maharashtra, India; (3) Army Hospital Research And Referral, Delhi, India; (4) PGIMER Chandigarh, Chandigarh, India

Aims: To assess radiation exposure reduction during PCI using a low-frame-rate fluoroscopy protocol (LFFP) and to study its effect on patient outcome.

Methods and results: 326 patients undergoing PCI were retrospectively analysed before and after the implementation of a low-frame-rate fluoroscopy protocol (LFFP). This protocol consisted of using a combination of fluoroscopy frame rates of 3.8fps and 7.5fps, the use of retrospectively stored fluoroscopy and limiting the use of cineangiography to only when needed as per the operator's discretion. A frame rate of 3.8fps was used for guide catheter hooking, coronary wiring, predilation and post-dilation and a frame rate of 7.5fps was used for lesion assessment and stent placement. All cineangiographic runs and images were recorded at 15fps in both the subgroups and there was no change in the catheterisation laboratory personnel or any other procedural and machine settings throughout the duration of this study. 41% (n=133) patients were included in the pre-LFFP group and underwent PCI at 15fps (frames per second) and 59% (n=193) were included in the post-LFFP group and underwent the procedure at a combination of 3.8fps and 7.5fps using the new protocol. The primary endpoint of this study was radiation exposure in the form of air kerma (mGy). This was measured in conjunction with fluoroscopy time (minutes). Patient outcome was analysed in the form of MACE (major adverse cardiac events) which for the purpose of this study was defined as a composite endpoint of all-cause mortality, target lesion failure, myocardial infarction and stroke. Patients in the post-LFFP group showed a 74.7% reduction in air kerma (mGy) as compared to the pre-LFFP group (433±382mGy vs 1714±1617mGy, $p<0.0001$). Multivariate analysis was also done and showed that increased fluoroscopy time ($p<0.001$, B= 53.63, 95% CI= 47.01-60.25) and lower frame rate ($p<0.001$, B=-1186.90, 95% CI=-1336.91 to -1036.89) were the factors that independently predicted radiation exposure. The use of lower frame rates did not lead to an increase in the fluoroscopy time (15.38±13.58 vs 17.06±14.93 mins, $p=0.529$). There was no difference in procedural complications or in patient outcome (MACE) at 6 months (3.8% vs 3.6%; $p=0.950$).

Conclusions: Low-frame-rate fluoroscopy protocol (LFFP- combination of 3.8 & 7.5 fps) is a feasible and effective method to significantly reduce the radiation exposure in the catheterisation laboratory during PCI without increasing the fluoroscopy time or compromising patient safety despite the lower image quality.

Left main and multivessel disease - Bypass surgery, Other Coronary interventions - Other

Do EXCEL and NOBLE translate into the real-world outcomes and is medical management a viable option? An observational study of five-year outcomes for left main stem disease

JOY George [(1)], JOY George [(1)], EISSA Hany [(2)]

(1) Barts Health NHS Trust, London, United Kingdom; (2) Queen Elizabeth The Queen Mother Hospital, Margate, United Kingdom

Aims: We aimed to uncover the 5-year real-world outcomes of patients with significant left mainstem (LMS) disease managed with PCI or CABG and compare these findings to that of the recent pivotal trials; everolimus-eluting stents or bypass surgery for left main coronary artery disease (EXCEL) and Nordic-Baltic-British Left Main Revascularisation Study (NOBLE). There is a paucity of data advocating for optimal medical management in those deemed too frail for either PCI or CABG. We also compared findings of those receiving medical management to those who were revascularised with either PCI or CABG.

Methods and results: We retrospectively analysed coronary angiogram reports from 1 January 2012 to 31 December 2012 to identify patients with reported significant LMS stenosis on the initial angiogram, defined as angiographic stenosis >50%. We analysed the following 5 years to include data from surgical discharge summaries, catheter lab reports, echo reports and clinic letters to identify outcomes of these patients. Patients were grouped using intention-to-treat and statistical tests included Student's t-test, chi-squared, Kruskal-Wallis, Mann-Whitney U and one-way ANOVA, as necessary. 119 patients were identified, 62% (74) received CABG and 12% (14) received PCI, therefore 74% (88) were revascularised (PCI or CABG) and 26% (31) were medically managed. In PCI vs CABG there was no significant difference in age (71±8 vs 69±8 years p=0.76) and SYNTAX score (25±8 vs 24±9 p=0.68). Risk factor profile was also similar between the groups. There were fewer males in the PCI group (71% vs 92% p=0.049). In PCI vs CABG, there were significantly higher rates of pre-treatment heart failure (mean EF 52%±13 vs 42%±10 p=0.01), and a trend of more emergent presentations (29% [4] vs 5% [4] p=0.08 and higher rate of bifurcation lesions (79% (11) vs 55 (41) p=0.09). There were similar rates of MI, target vessel revascularisation (TVR) and all-cause mortality between the two groups but a higher rate of stroke in the PCI group (14% [2] vs 1% [1] p=0.01). Overall MACE being a composite of stroke, MI, TVR and all-cause mortality were not statistically different but numerically higher in the PCI group (36% [5] vs 23% [17] p=0.12). Medically managed patients were significantly older than those who were revascularised (PCI or CABG n=88) (75± 11 vs 69± 9 years p=0.01) but had no significant difference in SYNTAX score (25±9 vs 24±9 p=0.75) or distal/bifurcation lesions (58% vs 59% p=0.54). Rates of stroke were numerically higher in the medically managed group 6% vs 3% but this did not reach statistical significance p=0.47. The medially managed group had higher MACE (74% [23] vs 25% [22] p=0.000002) driven by MI (19% [6] vs 2% [2] p=0.01) and all-cause mortality (52% [16] vs 19% [17] p=0.01) compared to those with revascularisation.

Conclusions: The results were numerically more reflective of NOBLE outcomes, (MACE 28%. vs 18% for PCI vs CABG p=0.0044) however in the setting of more emergent presentations, higher rates of pre-treatment heart failure and greater lesion complexity, supporting the use of LMS PCI in selected patients. Despite an older cohort in our study, medical management still carries poor outcomes and is remarkably similar to historical studies. This suggests careful consideration is needed before excluding these vulnerable patients from revascularisation.

Stable CAD - Invasive imaging and functional assessment

Diastolic flow predominance of right versus left coronary arteries in patients with coronary disease

SELIGMAN Henry [1,2,3], SELIGMAN Henry [1,2,3], NIJJER Sukhjinder [1,2,3], VAN DE HOEF Tim [4], DE WAARD Guus [5], SHUN-SHIN Matthew [1,2,3], HOWARD James [1,2,3], MEJÍA-RENTERÍA Hernán [6], ECHAVARRIA-PINTO Mauro [5], COOK Christopher [1,2,3], WARISAWA Takayuki [2,3], RAJKUMAR Christopher [1,2,3], NOWBAR Alexandra [1,2,3], ANDROSHCHUK Vitaliy [1,2,3], SEN Sayan [1,2,3], AHMAD Yousif [2,3], VAN LAVIEREN Martijn [4], DANAD Ibrahim [5], KNAAPEN Paul [5], CHAMIE Daniel [7], AL-LAMEE Rasha [1,2,3], MAYET Jamil [1,2,3], ESCANED Javier [6], PIEK Jan [4], VAN ROYEN Niels [5], DAVIES Justin [1], FRANCIS Darrel [1,2,3], PETRACO Ricardo [1,2,3]

(1) Hammersmith Hospital, London, United Kingdom; (2) National Heart & Lung Institute, London, United Kingdom; (3) Imperial College London, London, United Kingdom; (4) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (5) VUmc, Amsterdam, the Netherlands; (6) Hospital Clinico Universitario San Carlos, Madrid, Spain; (7) Instituto Dante Pazzanese, State of São Paulo, Brazil

Aims: Coronary flow is known to be predominantly diastolic in the left coronary artery, but such a pattern is often disputed for the right coronary. We aim to quantify the phasic flow patterns of right coronary arteries of different dominancy types and compare to those of left coronaries in patients with coronary artery disease.

Methods and results: Data from 482 simultaneous intracoronary pressure and flow velocity assessments from 301 patients were analysed from the Iberian-Dutch-English Collaborators (IDEAL) study dataset. Across all vessels, resting coronary flow was higher in diastole, with the magnitude of diastolic predominance being higher for the left coronary (mean diastolic-to-systolic velocity ratio [DSVRrest] was 1.84±0.50 for LAD, 1.87±0.94 for LCx and 1.53±0.34 for RCA). This pattern was also present during hyperaemia (DSVRhyp was 1.71±0.56 for LAD, 1.83±0.60 for LCx and 1.58±0.43 for RCA). The type of RCA dominance affected the magnitude of DSVRrest (RCAdom=1.55±0.35, n=89, RCAco-dom=1.40±0.27, n=9, RCAnon-dom=1.35±0.53, n=3, p[dom vs co-dom]=0.20). Systolic predominance of flow was found only very rarely (2.1%, 10/482), and equally observed in the LCA (7/381, 1.8%). Across all vessels, the pattern of diastolic predominance was not significantly affected by the severity of the underlying stenosis or microvascular dysfunction (DSVR x HSRlog R2=0.0085, p=0.12; DSVR x CFR R2=0.00, p=0.98).

Conclusions: In patients with coronary artery disease undergoing physiological assessment, diastolic flow predominance is seen in the left coronary as well as across all types of right coronary arteries, a pattern which is not largely affected by hyperaemia, stenosis severity or microvascular dysfunction.

Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - CT / MRI imaging

CT-derived FFR is safe, feasible and accurate for coronary artery assessment in patients with severe aortic stenosis: results from the CAST-FFR trial

MICHAIL Michael [1,2], MICHAIL Michael [1,2], IHDAYHID Abdul-Rahman [1], COMELLA Andrea [1], THAKUR Udit [1], CAMERON James [1], MCCORMICK Liam [1], GOOLEY Robert [1], NICHOLLS Stephen [1], MATHUR Anthony [2,3], HUGHES Alun [2], KO Brian [1], BROWN Adam [1]

(1) Monash Medical Centre, VIC, Australia; (2) University College London, London, United Kingdom; (3) Queen Mary University of London, London, United Kingdom

Aims: Coronary artery disease (CAD) is common in patients with severe aortic stenosis (AS) undergoing aortic valve replacement (AVR). Computed tomography-derived fractional flow reserve (CT-FFR) is a clinically utilised modality for the assessment of CAD. However, the feasibility and validity of CT-FFR in patients with severe AS has not been previously assessed.

Methods and results: Patients undergoing pre-AVR coronary angiography were prospectively recruited. Patients underwent invasive FFR using standard protocols with administration of intracoronary nitroglycerin and intravenous adenosine (140 mcg/kg/min). All patients then underwent same day 320-detector row coronary computed tomography angiography (CTA), receiving sublingual nitroglycerin and beta-blockers as necessary to achieve pre-scan heart rate of <60bpm. CTA images were analysed by a central core laboratory (HeartFlow, Inc., Redwood City, California) for independent evaluation of CT-FFR, blinded to invasive FFR values. Results were compared with invasively measured FFR, with ischaemia defined as FFR ≤0.80. 42 patients (68 vessels) underwent invasive FFR and CTA assessment. Of those, 39 patients (92.3%) and 60 vessels (88.2%) had interpretable CTA data enabling CT-FFR computation. CT calcium score was 1,373.3±1,392.9. Mean age was 76.2±6.7 years (71.8% male). Mean aortic valve gradient, valve area and left ventricular ejection fraction were 44.1±11.9 mmHg, 0.89±0.25 cm^2 and 62.9±10.7%, respectively. Mean pre-CTA scan heart rate was 54.2±6.6 beats/min. No patients incurred complications relating to the pre-medication, CTA or invasive FFR protocol. Mean FFR and CT-FFR were 0.83±0.10 and 0.77±0.14, respectively. 38.3% of vessels had an FFR ≤0.80 whilst 41.7% of vessels had CT-FFR ≤0.80. There was good correlation between FFR and CT-FFR (Pearson's rank 0.64, p<0.001). On a per vessel basis, sensitivity, specificity, positive predictive and negative predictive values were 73.9%, 78.4%, 68.0% and 82.9%, respectively with overall diagnostic accuracy of 76.7%. On a per patient analysis, sensitivity, specificity, positive predictive and negative predictive values were 76.5%, 77.3%, 72.2% and 81.0% with overall diagnostic accuracy of 76.9%. The Bland-Altman plot showed the mean bias±standard deviation between FFR and CT-FFR as 0.06±0.11. The area under the receiver operating characteristic curve for CT-FFR was 0.83 (95% confidence interval: 0.72 to 0.93, p<0.0001).

Conclusions: Our results demonstrate that CT-FFR is feasible and safe in patients with severe AS. These preliminary data suggest that the diagnostic accuracy of CT-FFR in this cohort is high and provides the foundation for future research into the use of CT-FFR for coronary evaluation pre-AVR.

Stable CAD - Tools, devices and techniques

Clinical outcomes of patients undergoing PCI with bioresorbable polymer sirolimus-eluting stent(s) for treatment of unstable angina and chronic coronary syndrome

POLAD Jawed [(1)], POLAD Jawed [(1)], ELSMAN Peter [(1)], DE LA FUENTE Sam [(1)], HABIB Najib [(1)]

(1) Jeroen Bosch Ziekenhuis, 's-Hertogenbosch, the Netherlands

Aims: Although compared to stable angina (SA), PCI in acute coronary syndrome is associated with a higher risk of thrombosis and poorer one-year outcomes, it remains unclear whether patients with unstable angina (UA) have higher risk than those with stable angina. In the 2019 ESC guideline, coronary artery disease has been categorised as either ACS or chronic coronary syndrome (CCS) which includes SA and silent ischaemia. The aim of this study is to investigate the frequency and clinical outcomes of patients with UA and CCS one year after PCI with bioresorbable polymer sirolimus-eluting stent(s).

Methods and results: The e-Ultimaster registry (NCT 01288355) is an all-comer, prospective, worldwide, multicentre registry, enrolling 36,916 patients undergoing PCI with thin-strut (80 µm) bioresorbable polymer Ultimaster sirolimus-eluting stents. So far, 34,538 patients reached one-year follow-up and were included in this analysis. The primary endpoint of target lesion failure (TLF) at one year was defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent clinical event committee adjudicated all endpoint related events. All patients were monitored online. At the time of index PCI, 4,103 patients (11.9%) presented with UA, whereas 15,540 patients (45.0%) CCS. Patients with UA were younger (63.8±10.9 vs 65.7±10.5 years, p<0.001) and frequently female (26.2% vs 23.9%, p=0.002), compared to patients with CCS. Regarding comorbidities, patients with UA had a higher prevalence of hypertension (73.0% vs 69.9%, p<0.001), but a lower prevalence of hypercholesterolaemia (57.4% vs 62.2%, p<0.001), and previous PCI (33.4% vs 35.2%, p=0.04). At 1 year after index PCI, dual antiplatelet therapy was continued in 72.0% of patients with UA and 64.9% of patients with CCS (p<0.0001). At 1 year, 86.4% in UA group and 90.9% in CCS group were angina-free (p<0.0001). There were 11.9% and 7.5% of patients reported stable angina at 1 year (p<0.0001), while only 1.1% and 0.6% had unstable angina (p<0.01). The rates of TLF at one year were not different in patients with UA and those with CCS (3.2% vs 2.9%, p=0.30). The rates of cardiac death (0.7% vs 1.0%, p=0.36), TV-MI (1.0% vs 0.8%, p=0.38), definite of probable stent thrombosis (0.5% vs 0.4%, p=0.43), and any bleeding (1.9% vs 1.8%, p=0.85) were also similar in the UA group and CCS group, although the rates of CD-TLR (2.1% vs 1.5%, p=0.01) were significantly higher in the UA group.

Conclusions: In this all-comer registry, approximately 12% of patients had UA at presentation as opposed to 45% presenting with CCS (stable angina and silent ischaemia). At one-year post-PCI, the TLF and stent thrombosis rates were similar in patients with UA and those with CCS. Interestingly, patients undergoing PCI for UA had a significantly lower rate of freedom from angina and a small but significant increase in clinically driven TLR rate.

STEMI - Adjunctive pharmacotherapy, Other Coronary interventions - Other

Clinical characteristics and prognosis of STEMI in young Korean patients

SUH Jon [4], SUH Jon [1], KONG Min Gyu [1], KIM Tae-Hoon [2], JANG Ho-Jun [2], PARK Sang-Don [3], KWON Sung Woo [3], OH Pyung Chun [4], MOON Jeonggeun [4], KANG Woong Chol [4]

(1) SoonChunHyang University Bucheon Hospital, Bucheon, Republic of Korea; (2) Sejong General Hospital, Bucheon, Republic of Korea; (3) Inha University Hospital, Incheon, Republic of Korea; (4) Gachon University Gil Hospital, Incheon, Republic of Korea

Aims: Acute myocardial infarction (AMI) is still one of the leading cause of mortality and disability in cardiovascular disease. AMI in young patients is a significant issue in recent socio-economic aspects. We evaluated clinical characteristics and prognosis in young patients with ST-segment elevation myocardial infarction (STEMI).

Methods and results: From 2007 to 2014, 1,537 consecutive patients of INTERSTELLAR (Incheon-Bucheon Cohort of Patients Undergoing Primary PCI for Acute STEMI) registry were divided into two groups according to age. 172 patients were in the young (under 45 years) age group and there were 1,365 patients aged over 45 years in the older age group. We compared clinical characteristics and outcomes between two groups. Primary endpoints were in-hospital and all-cause death within 1 year. The young age group revealed significantly higher prevalence of male gender and current smoking compared to the older age group. BMI was higher in the young age group as well. In contrast, there were lower rates of diabetes, hypertension, and multivessels disease in the young age group than the older age group. In-hospital and 1-year mortality were significantly lower in the young age group (1.7% vs 6.3%, p=0.016; 2.9% vs 9.7%, p=0.003).

Conclusions: In young age patients under 45 years, STEMI occured more often in patients with male gender, current smoker, and higher BMI. However, young patients with STEMI had better clinical outcomes than older patients with STEMI.

Bifurcation lesion - Tools, devices and techniques

Impact of stent strut thickness on clinical outcome after DES implantation for coronary bifurcation lesions: results from the European Bifurcation Club – P2BiTO registry

DI SERAFINO Luigi [1,4], DI SERAFINO Luigi [1], CIRILLO Plinio [1], ZIMARINO Marco [2], BARBATO Emanuele [1], BRIGUORI Carlo [3], CHIEFFO Alaide [4], PETROV I [5], RADICO F [2], NAKAMURA S [6], STANKOVIC G [7]

(1) University of Naples Federico II, Metropolitan City of Naples, Italy; (2) Institute of Cardiology "G. d'Annunzio" University, Chieti, Italy; Interventional cath lab, ASL 2 Abruzzo, Chieti, Italy; (3) Interventional Cardiology Unit, Clinica Mediterranea, Naples, Italy, Naples, Italy; (4) Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy., Milan, Italy; (5) City Clinic, Sofia, Bulgaria; (6) Department of Cardiology, New Tokyo Hospital, Chiba, Japan., Chiba, Japan; (7) Department of Cardiology, Clinical Center of Serbia, University of Belgrade, Serbia., Belgrade, Serbia

Aims: Stent strut thickness (SST) might impact the rate of stent thrombosis and target vessel revascularisation in patients undergoing PCI. However, in the context of a coronary artery bifurcation, it is not well known whether the total stent strut thickness (TSST), calculated as the theoretical sum of the thickness of all the stent strut layers deployed at the polygon of confluence (POC), might impact the clinical outcome. Thus, the aim of the present study was to assess this possible association in consecutive all-comer patients included in the European Bifurcation Club (EBC) P2BiTO registry.

Methods and results: Data on 5036 consecutive patients who underwent PCI on coronary bifurcation at 17 major coronary intervention centres between January 2012 and December 2014 were collected. The primary endpoint of the study was the cumulative occurrence of major adverse cardiac cerebrovascular events (MACCE), defined as a composite of overall death, non-fatal myocardial infarction (MI), target vessel revascularisation (TVR) and stroke during the follow-up; the secondary endpoints were the single occurrence of any of the above-mentioned events. Data about stent type and bifurcation technique adopted was available for 3,878 patients (77%). Patients were divided into 3 groups according to the TSST tertiles at the level of the POC: Group 1) TSST<81 mm (n=649); Group 2) TSST>81 mm but<112mm (n=1937); Group 3) TSST>112 mm (n=1292). Follow up was completed in 3,817 (98%) patients at a median of 20 months (CI: 12-28). MACCE occurred more frequently in patients with the largest TSST (Group 3) as compared with both Group 1 and 2 (respectively, 146 (11%) versus 52 (8%) and 168 (8%), HR: 1.25, 95% CI: 1.07-1.46, p=0.005). This difference was mainly driven by the higher rate of TVR (respectively, 109 (8%) vs 32 (5%) and 85 (4%), p<0.001) and it remained after adjustment for clinical and angiographic characteristics (HR: 2.01, 95% CI: 1.00-4.01, p=0.048). On the contrary, no significant difference was found between patients included in the Group 1 and Group 2. At the Kaplan-Meier analysis, freedom from MACCE survival was significantly lower in patients with the highest TSST (Group 3) (log-rank: 10.95, p=0.004).

Conclusions: A larger amount of total stent strut thickness deployed at the level of the POC is associated with a significantly higher risk of MACCE among patients undergoing DES-PCI for a bifurcation stenosis.

Stents and scaffolds - Adjunctive pharmacotherapy

Impact of bleeding and myocardial infarction on mortality in all-comer patients undergoing PCI: insights from the GLOBAL LEADERS trial

HARA Hironori [1], HARA Hironori [1], TAKAHASHI Kuniaki [1], TOMANIAK Mariusz [2], ONO Masafumi [1], KAWASHIMA Hideyuki [1], WANG Rutao [3], GAO Chao [3], WINDECKER Stephan [4], ONUMA Yoshinobu [5], SERRUYS Patrick W. [5,6]

(1) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (2) EMC, Rotterdam, the Netherlands; (3) Radboud Universiteit, Nijmegen, the Netherlands; (4) University hospital, Bern, Switzerland; (5) National University of Ireland Galway, Galway, Ireland; (6) Imperial College London, London, United Kingdom

Aims: Bleeding and myocardial infarction (MI) after percutaneous coronary intervention (PCI) are independent risk factors for mortality. This study sought to investigate the association of all-cause mortality after PCI with site-reported bleeding and MI, when considered as individual, repeated or combined events.

Methods and results: We used the data from the GLOBAL LEADERS trial, an all-comers trial of 15,968 patients undergoing PCI. Bleeding was defined as Bleeding Academic Research Consortium grade 2, 3 or 5, whilst MI included periprocedural and spontaneous MIs according to the Third Universal Definition. Each event was treated as time-dependent covariates in a Cox model. At 2-year follow-up, 1,061 and 498 patients (6.64% and 3.12%) experienced bleeding and MI, respectively. Patients with a bleeding event had a 10.8% mortality (HR 5.97; p<0.001) and the mortality of patients with an MI was 10.4% (HR 5.06; p<0.001), whereas the overall mortality in the whole cohort of the trial was only 2.99%. Albeit reduced over time, bleeding and MI increased the mortality shortly after the adverse event (<30 days), as well as between 31-365 days and between 367-730 days (p<0.001 for all). The mortality rates in patients with repetitive bleeding, repetitive MI, and combined events of bleeding and MI were 16.1%, 19.2%, and 19.0%, and the HRs for 2-year mortality were 8.58, 5.57, and 6.60, respectively (p<0.001 for all).

Conclusions: The fatal impact of bleeding and MI is highly significant, and albeit reduced, persisted beyond the first year. Repetitive and combined events of bleeding and/or MIs resulted in an even poorer prognosis. These results emphasize the importance the net adverse clinical event (NACE) end point including ischaemic and bleeding events.

Bifurcation lesion - Tools, devices and techniques

Impact of DAPT duration on clinical outcome after stent implantation for coronary bifurcation lesions: results from the European Bifurcation Club P2BiTO registry

DI SERAFINO Luigi [(1)], DI SERAFINO Luigi [(1)], CIRILLO Plinio [(1)], GAMRA H [(2)], ZIMARINO Marco [(3)], AMAT-SANTOS I.J. [(4)], BARBATO Emanuele [(1)], ERGLIS A [(5)], GIL R.J. [(6)], STAKOVIC G [(7)]

(1) University of Naples Federico II, Metropolitan City of Naples, Italy; (2) Cardiology Department, Fattouma Bourguiba Hospital, University of Monastir, Monastir, TUNISIA; (3) Institute of Cardiology "G. d'Annunzio" University, Chieti, Italy; (4) CIBERCV, Hospital Clínico Universitario de Valladolid, Valladolid, Spain; (5) Latvian Centre of Cardiology, Pauls Stradins Clinical University Hospital, Riga, Latvia; (6) Department of Invasive Cardiology, Central Clinical Hospital of the Ministry of Interior, Warsaw, Poland; (7) Department of Cardiology, Clinical Center of Serbia, University of Belgrade, Serbia., Belgrade, Serbia

Aims: Duration of dual antiplatelet therpy (DAPT) following acute coronary syndrome (ACS) or stable coronary artery disease (SCAD) treated with coronary stenting is still debated. The relationship between DAPT duration, treatment of bifurcations and its impact on clinical outcome has been poorly investigated in real-world registries. We evaluated the impact of DAPT duration on clinical outcomes in consecutive all-comer patients treated with stenting of coronary artery bifurcation lesions included in the European Bifurcation Club P2BiTO registry.

Methods and results: Data on 5,036 consecutive patients who underwent PCI on coronary bifurcation at 17 major coronary intervention centres between January 2012 and December 2014 were collected. The primary endpoint of the study was the cumulative occurrence of major adverse cardiac cerebrovascular events (MACCE), defined as a composite of cardiac death, non-fatal myocardial infarction (MI), target vessel revascularisation (TVR) and stroke during the follow-up; the secondary endpoints were the single occurrence of any of the above-mentioned events. Data on DAPT duration was available for 3,992 patients (79%). Patients were divided into 3 groups: Group 1) DAPT<6-months (n=720); Group 2) DAPT>6-months but <12-month (n=1602); Group 3) DAPT>12-months (n=1670). Follow-up was completed in 3,935 (98%) patients with a median of 20 months (CI:12-28). MACCE occurred more frequently in the DAPT<6-month group (Group 1) as compared with both Group 2 and 3 (respectively, 102 (14%) versus 154 [10%] and 164 [10%], HR: 0.72, 95% CI: 0.64-0.82, p<0.001). This difference remained after adjustment for clinical and angiographic characteristics (HR: 0.66, 95% CI: 0.58-0.77, p<0.001). On the contrary, no significant difference was found between Group 2 and Group 3 patients. At Kaplan-Meier analysis, freedom from MACCE survival was significantly lower in patients receiving DAPT for less than 6 months (Log-Rank: 29.5, p<0.001).

Conclusions: Short DAPT duration (< 6 months) is associated with a significantly higher risk of MACCE compared to longer DAPT in a real-world registry of patients treated with DES-PCI for coronary artery bifurcation stenosis.

Stable CAD - Invasive imaging and functional assessment

Is the ISCHEMIA trial relevant to a rapid access chest pain clinic?

MORA Jessica [1], MORA Jessica [1], KASHYAP Mavin [1], CONNOLLY Georgia May [1,2], SAMMUT Eva [1,2], DASTIDAR Amardeep [1], NIKHIL Joshi [1], DE SILVA Kalpa [1], DORMAN Stephen [1], STRANGE Julian [1], JOHNSON Thomas [1]

(1) Bristol Royal Infirmary, Bristol, United Kingdom; (2) University of Bristol, Bristol, United Kingdom

Aims: Ischaemic heart disease is a leading cause of mortality worldwide. The recently presented ISCHEMIA trial demonstrates that optimal medical therapy (OMT) is not inferior to an early interventional approach for patients with stable angina. These results have the potential to significantly impact future care pathways. However, it is important to consider how these apply to real-world clinical services.

Methods and results: Electronic notes of all patients assessed in a high-volume rapid access chest pain clinic (RACPC) within a 12-month period (2018–19) were reviewed. Patients retrospectively meeting the key inclusion criteria for the ISCHEMIA trial were selected. Information on demographics, symptoms, initial investigations and management were obtained. 2,416 patients were assessed in the RACPC during the study period. Of these, 378 (15.6%) presented with symptoms thought to represent typical anginal chest pain (CP), 1,357 (56.2%) had atypical CP and 681 (28.2%) had non-anginal CP. Of the typical CP group (n=378), 158 patients were excluded (62 due to ACS, 91 due to known CAD, 3 due to known severe LV impairment, 2 due to eGFR <30mL/min). This resulted in a total of 220 patients meeting key inclusion criteria of the ISCHEMIA trial, representing 58.2% of the typical chest pain population but only 9.1% of all patients seen in the RACPC. These patients had a median age of 60 years, 96 (44%) female, 44 (20%) had diabetes, 119 (54.1%) had high cholesterol, 104 (47.3%) had a family history of heart disease, 115 (52.3%) had hypertension and 32 (14.5%) were current smokers. From these 220 patients, 48 (21.8%) had a CT coronary angiogram (CTCA) requested as their first line investigation (42 completed). Of these patients, 1 (2.4%) patient had findings suggestive of significant left main stem (LMS) disease. 15 (6.8%) patients had stress echocardiography requested as their first line investigation (13 completed), 4 were positive for inducible ischaemia. 3 (1.4%) patients had stress CMR requested as their first line investigation (2 completed), both were negative tests. 143 (65%) patients had an invasive coronary angiogram (ICA) requested as their first line investigation (112 completed). 8 patients had severe LMS disease and were referred for surgical opinion. A further 11 patients were referred for surgical opinion due to multivessel disease or aberrant coronary anatomy. In total 24 (21.4%) patients were treated with PCI following ICA as their first line investigation. All patients were started on medical therapy for presumed CAD with up-titration while awaiting investigations. The median wait time for a CTCA was 55 days compared to ICA which was 165.5 days. Two patients from the cohort of 220 patients with typical angina have died to date during the follow up period.

Conclusions: In the real world, patients present with undifferentiated chest pain and consequently the outcomes of the ISCHEMIA trial must be considered cautiously. Within our cohort of 2,416 patients, only 220 patients met the trial's key inclusion criteria. Our patients were younger, more frequently female and not diabetic. Referral for invasive tests was the most common pathway, however service pressures resulted in a significant delay to treatment. Ultimately, only 19.5% received revascularisation, unlike 80% of patients in the invasive arm of ISCHEMIA. It is unclear how the results of the ISCHEMIA trial will ultimately impact on UK practice, but it is clear that OMT plays a central role.

Stable CAD - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

FFR vs quantitative flow ratio vs iFR: a comparison of the dose of ionizing radiation

ZIUBRYTE Greta [1], ZIUBRYTE Greta [1], JARUSEVICIUS Gediminas [1,2]

(1) Department of Cardiology, Hospital of Lithuanian University of Health Sciences Kaunas Clinics, Kaunas, Lithuania; (2) Institute of Cardiology, Lithuanian University of Health Sciences, Kaunas, Lithuania

Aims: The aim of this study was to assess the difference of ionizing radiation parameters such as dose area product (DAP) and fluoroscopy time (FT) among three intravascular functional assessment methods including FFR, quantitative flow ratio (QFR) and iFR.

Methods and results: In total, 379 patients who underwent coronary angiography revealing intermediate lumen stenosis of 35-75% by visual estimation and for whom FFR, QFR or iFR measurements were performed between 1 January 2018 and 31 December 2019 were retrospectively included into our single-centre study. Dose area product (DAP) and fluoroscopy time (FT) were the parameters chosen for ionizing radiation dose evaluation and comparison. Statistical analysis was performed using software package SPSS 20.0. The chosen level of significance was $p<0.05$. Of all included functional assessment analyses, 172 were FFRs, 130 were QFRs and 77 were iFRs. Mean DAP and FT were 2,134.67 (SD±166.61) cGy cm^2 and 5.94 (SD±0.34) min. vs 1616.38 (SD±140.25) cGy cm^2 and 2.83 (SD±0.24) min. vs 2345.39 (SD±255.01) cGy cm^2 and 9.67 (SD±0.71) min. during FFR vs QFR vs iFR procedures respectively. Compared to FFR as a reference, FT was almost 2-fold lower in QFRs and almost 2-fold higher in iFRs, $p<0.001$. It was found that iFR measurements take more than 3-times longer compared to QFR computation, $p<0.001$. Meanwhile DAP, which is closely related with angiography technique and patients' constitution, was higher in iFR compared to QFR (mean difference 730.01 (SD±289.79), $p=0.03$) without any statistically significant difference between other groups.

Conclusions: The increasing variety of intravascular functional assessment methods become an issue deciding which of them is the most convenient, easiest to use and reliable enough. Since FFR, QFR and iFR have been proved equal in their diagnostic accuracy and performance, the convenience and safety of them remain debatable. QFR might be appreciated for its minimal invasiveness without a decrease of accuracy, resulting in shortest FT, reducing the overall procedural duration and patient's exposure to ionizing radiation, while FFR representing average FT and DAP values remains the gold standard method giving the unambiguous answer in ambiguous situations.

Other Coronary interventions - Other

The use of topical haemostatic disc facilitates rapid and safe haemostasis following radial coronary angiography

SHUNMUGAM Ragunath [(1)], SHUNMUGAM Ragunath [(1)], CAUSTON Lucy [(1)], KUNNUMPURATH Anamika [(1)], AIMEN Umme [(1)], TAHILYANI Ashok [(1)], MARCINIACK Maciej [(1)]

(1) East Surrey Hospital, Redhill, United Kingdom

Aims: To assess the safety and efficacy of haemostasis using a topical haemostatic disc in addition to TR band following coronary angiography through transradial access.

Methods and results: Data was collected on 32 radial angiography procedures using Statseal in conjuction with TR band (Str) and 32 patients with TR band alone (TR). All patients were assessed following arterial sheath removal and at a minimum of 1 week post procedure for haematoma and radial artery occlusion. Radial artery patency was assessed using telephonic consultation, where patients were requested to palpate their radial pulse, or they were assessed physically during routine follow-up. There was no evidence of radial artery occlusion in any of the patients in both groups. Haematoma was observed in 2 patients in Str group and 3 patients in the TR group. There was no significant difference in the amount of heparin used between the two groups. Time to haemostatis was significantly less when Statseal was used in conjuction with TR band. Mean duration to haemostatsis was 63.28 minutes (Str) and 141.81 minutes (TR), with a two tailed P value <0.0001

Conclusions: The use of Statseal in conjunction with TR band significantly reduces time to haemostasis and is equally safe in comparison to using TR band alone.

Stents and scaffolds - Tools, devices and techniques

Size of the segment for BRS technologies in contemporary real-life coronary revascularisation: data from the FEAST.RU multicentre study in 1,575 patients

GANYUKOV Vladimir [1], GANYUKOV Vladimir [1], STOLYAROV Dmitry [3], PROTOPOPOV Alexey [2], LIKHACHEV Vitaliy [4], FEDORCHENKO Alexey [5], KOLEDINSKY Anton [6], MASASIN Vasily [7], VYGOVSKY Alexander [10], AKOBYAN Tigran [10], MUSIALEK Piotr [8,9]

(1) Federal State Budgetary Scientific Institution Research Institute for Complex Issues of Cardiovascular Diseases, Kemerovo, Russian Federation; (2) Regional Clinical Hospital, Krasnoyarsk, Russian Federation; (3) Federal Cardiovascular Center, Krasnoyarsk, Russian Federation; (4) Regional Hospital (FCCS), Perm, Russian Federation; (5) Regional Clinical Hospital S.V. Ochapovsky, Krasnodar, Russian Federation; (6) State Hospital S.S.Yudina of the Department of Health in Moscow, Moscow, Russian Federation; (7) Federal Center for Cardiovascular Surgery, Chelyabinsk, Russian Federation; (8) Jagiellonian University Dept. of Cardiac and Vascular Diseases, Krakow, Poland; (9) John Paul II Hospital, Kraków, Poland; (10) Federal Cardiovascular Center, Kaliningrad, Russian Federation

Aims: Development of BRS technologies continues to be an important target in cardiovascular medicine. However, fundamental data are lacking on BRS real-life segment size in contemporary coronary revascularisation. We evaluated feasibility of complete coronary revascularisation using Absorb BRS in an all-comer elective coronary revascularisation patient population in a large multicentre setting with external angiographic corelab analysis and external study monitoring.

Methods and results: FEAST.RU (FEasibility and outcomes of complete coronary revascularisation using bioresorbable vascular scaffold in All-comer patients with stable and unstable angina: a multicentre study) was a prospective study in unselected, consecutive patients in 14 centres. Complete revascularisation (CR) was defined as an angiography-effective revascularisation of all ischaemic lesions. Data collection (central unified database) and verification were external and involved an independent angiographic analysis in 100% study subjects, and 12-month clinical follow-up with event (including device thrombosis) adjudication by a clinical events committee. Absorb BRS use was the study protocol first-consideration strategy but BRS employment (vs a metallic stent) for any particular lesion was entirely per operator's decision. Target population was at least 1,500 consecutive coronary revascularisation patients. The study was monitored externally. Database management and statistical analysis were investigator-independent (contract research organisation). 1,575 patients were enrolled. PCI (radial access in 81.2%) was performed in 1,458 (93%; CABG-7%) subjects. There were 1,771 PCI-treated lesions using a total of 1,198 BRS (57.9%) and 870 metallic stents (42.7%). On a per-patient analysis, complete coronary revascularisation using only BRS (ie, no metallic stent/s) was achieved in 51.1% (95% CI: 48.6-53.6%), with 64.9% in 1-vessel disease, 24.4% in 2-vessel disease and 10.7% in multivessel disease. Mean total device/s-per-lesion length was 21.9±5.7 (BRS) vs 22.9±7.1 mm (metallic stent) (p=0.02). For BRS-treated lesions, non-compliant balloon use for pre-and post-dilatation showed a significant increase both per study duration terciles and per patient volume terciles (p<0.01 for all). The main reasons for metallic stent rather than BRS use were BRS instruction for use incompatibility (55.7%, including primarily vessel or lesion out of BRS size range, severe calcification or severe tortuosity), operator-anticipated issues with BRS delivery/use (41.4%) or clinical reasons that included incompatibility with 12-month dual antiplatelet therapy (1.4%). Residual diameter stenosis <10%, 10-30% and >30% (BRS vs metallic stent/s) occurred respectively in 96.6% vs 98.3%, 3.3% vs 1.6% and 0.1% vs0.2% (p=0.15). With judicious BRS use in this study, externally-adjudicated 12-month device thrombosis rate was 0.85% (BRS) and 0.89% (metallic stent) (p=0.7)

Conclusions: This large, externally-monitored multicentre study with 100% angiographic analysis and a unique design focused on anatomic feasibility and operator preferences in consecutive PCI patients, showed a BRS complete revascularisation in more than half of all-comer PCI population, including nearly 2/3 of patients with single-vessel disease. Treatment with BRS employing a first-line BRS consideration but not mandated BRS use (57.9% BRS-treated lesions, 51.1% entire-BRS complete coronary revascularisation) was clinically effective with <1% device thrombosis at 12 months.

Stable CAD - Adjunctive pharmacotherapy, Left main and multivessel disease - Adjunctive pharmacotherapy

Ticagrelor monotherapy following one-month DAPT in octogenarian patients undergoing PCI – a post hoc analysis of the randomised GLOBAL LEADERS trial

TOMANIAK Mariusz [1], TOMANIAK Mariusz [1], GAO Chao [2,3], ONO Masafumi [4], KAWASHIMA Hideyuki [4], VRANCKX Pascal [5], VALGIMIGLI Marco [6], WINDECKER Stephan [6], DOMINICI Marcello [7], ONUMA Yoshinobu [8], SERRUYS Patrick [8,9]

(1) Erasmus MC, Rotterdam, the Netherlands, Medical University of Warsaw, Warsaw, Warsaw, Poland; (2) Department of Cardiology, Xijing Hospital, Xi'an, China; (3) Radboudumc, Nijmegen, the Netherlands; (4) Amsterdam UMC, locatie AMC, Amsterdam, the Netherlands; (5) Department of Cardiology and Critical Care Medicine, Hartcentrum Hasselt, Jessa Ziekenhuis, Hasselt, Belgium; (6) Bern University Hospital, Bern, Switzerland; (7) Azienda Ospedaliera Santa Maria, Province of Terni, Italy; (8) National University of Ireland Galway, Galway, Ireland; (9) Imperial College London, London, United Kingdom

Aims: Elderly patients represent more than one-third of patients undergoing percutaneous coronary interventions (PCI) and with the ageing society, this percentage is expected to grow. However, the elderly undergoing PCI still tend to be under-represented in contemporary PCI trials, including the studies on novel antiplatelet regimens. We aimed to evaluate the efficacy and safety of ticagrelor monotherapy following 1-month dual antiplatelet therapy (DAPT) after PCI in the octogenarian patients (aged > 80 years) enrolled in the contemporary, all-comer PCI cohort of the GLOBAL LEADERS trial.

Methods and results: This is a *post hoc* analysis of the randomised multicentre GLOBAL LEADERS trial comparing the experimental strategy of 23-month ticagrelor monotherapy after 1 month DAPT (ticagrelor and aspirin) with the reference strategy of 12-month DAPT followed by 12-month aspirin monotherapy in 15,991 patients undergoing PCI. Impact of age on clinical outcome at 2 years was evaluated specifically in the octogenarian population (>80 years of age). The primary endpoint was a composite of all-cause mortality or non-fatal, centrally adjudicated, new Q-wave myocardial infarction (MI). In the octogenarian patient population (n=1,241) the primary endpoint occurred in 9.6 % of patients in the experimental group (n=626) and in 10.6% of patients in the reference group (n=615) (hazard ratio [HR] 0.90, 95% confidence interval [95% CI: 0.63 – 1.28, p=0.551]) at 2 years (p int=0.55); Bleeding Academic Research Consortium (BARC)-defined bleeding type 3 or 5 occurred in 6.7% and in 4.6% of patients (HR 1.49, 95% CI: 0.92-2.40, p=0.102, p int = 0.10), respectively. No significant differences in the rates of all-cause mortality (8.3% vs 8.9%, p=0.672), MI (3.8% vs 4.2%, p=0.736), stroke (2.6% vs 2.3%, p=0.749), revascularisation (7.8% vs 8.8%, p=0.549) and target vessel revascularisation (4.2% vs 6.3%, p=0.088) were observed between the experimental and the reference treatment group among the octogenarian patients.

Conclusions: No significant differences were found in the rates of the primary endpoint of all-cause death or non-fatal, new Q-wave MI among the very elderly patients undergoing PCI at the age of above 80 years treated with 23-month ticagrelor monotherapy after 1-month DAPT, as compared with subjects receiving 12-month DAPT followed by 12-month aspirin monotherapy.

Other Coronary interventions - Calcified lesions

Outcome of PCI with rotablation in chronic kidney disease patients

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Coronary calcification is prevalent among patients with chronic kidney disease (CKD). Percutaneous coronary intervention (PCI) is always challenging for interventional cardiologists in patients with calcified vessel because of necessity to rotablate. The aim of this study was to assess both short and long-term outcome of patients with CKD undergoing rotablation.

Methods and results: All consecutive CKD patients who underwent rotablation from January 2015 to October 2019 were included in this study. Patients were categorised into three groups: mild CKD (eGFR 60 -89.99 mL/min/1.73 m^2) group; moderate CKD (eGFR 30 -59.99 mL/min/1.73 m^2) group and severe CKD (eGFR 15 -29.99 mL/ min/1.73 m^2) group. Total patients with CKD were 203. Male were predominant (73.4% vs 26.6%). Thirty-eight percent (37.9%) patients were in mild CKD group; 55.7% patients were in moderate CKD and 6.4% patients were in severe CKD group. Mean age in mild CKD group was 59.53±7.77 years; in moderate CKD group was 65.77±7.68 years and in severe CKD group was 74.23±9.79 years. Most common risk factor was hypertension (90.6%) followed by diabetes mellitus (65.5%), dyslipidaemia (57%) and smoking (51%). Chronic stable angina was diagnosed in 73% cases and acute coronary syndrome in 27% cases. Good left ventricular (LV) function was present in 45% patients; mild LV dysfunction in 41.9% patients; moderate LV dysfunction in 11% patients and severe LV dysfunction in 1% patients. History of coronary artery bypass grafting (CABG) was present in 10% patients; percutaneous coronary intervention (PCI) in 16% patients; both in 2% patients; 14% patients had chronic total occlusion and 36% patients had left main involvement. Mean follow-up period was 24.11±1.8 months. Overall MACE was 10.8%; in-hospital mortality was 1.5% and long-term mortality was 10.3%. Symptom-driven check-CAG was done in 23 patients. In-stent restenosis was present in 0.49% patients.

Conclusions: With increasing age severity of CKD is increased. Rotablation is safe and effective tool for treating calcified lesion in CKD patients.

Other Coronary interventions - Other

Prognostic value of the residual SYNTAX score in octogenarians undergoing PCI

ABRAMIK Joanna [1], ABRAMIK Joanna [1], KONTOGIANNIS Nestoras [1], SCARSINI Roberto [2], DE MARIA Giovanni Luigi [2], RAINA Tushar [1], KASSIMIS George [3]

(1) Cheltenham General Hospital, Cheltenham, United Kingdom; (2) John Radcliffe Hospital, Oxford, United Kingdom; (3) Aristotle University of Thessaloniki, Thessaloniki, Greece

Aims: The residual SYNTAX score (rSYNTAX) is an objective measure of the degree and complexity of residual stenosis after percutaneous coronary intervention (PCI). A raised rSYNTAX has been shown to correlate with increased mortality. Octogenarians often pose the greatest challenges in terms of achieving complete revascularisation due to the complexity of coronary artery disease, vascular calcification requiring use of adjunctive therapies and limitations related to comorbidities. We assessed the association between incomplete revascularisation and one-year mortality in octogenarians undergoing PCI.

Methods and results: A retrospective analysis of 673 consecutive octogenarians who underwent emergency or elective PCI at a large non-surgical cardiac centre in the UK between January 2007 and December 2016 was performed. The SYNTAX scores before and after PCI were calculated. Patients were stratified according to terciles of baseline and rSYNTAX score. Furthermore, patients were classified as completely revascularised if the rSYNTAX was equal to 0, or incompletely revascularised otherwise. A residual (rSYNTAX) score of 0 was achieved in 269 (42%) of patients with multivessel disease. Using multivariate analysis, incomplete revascularisation was found to be an independent predictor of 1-year mortality (OR 1.04 (1.02-1.06), $p<0.0001$). Other predictors of mortality included age, diabetes mellitus, raised serum creatinine and presence of cardiogenic shock on presentation. Incomplete revascularisation was also associated with an increased risk of in-hospital complications ($p=0.001$) including in-hospital death ($p<0.0001$).

Conclusions: The residual SYNTAX score is a useful tool in quantifying incomplete revascularisation in patients undergoing PCI for multivessel coronary artery disease. In the very elderly patients studied in our cohort, incomplete revascularisation appears to confer a higher one-year mortality and increased risk of in-hospital complications.

STEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Prognosis of STEMI due to stent thrombosis versus de novo coronary thrombosis in the modern era

KATSIKIS Athanasios [(1)], KATSIKIS Athanasios [(1)], KONSTANTINOU Klio [(1)], ALSANJARI Osama [(1)], KEEBLE Thomas [(1)], GAMMA Reto [(1)], TANG Kare [(1)], KELLY Paul [(1)], DAVIES John [(1)], CLESHAM Gerald [(1)], KARAMASIS Grigoris [(1)]

(1) Basildon University Hospital, Basildon, United Kingdom

Aims: To investigate the prognosis of patients presenting with STEMI due to stent thrombosis (ST-STEMI) versus patients with *de novo* coronary artery thrombosis in the modern era of interventional cardiology.

Methods and results: Patients with STEMI presenting for primary PCI to our hospital between 2015-2019, who were treated either with a new-generation DES or non-stent treatment and were eligible to receive 12-months DAPT as a minimum were included in the study. This population was classified in two groups: patients with *de novo* STEMI (n=2,066) and patients with ST-STEMI (n=137). Using 1:1 propensity score matching, the two groups were matched for: age, sex, risk factors for CAD including diabetes, history of MI or CABG, renal function, LVEF, presentation with cardiac arrest or cardiogenic shock, mechanical ventilation, location of culprit vessel, use of IIb/IIIa inhibitors, thromboaspiration and intravascular imaging, initial TIMI-flow rate, access-site and performance of multivessel PCI. Follow-up was performed to document periprocedural complications, all-cause death (ACD) and target-lesion revascularisation (TLR), with the latter being used for censoring. Kaplan-Meier analysis was used to compare survival and standard paired-tests to compare other outcomes between the two groups. In the unmatched population, patients with ST-STEMI were more likely to be hypertensive, dyslipidemic and diabetic, present with cardiac arrest, have a history of MI and CABG and have invasive management using non-radial access and adjunctive intravascular imaging. After matching, two groups of 115 patients each were formed with no significant differences in all baseline and procedural characteristics ($p<0.05$, standardised mean differences ≤15%), except for mode of treatment. Patients with *de novo* STEMI received more frequently stent-treatment compared to ST-STEMI patients (92% vs 70%, $p<0.001$). Proportion of TIMI 3 flow-rate achieved after invasive management in the matched population was non-significantly higher in the *de novo* STEMI group (83% vs 77%, p=0.2). No difference in the composite of non-local, periprocedural complications and stroke rates was observed between ST-STEMI and *de novo* STEMI, in both the unmatched (11% vs 7%, p=0.08) and the matched (12% vs 7%, p=0.2) population. Rates of in-hospital death for the *de novo* STEMI and the ST-STEMI groups were 5% vs 7% (p=0.2) and 8% vs 8% for the unmatched and the matched population respectively. At 4-year follow-up, 283 deaths were observed. In Kaplan-Meier analysis, ACD-free survival at 4 years was significantly higher for the *de novo* STEMI group (87% vs 82%, p=0.02) in the unmatched population, but similar to the ST-STEMI group in the matched population (85% vs 80%, p=0.2). In a landmark analysis at 1-year, the *de novo* STEMI group had higher survival in the first year (p=0.02) but similar survival between 1 and 4 years (p=0.08) compared to the ST-STEMI group, in the unmatched population. Such a differential survival was not observed in the landmark analysis of the matched population.

Conclusions: In a contemporary treatment environment, the unadjusted survival of patients with STEMI due to ST is worse than that of patients with *de novo* coronary thrombosis, with the major differences being observed during the first year after presentation. However, when these groups are matched for differences in baseline characteristics, their prognosis after invasive management appears to be similar.

Other Coronary interventions - Calcified lesions

Real-world experience of use of intravascular lithotripsy with or without adjunctive therapy

UPADHYAYA Subramanya GN [1], UPADHYAYA Subramanya GN [1], VARMA Chetan [1], SHARMA Vinoda [1], LEE Leong [1]

(1) Birmingham City Hospital, Birmingham, United Kingdom

Aims: We describe the first-year real-world experience and outcomes of an intravascular lithotripsy (IVL) programme at a large non-surgical teaching hospital in the United Kingdom.

Methods and results: A 1-year retrospective analysis of all IVL cases between 29 November 2018 and 28 November 2019 was performed. Case and procedure notes data were obtained using electronic patient records at Birmingham City Hospital and British Cardiac Interventional Society database. A total of 31 patients underwent IVL in the initial year. The median age was 73 years with 71% male patients, and 64.5% with diabetes mellitus. All patients had hypertension and dyslipidaemia with appropriate therapies. The indications for PCI were acute coronary syndrome (n=8, 25.8%), stable angina (n=11, 35.4%), and staged revascularisation (n=12, 38.7%). The coronary artery treated with IVL was left main stem (16.1%), left anterior descending artery (35.4%), right coronary artery (35.4%) and circumflex artery (12.9%). Guide extensions and microcatheters were used in 35.4% and 29% of cases respectively. Pre- and post- IVL intracoronary imaging was performed in 48.4% (optical coherence tomography, 29% and intravascular ultrasound, 19.4%) of cases. IVL balloon sizes used were 2.5 mm (22.6%), 3 mm (16.1%) and 3.5 mm (16.1%) and 4 mm (45.2%). In the majority of cases (54.8%) an adjunctive device was required initially to facilitate delivery of the IVL balloon. Rotablation was used in 22.6% cases, scoring balloons in 16.1% cases, rotablation and scoring balloon both were used in 16.1% cases. There were 2 (6.4%) chronic total occlusions with severe tortuosity and calcified proximal caps requiring both rotablation and IVL. There was no statistical difference in baseline demographics (paired t–test, p-value=NS) and the intracoronary imaging guidance (chi square test, p-value=NS) between the adjunctive and no adjunctive therapy groups. Procedural success with angiographic residual stenosis of <50% was achieved in 100 % of cases. There was 1 (3.2%) serious periprocedural complication (Ellis-3 perforation requiring covered stent and pericardiocentesis). However, this complication was likely related to stent oversizing and not directly to IVL treatment. There were 3 (9.6%) minor periprocedural complications (2 small distal wire perforations, 1 septal branch perforation/haematoma), all of which spontaneously resolved without the need for additional intervention or pericardiocentesis. No periprocedural major adverse cardiac and cerebrovascular events (MACCE) or death were recorded. The median follow-up was 27 weeks (4-56 weeks) without any recorded mortality or MACCE.

Conclusions: Intravascular lithotripsy appears to be a safe and effective calcium modification technique. In our real-world practice, complementary adjunctive devices are often required to facilitate balloon and stent delivery. The complication rate reflects the complexity of coronary disease treated rather than the use of IVL.

Stable CAD - Invasive imaging and functional assessment

Interplay of patient temperament type and coronary ischaemia estimated with FFR

SRECKOVIC Miodrag [1,2], SRECKOVIC Miodrag [1,2], JAGIC Nikola [5], NESKOVIC Aleksandar [5,6], SRDANOVIC Ilija [3,4], KOVACEVIC Mila [3,4], ALEKSANDRIC Srdjan [6,7], VUCIC Rada [1,2], MILORADOVIC Vladimir [1,2], DAVIDOVIC Goran [1,2]

(1) Faculty of Medical Sciences University of Kragujevac, Kragujevac, Serbia; (2) Clinical Centre of Kragujevac, Kragujevac, Serbia; (3) Medical Faculty in Novi Sad, Novi Sad, Serbia; (4) Institute of Cardiovascular Diseases, Sremska Kamenica, Sremska Kamenica, Serbia; (5) Zemun Hospital, Belgrade, Serbia; (6) Medical School Belgrade, Belgrade, Serbia; (7) Clinical Centre of Serbia, Belgrade, Serbia

Aims: Psychological characteristics of patients are recognised as confounding risk factors for ischaemic heart disease. Aim of our study is to determine the interplay of patients temperament type with coronary ischaemia estimated with FFR. We wanted to determine if there is a statistically significant difference in the type of temperament in the group of patients with ischaemic lesions, defined as FFR ≤ 0.80, compared to the group of patients without ischaemic lesions, FFR> 0.80.

Methods and results: One hundred forty-seven patients were enrolled in our research. A multicentre, cross-sectional analytical study was performed. Coronary artery lesions were evaluated using quantitative coronary analysis (QCA) and they were considered as intermediate if they were within the range 50–80%. The study population consisted of patients for whom FFR measurement was planned to evaluate the ischaemic potential of intermediate coronary lesions. Psychological characteristics of patients were evaluated using Temperament Evaluation of Memphis, Pisa, Paris and San Diego Autoquestionnaire (TEMPS-A) self-report questionnaire, that examines and evaluates 5 types of affective temperaments: hypertensive (manic), depressed, irritable, cyclotomic, and anxious. Study sample consists of 147 patients. 74.1% were male, 99.3% suffer from hypertension, 81% are married, while 65.3% of the study population were retired. 63 patients (42.8%) had an FFR value of ≤0.80 and they represent an ischaemic group, 84 patients (57.1%) had a FFR value of >0.80 and they represent a non-ischaemic group. The average value of FFR measurements in the study population was 0.82±0.8, the average stenosis value estimated by QCA was 66.24±8.60. The average age of the patients included in the study was 63 years. The highest scores on TEMPS A scale were obtained for hyperthymic and anxiety temperaments. Analysing the data, we found that there is a statistically significant difference between the tested groups by depressive tempperament (p=0.028), and that the difference is close to statistical significance by irritable temperament (p=0.058) and cyclothymic (p=0.075). We also determined that there is no statistically significant difference between the study groups according to whether the patient had a previous IM (for depressed temperament p=0.244, for hyperthymic p=0.620, for anxious p=0.788, for irritable p=0.150, for cyclotmic p=0.384).

Conclusions: Previous studies concluded that depressive, cyclothymic and anxious temperament is more frequent in women, whereas hyperthymic and irritable temperaments predominate among men. In a study conducted by Eory et al. it was shown that dominant cyclothymic affective temperament may be an additional risk factor in cardiovascular morbidity. When we compare our results with a study conducted by Stetkiewicz-Lewandowicz et al, we can conclude that our results, as far as the type of temperament of patients with coronary artery disease, are in contrast with the results obtained in the aforementioned study. The explanation may lie in the fact that, in addition to our predominantly male population, who scored higher on the hyperthymic temperament scale, we also use superior diagnostics to determine the presence of coronary ischaemia.

STEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Self-apposing stent in STEMI: 12-month clinical results of two prospective, multicentre and observational studies

ANGIOI Louis [(1)], HUYNH Vi-Phong [(1)], COLES Tom [(1)]

(1) Stentys, Paris, France

Aims: to assess the safety and efficacy of a nitinol, self-apposing, sirolimus-eluting stent, pre-mounted on a novel balloon delivery system in a subgroup of patients presenting with STEMI.

Methods and results: SIZING and WIN registries were designed to assess the safety and efficacy of a self-apposing stent in various lesion subsets. Both registries are prospective, multicentre and observational studies. Combining both registries, there is a total of 1,483 patients treated, which includes 473 STEMI patients (31.89%). The objective is to validate the use of a self-apposing stent in patients presenting with ST-elevated MI. Patients were clinically followed 12 months after the index procedure. Most of the lesions treated were *de novo* lesions with 72.8% of class B2/C lesions. The mean reference vessel diameter was 4.06±0.71 mm and the mean lesion length was 22.39±10.04 mm. The target lesion diameter stenosis was 94.52±12.3% preprocedure. A severe or moderate presence of thrombus was observed in 60.6% of the cases. TIMI flow preprocedure grade 0 & 1 represented 67.1% of the cases. Thrombus aspiration was performed in 44.6% of the procedures. Predilatation was performed in 74.0% of procedures with a max pressure of 14.27±4.02atm and post-dilatation in 85.6% with a max pressure of 16.87±4.38atm. The mean residual stenosis was 2.52±8.11% post-procedure. The procedure success was 95.1% of cases. The MACE rate at a mean follow-up duration of 373±42 days was 3.53%, which included 1.51% of cardiac death, 1.26% of target vessel-related myocardial infarction and 1.26% of target lesion revascularisation. We detected 3 cases of definite and 2 cases of probable stent thrombosis, giving rates of definite and probable stent thrombosis of 0.76% and 0.50% respectively.

Conclusions: In this large data analysis on the treatment of STEMI patients with a self-apposing stent, we observed very low rates of clinical events at 12 months post procedure. These results confirm the interest of the self-apposing Xposition S for the treatment of this challenging patient population alongside its safety and efficacy.

Stable CAD - Vascular access and bleeding, Other Coronary interventions - Other

Nitroglycerin for the prevention of radial artery complications during percutaneous coronary angiography: a systematic review and meta-analysis

MEREDITH Thomas [1], O'DRISCOLL Ronan [2], MAMO Andrew [3], JAIN Pankaj [1], MULLER David [1]

(1) St Vincent's Hospital, NSW, Australia; (2) St George Hospital, NSW, Australia; (3) The Sutherland Hospital, NSW, Australia

Aims: The aim of this systematic review was to explore the role of nitroglycerin (GTN) in reducing radial artery complications in patients undergoing transradial coronary artery procedures.

Methods and results: Five databases (CINAHL, SCOPUS, PubMed, Medline, and Web of Science) were queried from their inception until October 2019 for randomised and non-randomised trials with a referent non-vasodilatory control arm, reporting on the prophylactic use of GTN in patients undergoing coronary angiography via the transradial approach. Outcome data of interest were radial spasm, radial occlusion/thrombosis, puncture attempts, access time and bleeding complications. Data were analysed using RevMan 5.3 software (The Nordic Cochrane Centre, Copenhagen, Denmark). Outcomes were stratified by mode of administration. Differences were expressed as relative risk (RR) with 95% confidence intervals (CI) for dichotomous outcomes, and the mean difference (MD) with 95% CI: for continuous outcomes. The Mantel-Haenszel (M-H) random effects model was used. Heterogeneity was assessed using the I^2 statistic, with an I^2 >50% indicating significant heterogeneity. Non-pooled data are presented qualitatively. Of 1,876 titles retrieved, 33 full texts were assessed for eligibility after title and abstract screening. Of these, 23 were excluded leaving 10 studies for inclusion in the systematic review, encompassing 3,487 patients with mean ages between 54.1 and 63.7 years old. GTN was administered subcutaneously (SC) in five studies, intra-arterially (IA) in four, and topically in one study. In pooled analysis, prophylactic SC GTN was associated with a significant reduction in mean puncture attempts compared to control (MD -0.26, 95% CI: -0.44 to 0.09, p=0.003, I^2 = 0%). SC GTN was associated with a mean reduction in access time of 30.2 seconds (95% CI: -51.72 to -8.71, p<0.001), though owing to variable outcome definitions there was significant heterogeneity (I2 = 97%) of these pooled data. There was no difference in the incidence of radial site bleeding with the use of SC GTN (RR 1.0, p=1.0), though outcome definitions were highly variable. Prophylactic GTN administered through the radial sheath (IA) significantly reduced the risk of intra-procedural radial spasm (RR 0.31, 95% CI: 0.2 to 0.48, p<0.001) as did subcutaneous GTN (RR 0.43, 95% CI: 0.19 to 0.97, p=0.04), though transdermal GTN was not significantly different from control (RR = 1.0, p=1.0) . Two studies examined the effect of GTN as prophylaxis against post-procedural radial occlusion. SC administration was associated with a numerical though non-significant reduction in occlusion (RR 0.38, 95% CI: 0.14 to 1.01, p=0.05) whilst GTN administered through the radial sheath was associated with a significantly reduced risk (RR 0.7, 95% CI: 0.52 to 0.94, p=0.02).

Conclusions: Routine use of nitroglycerin in transradial coronary angiography reduces the risk of radial spasm, with a trend towards reduced incidence of post-procedural occlusion. Administration via the subcutaneous route confers the additional benefits of reduced puncture attempts and time to cannulation.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Assessment of the conventional radial artery with OCT after the distal transradial approach using a 6Fr sheath

KIM Yongcheol [1], KIM Yongcheol [1,4], LEE Sang Yeub [2], BAE Dae-Hwan [2], LEE Dae In [2], LEE Ju-Hee [2], KIM Sang Min [2], BAE Jang-Whan [2], HWANG Kyung-Kuk [2], KIM Dong-Woon [2], OH Sung Sik [3], CHO Myeong-Chan [2], JEONG Myung Ho [4]

(1) Yongin Severance Hospital, Yongin, Republic of Korea; (2) Chungbuk National University Hospital, Chungcheongbuk-do, Republic of Korea; (3) Presbyterian Medical Center, Jeonju, Republic of Korea; (4) Chonnam National University Hospital, Gwangju, Republic of Korea

Aims: This study aimed to evaluate acute injuries of the radial artery (RA) using optical coherence tomography (OCT) in patients who underwent coronary intervention via the distal transradial approach (dTRA).

Methods and results: Forty-six patients, who underwent coronary intervention and assessment of the conventional RA using OCT via dTRA, were enrolled from two university hospitals between August 2018 and August 2019. The mean age of the patients was 65.1 years. In this study population, 6 French (Fr) sheaths were used. The mean diameter of the conventional RA was 2.89±0.33 mm, and the mean lumen area of the conventional RA was 6.68±1.56 mm^2. Acute injuries of the conventional RA, after the dTRA, were observed in 5 patients (10.9%). Intimal tear was observed in the RA in one case (2.2%). Intraluminal thrombi, without vessel injuries, were detected in the RA in four cases (8.7%). However, medial dissection was not observed in the OCT analysis.

Conclusions: This retrospective OCT-based study showed that the diameter of the conventional RA was 2.89 mm and acute vessel injury of the conventional RA was rare in patients who underwent coronary intervention via the dTRA using the 6 Fr sheath.

Other Coronary interventions - Other

Radiation safety with current-generation cardiac fluoroscopy imaging system

GHOSE Tapan [(1)], KACHRU Ranjan [(1)], DEY Jaideep [(1)], SHAMS Akmal [(1)], PANT Aparna [(1)]

(1) Fortis Flt. Lt. Rajan Dhall Hospital, Vasant Kunj, Delhi, India

Aims: There are limited studies on radiation dose with new-generation cardiac fluoroscopy systems in cardiac catheterisation laboratories. The aim of this study is to compare a latest-generation imaging system with an older-generation system for radiation dose during coronary angiography (CAG)/percutaneous coronary intervention (PCI).

Methods and results: Between September 2019 and December 2019, 108 all-comer patients undergoing CAG (48 patients)/PCI (60 patients) were divided into 2 groups based on fluoroscopy system utilised during procedure; Philips Azurion 7M12, Group I (new-generation with stent boost live technology) and Philips Allura Xper FD-10, Group II (old-generation with stent boost subtract imaging technology). During a comparative study, in the CAG cohort, parameters recorded were mean procedure time (31.14±13.22 vs 36.77±18.90 minutes; p=0.19), mean fluoroscopy time (3.17±2.02 vs 5.34±6.71 minutes; p=0.10), mean fluoroscopy dose (533.24±206.70 vs 1068.47±1865.62 mGy; p=0.13) & mean dose-area product (36.12±13.54 vs 38.61±38.35 Gy-cm^2; p=0.74) while in the PCI cohort, mean procedure time (88.71±31.97 vs 75.00±31.28 minutes; p=0.14), mean fluoroscopy time (24.70±12.12 vs 18.97±10.65 minutes; p=0.09), mean fluoroscopy time (3742.04±1990.82 vs 3148.74±1575.29 mGy; p=0.26) & mean dose-area product (242.95±128.82 vs 141.53±94.69 Gy-cm^2; p=0.003) were noted respectively.

Conclusions: There were no significant differences in radiation dose parameters between new- and old-generation cardiac fluoroscopy systems during CAG/PCI except significantly higher mean dose-area product during PCI with new-generation system. Further large studies are needed to assess the full impact of newer fluoroscopy imaging techniques on radiation dose in cardiac catheterisation laboratory.

Stable CAD - Tools, devices and techniques

Acute angiographic results comparing lesion preparation by cutting balloon, scoring balloon, and non-compliant balloon before DEB angioplasty in in-stent restenosis

YUKI Katagiri [(1)], KATAGIRI Yuki [(1)], HOSOI Yuichiro [(1)], BOTA Hiroki [(1)], TANI Tomoyuki [(1)], YAMASAKI Kazumasa [(1)], TAKENOUCHI Go [(1)], GOHIRA Yasunobu [(1)], KURODA Ken [(1)], OTOMARU Yuri [(1)], YAMAZAKI Seiji [(1)]

(1) Sapporo Higashi Tokushukai Hospital, Hokkaido, Japan

Aims: In lesion preparation before drug-coated balloon (DCB) angioplasty in in-stent restenosis (ISR), scoring balloon showed superior angiographic outcome as compared to standard lesion preparation. However, the efficacy of cutting balloon predilatation has not been well investigated before DCB angioplasty in ISR as compared to scoring balloon predilatation. The aim of the present study is to compare acute angiographic results with lesion preparation by cutting-balloon, scoring balloon, and non-compliant balloon before DCB angioplasty in ISR.

Methods and results: We retrospectively enrolled 109 patients with 147 ISR lesions who underwent DCB angioplasty after lesion preparation either by cutting balloon (Wolverine, Boston Scientific, Natick, MA), scoring balloon (NSE Alpha, Goodman, Japan), or non-compliant balloon in our centre from April 2018 to July 2019. The mean age was 74.2 years old and 67.6% were male. Cutting balloon, scoring balloon, and non-compliant balloon were used in 53/147 (36.1%), 46/147 (31.3%), 48/147 (32.7%) lesions, respectively. Preprocedural minimal lumen diameter (MLD) was 1.15±0.56, 1.09±0.45, 1.23±0.56 mm, respectively (p=0.406). Post-procedural MLD after DCB inflation was 2.24±0.64, 2.27±0.46, 2.04±0.50 mm, respectively (p=0.093). Acute gain was 1.09±0.63, 1.18±0.48, 0.81±0.56 mm, respectively (p=0.005). Acute recoil after DCB inflation was 4.6±20.8, 9.8±16.1, 13.0±15.9%, respectively (p=0.061).

Conclusions: Acute angiographic results of lesion preparation before DCB angioplasty by cutting balloon was superior to those by non-compliant balloon and similar to those by scoring balloon. Acute recoil in the cutting balloon group was numerically smaller than the other predilatation balloon groups. The future study is needed to confirm the repercussions of acute angiographic results on late angiographic and clinical outcome.

Stable CAD - Tools, devices and techniques

Incidence of complications after PCI: analysis from all-comers registry

VASSILEV Dobrin [(1)], MILEVA Niya [(1)], VASSILEV Dobrin [(1)], NIKOLOV Pavel [(1)], DIMITROV Georgi [(1)], KARAMFILOFF Kiril [(1)]

(1) Aleksandrovska University Hospital, Sofia, Bulgaria

Aims: Despite the numerous proved benefits of percutaneous coronary intervention, serious and potentially life-threatening complications can occur. The purpose of this study is to evaluate the relationship between various predictors and the incidence of different complications.

Methods and results: We analysed patients from all-comers registry who had complicated percutaneous coronary intervention (PCI) for a 5-year period. Continuous variables were compared using an unpaired Student's t-test and categorical data using chi-square test. If distribution was not norma,l Wilcoxon signed-rank test and Mann-Whitney test were applied. Logistic regression analysis was used to evaluate relationship between various predictors and different complications. A total of 147 patients with complicated PCI (2.4% from all 6,126 PCIs) for the period July 2014 – July 2019 were included in the analysis. The mean age was 69±11 years, 37% females, 97% hypertensive, 35% diabetics, 59% smokers, 26% with atrial fibrillation, 45% with previous PCI, 33% with previous MI and 6% previous CABG, 18% with cerebrovascular disease, 9% with carotid artery disease, 61% renal failure (eGFR <60 ml/min). The distribution of the different type of complications were as follows: bleeding (BARC 2, 3 or 5) 17%; contrast induced nephropathy 11.6%; access site complication 6.8%; coronary perforation 27.2%; coronary intramural haematoma 4.8%; cardiogenic shock 12.9%. Overall in-hospital mortality for the complicated PCI group was 26%. We analysed the group of the two most common type of complications, coronary perforation occurring in 0.65% of all PCIs and bleeding, in 0.4% of all PCIs. These groups differed significantly regarding Syntax score (CI: 3.63-10.418, p<0.001), LDL-cholesterol levels (95% CI: 0.318-1.610, p=0.004) and lesion length (95% CI: 13.345-37.454, p<0.001), while there were no significant differences regarding comorbidities. On binary logistic analysis, predictors for coronary perforation were smoking (OR=0.300, 95% CI: 0.115-0.785, p=0.014), treatment of chronic total occlusion (OR=7.932, 95% CI: 3.254-14.218, p=0.011) and diabetes (OR=5.236, 95% CI: 1.125-3.289, p=0.026). The only significant predictor for incidence of bleeding complication was the presence of renal failure (OR=5.071, 95% CI: 1.461-22.411, p=0.012).

Conclusions: Complications after percutaneous coronary intervention are associated with increased in-hospital mortality. Independent predictors from the most common type of complications were the presence of diabetes, smoking, renal failure and the treatment of chronic total occlusion.

Stents and scaffolds - Tools, devices and techniques

Time series radial expansion performance of a magnesium-alloy BRS deployed in a stenotic coronary artery model: investigation under a pulsatile and biochemically duplicated circulation

ISHIZUNA Yumi [(1)], SUGIYAMA Kota [(1)], MATSUBARA Kaito [(1)], ITO Ryota [(1)], CHEN Zeyu [(1)], ZHU Xiodong [(1)], UMEZU Mitsuo [(1)], IWASAKI Kiyotaka [(1)]

(1) TWIns Waseda, Tokyo, Japan

Aims: Bioresorbable magnesium-alloy (Mg-alloy) scaffolds theoretically expand stenotic lesions and are resorbed after lesion healing. Discrepancy between *in vitro* and *in vivo* test data is an unsolved issue which renders development of Mg-alloy resolved by corrosion challenging. The aim of this study was to develop an *in vitro* test system which simulates coronary circulation and *in vivo* biochemical environments. Moreover, time series radial expansion performance of a bioresorbable Mg-alloy scaffold deployed in a stenotic lesion model was investigated.

Methods and results: Resorption of Mg-alloy could be affected by flow and pressure environment, radial-direction load from expanded stenotic lesion, and biochemical components in blood. We developed a circulation system which simulates *in vivo* left anterior descending (LAD) coronary artery flow and pressure. A 75% stenotic coronary artery model was developed using silicone. The stenotic model of which expansion ratio is consistent between *in vitro* and clinical data using a cobalt-chromium metallic stent was prepared by regulating elastic modulus of lesion and artery model. Because Mg-alloy is resolved by corrosion, we hypothesised that the concentration of chloride would impact on time series mechanical integrity of Mg-alloy scaffolds. As circulation fluid, we investigated foetal bovine serum (FBS), because concentrations of chloride ion and proteins in the FBS are comparable to those of human blood (concentration of chloride: 98 mmol/L). For comparison, phosphate buffered saline (PBS) (concentration of chloride: 139.6 mmol/L) and simulated body fluid (SBF) (ionic concentrations of Na+, K+, Mg2+, Ca2+ are equivalent and Cl2- is higher than human blood) were used (concentration of chloride: 148.8 mmol/L). To keep a pH range of FBS within the range of 7.30-7.45, 10% carbon dioxide gas was supplemented through a compliant silicone tube. A two-peaked LAD flow waveform with mean flow rate of 60 mL/min and mean pressure of 100 (120/80) mmHg was duplicated. In total, five scaffolds with 3 mm in diameter and 18 mm in length were tested, one in phosphate buffered saline, two in simulated body fluid, and two in FBS. Time series changes in scaffold diameters were measured using a digital microscope. Acute recoil of the scaffolds was 6.7% in PBS, 10.4%, and 6.6% in SBF, and 6.3% and 4.3% in FBS, and there are no differences. Distinct diameter reduction was observed when PBS and SBF were used. In PBS, the scaffold fracture was observed at 18 days, and diameter at the stenosis was reduced after the fracture by 2.4% at 28 days and 16.3% at 67 days. In SBF, scaffold fractures were also observed at 12 days and 18 days, respectively. The diameters were gradually reduced before and after the fractures. The diameter was reduced by 7.3% at 33 days and by 22.4% at 47 days for one scaffold, and reduced by 12.4 % at 15 days and by 30.3% at 30 days for the other scaffold. In contrast, under the circulation of FBS, the diameters plateau through 18 days' circulation and no scaffold fracture was observed.

Conclusions: Our study elucidated that adjustment of chloride concentration in the circulating fluid to human blood could be essential to conduct reliable *in vitro* tests. From our study, FBS was considered useful. Moreover, under the pulsatile flow and pressure circulation of FBS, the Mg-alloy scaffold deployed in the 75% stenotic lesion model sustained the luminal diameter without reduction through 18 days.

Other Coronary interventions - Other

A simplified technique of cannulating left distal radial artery with comparative analysis with right radial artery cannulation during coronary intervention

GHOSE Tapan [(1)], KACHRU Ranjan [(1)], DEY Jaideep [(1)]

(1) Fortis Flt. Lt. Rajan Dhall Hospital, Vasant Kunj, Delhi, India

Aims: Left distal radial arterial access (ldTRA) is a patient-friendly access site for coronary intervention. Previous studies had adopted a complicated vascular access technique. This study aims to assess feasibility and safety of a simplified technique of left distal radial artery cannulation.

Methods and results: As part of ongoing study (VKLITE- Vasant Kunj Left dIstal Transradial artEry approach study, CTRI/2019/07/020002), between April 2018 and September 2019, 103 consecutive patients ≥20 years of age with palpable ldTRA undergoing coronary angiography (CAG)/percutaneous coronary intervention (PCI) were enrolled. Nonpalpable ldTRA or positive modified Allen's test were exclusion criteria. Diameter and flow in left radial artery were assessed at wrist, anatomical snuff box and distal vessel using ultrasonography. After subcutaneous infiltration with 2.0cc lidocaine solution, radial artery was punctured distally or at anatomical snuff box using a 20-gauge needle under ultrasound guidance (Seldinger technique). A 0.025'' guidewire was introduced through the needle and exchanged for 5 Fr radial sheath. In PCI cases, 5 Fr sheath was exchanged for a 6 Fr sheath. On confirming arterial pressure tracing, 5,000U unfractionated heparin, 2.0cc verapamil, 5.0cc nitroglycerine was injected through sheath. CAG & PCI were performed by usual technique. After completion of procedure, radial sheath was withdrawn, manual compression was applied at puncture site and adjoining area till haemostasis achieved. In case of puncture site complication, further compression was applied till complete haemostasis was achieved. Puncture site was covered with non-compressive tape and local examination done hourly for 3 hours to look for arterial pulse or any new complications. Successful arterial puncture, CAG and PCI rates were 95.15% (98/103), 90.00% (90/100), 93.93% (31/33). Mean puncture time, procedure duration, haemostasis duration and fluoroscopy time (minutes) were 7.26±7.14,56.55±32.23,23.84±12.26&11.82±11.81 respectively. Puncture site complications occurred in 12 patients (11.65%): minor haematoma in 9 patients (8.74%), 2 patients (1.94%) had major haematoma resolving within 3 weeks' time, 1 patient had guidewire embolisation which was retrieved successfully. Mean pain score and satisfaction score was 2.4±2.3 and 9.0±1.3. There was no radial artery loss, dissection, pseudoaneurysm, arteriovenous fistula formation or nerve injury. In a comparative study with 82 patients simultaneously undergoing CAG/PCI via the right radial artery access there was no significant difference in mean radiation dose 78.11±84.07 vs 62.01±53.47 Gray-cm^2, p=0.15 and fluoroscopic time during CAG 5.52±4.60 vs 4.87±3.01 minutes, p=0.36. There was a trend towards increased fluoroscopic time during PCI in ldTRA patients with more complex target lesions in the ldTRA cohort. Mean procedure duration 56.55±32.23 vs 44.15±22.73 minutes, p=0.004 was significantly more in ldTRA patients driven by increased puncture time in the first 22 cases.

Conclusions: ldTRA access is feasible and safe with low incidence of complications during CAG/PCI with conventional hardware & a simplified puncture technique under ultrasound guidance. Less patient discomfort and high level of patient satisfaction makes this approach an attractive option for coronary intervention.

Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

Prognostic implications of three-vessel, 3D quantitative coronary angiography-based vessel FFR among patients with coronary artery disease

TOMANIAK Mariusz [1,2], TOMANIAK Mariusz [1,2], MASDJEDI Kaneshka [1], NELEMAN Tara [1], DEN DEKKER Wijnand [1], WILSCHUT Jeroen [1], DILETTI Roberto [1], KARDYS Isabella [1], ZIJLSTRA Felix [1], VAN MIEGHEM Nicolas [1], DAEMEN Joost [1]

(1) Erasmus MC, Rotterdam, the Netherlands; (2) Medical University of Warsaw, Warsaw, Poland

Aims: Patients with high as compared to low total physiologic atherosclerotic burden assessed by three-vessel (3V) invasive FFR have a higher risk of 2-year clinical events. However, invasive functional lesion assessment entails inherent costs, time investment and patient discomfort in case an hyperaemic agent is used. We aimed to evaluate the prognostic value of the sum of the three dimensional (3D) quantitative coronary angiography (QCA)-derived vessel fractional flow reserve (vFFR) computed in three vessels (3V-vFFR) in patients with coronary artery disease (CAD).

Methods and results: Consecutive CAD patients referred for Heart Team consultation were screened for eligibility and vFFR was computed in all 3 major epicardial arteries. Exclusion criteria involved: presentation with STEMI, significant valve disease, LVEF<30%, severe chronic kidney disease, previous CABG or CABG planned following Heart Team discussion, inadequate quality of angiogram precluding vFFR computation in all 3 epicardial coronary arteries (i.e. absence of a minimum of two angiographic projections with views of at least 30° apart, substantial foreshortening or overlap of the vessel, ostial left or right coronary artery disease) and unavailability of baseline aortic root blood pressure. 3V-vFFR burden defined as the sum of the vFFR in three vessels was estimated. Rates of major adverse cardiac events (MACE), defined as the composite of cardiac death, myocardial infarction (MI) and clinically driven revascularisation, were reported in patients stratified according to the median vFFR. Cox proportional hazard model was built to evaluate the relationship between 3V-vFFR and clinical outcomes. 3V-vFFR could be computed in 309/734 patients (age 65.2±10.8, 68.3% male, 45.6% ACS). Median (interquartile range, IQR) vFFR of the individual vessels was 0.84 (0.69-0.93). Median 3V-vFFR of the patients was 2.51 (2.27-2.68). During a median follow-up of 962 (604-1274) days, 58 patients experienced MACE. Patients with a low (≤2.50) 3V-vFFR (n=153) had a higher rate of MACE, compared with patients with a high (>2.50) 3V-vFFR (26.1% vs 14.5%, hazard ratio [HR] 2.06, 95% confidence interval [95% CI] 1.21-3.53, p=0.008). In the multivariable Cox proportional hazard model, low 3V-vFFR remained a significant independent predictor of MACE (HR 2.32, 95% CI: 1.33-4.03, p=0.003) after adjustment for age, gender, diabetes, mild-to-moderate renal dysfunction, prior MI, multivessel disease and presentation with ACS.

Conclusions: 3V-vFFR computation was associated with risk of MACE in patients with multivessel CAD referred for Heart Team consultation. 3V-vFFR calculated from routine angiograms proved able to provide prognostic information in patients with CAD incremental to conventional risk factors.

Bifurcation lesion - Tools, devices and techniques

Survival analysis of functionally-guided strategy of treatment coronary bifurcation lesions – insights from FIESTA registry

SERRUYS Patrick [5], VASSILEV Dobrin [1], MILEVA Niya [1], NIKOLOV Pavel [1], DIMITROV Georgi [1], KARAMFILOFF Kiril [1], NAUNOV Vladimir [1], RIGATELLI Gianluca [2], COLLET Carlos [3], GIL Robert [4]

(1) Aleksandrovska University Hospital, Sofia, Bulgaria; (2) Rovigo Medica, Province of Rovigo, Italy; (3) Olv Ziekenhuis, Aalst, Belgium; (4) Medical Centre of Postgraduate Education, Warsaw, Poland; (5) Imperial College London, London, United Kingdom

Aims: The purpose of this study is to evaluate mortality after functionally (e.g. fractional flow reserve)-guided strategy of coronary bifurcation lesions.

Methods and results: We analysed patients from FIESTA registry, which was continuation of FIESTA study (Ffr vs IcEcgSTA, ClinicalTrials.gov Identifier: NCT01724957). Patients with stable angina were included. The inclusion criterion were angiographic bifurcation lesions in a native coronary artery with diameter ≥2.5 mm and ≤4.5 mm and SB diameter ≥2.0 mm. We excluded patients with ST-segment elevation myocardial infarction, left main, haemodynamic instability. PCI was performed according to the current guidelines. Provisional stenting was the default strategy in all patients. Fractional flow reserve (FFR) was performed using the PrimeWire or PrimeWire Prestige (Volcano Corp., USA). For all FFR measurements, intracoronary adenosine was given in increasing doses of 60 mcg, 120 mcg, and 240 mcg. The minimum value of FFR measurements was taken for analysis. All patients received dual antiplatelet therapy with ADP-antagonist and aspirin for at least 12 months. A total of 160 consecutive patients with coronary bifurcation stenoses were included. The mean age was 67±10 years, 66% males, 96% hypertensive, 38% diabetic, 96% dyslipidaemic (or on treatment with statin), 46% smokers, 19% with previous myocardial infarction, 51% with previous PCI. From these, 74 had positive FFR<0.80 in main vessel of bifurcation lesion (46% functionally significant lesions). The rates of all-cause and cardiac deaths at median 33 months (IQR 16-49 months) (FFR≤80 vs FFR>80): all-cause death 16.2% (n=12/74) vs 7.1% (n=6/86), p=0.069; cardiac death 12.2% (n=9/74) vs 5.9% (n=5/86), p=0.163. On multivariate Cox regression analysis the independent predictors of death were: renal failure (HR=7.240, CI: 2.323-22.568, p=.001), platelet count >256.106/ml (HR=1.009, CI: 1.001-1.017, p=.032), SYNTAX score >12 (HR=1.129, 1.012–1.259, p=0.029).

Conclusions: Deferring bifurcation lesions based on FFR was safe. The rates of death were not-significantly different between treated and deferred stenoses based on 4-year follow-up.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Other

Clinical and interventional key points in patients with myocardial bridges

TASNIC Mihail [1]

(1) Medpark International Hospital, Chisinau, Republic of Moldova

Aims: To determine the incidence of myocardial bridges detected by coronary angiography, the clinical features and management peculiarities of patients with myocardial bridges.

Methods and results: We have retrospectively analysed 6,168 cases of diagnostic angiography and coronary angioplasty between 2013 and 2019. Myocardial bridges were detected in 357 cases (4.9%). Patients with documented myocardial bridges were divided into 2 groups: with and without severe atherosclerotic coronary lesions. For the study of the clinical aspects of patients with myocardial bridges, only cases of angiography with myocardial bridges and coronary arteries with mild or without atherosclerotic lesions were selected: 226 cases. The complications and difficulties of the interventional procedures in the presence of myocardial bridges and severe coronary atherosclerotic lesions have been studied in a group of 131 patients. Preferential localisation of the myocardial bridges (97% of cases) was on the anterior interventricular artery, 1.81% on the diagonal branch, in 0.9% of cases on posterolateral and marginal branches, 0.6% on the right coronary artery, and 0.3% along the circumflex artery. In the detected cases, the degree of arterial systolic stenosis exceeded 75% in 16% of cases, 50-75% in 36% and in 46% of cases the stenosis was below 50%. In 48% of cases the stress test was considered as typical positive in patients with myocardial bridges with documented myocardial ischaemic change on ECG and without severe coronary atherosclerotic stenosis. There was no interdependence between the degree of stenosis caused by the bridge and the degree of ST-segment depression in the effort test. In the conducted study, in only 3 cases the reason for hospitalisation for diagnostic coronary angiography was acute coronary syndrome in the arterial territory covered by a myocardial bridge. In 9 cases, due to myocardial ischaemia caused by the myocardial bridge, revascularisation by aortocoronary bypass was recommended. In 6 cases the arterial portions under the bridge were stented, with mechanical compression recurrence of the installed stent after 3 months in 3 cases. Within the group of patients with severe atherosclerotic coronary lesions and myocardial bridges who need PCI, in 6 cases, due to coronary deformation at the entrance under the bridge, the stent crossing was difficult in the respective segment. In 14 cases, the presence of the bridge and the entrance of the distal end of the stent under the myocardial bridge when stenting the proximal to bridge atherosclerotic lesions, induced prolonged coronary spasm or coronary dissection.

Conclusions: Although no correlation between the degree of compression caused by the bridge and the degree of myocardial ischaemia has been established, myocardial bridges could cause myocardial ischaemia by possibly an addition to the mechanical action on the artery under the bridge of the coronary spasm, determining thereby acute coronary syndromes. The treatment of patients with significant myocardial bridges with recurrent ischaemia on optimal drug therapy would preferably be by coronary bypass due to the mechanical action of the myocardial bridge on the stent. Coronary stenting with penetration of the stent distal end under the myocardial bridge may be associated with coronary dissection, coronary spam and/or mechanical deformation of the stent.

STEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Early vessel healing in ACS: OCT analysis from the RESTORE registry

OMATSU Takashi [(1)], OMATSU Takashi [(1)], SOTOMI Yohei [(1)], KOBAYASHI Tomoaki [(1)], HAMANAKA Yuma [(1)], MORI Naoki [(1)], ICHIBORI Yasuhiro [(1)], HIRATA Akio [(1)], HIRAYAMA Atsushi [(1)], HIGUCHI Yoshiharu [(1)]

(1) Osaka Police Hospital, Osaka, Japan

Aims: We aimed to assess a possible difference of the neointimal coverage status and its quality after implantation of drug-eluting stents (DES) or drug-coated stents (DCS) in acute coronary syndrome (ACS) vs non-ACS patients.

Methods and results: We conducted a single-centre all-comer prospective cohort study: the RESTORE registry (UMIN000033009). All patients who received successful optical coherence tomography (OCT) examination at planned 3-month follow-up after DES or DCS implantation were analysed. Study population was divided into 2 groups, ACS vs non-ACS groups. We evaluated standard OCT variables, coverage percent, and the quantitative light property values including light intensity, attenuation, and backscatter. We performed OCT analyses of 177 lesions in 163 patients (ACS 44 lesions vs non-ACS 133 lesions). ACS patients had larger stent diameter (3.14±0.44 vs 2.94±0.50 mm, p=0.020) and slightly shorter stent length (33.5±17.5±0.44 vs 40.0±20.6 mm, p=0.062) than non-ACS patients. At 3-month follow-up, coverage percent (ACS 91.5±9.5% vs non-ACS 91.8±9.0%, p=0.844) and neointimal thickness (ACS 45.1±4.1 µm vs non-ACS 51.6±5.0 µm, p=0.440) did not significantly differ. Light property values were similar between both groups (light intensity 159.29±72.20 vs 159.45±63.78, p=0.989; light attenuation 0.88±0.26 vs 0.87±0.24 m-1, p=0.817; backscatter 4.86±0.58 vs 4.83±0.57, p=0.720). The similarity of the neointimal quality in ACS and non-ACS patients was consistent across the 5 different types of current DESs (SynergyTM, UltimasterTM, OrsiroTM, XIENCETM, Resolute OnyxTM) and the drug-coated stent (BioFeedomTM) (p>0.05).

Conclusions: OCT analysis demonstrated not only neointimal coverage but also neointimal quality 3 months after implantation of current generation DES and DCS were similar in ACS and non-ACS patients.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Guideline-recommended optimal medical therapy in AMI patients undergoing PCI with DES: adherence and clinical outcomes using national health insurance data

PARK Mahn-Won [(1)], PARK Mahn [(1)], HER Sung-Ho [(1)], CHO Chung-Sun [(1)], PARK Ha-Wook [(1)], KIM Dae-Won [(1)], LEE Kyu-Seop [(1)], CHANG Kiyuk [(2)]

(1) The catholic university of Korea, Daejeon St. Mary's hospital, Daejeon, Republic of Korea; (2) The Catholic University of Korea, Seoul St Mary's Hospital, Seoul, Republic of Korea

Aims: We sought to evaluate the adherence to guideline-recommended optimal medical therapy (OMT) and compare the clinical outcomes between OMT vs non-OMT in AMI patients undergoing PCI with DES.

Methods and results: From national health insurance claims data in South Korea between 2011 and 2015, overall 28,516 AMI patients (OMT: n=17,900, non-OMT: n=10,616) who underwent PCI with DES were enrolled. The OMT was defined as the combination of at least 1 antiplatelet drug, statin, β-blocker, and angiotensin receptor blocker (ARB)/angiotensin-converting enzyme inhibitor (ACEi). Medication status over time was checked at discharge, 1 month, 6 months, 1 year, and 3 years. The primary end point was all-cause death and secondary endpoint was composite of all-cause death and percutaneous revascularisation. To reduce bias and confounding that may occur in registry data, we did propensity-score matching and 10,591 matched pairs were developed. In overall population, mean age was 62.7 year-old and 69.3% were male. The OMT adherence was not so high and the rate at discharge, 6 months, 1 year, 2 years and 3 years after PCI was as follows: 62.8%,60.1%,55.5%, 50.8% and 47% respectively. During median follow-up of 2.1 years, the incidence of primary endpoint (3.7% vs 5.5%, p<0.001) and secondary endpoint (14.1% vs 17.0%, p<0.001) of OMT group was significantly lower than non-OMT group. Moreover, on multivariate Cox analysis, OMT group showed significantly lower risk for primary endpoint event (adjusted HR, 0.82; 95% CI: 0.72-0.93; p=0.003) and secondary endpoint event (adjusted HR, 0.83; 95% CI: 0.78-0.89; p<0.001) than non-OMT group. In propensity-score matched pairs, similar to main result, OMT group showed significantly lower risk for primary endpoint event (HR, 0.74; 95% CI: 0.66-0.84; p<0.001) and secondary endpoint event (HR, 0.79; 95% CI: 0.74-0.85; p<0.001) than non-OMT group.

Conclusions: In AMI patients who underwent PCI with DES, guideline-based OMT significantly improved clinical outcomes. However, the adherence rate to OMT was just 47% at 3 years after PCI.

Stable CAD - Invasive imaging and functional assessment

Association between coronary slow-flow phenomenon and epicardial fat tissue – the fatter, the slower?

WEFERLING Maren [1], WEFERLING Maren [1], VIETHEER Julia [1], KELLER Till [1,2], FISCHER-RASOKAT Ulrich [1,2], HAMM Christian [1,2], LIEBETRAU Christoph [1,2]

(1) Kerckhoff-Klinik GmbH, Bad Nauheim, Germany; (2) Universitätsklinikum Gießen, Giessen, Germany

Aims: Coronary slow-flow phenomenon (CSFP) is defined as delayed opacification of contrast media in coronary vessels in the absence of obstructive epicardial coronary artery disease (CAD). Endothelial dysfunction is thought to be the underlying cause, but the exact pathophysiology remains poorly understood. Epicardial fat tissue (EFT) directly surrounding the epicardial coronary arteries has potential paracrine effects which presumably impact endothelial function. We aimed to evaluate EFT thickness in CSFP patients and compare them with a matched control cohort without CSFP.

Methods and results: Between January 2008 and December 2018 electronic research on the term "slow-flow " and associated wording was performed on all records of coronary angiograms undertaken at the Kerckhoff Heart Center in Bad Nauheim, Germany. Patients with slow-flow associated with coronary intervention, coronary aneurysm/ectasia or stenosis (>50%) and moderate or severe impaired left ventricular function were excluded. EFT measurements were undertaken on the available echocardiographic records in the parasternal long and short axis view by two experienced clinicians. Clinical, echocardiographic and angiographic data were analysed and compared with a control cohort of patients without CSFP matched for age, gender and body mass index (BMI). A total of 48 patients was identified as having CSFP resulting in a prevalence of 0.13%. Mean age was 64 years (±11,4); 90% were male. CSFP was most common in the left anterior descending artery (LAD) with 87.5% of all cases and second common in the right coronary artery (RCA) with 50%. The circumflex artery (RCX) was least affected with 12.5%. Almost half of patients revealed CSFP in more than one vessel (46%). Arterial hypertension, diabetes, hyperlipidaemia and family history for cardiovascular diseases were not significantly different between CSFP and control cohort patients. CSFP patients had more often a smoking history (31% vs 13%, p=0.03). Median EFT thickness was 4.9mm (IQR 4.0-6.1 mm) in the CSFP cohort and 3.9 mm (IQR 3.1-4.9 mm) in the control cohort (p=0.002). Mean follow-up time was 29 months and 35 months in the CSFP and control cohort, respectively. In the CSFP cohort no patient died whereas in the control cohort one patient died.

Conclusions: Epicardial fat is thicker in CSFP patients compared to matched controls and does not have an impact on long-term outcome. Further studies are needed to elucidate the role of EFT in the context of CSFP.

Stable CAD - Tools, devices and techniques

Use of furosemide-induced diuresis with matched isotonic intravenous hydration in preventing contrast-induced nephropathy

MILITARU Cristian [1], MILITARU Cristian [1], ABDELHAFEZ Ahmed [1], WASSEF Nancy [2], RAJU Prashanth [1], SHAUKAT Naeem [1], EHTISHAM Javed [1]

(1) Kettering General Hospital, Kettering, United Kingdom; (2) Derriford Hospital, Plymouth, United Kingdom

Aims: To evaluate the effectiveness of furosemide-induced diuresis with matched isotonic intravenous hydration using the RenalGuard system on prevention of contrast-induced nephropathy (CIN).

Methods and results: This is a single-¬centre, retrospective cohort study of all patients who had the RenalGuard system used during percutaneous coronary angiography/intervention, between August 2014 and November 2016. A total of 41 patients deemed to be at risk of developing CIN due to pre-existing renal impairment and/or anticipated high contrast volume use, underwent 47 procedures at Kettering General Hospital, United Kingdom. The procedures ranged from coronary angiogram to complex CTO interventions. The primary endpoint was the occurrence of CIN at one week post procedure and at a one-month follow-up. Kidney injury was defined as an increase of 25% and/or 0.5 mg/dl in serum creatinine (sCr). Estimated glomerular filtration rate (eGFR) was also calculated according to the Modification of Diet in Renal Disease (MDRD) equation. The patient mean age was 73.5±12.3 and 68.1% of patients were male. The mean preprocedure sCr was 1.99±1.65 mg/dl and mean contrast volume used was 129±122.4 ml. At baseline, 42.6% of patients had grade IV renal impairment (eGFR 29.9¬15 ml/min/1.73 m^2) and 36.2% had grade IIIb (GFR 30¬44.9 ml/min/1.73 m^2). The risk of developing CIN for the patients who underwent PCI was calculated using the Mehran score, as such 4.3% had low risk, 29.8% moderate risk, 53.2% high risk, and 12.8% very high risk. Only one patient developed CIN during the first week post procedure, but his renal function improved at the one-month follow-up, so no patient met the CIN criteria at one month. This patient's baseline creatinine was 1.89 mg/dl, he had a moderate risk of developing CIN according to the Mehran score, and had only 60 ml of contrast used during the procedure. The whole cohort's mean sCr at one week was 1.89±0.65 mg/dl and 1.99±0.75 mg/dl at one month.

Conclusions: Our study showed that furosemide-induced diuresis with matched isotonic intravenous hydration using the RenalGuard system is an effective therapeutic tool in significantly reducing the occurrence of kidney injury in patients undergoing coronary angiography or intervention.

Stable CAD - Adjunctive pharmacotherapy

Association of serum sclerostin concentration and atherosclerosis advancement in coronary and renal arteries: results of KORONEF study

KERN Adam [2], KERN Adam [2], STOMPÓR Tomasz [2], KIEWISZ Jolanta [2], KRAZINSKI Bartlomiej [2], GORNY Jerzy [2], SIENKIEWICZ Ewa [2], DROZDOWSKA Beata [2], BIL Jacek [1]

(1) Centralny Szpital Kliniczny MSWiA w Warszawie, Warsaw, Poland; (2) University of Warmia and Mazury in Olsztyn, Olsztyn, Poland

Aims: As far as we know there is no data on the association between serum sclerostin and precisely defined cardiac pathology in 'non-renal' populations (i.e. patients with normal or borderline declined renal function). Thus, the aim of this study was to analyse serum sclerostin concentration in a group of patients who underwent coronary angiography for different reasons as well as to search for correlations between sclerostin and several clinical and biochemical parameters in this group of patients.

Methods and results: Blood serum samples were collected from 500 consecutive patients who underwent coronary angiography in the Cardiology Department of Regional Specialised Hospital in Olsztyn, Poland between June and November 2011. To select the patient cohorts included in further analyses the defined inclusion criteria were implied: age (between 40 and 80), ejection fraction (EF≥30%), creatinine (≤1.2 mg/dL), eGFR (≥30 mL/min/1.73m^2), complete record of medical data including BMI, blood pressure, EF, HDL, LDL, TG, glucose, blood urea, creatinine, eGFR, haemoglobin, hematocrit, RBC, serum potassium, sodium, chlorides, calcium and phosphate and medical history with particular emphasis to clinical indication for coronary angiography (stable coronary artery disease or acute coronary syndrome). For the purpose of the study, the total number of 193 patients were selected. Patients were assigned to four cohorts according to their coronary angiography result: no lesions (NL, n=40); single-vessel disease (1VD, n=49); two-vessel disease (2VD, n=49); left main or multivessel disease (LM/MVD, n=55). All four study groups identified based on the advancement of CAD were well matched in terms of age, sex, BMI, systolic and diastolic blood pressure. Patients without lesions in coronary arteries were characterised with the lowest serum LDL-cholesterol and glucose, and with the highest serum HDL-cholesterol. When we divided our patients according to indication to coronary angiography, we found that serum sclerostin level significantly differs between the groups, being lowest in the NSTEMI group and highest in stable CAD (p=0.041). Also, significant difference was observed in serum sclerostin in obese vs non obese patients (BMI < 30 kg/m^2, serum sclerostin 238.3±28.7 vs BMI ≥ 30 kg/m^2, serum sclerostin 327.7±52.1 pg/ml, p=0.021). It is also important to notice the following correlations between serum sclerostin and clinical and biochemical parameters: inverse association with age in patients without coronary lesions on angiography (r= -0.289, p=0.044) and in subjects with NSTEMI (r= -0.452, p=0.026) as well as positive correlation with serum creatinine in ACS (r= 0.255, p=0.032) and STEMI patients (r= 0.468, p=0.012); in the latter group of patients inverse significant correlation with eGFR was also found (r= -0.379, p=0.047). Only in one patient group classified based on symptoms, namely those with NSTEMI, was sclerostin also inversely correlated with EF% (r=-0.458, p=0.024). Importantly, sclerostin proved to be an independent predictor of mortality in patients with 3-vessel CAD at 8-year follow-up (HR 3.45, 95% CI: 1.24-9.47).

Conclusions: Our study showed that sclerostin concentration correlates well with the clinical presentation of coronary atherosclerotic disease. Long-term data are pending.

Stable CAD - Diabetes, Stents and scaffolds - Tools, devices and techniques

10-year clinical outcomes of a new-generation polymer-free sirolimus- and probucol-eluting stent vs a new-generation durable polymer zotarolimus-eluting stent in diabetic patients: results from the ISAR-TEST 5 randomised trial

LENZ Tobias [1], LENZ Tobias [1], CASSESE Salvatore [1], KOPPARA Tobias [2], XHEPA Erion [1], WIEBE Jens [1], LAUGWITZ Karl L. [2], SCHUNKERT Heribert [1], BYRNE Robert A. [3], KASTRATI Adnan [1], KUFNER Sebastian [1]

(1) German Heart Centre Munich / Deutsches Herzzentrum München, Munich, Germany; (2) Klinikum rechts der Isar der Technischen Universität München, Munich, Germany; (3) Mater Private, Dublin 7, Ireland

Aims: The durable polymer zotarolimus-eluting stent (DP-ZES) is a new-generation drug-eluting stent (DES) that is frequently used in patients with coronary artery disease undergoing percutaneous coronary intervention (PCI). The polymer-free sirolimus- and probucol-eluting stent (PF-SES) is a DES with a unique design that enables effective drug release without the need of a polymer. Very long-term outcomes of diabetic patients treated with either of these DES have not been assessed to date.

Methods and results: This study includes the pre-specified subgroup of 870 patients with diabetes mellitus randomly assigned to treatment with PF-SES (n=575) versus PP-ZES (n=295) in the setting of the ISAR-TEST 5 trial. The primary endpoint was the composite of cardiac death, target vessel-related myocardial infarction or target lesion revascularisation (a device-oriented composite endpoint, DOCE). Additional endpoints of interest were the patient-oriented composite endpoint (POCE), including all-cause death, any myocardial infarction or any revascularisation and individual components of the composite endpoints including definite/probable stent thrombosis. At ten years, there was no difference in the incidence of DOCE between the PF-SES and DP-ZES, (54.4% versus 56.4%, hazard ratio = 0.96, 95% CI: 0.79-1.18; p=0.69). The rates of the individual components of DOCE were comparable in both groups. The incidence of POCE was numerically lower in PF-SES group as compared to DP-ZES group (POCE: 74.6% versus 79.6%, hazard ratio = 0.86, 95% CI: 0.73-1.01; p=0.07), however without statistical significance. The incidence of definite/probable stent thrombosis over 10 years was similar between the PF-SES and DP-ZES (2.5% in both groups; hazard ratio = 1.02 [95% CI: 0.41-2.52], p=0.97).

Conclusions: In this unique long-term analysis up to 10 years, high cumulative clinical event rates were observed during 10-year follow-up, reflecting the high-risk profile of patients with diabetes mellitus. In this subgroup, there were no measurable differences concerning device-related outcomes after treatment with a polymer-free sirolimus- and probucol-eluting stent versus durable polymer zotarolimus-eluting stent.

NSTEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

A single-centre experience with paclitaxel drug-eluting balloons comparing scoring balloon and non-scoring balloon for lesion preparation

SUNDRAN Rhuban [1], SUNDRAN Rhuban [1], NURUDDIN Amin [1], NAZEEB Nazrul [1], STANISLAUS rohith [1], KHAIRUDDIN Ahmad [1]

(1) Institut Jantung Negara, Federal Territory of Kuala Lumpur, Malaysia

Aims: To compare the safety and efficacy of drug-eluting balloons (DEB) using scoring balloon and non-scoring balloon for lesion preparation in the treatment of both in-stent restenosis (ISR) and *de novo* lesions.

Methods and results: We retrospectively studied 1,348 patients and a total of 1,552 lesions treated at our institution over 2017-2018 with either scoring balloon or non-scoring balloon for lesion preparation followed by paclitaxel-coated SeQuent Please Neo DEB. 488 lesions treated with scoring balloon were compared to 1,064 lesions treated with non-scoring balloon which included semi-compliant and non-complicant balloons for lesion preparation. Endpoints analysed were clinically driven target lesion revascularisation rate (TLR) as a primary endpoint and major adverse cardiac events (MACE) at 1-year follow-up. There were 247(50.6%) *de novo* lesions and 241(49.4%) ISR lesions in the scoring group, compared to 801(75.3%) *de novo* and 262 (24.6%) ISR lesions in the non-scoring group. The mean age and gender were similar in both groups, 60.1±9.8 years old, 332 (85.1%) males in the scoring group and 59.8±9.9 years old, 811 (84.7%) males in the non-scoring group. Given the patients were all from the same population, they had very similar cardiac risk factors. The mean vessel size treated was 3.0±0.5 mm with a mean lesion length of 26±15.9 mm in the scoring group compared to 2.6±0.5 mm with a length of 26±18.5 mm in the non-scoring group. Percentage of stenosis pre-PCI was 88.1±12.3% improving to 17.8±12% post PCI using a scoring balloon as opposed to a pre-PCI stenosis of 92±11.6% improving to 17.2±14% post PCI in the non-scoring group showed very similar results. There were a total of 24(4.9%) dissections in the scoring balloon group and 63(5.9%) in the non-scoring group (p=0.425). Bail-out stenting was used in 25(5.1%) after predilation with a scoring balloon and 57(5.4%) in the non-scoring group (p=0.903). TLR was required in 4(1.0%) patients in the scoring group and 7(0.7%) in the non-scoring group (p=0.743). MACE at follow-up occured in 13(3.2%) patients in the scoring group and 17(1.8%) patients in the non-scoring group (p=0.157).

Conclusions: The findings after predilation with either scoring or non-scoring balloon showed similar residual stenosis. Requirement for bail-out stenting, TLR and MACE did not reveal any statistical difference in either group.

STEMI - Tools, devices and techniques

Single-centre experience using DEB angioplasty for de novo lesions in patients with STEMI

MOHAMED NAZEEB mohamed nazrul [1], MOHAMED NAZEEB Mohamed [1], KHAIRUDDIN Ahmad [1], NURRUDDIN Amin [1], SUNDRAN Rhuban [1]

(1) Institut Jantung Negara, Federal Territory of Kuala Lumpur, Malaysia

Aims: To assess the safety and effficacy of drug-coated balloon (DCB) angioplasty for the treatment of *de novo* lesions in patients undergoing primary percutaneous coronary intervention.

Methods and results: 42 patients (79% male) who had *de novo* lesions treated with DCB between January 2015 and January 2018 during primary PCI were identified and analysed. Endpoints were target lesion revascularisation (TLR) and clinical MACE events at 9±6-months follow-up. The right coronary artery was the most common target artery (43%). The majority of patients had traditional risk factors for coronary artery disease (CAD), such as hypertension (79%), diabetes mellitus (57%) and dyslipidaemia (19%). The mean vessel diameter treated was 2.6 mm±0.4 mm. 3 patients had non-flow limiting dissection post DCB inflation. In hospital mortality was 7% (3 patients) due to cardiogenic shock with multiorgan failure. During follow-up period, there were 3 reported deaths.

Conclusions: DCB angioplasty to *de novo* lesions in the setting of STEMI appears to be a feasible option. However, further study with a larger cohort of patients is required to ascertain this hypothesis.

STEMI - Adjunctive pharmacotherapy

Mexican primary PCI experience, results from a single centre

JIMÉNEZ-RODRÍGUEZ Gian Manuel [(1)], PEÑA-DUQUE Marco-Antonio [(1)], ABUNDES-VELASCO Arturo [(1)], PEÑA-CABRAL Marco-Antonio [(1)], DAMAS-DE LOS SANTOS Felix [(1)], PIÑA-REYNA Yigal [(1)], ARIAS-SANCHEZ Eduardo Agustin [(1)], FARJAT-PASOS Julio [(1)]

(1) National Institute of Cardiology Ignacio Chavez, CDMX, Mexico

Aims: Primary PCI is the treatment of choice for STEMI whenever possible. This study describes 15-year experience of primary PCI for STEMI patients from a Mexican tertiary single centre.

Methods and results: From May 2004 to May 2019, primary PCI was performed on 795 patients (64 were excluded because incomplete data) so 731 were included in the study. The mean age was 59.74 years (±11.28); body mass index 27.06 (±0.17), 84.1% were male, the most common risk factor was smoking (62%), followed by hypertension (49.1%), diabetes mellitus (35.9%), dyslipidaemia (26.6%), obesity (25.2%); other comorbidities were distributed as follows: previous myocardial infarction (14.9%), followed by chronic kidney disease (5.6%), chronic heart failure (1.9%) and previous cerebrovascular event (1.0%). The most common anatomical location for the STEMI was the anterior wall (59.1%), the left anterior descending was the most common involved (58.2%) followed by the right coronary artery (40.2%). Single vessel disease (SVD) was observed in 61% of patients, triple-vessel disease in 8%. Mean door-to-balloon time was 82.1±32.2 min. The vast majority of cases were performed with a radial approach (83.8%). The mean volume of contrast was 165.2ml±56 min and acute renal failure was seen in 3.4% (at 48 hours). The development of cardiogenic shock occurred in 6.95% and the in-hospital mortality was 8.5%.

Conclusions: The results from the PCI program in our institution are comparable with the international references, with excellent procedural success and very low incidence of complications.

STEMI - Adjunctive pharmacotherapy

The impact of pre-hospital medications on outcomes in patients presenting with STEMI

CIOFANI Jonathan [(1)], CIOFANI Jonathan [(1)], ALLAHWALA Usaid [(1)], WARD Michael [(1)], FIGTREE Gemma [(1)], NELSON Gregory [(1)], RASMUSSEN Helge [(1)], HANSEN Peter [(1)], BHINDI Ravinay [(1)]

(1) Royal North Shore Hospital, NSW, Australia

Aims: There is increasing pharmacological treatment of traditional cardiovascular risk factors in the community. However, the impact of prior treatment of these risk factors on outcomes in patients presenting with ST-elevation myocardial infarction (STEMI) is uncertain. We sought to determine whether prior treatment with a beta-blocker, angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB), calcium channel blocker (CCB), aldosterone antagonist or statin affected in-hospital outcomes following STEMI.

Methods and results: We reviewed 1,625 patients with STEMI presenting to our centre for primary percutaneous coronary intervention (pPCI) or rescue PCI from July 2010 to January 2019. Mean age was 64.7 (±13.7) with 22.8% female and mean BMI 27.2 kg/m^2 (±2.8). The left anterior descending artery was the most common culprit vessel (47.2%), followed by the right coronary artery (38.0%) and left circumflex artery (14.8%). 326 patients (22.1%) were taking a statin, 158 (48.5%) of whom were on a high dose. Prior statin use was associated with increased rates of ICU admission (17.0 vs 12.2%, $p<0.05$), however the dose used was not related to clinical outcomes. Use of beta-blockers increased risk of in-hospital mortality (7.0 vs 3.5%, $p<0.05$) whilst aldosterone antagonist use was associated with left ventricular impairment (83.3 vs 60.6%, $p<0.05$). The prior use of ACE-I, ARB or CCB did not affect outcomes. Patients that took medications from more than one of these drug classes were also at higher risk of ICU admission (16.3 vs 12.3%, $p<0.05$) and in-hospital mortality (5.7 vs 3.3%, $p<0.05$). On multivariate analysis, after correcting for age, sex and BMI, only aldosterone antagonist use remained independently predictive of left ventricular impairment ($p<0.05$).

Conclusions: In patients presenting with STEMI, prior treatment of traditional cardiovascular risk factors did not seem to affect in-hospital outcomes. This may reflect differing population risk groups, however mechanistic effects of prior treatment of these medications on acute haemodynamics and metabolic changes following STEMI should be investigated.

Stents and scaffolds - Tools, devices and techniques

Incidence and five-year clinical outcomes of longitudinal stent deformation after the PROMUS Element platinum-chromium, everolimus-eluting stent implantation

HIROMASA Takashi [(1)], HIROMASA Takashi [(1)], KURAMITSU Shoichi [(1)], DOMEI Takenori [(1)], YAMAJI Kyohei [(1)], HYODO Makoto [(1)], ANDO Kenji [(1)]

(1) Kokura Memorial Hospital, Fukuoka, Japan

Aims: The PROMUS Element platinum-chromium everolimus-eluting stent (PtCr-EES) has a novel metal and stent design intended to improve deliverability, comformability, and radial strength, whereas such features might have the trade-off of reducing longitudinal stent strength, which would account for the occurrence of longitudinal stent deformation (LSD) as reported previously. However, the incidence and clinical impact of LSD after PtCr-EES implantation in clinical practice have not been fully evaluated.

Methods and results: A total of 809 patients with 1,052 lesions undergoing PtCr-EES implantation between March 2012 and August 2013 were analysed. LSD was defined as the distortion or shortening or elongation of a stent in the longitudinal axis following successful stent deployment. We assessed the incidence of longitudinal stent deformation and cumulative incidence of major adverse cardiac events (MACE), defined as a composite of cardiac death, non-fatal myocardial infarction, definite stent thrombosis, and clinically driven target lesion revascularisation within 5 years. Of 809 patients with 1,052 lesions, we performed an intravascular ultrasound (IVUS) and post-dilatation in 759 patients (93.8%) with 994 lesions (94.5%) and in 407 patients (50.6%) with 512 lesions (48.7%). LSD was observed in 20 patients (2.5%) with 20 lesions (1.9%). The mechanism of LSD was due to the following reasons: compression by post-dilatation balloons (n=4, 20.0%), entrapped IVUS (n=14, 70.0%) and pulled back jailed guide wire (n=2, 10.0%). At 5 years, the cumulative incidence of MACE, cardiac death, myocardial infarction, stent thrombosis and clinically driven target lesion revascularisation were not significantly different between the LSD and non-LSD groups (15.0% vs 10.7%, p=0.40; 0% vs 2.9%, p=0.49; 5.0% vs 3.5%, p=0.54; 0% vs 0.9%, p=0.67; 15.0% vs 6.6%, p=0.13, respectively).

Conclusions: LSD after PtCr-EES implantation occurs in 1.9% of lesions. However, LSD is not associated with MACE within 5 years.

Other Coronary interventions - Other

Biochemical markers of physiological stress and poor nutrition predict mortality and left ventricular impairment in patients presenting with STEMI

CIOFANI Jonathan [1], CIOFANI Jonathan [1], ALLAHWALA Usaid [1], WARD Michael [1], FIGTREE Gemma [1], NELSON Gregory [1], RASMUSSEN Helge [1], HANSEN Peter [1], BHINDI Ravinay [1]

(1) Royal North Shore Hospital, NSW, Australia

Aims: Early risk stratification is critical for the appropriate management of patients presenting with ST-elevation myocardial infarction (STEMI) following revascularisation. We sought to determine biochemical predictors of adverse outcomes in the era of contemporary STEMI management.

Methods and results: We reviewed 1,625 patients presenting to our centre for primary percutaneous coronary intervention (pPCI) or rescue PCI from July 2010 to January 2019. Mean age was 64.7 (±13.7) with 22.8% female and mean BMI 27.2 kg/m^2 (±2.8). The left anterior descending artery was the most common culprit vessel (47.2%), followed by the right coronary artery (38.0%) and left circumflex artery (14.8%). 105 patients (6.5%) died in hospital. In-hospital mortality was portended by pre-hospital cardiac arrest, ventricular arrhythmia during PCI, requirement for inotropes, ICU admission and left ventricular (LV) impairment ($p<0.0001$ for each association). Following multivariate logistic regression, correcting for age, sex and BMI, the independent biochemical predictors of in-hospital mortality included high white cell count (WCC, 15.1 vs 11.5 x109/L, $p<0.01$), hypoalbuminaemia (34.2 vs 38.0 g/L, $p<0.05$), acidosis (7.19 vs 7.36, $p<0.01$), hyperglycaemia at admission (BSL, 14.2 vs 8.3 mmol/L, $p<0.05$) and high lactate (6.1 vs 3.1 mmol/L, $p<0.05$). LV impairment was associated with acidosis (7.31 vs 7.38, $p<0.0001$), high lactate (3.8 vs 2.8 mmol/L, $p<0.01$) and high monocyte count (0.8 vs 0.7 x109/L, $p<0.01$). Patients with elevated inflammatory markers were additionally more likely to require inotropic support (WCC 13.0 vs 11.5 x109/L, $p<0.05$) and ICU admission (neutrophils 10.6 vs 8.1 x109/L, $p<0.0001$), whilst patients with hypoalbuminaemia were more likely to be admitted to ICU (34.9 vs 38.4 g/L, $p<0.0001$).

Conclusions: Biochemical markers of physiological stress, inflammation and poor nutrition are associated with adverse outcomes in patients presenting with STEMI. Appreciation of these factors may facilitate identification of patients at high risk of deterioration who require closer monitoring in the peri-infarct setting.

Stable CAD - Invasive imaging and functional assessment

A novel angiography-based method to assess coronary microcirculation? Coronary sinus volume change and filling time

TORRE GARCIA Alvaro Jose [1], TORRE GARCIA Alvaro Jose [1], JIMENEZ RODRIGUEZ Gian Manuel [1], ABUNDES VELASCO Arturo [1]

(1) Instituto Nacional de Cardiología Ignacio Chávez, CDMX, Mexico

Aims: An increased coronary sinus filling time is related to microvascular disease. The inflation and deflation of a balloon inside the coronary sinus has shown improvement in the microvascular resistance index and a reduction of infarct size. One of the suggested mechanisms is through enhanced washout of coronary microcirculation during ballon deflation. If by natural means the coronary sinus volume changes during cardiac cycle, whether this might lead to similar effects is still unknown and hasn't been studied.

Methods and results: In 26 patients who were taken to the catheterisation laboratory we prospectively recorded cine angiographic images at anterior-posterior cranial view until an adequate opacification of the coronary sinus was seen. Using the angiographic recordings we designed a method to measure the coronary sinus volume change during the cardiac cycle using a single angiographic view. We then measured coronary sinus volume change using multiphasic coronary computed tomography from a similar patient population for comparison. Coronary sinus volume during maximal and minimal distention, volume change and filling time were calculated. The volumetric change of the coronary sinus during cardiac cycle using angiography was 45.87% (SD 17.74) and by computed tomography 44.01% (SD 16.72), p 0.75. The coronary sinus filling time was 4.33 seconds±1.38, we didn't find a linear correlation with coronary sinus volume change, R2 0.07.

Conclusions: In the present study we propose the hypothesis that the effects of coronary sinus volume change within the microvasculature might be studied by measuring the correlation of coronary sinus volume change with filling time. A linear correlation would provide evidence that the absence of coronary sinus contraction, for example during atrial fibrillation, or the amount of volume change during cardiac cycle, could have an effect in coronary physiology and therapeutics. Although we couldn't find a correlation between these two variables, we demonstrated that measurement of coronary sinus volume by a single standard angiographic view can be done. The present study explores the idea than the effects of coronary sinus volume change within the microvasculature might be studied using the above-mentioned angiographic method.

Stable CAD - Invasive imaging and functional assessment

Drift – the role of blood

NEVES David [1], NEVES David [1], FERNANDES Renato [1], BENTO Angela [1], RIBEIRO Ricardo [1], SERRANO Marisa [1], VICENTE Marcia [1], BANHA Maria [1], EMERENCIANO Tania [1], PATRICIO Lino [1]

(1) Hospital do Espírito Santo, Évora, Portugal

Aims: The content of the catheter may influence the drift phenomenon due to different viscosity, temperature, etc. Manufacturers recommend it not to use contrast. In our centre, we routinely equalise pressures with the catheter filled with blood. Potential advantages of blood are related to the avoidance of saline administration, which may have hydrostatic, hyperaemic and vasoconstrictor effects, especially when administered at room temperature. The aim of this work was to determine the effect of the content of the catheter (blood vs contrast) on drift during a coronary physiologic examination.

Methods and results: After performance of physiological evaluation according to the local protocol, drift check was recorded on consecutive patients during 2019. In the beginning of the procedure, pressure equalisation was performed with the catheter filled with blood. After the necessary measurements, we performed drift-check by pulling the guidewire back until its sensor was at the catheter tip. We allowed for backflow of blood, in order to eliminate some contrast in the catheter. We compared distal/proximal pressure ratio (Pd/Pa) drift before and after backflow of blood (i.e. with the catheter filled with contrast vs with blood). We recorded drift-check on 28 patients, with an average Pd/Pa of 0.97 (drift: -0.03±0.015) before backflow and 1.00 (drift: 0,00±0.008) ($p<0.01$). In 18 patients there was a drift-check of >0.03 before backflow, which would require re-mesurement. After backflow, there was not a single case with a drift >0.03.

Conclusions: The content of the guiding catheter greatly influences pressure measurements and should be taken into account on every step of physiological evaluation. Every measurement should be made with the same content of the equalisation step - which should not be contrast due to its high viscosity. Blood seems to be a good option, avoiding the need of another injection with saline. We report a very low drift effect with the use of blood and a dedicated local protocol.

Stable CAD - Invasive imaging and functional assessment

Contrast-induced hyperaemia – the role of blood

NEVES David [1], NEVES David [1], FERNANDES Renato [1], BENTO Angela [1], BANHA Maria [1], SERRANO Marisa [1], EMERENCIANO Tania [1], BOIEIRO Liliana [1], RIBEIRO Ricardo [1], PATRICIO Lino [1]

(1) Hospital do Espírito Santo, Évora, Portugal

Aims: To assess the influence of the volume of contrast administered during contrast-induced hyperaemia on the measured value of distal/aortic pressure ratio (Pd/Pa) under contrast-induced hyperaemia (cHyp).

Methods and results: Consecutive patients undergoing physiologic evaluation in a cath lab in 2018-2019 were included in the study, under a dedicated physiology assessment protocol. This protocol includes a series of increasing ischaemia-inducing stimuli, from resting indices (Pd/Pa, iFR) to cHyp and FFR, when deemed necessary. A first contrast injection was made for cHyp after rest evaluation, with the catheter pre-filled with blood (partial cHyp). A second injection was made for cHyp with the catheter now prefilled with contrast (full cHyp). Injections were made using an automatic injector with a standardised injection volume and rate (6ml at 4ml/sec in the left coronary, 5 ml at 3 ml/sec on the right). Lumen volume of the catheter was measured (range 2.5- 3.0 ml, relating to 6-7F catheters), corresponding to the difference in contrast media administered. All cHyp runs were recorded and analysed. Drift check was performed for measurement validation in all patients. Measurements were considered valid if drift was ≤0.02. During this time period, 106 patients had physiological evaluation in our cathlab. A total of 61 lesions (46 patients) were analysed with the full cHyp protocol. Partial cHyp measurements were an average 0.86 (±0.084), whereas in total cHyp were 0.83 (±0.087). There was a difference 0.02±0.017 ($p<0.00001$).

Conclusions: A small change in contrast volume administered for cHyp evaluation (such as that of the catheter itself) seems to have a small but measurable and reproducible effect on the obtained values. Whether or not this can have a significant influence on the decision of the operator is difficult to assess, but it sounds reasonable to standardise this technique in order to produce more robust data, since small differences in a grey zone may dictate different decisions.

Stable CAD - Adjunctive pharmacotherapy

Comparative assessment of predictive performance of PRECISE-DAPT, CRUSADE and ACUITY scores in stratifying the risk of 30-day bleeding events

KAWASHIMA Hideyuki [1,2], KAWASHIMA Hideyuki [1,2], GAO Chao [1], TAKAHASHI Kuniaki [2], TOMANIAK Mariusz [5], ONO Masafumi [1,2], HARA Hironori [1,2], WANG Rutao [1], MODOLO Rodrigo [2,4], ONUMA Yoshinobu [1], SERRUYS Patrick [1]

(1) University Hospital Galway, Galway, Ireland; (2) University of Amsterdam, Amsterdam, the Netherlands; (3) Erasmus Universiteit Rotterdam, Rotterdam, the Netherlands; (4) University of Campinas, State of São Paulo, Brazil; (5) University of Warsaw, Warsaw, Poland

Aims: The utility of the PRECISE-DAPT score in predicting short-term bleeding events, either alone, or in comparison with the CRUSADE and ACUITY scores, have not been investigated. This analysis compared the predictive performances of the PRECISE-DAPT, CRUSADE, and ACUITY bleeding scores in stratifying the risk of 30-day bleeding events post-PCI in patients with DAPT in the GLOBAL LEADERS population.

Methods and results: In this *post hoc* sub-analysis of the GLOBAL LEADERS trial, patients were assigned in the experimental strategy with 1-month DAPT (aspirin and ticagrelor) followed by 23-month ticagrelor monotherapy or the reference regimen with 12-month DAPT (clopidogrel for chronic coronary syndrome [CCS] followed by 12-month aspirin monotherapy or aspirin and either ticagrelor for acute coronary syndrome [ACS], respectively). The primary safety objective (bleeding according to the Bleeding Academic Research Consortium [BARC] criteria [grade 3 or 5]) was assessed at 30 days according to three bleeding scores in the overall population, and in patients with ACS and CCS. In a total of 15,968 patients, we calculated all 3 scores in 14,709 patients (92.1%) and those patients were analysed in the present study. Irrespective of clinical presentation (the overall population, ACS patients, and CCS patients, respectively), the PRECISE-DAPT (C-statistics: 0.648, 0.653, and 0.641, respectively), CRUSADE (C-statistics: 0.641, 0.639, and 0.644, respectively), and ACUITY (C-statistics: 0.633, 0.638, and 0.623, respectively) scores had possibly helpful discriminative abilities for BARC 3 or 5 bleeding, with no significant between-score differences in discriminatory performance. In ACS patients, the PRECISE-DAPT score had a good calibration ability for BARC 3 or 5 bleeding (Hosmer-Lemeshow goodness-of-fit [GOF] chi square =3.480, p=0.901) at variance with the CRUSADE score (GOF chi square=15.561, p=0.049, respectively). In CCS patients, the PRECISE-DAPT score had poor calibration for BARC 3 or 5 bleeding (GOF chi square=15.758, p=0.046).

Conclusions: The PRECISE-DAPT score as well as the CRUSADE and ACUITY score showed possibly helpful discriminative capacities for 30-day bleeding events post-PCI in patients with DAPT, irrespective of clinical presentations. The PRECISE-DAPT score might be clinically useful for the prediction of short-term bleeding events considering its possibly helpful discrimination and good calibration.

Left main and multivessel disease - Tools, devices and techniques

Angiographic SYNTAX score reduction in de novo left main coronary stenosis patients over the last decade: implications of revascularisation approach

CHMIEL Jakub [1], CHMIEL Jakub [1], KSIAZEK Milosz Kacper [1], DRADRACH Jagoda [1], WNUK Grazyna [1], MALINOWSKI Krzysztof Piotr [2], IWASZCZUK Pawel [1], PODOLEC Piotr [1], MUSIALEK Piotr [1]

(1) Department of Cardiac and Vascular Diseases, Jagiellonian University Medical College, John Paul II Hospital, Kraków, Poland; (2) Institute of Public Health, Faculty of Health Sciences, Jagiellonian University Medical College, Kraków, Poland

Aims: We aimed to investigate potential angiographic trends in *de novo* left main coronary artery stenosis patients. These may impact revascularisation mode but remain undetermined.

Methods and results: Clinical records and all consecutive coronary angiograms in our Institution from t January 2010 to 31 December 2019 were evaluated to identify those with newly diagnosed angiography-significant (≥50% lumen diameter reduction) left main coronary artery stenosis. Angiographic SYNTAX score assessment was performed by agreement of two experienced analysts (an angiographic core lab analyst and a Heart Team interventional cardiologist) on anonymised angiograms. Values of the overall SYNTAX score, SYNTAX score of the left main lesion and SYNTAX score beyond left main were determined according to SYNTAX score assessment methodology. In addition, prevalence of single vs two-vessel vs three-vessel disease beyond the left main stenosis was evaluated. Pearson's correlation and Fisher transformation were used to evaluate parametric variables. Spearman's rho was used to determine trends. P-values of <0.05 were considered statistically significant. Overall, out of 12,315 coronary angiographies performed in *de novo* referrals in the last decade, 357 (2.90%) showed significant left main stenosis; the proportion varied from 2.30% to 3.48% annually. Patient mean age was 68.8 years (23.3% women). No temporal trends in patient age or gender occurred over the last decade while the overall SYNTAX score deceased from a mean value of 35 to 28 (SC= –0.16, p=0.003). Further analysis showed a particular negative trend in the beyond-left main-SYNTAX score (SC= –0.17, p=0.001) but not in the left main-SYNTAX score (SC=0.04, p=0.47). No temporal trend was present in the prevalence of isolated left main stenosis (p=0.48) and no temporal trend in the left main stenosis angiographic severity (<70% vs ≥70%; p=0.61), left main stenosis location (ostial/mid/bifurcation/entire left main; p=0.30) nor in the number of left main segments affected (SC=0.05, p=0.30). Reduction in the beyond-left main-SYNTAX score was associated with a decrease in the number of coronary arteries with a significant angiographic atherosclerotic involvement (SC= –0.12, p=0.03) and in the number of coexisting total occlusions (SC= –0.25, p<0.001).

Conclusions: (1) In patients with newly diagnosed left main critical stenosis overall angiographic SYNTAX score showed a statistically significant negative trend over the last decade, with a reduction from mean 35 (2010) to 28 points (2019); a finding that may be related to a change in the angiographic presentation of the disease or an earlier identification of left main stenosis patients over time. (2) The overall SYNTAX score reduction was driven by a decrease in beyond-left main-SYNTAX score. This, taken together with the overall SYNTAX score reduction from above 32 to below 32, favours (as per current guidelines) the endovascular approach to left main revascularisation. Our findings suggest an increase in the proportion of left main stenosis patients with angiography feasible to percutaneous intervention.

CTO - Invasive imaging and functional assessment

Modification of the right ventricular function after successful recanalisation of the right coronary artery CTO

DIMITRIADIS Zisis [(1)], DIMITRIADIS Zisis [(1)], DIESTELMEIER Simon [(1)], QUESADA-OCETE Blanca [(1)], WENZEL Philip [(1)], GEYER Martin [(1)], GORI Tommaso [(1)], MUENZEL Thomas [(1)], BLESSING Recha [(1)]

(1) Mainz University, Mainz, Germany

Aims: Coronary CTOs are common and occur in 15-25% of patients with coronary artery disease. The right coronary artery (RCA) is the most affected vessel with about 50% of all cases, and it remains unclear whether recanalisation of RCA-CTOs is associated with an improvement in right ventricular (RV) function. The aim of the study was to investigate the impact of a successful RCA-CTO-PCI on right ventricular (RV) function 6 months after the procedure.

Methods and results: 53 patients (age: 68 years ±10.7, 72% male) with confirmed RCA-CTO underwent successful recanalisation by percutaneous transluminal coronary intervention in the time period from June 2018 to November 2019 in our institution. Transthoracic echocardiography was performed before intervention and at a 6-month follow-up following invasive confirmation of vessel patency without relevant stenosis. Right ventricular function was assessed by standardised measurement of the tricuspid annular systolic excursion (TAPSE), RV fractional area changes (RVFAC), peak systolic tissue velocity at the tricuspid annulus (sTDI) as well as global longitudinal RV strain (RV LS). At 6 months after successful RCA-CTO recanalisation all four parameters showed an improvement (TAPSE mean±SD 20.6 mm ±4.67 vs 22.0 mm ±4.82, p=0.06), RVFAC (mean± SD 37.2% ± 4.0 vs 42.24% ± 4.59, p=0.03), sTDI (mean± SD 12.16cm ±1.64 vs 13.5cm ±1.53, p=0.07), RV LS (mean± SD -15,11% ±4.64 vs -17, 39% ±5.28, p=0.04).

Conclusions: Chronic occlusion of the RCA is very common and it is associated with impaired right ventricular function. Our study demonstrates that RV function can improve 6 months after successful recanalisation.

STEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Does the PCI operator's gender matter? The national registry of PCI practice patterns

LANOCHA Magdalena [1,2], LANOCHA Magdalena [1,2], MALINOWSKI Krzysztof [3], WLODARCZAK Adrian [2], LESIAK Maciej [4], TARCHALSKI Janusz [2], SIUDAK Zbigniew [3]

(1) Cardiovascular Imaging & Research, Poznan, Poland; (2) Copper Health Center, Departament of Cardiology, Lubin, Poland; (3) University of Jan Kochanowski, Kielce, Poland; (4) Poznan University of Medical Sciences, Poznan, Poland

Aims: There is limited information about the practice patterns, procedural volume and outcomes of percutaneous coronary procedures performed by female interventionalists (FO).

Methods and results: The presented analysis is based on a national registry of 1,272,396 consecutive percutaneous coronary interventions performed in Poland between 2014 and 2017 by 867 diagnostic coronary (DC) operators (46 women vs 821 men) and 757 PCI operators (31 women vs 726 men). During 4 years the number of FO increased from 3.6% to 4.5%. FO performed 29,721(3.6%) DC and 12,935 (2.8%) PCI. FO performed 75 PCI/year compared to MO 139 PCI/year ($p<0.01$). The main indication for all DC was stable angina pectoris, but for FO it was a more frequent indication compared to MO (43.89% vs 38.33%, $p<0.0001$). FFR during DC was more often used by MO than FO (2.24% vs 1.35%, $p<0.0001$). Propensity score matching (PSM) revealed that probability of FFR use during DC by FO was lower than by MO ([OR]=0.47; 95% [CI]= 0.4-5.5; $p<0.001$). However, the number of FFR assessment during DC among FO has trended upwards annually from 74 (0.94%) cases in 2014 to 126 (1.69%) cases in 2017 ($p<0.001$). OCT was preferred by FO (0.42% vs 0.08%, $p<0.0001$) as opposed to IVUS (0.39% vs 0.50%, $p<0.001$) which was more often performed by MO. PSM revealed a high probability of OCT assessment by FO during DC ([OR]=7.7; 95%; [CI]= 4.4-.5; $p<0.001$). The access site during angiography did not differ according to the operator's gender. During the observation, the radial access increased from 62% to 80% ($p<0.001$). The main PCI indication for all operators was ACS but FO compared to MO performed a higher proportion of STEMI (27.43% vs 24.48%, $p<0.0001$). Patients of FO vs MO had lower cardiovascular risk factors and mainly single-vessel disease (87.02% vs 84.72%, $p<0.0001$) except the left main (2.26% vs 3.21%, $p<0.0001$), by-pass grafts (0.94% vs 1.28%, $p=0.0006$) and CTO (1.39% vs 2.36%, $p<0.0001$) which, with multivessel disease, were indications more often for MO. DES were widely used by all operators (82.63%), but MO used more stents during the single procedure than FO (15.72% vs 14.42%, $p<0.0001$). Propensity score matching (PSM) revealed that the use of LMWH is less probably by FO than MO ([OR]=0.60; 95%; [CI]= 0.44 -0.80; $p<0.0001$) and opposite results were achieved for the use of UFH ([OR]=1.19; 95%; [CI]= 1.11-1.28; $p<0.0001$). Also, PSM revealed that probability of using GP IIb/IIIa during PCI by FO was significantly higher than by MO ([OR]=2.34; 95% confidence interval [CI]= 1.59-3.51; $p<0.0001$). FO used a higher amount of contrast during PCI (170.36±77.54 ccm vs 173.48±77.54 ccm, $p<0.0001$) and higher radiation dose (1083.53±907.51 mGy vs 1087.42±1009.43 mGy, $p=0.01$). PSM analysis confirmed a significantly higher total radiation dose by 54.8mGy per PCI procedure for FO ($p<0.001$). However, in the group of FO a significant reduction of the mean amount of contrast (from 175±81 ccm to 167±78 ccm, $p<0.001$) and radiation dose (from 1297±1101 mGy to 952±750 mGy, $p<0.001$) was observed over analysed years. Regarding the safety procedures, there were no differences between the operator's gender.

Conclusions: Women represent a minority of operators in interventional cardiology and are responsible for a small percentage of PCI. Their practice patterns are significantly influenced by case selection biases. The safety and outcomes of PCI performed by FO are comparable with MO and comply with the ESC guidelines on myocardial revascularisation.

Bifurcation lesion - Tools, devices and techniques

Mid-term clinical outcomes of functionally guided treatment of coronary bifurcation lesions – insights from FIESTA registry

VASSILEV Dobrin [1], VASSILEV Dobrin [1], MILEVA Niya [1], NIKOLOV Pavel [1], DIMITROV Georgi [1], KARAMFILOFF Kiril [1], NAUNOV Vladimir [1], RIGATELLI Gianluca [2], COLLET Carlos [6], GIL Robert [4], SERRUYS Patrick [4]

(1) Aleksandrovska University Hospital, Sofia, Bulgaria; (2) Rovigo Medica, Province of Rovigo, Italy; (3) Aalst MAES, Aalst, Belgium; (4) Medical Centre of Postgraduate Education, Warsaw, Poland; (5) Imperial College London, London, United Kingdom; (6) Olv Ziekenhuis, Aalst, Belgium

Aims: The purpose of the study is to address clinical outcomes after functionally (e.g. fractional flow reserve) guided strategy of coronary bifurcation lesions.

Methods and results: We analysed patients from FIESTA registry, which was continuation of FIESTA study (Ffr vs IcEcgSTA, ClinicalTrials.gov Identifier: NCT01724957). Patients with stable angina were included. The inclusion criterion were angiographic bifurcation lesions in a native coronary artery with diameter ≥2.5 mm and ≤4.5 mm and SB diameter ≥2.0 mm. We excluded patients with ST-segment elevation myocardial infarction, left main, haemodynamic instability. PCI was performed according to the current guidelines. Provisional stenting was the default strategy in all patients. Fractional flow reserve (FFR) measurements were performed using intracoronary adenosine at increasing doses of 60 mcg, 120 mcg, and 240 mcg. The minimum value of FFR measurements was taken for analysis. All patients received dual antiplatelet therapy with ADP-antagonist and aspirin for at least 12 months. Overall, 160 consecutive patients with coronary bifurcation lesions were included. The mean age was 67±10 years, 66% males, 96% hypertensive, 39% diabetic, 96% dyslipidemic (or on treatment with statin), 55% smokers, 22% with previous myocardial infarction, 51% with previous PCI. Seventy-four patients had positive FFR<0.80 in main vessel of bifurcation lesion (46% functionally significant lesions). Bifurcation lesion with FFR above 0.80 were deferred from PCI. The rates of major adverse events in treated and deferred lesions at 48±13 months were: all-cause death 16.2% (12/74) vs 7.1% (6/86), p=0.069; cardiac death 12.2% (9/74) vs 5.9% (5/86), p=0.163; MI 1.2% (1/74) vs 0%, p=0.282. There was no significant difference regarding rates of rehospitalisation, because of symptom recurrence, 20% vs 17.6% (p=0.065).

Conclusions: Less than a half of angiographically significant coronary bifurcation lesions were functionally significant requiring stent implantation. The rates of clinical outcomes were not-significantly different in deferred and treated stenoses up to 5-year follow-up.

Left main and multivessel disease - Bypass surgery, Other Coronary interventions - Other

ACS in patients with prior CABG: clinical, angiographic profiles and management practices

CADER Aaysha [(1)], CADER Aaysha [(1)], HAQ M. Maksumul [(1)], KHAN Saidur Rahman [(1)]

(1) Ibrahim Cardiac Hospital & Research Institute, Dhaka, Bangladesh

Aims: ACS among post-CABG patients is now commonly encountered in current clinical practice. This study aimed to investigate the clinical, angiographic profiles and management strategies among post-CABG patients presenting with ACS at a tertiary-care cardiac centre.

Methods and results: This retrospective observational study included all ACS patients with prior CABG presenting to our institute and undergoing coronary angiography from February 2015 to October 2019. Data were collected from hospital and catheterisation laboratory database and statistically analysed. From a total of 591 post-CABG cases that underwent angiography, 223 (37.7%) presented with ACS. Mean age was 62.15±8.28 years. 90.6% of the patients were male. 61.9% presented with NSTEMI, followed by unstable angina (32.7%) and STEMI (5.4%). Most males presented with NSTEMI (63.9%). Most females presented with unstable angina (52.4%). 79.9% were hypertensive, 48.9% dyslipidaemic, 70% diabetic and 49.8% were smokers. Troponin I was elevated in 143 (64.1%). Mean left ventricular ejection fraction was 48.31±9.48 %. Graft vessel disease was identified as culprit in 60.2% of cases and native artery in 24.8%. Among those with graft vessel disease, 129 (58.1%) had saphenous venous graft lesions, 12 (5.4%) had arterial graft lesions and 15 (6.8%) had both arterial and venous graft disease. 64.1% underwent angiography by left radial approach, followed by right radial (24.2%), right femoral (11.2%) and left ulnar (0.4%). As for management strategy, 148 (66.7%) were recommended revascularisation by PCI, 69 (31.1%) were treated with optimal medical therapy and 5 (2.3%) were referred for re-do CABG. In total, 93 (41.9%) of patients underwent PCI, of which 82.8% were *ad hoc* and 17.2% were elective procedures during index admission. PCI target was a native coronary artery in 53.8% and a bypass graft in 37.6%. In 8.6%, PCI was performed to both a native coronary and a graft.

Conclusions: NSTEMI was the most common ACS presentation in post-CABG patients. Women presented more frequently with unstable angina. SVG's were the predominant culprit vessel. PCI remains the most frequently utilised strategy for revascularisation, with native artery PCI taking precedence over bypass grafts.

CTO - Adjunctive pharmacotherapy

PCI versus optimal medical treatment for CTO, results from the CTO-MEX registry

JIMÉNEZ-RODRÍGUEZ Gian Manuel [1], DAMAS-DE LOS SANTOS Félix [1], ARIAS-SANCHEZ Eduardo Agustin [1], PIÑA-REYNA Yigal [1], FARJAT-PASOS Julio [1]

(1) National Institute of Cardiology Ignacio Chavez, CDMX, Mexico

Aims: Chronic total occlusion (CTO) is a challenging and expensive entity in coronary interventions. The aim of the study was to determine the effectiveness of successful percutaneous coronary intervention (PCI) on clinical outcomes in patients with CTO.

Methods and results: A total of 426 patients with at least one CTO were included in a single-centre registry from December 2006 to December 2018, to compare the treatment by PCI (n=229) vs optimal medical treatment (n=197). The primary outcome was the reduction in the frequency of angina according to the Canadian Society of Cardiology (CSC) classification. All the patients had a minimal follow-up of 12 months. A statistically significant difference was obtained in the frequency of angina according to the CSC (5.5 % vs 20.2%, p=0.0001), rehospitalisation at 1 year (11.3% vs 20.9%, p=0.01) and in the prevalence of residual ischaemia diagnosed by perfusion single-photon emission computed tomography (SPECT) (12.2% vs 25.8%, p=0.0001), all of which were more frequent in the optimal medical treatment group.

Conclusions: In patients considered for CTO intervention, a successful PCI reduced the frequency of angina, rehospitalisation at 1 year and the prevalence of residual ischaemia by SPECT.

Other Coronary interventions - Other

Retrospective analysis of consecutive left main coronary disease PCI done in a single centre in the last five years

TAN Tze Khiang [1], TAN Tze [1], UPADHYAYA BELLE Chetan [1]

(1) Glan Clwyd Hospital, Rhyl, United Kingdom

Aims: The EXCEL study five-year outcomes compared the results of LMCD PCI to CABG.The authors report that death from any cause occurred more frequently in the PCI group than in the CABG group (in 13.0% vs 9.9%; difference, 3.1 percentage points; 95% CI: 0.2 to 6.1). We aimed to analyse the incidence and cause of all death from LMCD PCI at our centre

Methods and results: All consecutive LMCD PCI done in the last 5 years were retrospectively analysed. In our centre 109 LMCD PCI were performed and 23 of these patients died folllowing the procedure. 9 of these patients died from acute cardiogenic shock resulting from severe LMS disease. No patients who had successful LMCD PCI died in the first month. However 4 patients died in the first 12 months and 10 patients managed to survive for more than a year. Of the patients who died within a year one had CRT device for ESHF, one was 93 years old, one had metastatic breast cancer and one was current smoker with large BMI. Of the 10 who died after 12 months, 2 had malignancy, 2 were over 90 years old, 2 had previous CABG, 2 had severe LVSD, one had lung fibrosis, one had dementia.

Conclusions: Our study shows that patients with left main coronary disease have increased mortality especially when associated with other comorbid conditions. Most in-patient deaths were in patients who had LMCD and cardiogenic shock. Of the people who survived the admission, all patients survived more than a month. Patients who died after LMCD had significant comorbidities. When the actual cause of death is looked at, It appears that LMCD PCI is safer than CABG as PCI procedure in itself did not appear to cause the death in any of these patients. More detailed analysis of the cause of the death in both arms should be looked into before coming to conclusions.

NSTEMI - Adjunctive pharmacotherapy, Stable CAD - Adjunctive pharmacotherapy

Standard vs short-time hydration for contrast-induced acute kidney injury prevention in patients with normal preprocedural fluid status (the HYDRA II study)

CHIRIATTI Niccolò [(1)], MAIOLI Mauro [(1)], CHIRIATTI Niccolò [(1)], TOSO Anna [(1)], GRIPPO Gabriele [(1)], LEONCINI Mario [(1)], MUSILLI Nicola [(1)], BELLANDI Francesco [(1)]

(1) Cardiology Unit - S. Stefano Hospital, Prato, Italy

Aims: Intravascular volume expansion at the time of contrast media administration is the key protective strategy for prevention of contrast-induced acute kidney injury (CI-AKI). In this study we compare the effects of two different protocols of i.v. isotonic saline infusion in coronary artery disease (CAD) patients scheduled for coronary angiographic procedures who present normal total body fluid levels on hospital admission

Methods and results: Total body fluid levels were assessed by bioimpedance analysis (BIVA) in 1,420 CAD patients at hospital admission and after angiographic procedure. The 1,060 patients (68±11 yrs) with "normal" fluid status were randomised (530 patients per group) to receive "standard" (1 ml/kg/h for 12 hours before and after procedure) or "short"-time (3 ml/kg for 1 hour before and 1ml/kg/h for 6 hours after procedure) i.v. saline infusion. CI-AKI was defined as an increase in cystatin C ≥10% above baseline at 24 hours after contrast administration (iodixanol). Baseline clinical characteristics were well balanced between the two groups. The overall incidence of CI-AKI was 10.6% without significant difference between the two groups: 10.8% in the "standard" group and 10.6% in the "short" group (odds ratio 0.98; confidence interval [CI] 0.66-1.14; p=0.92). Post-procedural BIVA showed that 49 patients (9.2%) in the "standard" group and 71 (13.4%) in the "short" group had lower total body fluid levels than on admission, with no significant difference in the incidence of CI-AKI (16.3% vs 16.9%, respectively; p=0.93).

Conclusions: Standard and short-time periprocedural hydration protocols have similar impact on CI-AKI occurrence in CAD patients with normal BIVA status at hospital admission.

Stents and scaffolds - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

PCI of de novo lesions in the left main coronary artery using a DEB-only strategy

USKELA Sanna [1], USKELA Sanna [1], ERANTI Antti [1], KÄRKKÄINEN Jussi M. [2], RISSANEN Tuomas T. [1]

(1) North Karelia Central Hospital, Siun sote, Joensuu, Finland; (2) Kuopion yliopistollinen sairaala, Kuopio, Finland

Aims: The standard treatment of the left main disease is percutaneous coronary intervention (PCI) with drug-eluting stents. Drug-coated balloon-only (DCB-only) strategy has been mainly used for in-stent restenosis and *de novo* lesions in small vessels and bifurcations. Recently, DCB-only strategy has been found effective and safe in PCI of large *de novo* lesions in patients with high bleeding risk. The aim of this registry-based study was to assess the efficacy and safety of PCI using the DCB-only strategy for the left main disease.

Methods and results: This retrospective single-centre study included all consecutive patients who underwent PCI for *de novo* lesion in the left main coronary artery using the DCB-only strategy between August 2011 and December 2018. Major adverse cardiovascular events (MACE, the composite of death, non-fatal myocardial infarction, and target lesion revascularisation [TLR]) and bleeding events were studied. The patients were followed for 12 months. 69 patients were included (mean age 75 years, 74% male). 35 (51%) had stable coronary artery disease and 34 (49%) had acute coronary syndrome. 44 (64%) out of 69 treated lesions were bifurcations. 28 (41%) patients had diabetes and 18 (26%) had suffered prior myocardial infarction. 53 (77%) patients had at least one bleeding risk factor. There was no procedural mortality and no acute closures of the treated left main occurred. Bailout stenting was not needed. At 12 months MACE occurred in 20 (29%) patients, 12 (17%) patients died and six (9%) had non-fatal myocardial infarction. TLR occurred in four patients (6%). In three of these patients, more than 30% recoil had been accepted after the index DCB-only PCI. The median duration of DAPT was only two months. Nine (13%) patients did not receive $P2Y_{12}$ inhibitor at all due to high bleeding risk. 14 (20%) patients had at least BARC-2 bleeding during the follow-up. No fatal bleedings occured.

Conclusions: This study is the first report of outcomes of the DCB-only strategy for *de novo* lesions in the left main. Left main PCI without stenting was safe and effective. The patient population was elderly with high number of comorbidities and the majority had a high risk for bleeding. Mace was mainly driven by all-cause mortality. When the guidelines (recoil<30% and no flow-limiting dissection after DCB treatment) of the international DCB consensus group were followed, the rate of TLR was very low. The advantage of DCB-only strategy is the possibility for short or even no DAPT in patients at risk for bleeding.

CTO - Tools, devices and techniques

Antegrade CTO recanalisation: angiographic predictors of success

STELMASHOK Valeriy [1], STELMASHOK Valeriy [1], MROCHEK Alexander [1], POLONETSKY Oleg [1], STRYGO Nikolai [1]

(1) Republican Scientific and Practical Centre «Cardiology», Minsk, Belarus

Aims: We analysed 217 cases of antegrade CTO recanalisation from our single centre study. Patients were divided into two groups: group 1 with successful CTO recanalisation and group 2 with unsuccessful CTO recanalisation. Angiographic characteristics of coronary arteries and CTO lesions were evaluated in terms of CTO recanalisation success.

Methods and results: 217 patients in our analysis were divided into: group 1 with successful CTO recanalisation – 158 patients and group 2 with unsuccessful attempt - 59 patients. Recanalization rate evaluated as 72.8%. Groups 1 and 2 did not differ in terms of demographic and clinical data. Strong predictor of success was LAD CTO localisation: 72 patients (45%) in group 1 versus 10 patients (17%) in group 2 ($p=0.0004$), when RCA localization connected to unsuccessful recanalisation: 55 (35%) versus 36 (61%) patients ($p<0.0024$). Also, long CTO duration around 14 months, CTO length around 19 mm and more, blunt stump proximal CTO segment and J-CTO more than 1 had high significance as predictors of unsuccessful procedure ($p<0.005$). Less strong predictors of unsuccessful recanalisation were significant side branches proximal and distal to CTO and bridging collaterals ($p<0.05$).

Conclusions: In our analysis, statistically significant predictors of successful antegrade CTO recanalisation were lesion localization in LAD, short duration of occlusion, short CTO length and low J-CTO score. Contrary, predictors of unsuccessful recanalisation were established as lesion localization in RCA, long duration of occlusion, CTO length up to 19 mm and high J-CTO score. Total recanalisation rate 72.8% give as a good chance for successful CTO PCI.

Stable CAD - Vascular access and bleeding, Other Coronary interventions - Other

Patient preferences for transradial access over transfemoral access for elective coronary procedures

KINTIS Konstantinos [1], KINTIS Konstantinos [1], MANTIS Christos [1], KATSAROS Lampros [1], SOUSONIS Vasilis [1], PAPADAKIS EMMANOUEL [1], ANTONATOS Dionisis [1], KOUTOUZIS Michael [2], POULIANITOU Areti [1], KIRIAKOPOULOS Vasilis [1], PATSILINAKOS Sotiris [1]

(1) Konstantopoulio General Hospital, Nea Ionia, Greece; (2) Erythros Stavros HOSPITAL, Athens, Greece; (3) Elena Hospital, Athens, Greece

Aims: While transfemoral access (TFA) had been the universal default, there is an increasing interest in transradial access (TRA) as it is associated with a reduction in haemorrhagic entry site complications and permits earlier patient ambulation. However, little is known about patient preferences within percutaneous coronary procedures. The aim of this study was to explore patient preference for vascular access site in percutaneous coronary procedures, the perceived importance of benefits and risks of TRA and TFA were assessed.

Methods and results: This study was a single-centre, prospective, and consecutive survey of 653 patients undergoing TRA for coronary imaging and intervention. Primary inclusion criteria were patients who had previously undergone a TFA procedure. The survey questions were assessed on a 1–5 Likert scale and it was used to determine patient preference for treatment attributes including complications, painful, mobilisation and comfort, and over-night stay. No major complications (including haematomas, infection, or increased rate of radial artery occlusion) were encountered during the immediate post-procedural period or on outpatient follow-up (average 8 days). On post-procedural examination, 12% had mild bruising, 14% had mild pain at the radial access site and 8% had radial artery occlusion. Of the 653 patients included in this study, 617 strongly preferred radial access over femoral access and reported that, if they needed another procedure, they would prefer radial access.

Conclusions: There was nearly unanimous patient preference for radial over femoral access for percutaneous coronary procedures in this single-centre prospective analysis. There were no major complications and no increased rate of radial occlusion. In the current age of value-based and patient-centred medicine, the radial approach should be considered for percutaneous coronary procedures.

Stable CAD - Tools, devices and techniques

Quality of life one year after BRS implantation in long coronary lesions: comparison with DES

STELMASHOK Valeriy [1], STELMASHOK Valeriy [1], MROCHEK Alexander [1], POLONETSKY Oleg [1], STRYGO Nikolai [1]

(1) Republican Scientific and Practical Centre «Cardiology», Minsk, Belarus

Aims: In clinical trials, we usually control patient's clinical status and visualisation results and do not pay much attention to patient's quality of life. In our study we analysed patient's psychological, emotional, and mental status after endovascular correction of long coronary lesions in mid-term period.

Methods and results: In our single-centre, randomised, prospective clinical study we analysed patient's psychological, emotional and mental status after endovascular correction of long coronary artery lesions. 80 patients with stable angina and *de novo* stenotic and occlusive long coronary (length >25 mm) lesions were included in the study. Patients were randomised into two groups: group 1 (n=40) with BRS Absorb implantation and group 2 (n=40) with DES XIENCE implantation. All patients were assessed with SF-36 survey before implantation and at 1-year control. Groups had no statistical difference by demographic, angiographic and clinical parameters. Basic results of the survey before procedure were lower than normal levels in all scales of SF-36. Interpretation of Sf-36 survey revealed improvement in all scales of the survey at one-year control in both groups with a positive dynamic from 23 till 28% (in a majority of parameters deference was statistically significant, $p<0.001$). Especially big progress was seen in role-physical and role-emotional functioning, which means one year after long coronary lesions correction patients had achieved a much better adaptation in terms of social and professional activity. Group 1 showed a better improvement in quality of life at one-year control.

Conclusions: Endovascular correction of long coronary lesions demonstrates improvement in quality of life for all patients at one-year control. Lesion correction with bioresorbable scaffolds revealed better results in terms of quality of life.

NSTEMI - Adjunctive pharmacotherapy, Other Coronary interventions - Other

The relationship between routine hydration therapy and development of contrast-induced acute kidney injury in NSTEMI patients at low risk for nephropathy

ABACI Okay [1], ARSLAN Sukru [1], DALGIC Nur [1], ABACI Okay [1], KOCAS Cuneyt [1], DALGIC Yalcin [2], BATIT Servet [3], YILDIZ Ahmet [1]

(1) İstanbul Üniversitesi - Cerrahpaşa Kardiyoloji Enstitüsü, Istanbul, Turkey; (2) Kocaeli Sağlık Bilimleri Üniversitesi Derince Eğitim Araştırma Hastanesi, Kocaeli, Turkey; (3) Kilis Devlet Hastanesi, Kilis, Turkey

Aims: Routine hydration therapy investigation studies frequently included patients with stable coronary artery disease and with a high risk of CI-AKI (GFR <60ml / min). However, data on routine hydration treatment in non–ST-segment elevation myocardial infarction (NSTEMI) patients with GFR ≥ 60ml / min are insufficient. In our study, we aimed to investigate the relationship between routine hydration therapy and CI-AKI development in patients with NSTEMI and low risk for nephropathy.

Methods and results: NSTEMI patients who has undergone coronary angiography were enrolled study. Randomisation was performed in a 1:1 ratio with computer-generated random numbers. 462 patients with NSTEMI that 31 patients had GFR<60 ml/min, 22 had EF less than 30%, 5 had a Killip score of 3-4, 3 had cardiac arrest who were excluded from the study. Thus, 401 patients were included study, 203 patients in the non-hydration group and 198 patients in the hydration group. Intravenous hydration with isotonic saline (1 ml/kg/h, 0.9% sodium chloride) was given for 3-12 hours before, and 24 hours after, contrast exposure to the hydration group. CI-AKI is defined as the increase in serum creatinine values 0.5 ml/min or 25% at the 48-72th hour after CAG compared to baseline. Results: In our study, the incidence of CI-AKI development in the routine hydration group (7.1%) was significantly lower than the non-hydration group (14.1%) (p=0.02). The MEHRAN risk score was found to be ≤ 5 in 77.6% of the patients participated in the study. In addition, the MEHRAN risk score was significantly higher in the routine hydration group (mean 4) than in the non-hydration group (mean 3) (p<0.01). The median age (63 years) was significantly higher in the routine hydration group than the non-hydration group (58 years) (p<0.01). The predictors of CI-AKI in the univariate analysis were older age (68.5 vs 60.1 years; p<0.01), lower haemoglobin level before the procedure (13.2 vs 13.5 g/dl; p: 0.03) and no hydration therapy (32.6% vs 51.4%; p<0.02). This study revealed that older age (OR: 1.06, CI 95% [1.03-1.10], p<0.01), amount of contrast media (OR: 1.01, CI 95% [1.00-1.02], p: 0.04) and routine hydration (OR: 0.30, CI 95% [0.14-0.63], p<0.01) were independent risk factors for developing CI-AKI.

Conclusions: Routine hydration therapy mitigates the development of CI-AKI in patients with NSTEMI who are at low risk for nephropathy. Advanced age and large amount of contrast media usage increase development of CI-AKI, while the incidence of CI-AKI decreases in patients receiving routine hydration therapy. Routine use of hydration therapy in patients with NSTEMI may reduce mortality and morbidity associated with CI-AKI that further studies are needed.

STEMI - CT / MRI imaging

Cardiac MRI: changing management in acute STEMI set-up

KUMAR Purushottam [(1)], VARSHNEY Amit [(1)], KUMAR Purushottam [(1)], MANI Siddhart [(1)], PADOLE Dinesh [(1)], GHOSH HAZRA Kashinath [(1)]

(1) Rabindranath Tagore International Institute Of Cardiac Sciences, West Bengal, India

Aims: To study the viability of an infarcted artery segment helping to decide the plan of treatment in an acute setting.

Methods and results: Case selection: a 69-year-old normotensive gentleman admitted through emergency with a temporary pacemaker *in situ* with chest pain and shortness of breath. Case history: he had severe chest pain and was managed locally. Case investigations: he had ECG and echocardiogram suggestive of evolved anterior wall myocardial Infarction. Ejection fraction calculated through Simpson's method was 25%. Troponin I was >50.0000. Mild leucocytosis. Raised CRP. Hb of 6.6gm/dl, 2 units packed red blood corpuscles transfused. Intervention findings: coronary angiography revealed triple vessel coronary artery disease. Cardiac MRI: cardiac MRI revealed normal sized left ventricle with systolic dysfunction. Ejection fraction of 16% and transmural infarction of basal, mid, apical septum and inferior, apical, anterior, apex myocardium, of 17 segments 10 were non-viable (5 RCA & 5 LAD territory). Remaining segments were viable. No hibernating segments. After receiving consent, percutaneous transcatheter angioplasty to LCX OM1 was performed. The patient was stable post-procedure.

Conclusions: In the assessment of coronary artery disease (CAD) by CMR, analysis of the global and regional myocardial function is enhanced by examination of myocardial viability and perfusion. This non-invasive diagnostic ''triad'' confers CMR a unique methodological strength for a comprehensive evaluation of CAD within one single exam session. In particular, late gadolinium enhancement scar imaging by CMR is currently the most accurate non-invasive method to examine myocardial viability. In several studies on the prognostic value of CMR in CAD assessment, normal adenosine-stress CMR was highly predictive for a good prognosis, thus able to identify patients in whom invasive coronary angiography can be deferred safely. Regarding myocarditis, CMR is evolving as the most accurate imaging technique. It is in this regard that we present this case report of a 69-year-old male who had acute anterior wall myocardial infarction in which we show the usefulness of these techniques in an acute setting where cardiac MRI also changed the course of treatment.

Left main and multivessel disease - Invasive imaging and functional assessment, Bifurcation lesion - Invasive imaging and functional assessment

OCT-guided PCI of the left main, a single-centre retrospective study

ERTMAN Vladislav [1], SOZYKIN Alexey [1], NIKITIN Alexey [1], SHLYKOV Alexander [1], LITYAIKIN Alekxander [1], NOVIKOVA Natalya [1], EMELYANOV Pavel [1], KAMINSKAYA Ekaterina [1], AVERIN Evgeniy [1]

(1) Central Clinical Hospital of the Russian Academy of Sciences, Moscow, Russian Federation

Aims: It is known that PCI using only angiography for lesions of the left main as well as for bifurcation lesions is associated with non-optimal implantation of stents, which is associated with a high risk of adverse long-term results. The use of OCT for stenting the left main makes it possible to achieve optimal stent implantation and improve clinical outcomes.

Methods and results: We conducted a single-centre randomised study, which should show the advantage of stent implantation in left main bifurcation under OCT control compared with standard implantation under angiographic control. The follow-up period was 1 year, and 100 patients randomised 1:1 were included in the study. The outcome is the final combined point: cardiac death, ischaemia, or myocardial infarction due to changes in the revascularisation zone. All patients were elective, with angina pectoris of high functional class. With damage to the bifurcation of the left main in more than 50%. PCI was performed by the technique of one or two stents, performing kissing dilation and POD using OCT or without OCT. As a result of the analysis of the data of 100 patients with PCI bifurcation LM using or not using OCT, primary endpoint indicators in the group without OCT was 16% and 10% for the OCT group. In 13% of cases, when using OCT, a single-stent tactic was chosen instead of a two-stent one. Additional stent optimisation is 20% more common in the OCT group. A 3-month follow-up in the OCT group demonstrated in 95% of cases full or partial endothelisation of the stent stratum, which made it possible to cancel DAPT earlier, which is important in patients with a high risk of major bleeding.

Conclusions: The use of OCT can improve the intraoperative results of PCI for bifurcation of the left main using controlled factors for optimal stent implantation. As a result, the long-term results of treatment are improved, the time for taking DAPT is reduced, and the number of implantable stents is reduced, which is important in patients with atrial fibrillation and a high risk of painful bleeding

Other Coronary interventions - Other

Acute effect of left ventricular unloading on the pulmonary circulation

BASTOS Marcelo [(1)], BASTOS Marcelo [(1)], DAEMEN Joost [(1)], SCHREUDER Jan [(1)], DEN UIL Corstiaan [(1)], VAN MIEGHEM Nicolas [(1)]

(1) Erasmus Universiteit Rotterdam, Rotterdam, the Netherlands

Aims: Mechanical Circulatory Support (MCS) devices provide partial left ventricular support and are increasingly used in percutaneous coronary interventions (PCIs) to unload the left ventricle (LV) and to optimise central haemodynamics and peripheral circulation. Many patients, but not all, show a clear response to acute LV unloading (responders). The variation in mean pulmonary capillary wedge pressure (mPCWP) in response to MCS has shown important interindividual variability and its mechanisms are unknown.

Methods and results: Following implementation of PulseCath iVAC2L (n=21) or Impella CP (n=3), haemodynamic data were recorded pre- and post- MCS activation. Patient characteristics and haemodynamic response to MCS were compared between the two groups with negative or positive variations in mPCWP. Patients in whom mPCWP decreased after MCS initiation (responders) had more often COPD with a more frequent clinically relevant mitral and aortic regurgitation but similar SYNTAX scores, baseline mPCWP, forward stroke volume (fSV) and mean arterial pressure (MAP) than those with no change in mPCWP. Only these early MCS responders had improvements in fSV (+24% IQR: 5-47 vs +0.24% IQR: -14-8, p=0.065), MAP (+10% IQR 9-15 vs 1% IQR: -4-6, p=0.068). The percent variation in forward cardiac output (fCO) significantly correlated with the percent changes in mPCWP (rho:-0.7, p<0.01).

Conclusions: Patients with clinically relevant COPD as well as mitral or aortic disease are more likely responsive to immediate haemodynamic unloading upon MCS activation.

STEMI - Adjunctive pharmacotherapy

15-year experience of pharmaco-invasive strategies in patients with STEMI

MILENKINA Sofia [(1)], MILENKINA Sofia [(1)], STAROVEROV Igor [(1)], MILENKIN Boris [(1)]

(1) 'National medical research centre of cardiology' of the Ministry of healthcare of the Russian Federation, Moscow, Russian Federation

Aims: To investigate pharmaco-invasive strategy aspects in patients with STEMI over a 15-year period admitted to the Cardiology Centre.

Methods and results: The investigation included all patients with STEMI admitted to the coronary care unit in the period from 2003 to 2018, who had undergone thrombolytic therapy (TLT) within 6 hours after the first signs of the development of MI with subsequent PCI. The inclusion and exclusion criteria match generally accepted indications for TLT and PCI. The study included 2478 patients, of whom 1449 were conducted by the TLT with recombinant prourokinase (as the most commonly used drug), 1029 – streptokinase (one of the most studied and common drugs). The groups were comparable by sex, age, localisation of MI. Total ischaemic time less than 90 minutes was registered in 34.4% cases. This might be due to logistic and social-economic reasons, as well as the low education of the population and delay in calling an ambulance. Indirect criteria for reperfusion did not match the results of PCI. Reperfusion (as the main criteria of the effectiveness of the drug) according to coronary angiography was achieved in 72.1% of cases in recombinant prourokinase group, and in 54.4% of cases in the streptokinase group (p=0,000). Survival during hospitalisation did not differ significantly. 91.9 % of patients were alive after 1 year of follow-up, 80.6% of patients were alive after 5 years of follow-up. Cardiovascular death was registered in 5.9% after the 1-year follow-up and in 14.2% after the 5-year follow-up. The evaluation of long-term results after 5 years is statistically unreliable due to loss of contact with the majority of patients.

Conclusions: On-time reperfusion therapy determines the size of myocardial necrosis, immediate and long-term results of treatment of STEMI. Primary PCI is a gold standard for STEMI treatment, but in regions where it is impossible to proceed to endovascular intervention in the recommended time, it is necessary to start TLT as soon as possible in order to regain myocardial perfusion. Recombinant prourokinase has shown itself as an effective and safe drug in the treatment of STEMI, which can be used in pharmaco-invasive approach, as well as any other investigated drug with proven efficacy in case if it is not possible to deliver the patient to the cathlab in an adequate time.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Prevalence of vulnerable plaque features in non-ischaemic vessels of diabetes mellitus patients with or without myocardial infarction

BERTA Balazs [12,14], BERTA Balazs [12,14], ROLEDER Tomasz [11,14], HERMANIDES Renicus S [12], IJSSELMUIDEN Alexander JJ [3], ALFONSO Fernando [4], ESCANED Javier [6], KAUER Floris [5], DE LUCA Giuseppe [9], WOJAKOWSKI Wojciech [10], KEDHI Elvin [13]

(1) Heartcentrum, Zwolle, the Netherlands; (2) Research and Development Centre, Wroclaw, Poland; (3) Amphia Hospital, Breda, the Netherlands; (4) Hospital Universitario de La Princesa, Madrid, Spain; (5) Albert Schweitzer Ziekenhuis, Dordrecht, the Netherlands; (6) Hospital Clínico San Carlos, Madrid, Spain; (7) Radboud Universiteit, Nijmegen, the Netherlands; (8) Beaumont Hospital, Dublin, Ireland; (9) Azienda Ospedaliera-Universitaria "Maggiore della Carità", Eastern Piedmont University, Novara, Italy; (10) Medical University of Silesia, Department of Cardiology and Structural Heart Diseases, 3rd Division of Cardiology, Katowice, Poland; (11) Regional Specialist Hospital in Wroclaw, Research and Development Centre, Wroclaw, Poland; (12) Isala Clinics, Heartcentrum, Zwolle, the Netherlands; (13) AZ Sint-Jan, Cardiology Department, Brugge, Belgium; (14) Diagram CRO, Zwolle, the Netherlands

Aims: Vulnerable plaque features like thin-cap fibroatheroma, plaque rupture, plaque erosion and calcified nodule with apposed thrombus are believed to be more frequent in non-culprit lesions of patients with myocardial infarction (MI). We aimed to study whether the same is true in non-ischaemic lesions of diabetes mellitus patients.

Methods and results: All patients of the COMBINE (FFR-OCT) trial underwent both fractional flow reserve (FFR) and optical coherence tomography (OCT) investigation. The OCT findings of the FFR-negative non-culprit lesions were studied in 2 subgroups of patients: patients with myocardial infarction, previously or at presentation (MI group) vs patients with no myocardial infarction (non-MI group). The primary endpoint was the combined prevalence of thin-cap fibroatheroma, plaque rupture, plaque erosion and thrombotic calcified nodule in FFR-negative lesions. From the 391 patients studied, 162 (41.4%) were assigned to the MI group vs 229 (58.6%) to the non-MI group. OCT analysis was performed in 195 lesions in MI vs 268 lesions in non-MI group. The mean age of patients was 67.5±9.4 years and 246 (62.9%) were male. There were no significant differences in terms of quantitative lesion measurement such as FFR values [87 (84-92) vs 88 (85-92); p=0.484], minimal lumen area (2.79±1.34 vs 2.87±1.39 mm^2; p=0.584), percentage area stenosis (62.7±12.4% vs 61.5±12.1, p=0.326) in MI vs non-MI group, respectively. The primary endpoint occurred in [69 (35.4%) vs 77 (28.7%), p=0.128] in MI vs non-MI group, respectively. Thin-cap fibroatheroma had similar prevalence in MI vs non-MI group, respectively: 46 (23.6%) vs 49 (20.5%); p=0.163. Prevalence of plaque rupture [19 (9.7%) vs 32 (11.9%); p=0.456] and thrombotic calcified nodule [15 (7.7%) vs 21 (7.8%); p=0.955] did not differ between MI vs non-MI group, respectively. Only the plaque erosion was more frequent in MI vs non-MI group: 13 (6.7%) vs 7 (2.6%); p=0.034.

Conclusions: In diabetes mellitus patients, the prevalence of vulnerable and complicated plaques in non-ischaemic lesions is high in both MI and non-MI subgroups and not significantly different. Because of fast progressing atherosclerosis, diabetes mellitus patients might be exposed to a higher risk of future coronary events independently from previous or current clinical presentations such as MI.

STEMI - Tools, devices and techniques

Impact of direct stenting on 10-year clinical outcomes in patients with STEMI

SCARPARO Paola [1], SCARPARO Paola [1], IMPROTA Riccardo [1], WILSCHUT Jeroen [1], DEN DEKKER Wijnand [1], DAEMEN Joost [1], DE JAEGERE Peter [1], ZIJLSTRA Felix [1], VAN MIEGHEM Nicolas M. [1], DILETTI Roberto [1]

(1) Erasmus MC, Rotterdam, the Netherlands

Aims: Direct Stenting (DS) could be associated with reduced distal embolisation and improved reperfusion parameters in patients with ST-segment elevation myocardial infarction (STEMI). However, the impact of DS on long-term clinical outcomes remains unclear. We evaluated DS on very long-term clinical outcomes in STEMI patients and according to thrombus burden.

Methods and results: Between 2002 and 2004, consecutive patients with STEMI undergoing percutaneous coronary intervention were investigated. The study population was stratified in two groups: DS and conventional stenting (CS). Large thrombus burden (LTB) was defined as thrombus ≥2 vessel diameters and small thrombus burden (STB) as thrombus <2 vessel diameters. Major adverse cardiac event (MACE) defined as composite of all-cause death, repeat myocardial infarction, and infarct related artery re-intervention were evaluated at 10 years. A landmark analysis was performed at 30 days. A total of 806 patients were analysed, 450 (55.8%) underwent DS and 356 (44.2%) CS. At 10-year, MACE and mortality rates were significantly increased in CS group than in DS (MACE: 47.9% vs 38.1%, p=0.006; mortality: 31.3% vs 22.9%, p=0.008). DS was identified as an independent predictor of reduced 10-year mortality (HR 0.54, 95%, CI 0.32-0.91; p=0.02). In CS group, during the first 30 days after STEMI, MACE and mortality rates were significantly higher among patients with LTB than STB (21% vs 10.2%, p=0.006; and 14.3% vs 7.6%, p=0.048), and beyond 30 days, no differences were identified (p=0.72 and p=0.83). In DS group, MACE and mortality rates between LTB and STB were similar in the first 30 days (p=0.21 and p=0.81) and also after 30 days (p=0.24 and p=0.42).

Conclusions: DS was associated with a reduced 10-years MACE and mortality rates among patients with STEMI. Thrombus burden only seemed relevant with CS.

STEMI - Vascular access and bleeding

Radial access vs the conventional radial approach in cardiac catheterisation and coronary angioplasty

ALEJOS Edson [1], ROMO Miguel [1], GALVÁN Eduardo [1], PALACIOS Juan Manuel [1], JAUREGUI Oddir [1], RODRÍGUEZ Juan Manuel [1]

(1) UMAE Hospital de Cardiologia No. 34, Nuevo Leon, Mexico

Aims: To compare the clinical results and complications of the distal radial access compared to conventional radial approach in diagnostic catheterisation and coronary angioplasty.

Methods and results: Patients undergoing angiography or coronary angioplasty between November 2018 and November 2019 were included. Clinical and angiographic characteristics, vascular complications, and success of the procedure are reported, plethysmography was performed at 24 hrs to assess radial artery occlusion. Of the 2,003 cases were included, distal access was attempted in 1,066 patients, with failure in 258 (19%) and 937 cases by conventional radial approach. In the distal radial group 76.2% were men and 23.8% women. In 1,848 (91.8%) cases were performed in patients with ischaemic heart disease and 8.1% with valvulopathy or cardiomyopathy. In 1,028 patients (51.09%) coronary intervention was performed, 690 (66.9%) elective angioplasties and 338 (33%) in acute myocardial infarction, of which 156 were performed by distal radial access. 6 Fr introducers, 5000 units of heparin and 99% 6 Fr catheters were routinely used. Radial occlusion in distal access was presented in 2% versus 10.2% (p=0.001) in conventional approach. 1 patient presented pseudoaneurysm and another arteriovenous fistula in the distal radial group (p=0.532).

Conclusions: The distal radial access is a reasonable alternative, demonstrating safety and efficacy, with a lower occlusion rate compared to the conventional approach without a significant increase in complications.

STEMI - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

Sex-related differences in a multicentre observational registry of patients treated with IMPella mechanical circulatory support device: the IMP-IT women study

ZIVIELLO Francesca [1], CHIEFFO Alaide [1], ZIVIELLO Francesca [1], BURZOTTA Francesco [2], BRIGUORI Carlo [3], TRANI Carlo [2], NICOLINI Elisa [4], MASIERO Giulia [5], PAGNOTTA Paolo [6], MONTORFANO Matteo [1], TARANTINI Giuseppe [5]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy; (2) Fondazione Policlinico Universitario A. Gemelli, Metropolitan City of Rome, Italy; (3) Clinica Mediterranea - Ospedale e Centro Diagnostico, Metropolitan City of Naples, Italy; (4) Ospedali Riuniti, Province of Ancona, Italy; (5) University of Padua, Province of Padua, Italy; (6) Humanitas Research Hospital, Metropolitan City of Milan, Italy

Aims: To analyse the characteristics of the female population enrolled in IMP-IT registry and to assess differences in presentation, timing to interventions and outcomes between men and women.

Methods and results: The Women-IMP-IT study is a multicentre observational national registry focusing on female population enrolled in IMP-IT study. Baseline, procedural and haemodynamics characteristics, such as outcome were collected. Differences between men and women were examined. Mean age of female population was 66.9±16.1 years, Body mass index was 26.3±5.5 kg/m^2. There was a higher rate of cardiogenic shock (66.7% vs 49.1%; p=0.06), NSTEMI (18% vs 9%, p=0.03) and acute myocarditis (9.6% vs 1.4%, p=0.01) in women vs men, associated with a lower rate of protected PCI (33.3% vs 50.9%, p=0.06). We did not observe a statistical difference in device related complications (27.4% vs 23.3%; p=0.50), respectively in women compared to men. In particular, no differences were observed in access site bleedings (10.8 % vs 9%; p=0.70) and life threatening or severe bleeding (15.3% vs 11.4%; p=0.40). At one-year, all-cause death rate was 45.1% in women vs 30.1% in men (p=0.016), and cardiac death rate was 42.5% in women and 27.5% in men (p=0.013). At 1-year no significant difference was observed in the rate of myocardial infarction (3.7% vs 2.3%; p=0.44), stroke (3.7% vs 2.6%; p=0.70), heat-failure hospitalisation (7.7% vs 7.5%; p=1.0), need for left ventricular assist device or heart transplantation (1.3% vs 5.5%; p=0.21).

Conclusions: In our series, use of Impella is cardiogenic shock and high-risk-PCI is increasing in female population. Sex-differences in mortality are mostly explained by clinical differences at presentation.

Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

Novel machine learning methodology for improved NIRS-IVUS end-diastolic frame detection

BAJAJ Retesh [1,2], BAJAJ Retesh [1,2], HUANG Xingru [2], KILIC Yakup [1], RAMASAMY Anantharaman [1,2], PARKER Maurizio K. [2], TORII Ryo [3], MOON James [1,3], KOH Tat [1], JAIN Ajay [1], PUGLIESE Francesca [1,2], MATHUR Anthony [1,2], BAUMBACH Andreas [1,2], DIJKSTRA Jouke [4], ZHANG Qianni [2], BOURANTAS Christos V. [1,2,3]

(1) St Bartholomew's Hospital, London, United Kingdom; (2) Queen Mary University of London, London, United Kingdom; (3) University College London, London, United Kingdom; (4) Leiden University Medical Center (LUMC), Leiden, the Netherlands

Aims: Several methodologies over recent years have been developed for accurate detection of end-diastolic IVUS frames. However, most of them have no application in research and there are limited validation studies assessing their efficacy against ECG estimations. The aim of the present study is to examine the efficacy of an established methodology in detecting end-diastolic frames - that relies on the relative movement of the lumen with regards to the IVUS catheter - against the ECG estimations and develop and validate a novel machine learning algorithm for better end-diastolic frame detection.

Methods and results: Twenty vessels (6 LAD, 9 LCx and 5 RCA) from six patients that underwent near-infrared spectroscopy-IVUS (NIRS-IVUS) imaging, were included in the present analysis. The NIRS-IVUS pull-back and a concurrent ECG tracing during the pull-back were imported in a mixed viewer that enabled simultaneous display of the ECG and the NIRS-IVUS images allowing accurate detection of the end-diastolic frames that corresponded to the peak of R-wave. These estimations were compared to the estimations of a well-established methodology that relies on the relative movement of the lumen with regards to the NIRS-IVUS catheter to detect the end-diastolic frame, assuming that this is the frame prior to the largest movement of lumen contour. In addition, a machine learning algorithm based on recurrent neural network was developed with a bidirectional gated-recurrent-units structure to analyse the NIRS-IVUS data. These extracted patterns of pixel movement corresponding to the cardiac cycle and was used to train a model to identify the end-diastolic frames for each vessel type, acknowledging their different movement patterns. Training was done for each vessel type using a leave-one-out cross validation, whereby all the vessels except one were used for training and the last for validation; this process was repeated until all the vessels were used for validation. The accuracy of both methodologies was tested against the ECG estimations: it was assumed that the estimations of the methodologies correctly identified the end-diastolic frame when their estimations were within ±100 ms from the peak of the QRS. In total 3095 end-diastolic frames were identified by ECG and included in the final analysis. The image-based methodology identified 3046 end-diastolic frames. The mean differences between the image-based methodology and the ECG estimations were: 84±145 ms for the LAD, 82±239 ms for the LCx and 6±223 ms for the RCA. Using the cut-off of ±100 ms the image-based methodology was able to correctly identify 42.9% of the end-diastolic frames. The machine learning algorithm identified 2981 end-diastolic frames. The mean differences between machine learning and ECG estimations were 6±110ms for the LAD, 7±112ms for the LCx and 5±114ms for the RCA. Machine learning was more effecting than the image-based methodology in correctly detecting the end-diastolic frames as it was capable to identify 80.4% of the frames ($p<0.0001$).

Conclusions: The present study demonstrated that an established image-based methodology has a poor efficacy in correctly detecting the end-diastolic frames using ECG as reference standard. Conversely, the machine-learning approach proposed in this study seems to accurately identify the end-diastolic frames and therefore it should be preferred over imaging-based methodologies for this purpose.

NSTEMI - Tools, devices and techniques

Mechanical circulatory support with the Impella device in the percutaneous treatment of patients with severe aortic valve stenosis

PAGNOTTA Paolo [1], PAGNOTTA Paolo [1], SANZ SANCHEZ Jorge [1], CHIARITO Mauro [1], FERRANTE Giuseppe [1], BRIANI Martina [1], REGAZZOLI Damiano [1], CORRADA Elena [1], STEFANINI Giulio [1], REIMERS Bernhard [1], NICOLINI Elisa [2], BRIGUORI Carlo [3]

(1) Humanitas Research Hospital, Metropolitan City of Milan, Italy; (2) Ospedali Riuniti Torrette Di Ancona, Province of Ancona, Italy; (3) Clinica Mediterranea - Ospedale e Centro Diagnostico, Metropolitan City of Naples, Italy

Aims: Both aortic stenosis (AS) and regurgitation (AR) are considered relative contraindication for the use of different percutaneous mechanical circulatory support (MCS). Therefore, their use in this subset of patients is extremely limited. Driven by the paucity of pooled data on the outcomes of patients affected by AS or AR and needing for MCS, we aim to evaluate the outcome of these subset of patients supported with the use of the Impella device.

Methods and results: All consecutive patients with moderate-severe or severe AS or AR undergoing high-risk PCI, aortic valvuloplasty or transcatheter valve replacement, supported by micro-axial continuous flow percutaneous left ventricular assist device (Impella 2.5, Impella CP) were enrolled in this multicentre retrospective registry. A total of 19 patients with AS (n=17, 89%) or AR (n= 2, 11%) were enrolled in the present study. The Impella device was placed electively prior to percutaneous procedure in all cases except for two patients (11%). The majority of patients underwent BAV with concomitant PCI (n=15, 79%), while 2 patients (11%, 1 with AS and 1 with AR) underwent TAVR without PCI, and 2 patients (one with AS and one with AR) underwent PCI due to high-risk NSTEMI followed by TAVR during the same hospital stay. The patient with AR treated with TAVR without concomitant PCI was also affected by severe functional mitral regurgitation and underwent percutaneous mitral edge-to-edge repair during the same procedure. The only periprocedural complication was an acute severe mitral regurgitation due to mitral chordal rupture, probably caused by removal of the Impella device from the left ventricle. This patient was successfully treated with percutaneous mitral edge-to-edge repair after 4 days. All the other patients were discharged without any major clinical events.

Conclusions: These preliminary results suggest that the Impella device should be considered a feasible option for patients with AS and AR undergoing percutaneous procedures, with a very low rate of periprocedural complication. Further prospective large studies are needed to confirm our data.

STEMI - Tools, devices and techniques

Prognostic availability of creatinine clearance and haemoglobin composite index in patients with STEMI undergoing primary PCI

YANG Tae-Hyun [1], YANG Tae-Hyun [1], LEE Yeong-Min [1], PARK Eunji [1], PARK Young-Ah [1], JIN Han-Young [1], SEO Jeong-Sook [1], JANG Jae-Sik [1], KIM Dae-Kyeong [1], KIM Dong-Soo [1]

(1) Inje University Busan Paik Hospital, Busan, Republic of Korea

Aims: A Creatinine clearance (CCr) and haemoglobin (Hb) has been a readily available routine laboratory test that can predict clinical outcomes in patients with acute coronary syndrome. The aim of this study was to evaluate the impact of CCr and Hb composite Index (CHI) on long-term clinical outcomes in patients with STEMI undergoing primary PCI with DES.

Methods and results: We analysed 326 consecutive STEMI patients treated with primary PCI. The Cox proportional hazards model determined the optimal combination of CCr and Hb into a CHI. Patients were divided into quintiles according to a CHI. The discriminative abilities of CHI, CCr and Hb in predicting 12-month MACE, a composite of all-cause of death, nonfatal MI and ischaemic stroke were compared using area under the receiving operating characteristic curve. The optimal weighting of CCr and Hb to form a CHI to predict a 12-month MACE was Hb + CCr/12. A positive trend was observed between a 12-month MACE and CHI quintiles; 39.4%, 9.4%, 6.1%, 0.0%, 1.5% of MACE occurred from quintiles 1 to 5 ($p<0.001$). A positive trend was also demonstrated between a 12-month cardiovascular death and CHI quintiles (36.4%. 9.4%, 4.5%, 0.0%, 0.3%, respectively, $p<0.001$). In the multivariate setting, the lowest quintile was an independent predictor of 12-month MACE (HR: 23.15, 95% CI: 2.40~222.87, $p=0.007$) after adjusting for gender, left ventricular ejection fraction, creatinine clearance and factors included in the Thrombolysis In Myocardial Infarction risk score for STEMI. MACE-free survival rate was significantly lower in patients with the lowest quintile compared to patients with other quintiles ($p<0.001$). The area under the curve of a CHI for a 12-month MACE was significantly greater (0.857) than for Hb (0.777, $p=0.003$) and CCr (0.802, $p=0.039$).

Conclusions: The CCr and haemoglobin composite index is a useful and powerful marker to predict a 12-month MACE in patients with STEMI who underwent primary PCI with a superior discriminative ability than CCr or Hb.

Other Coronary interventions - Calcified lesions

Clinical outcomes at midterm follow-up of patients with calcified lesions treated with rotational atherectomy

ZLATANCHEVA Galina [(1)], ZLATANCHEVA Galina [(1)], VASSILEV Dobrin [(1)], KARAMFILOFF Kiril [(1)], NIKOLOV Pavel [(1)], DIMITROV Georgi [(1)]

(1) Aleksandrovska University Hospital, Sofia, Bulgaria

Aims: Clinical results and predictors of mortality over a 2-year period in patients with calcified lesions treated with rotational atherectomy in the Bulgarian population are unknown.

Methods and results: All patients with rotational atherectomy performed in our centre were included in a prospective registry and followed-up since January 2015. The access site was the transradial or transfemoral artery according to operator preference and access vessel size. A 7 Fr guide was used, with a burr size of 1.25-2.0 mm, at 130,000-180,000 revolutions, as needed. 76 patients were included, at a mean 71±10 years, 32% female, with angina CCS III-IV in 72%, arterial hypertension (96.1%), diabetes mellitus (41%), dyslipidaemia 86%, active smokers 55%, 18% with peripheral artery disease, 22% with neoplastic disease and 25% with cerebrovascular disease. Previous coronary bypass had 12%, 32% experienced myocardial infarction and 60% had previous PCI, 88% had multivessel coronary disease, 45% had left main stenosis, 2,6% had chronic coronary occlusions. At a follow-up of 25±13 months, 18 patients died (23%), two during hospitalisation – one of a ruptured artery after stenting and the other from cardiogenic shock unrelated to the procedure. Univariate predictors of mortality are: the degree of angina and heart failure, presence of peripheral artery disease and/or neoplasm, presence and degree of chronic kidney disease, intake of statin and/or angiotensin receptor blockers, left ventricle hypertrophy, degree of mitral insufficiency, degree of mitral insufficiency, pre- and post-procedural troponin, rise and degree of increase of CK-MB. In Cox multiple regression analysis, independent predictors of mortality were periprocedural increase in CK-MB (OR=2.286,1.339-3.901, p=0.002) and neoplastic disease (OR =3.676, 1.005-13.333, p=0.049).

Conclusions: Peri-procedure elevation of CK-MB is a major independent predictor of mortality after rotational atherectomy of calcified coronary stenoses.

Left main and multivessel disease - Tools, devices and techniques, CTO - Tools, devices and techniques

Impella and IABP for high-risk PCI: a systematic review and meta-analysis

SHAIKH Anum [(1)], SHAIKH Anum [(1)], MARTIN Antony P. [(1)], PEDRA Gabriel [(1)], O'HARA Jamie [(1,2)], WOLLNY Mathias [(3)], GOETZENICH Andreas [(3)], HILL Jonathan [(4)]

(1) HCD Economics, Daresbury, United Kingdom; (2) Faculty of Health and Social Care, University of Chester, Chester, United Kingdom; (3) Abiomed Europe GmbH, Aachen, Germany; (4) Royal Brompton and Harefield NHS Foundation Trust, London, United Kingdom

Aims: A systematic literature review (SLR) and meta-analysis was undertaken to compare health outcomes associated with the use of Impella and intra-aortic balloon pump (IABP) in patients undergoing high-risk percutaneous coronary intervention (HR PCI).

Methods and results: A SLR of published randomised and non-randomised studies from Sep 1999-2019 (20 years) was undertaken through a search of MEDLINE®, Web of Science, Cochrane Library, and Scopus. Forward and backward citation searching was conducted using Google Scholar and supplemented with a search of the grey literature. For studies which met the inclusion criteria, data extracted included respondent characteristics, study design, and the reporting of mortality, myocardial infarction, complication rates, and other clinical outcomes. A comparison of clinical outcomes was synthesized using a meta-analysis and a random-effects model was fitted to account for heterogeneity between studies. Small study effect, including publication bias, was tested using funnel plots and Egger's test. Meta-analyses of patient subgroups were also conducted where data permitted. Of 638 titles and abstracts screened, 22 studies met the study inclusion criteria. Studies tended to report superior health outcomes for patients who received Impella compared to IABP in terms of lower mortality, major bleeding, vascular complications, revascularisation, stroke/transient ischaemic attack, renal complications, and major adverse cardiovascular events (MACE)/major adverse cardiovascular and cerebrovascular events (MACCE). Although funnel plots were not always found to be symmetrical, no evidence of publication bias (with the exception of the IABP pooled MACE/MACCE ($p=0.033$) outcome) was found with the Egger's test ($p>0.05$).

Conclusions: The results of our SLR and meta-analysis indicate that Impella is associated with superior health outcomes when compared to IABP in terms of mortality, major bleeding, vascular complications, revascularisation, stroke/ transient ischaemic attack, renal complications, and MACE/MACCE. Further research is needed to explore the conclusions regarding the presence of publication bias with the IABP pooled MACE/MACCE outcome. Moreover, further studies and/ or real-world data (RWD) are needed to confirm and identify the optimal approach for patients undergoing HR PCI in clinical practice. This will enable the aforementioned patients to gain maximal health status by using available resources.

Stents and scaffolds - Tools, devices and techniques

Incidence and predictors of in-stent restenosis in ostial circumflex disease

KHOKHAR Arif [1], KHOKHAR Arif [1], GALLO Francesco [1], LARICCHIA Alessandra [1], RUGGIERO Rossella [1], PONTICELLI Francesco [1], STICCHI Alessandro [1], FERRARO Massimo [2], MANGIERI Antonio [1], GIANNINI Francesco [1], COLOMBO Antonio [1,2]

(1) Maria Cecilia Hospital, Province of Ravenna, Italy; (2) EMO GVM - Centro Cuore Columbus, Metropolitan City of Milan, Italy

Aims: Ostial circumflex stenting is associated with high rates of in-stent restenosis (ISR). Multiple mechanisms have been postulated but conventional risk factors for ISR have not been studied exclusively in this setting. Therefore, we sought to evaluate the incidence and predictors of ISR in all patients who underwent ostial circumflex stenting.

Methods and results: We retrospectively collated data from all patients who underwent stent implantation in the ostium of the circumflex artery between February 1995 till October 2018 at our single-centre. All patients with clinically driven angiographic follow-up were included and the cohort split into two groups: those with in-stent restenosis (ISR+) and those without in-stent restenosis (ISR-). Differences in patient, lesion or procedural characteristics as well as lesion preparation and treatment between the two groups were evaluated using Chi-squared analysis. A total of 270 patients (median age 66 years, 91% male) underwent stenting of the circumflex ostium (median size 3.5 mm, length 16 mm) for stable coronary disease. Angiographic follow-up was available in 170/270 (63%) of cases. Over a median follow-up of 45.5 months (IQR 26.7), 70/170 (41%) patients developed angiographically significant ISR. There was no statistically significant difference demonstrated between the ISR+ and ISR- groups in terms of patient characteristics (male sex p=0.92, hypertension p=0.49, smoking history p=0.41, diabetes p=0.30, previous PCI p=0.40, previous AMI p=0.28), the type of lesions treated (bifurcations p=0.11, type B2/C lesions p=0.75, calcified lesions p=0.44), the method of lesion preparation (balloon type, use of cutting balloon or rotablator therapy), post-stenting post-dilatation (p=0.18) and use of IVUS (p=0.64).

Conclusions: In our study, stenting the ostium of the circumflex was associated with high rates of ISR (41%). There was no difference between the two groups in conventional risk factors for ISR, lesion type, preparation or treatment and use of IVUS. These findings suggest that alternative mechanisms maybe responsible for the high rates of restenosis observed following stenting of the ostial circumflex.

CTO - Vascular access and bleeding

Safety and feasibility of a transradial access program for PCI in CTOs

TREJO VELASCO Blanca [1], DIEGO-NIETO Alejandro [1], NÚÑEZ Jean [1], GONZÁLEZ-FERREIRO Rocío [1], HERRERO-GARIBI Jesús [1], RODRÍGUEZ-COLLADO Javier [1], CRUZ-GONZÁLEZ Ignacio [1], MARTÍN-MOREIRAS Javier [1]

(1) Hospital Clínico Universitario de Salamanca, Salamanca, Spain

Aims: Transfemoral access represents the default vascular approach for percutaneous coronary interventions (PCI) in chronic total occlusions (CTO). Transradial CTO-PCI significantly reduces bleeding and access-site related complications and facilitates same-day hospital discharge but is less frequently used in this setting. The aim of this study is to evaluate the safety and feasibility of a transradial-access program in CTO-PCI and its impact on same-day hospital discharge and length of in-hospital stay.

Methods and results: This was a retrospective single-centre cohort study including 237 consecutive CTO patients undergoing PCI between May 2013 and December 2019. From November 2018 onwards, a transradial program was implemented and the radial artery was established as the vascular access of choice for CTO-PCI, whenever technically feasible. 47 patients included in the transradial program comprised the transradial cohort and were compared to a historical cohort of 190 CTO patients undergoing PCI at the same institution. Mean age was 66.9±11.4 and 199 (83.9%) patients were male. Mean J-CTO Score was similar in both groups (2.6±1.1 vs 2.5±1.1). Difficult CTO lesions (J-CTO score >2) were more frequent in the transradial cohort although this difference did not achieve statistical significance (66.7% vs 49.5%, p=0.085). Femoral access was employed in 9 (19.1%) and 150 (78.9%) patients in the transradial- and historical-cohorts, respectively, p<0.001. Bilateral vascular access represented 170 (71.7%) cases, overall. Successful revascularisation was achieved in 208 (87.8%) cases, without differences between both cohorts. Moreover, no significant differences in periprocedural complications between both groups existed (6.4% vs 4.7%, p=0.645). However, a non-significant trend towards lower in-hospital complications in the transradial group was observed: 4.3% vs 13.7% in the historical cohort, p=0.072. CTO-PCI was performed during admission for an acute coronary syndrome in 10 (21.2%) patients in the transradial cohort. In the remaining 37 (78.7%) outpatients scheduled for an elective procedure, same day discharge was successfully accomplished in 21 (56.7%) cases. In comparison, same-day discharge was only conducted in 5 (3.4%) elective patients in the historical cohort, p<0.001. Mean hospital stay was significantly lower in the transradial access group (0.89±1.4 vs 2.2±3.2 days, p<0.001).

Conclusions: A transradial program for CTO-PCI is safe and effective in most CTO lesions and provides a numerical reduction in post-procedural access-site complications. Adoption of a transradial protocol for CTO-PCI may have important implications on healthcare resource management as it enables same-day hospital discharge in over half of elective procedures and reduces the length of in-hospital stay.

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Stable CAD - Vascular access and bleeding, Stents and scaffolds - Adjunctive pharmacotherapy

Safety of PCI without withdrawal of oral anticoagulation: data from a multicentre registry

CÓRDOBA SORIANO Juan Gabriel [1], CÓRDOBA SORIANO Juan Gabriel [1], PORTERO PORTAZ Juan José [1], OTEO Juan Francisco [2], ESCUDERO DÍAZ Andrés [3], GUTIÉRREZ DÍEZ Antonio [1], SALINAS SANGUINO Pablo [3], GALLARDO LÓPEZ Arsenio [1], MELEHI Driss [1], MORENO Victor Hugo [1,3], JIMÉNEZ MAZUECOS Jesús [1]

(1) Complejo Hospitalario Universitario de Albacete, Albacete, Spain; (2) Hospital Puerta de Hierro-Majadahonda, Majadahonda, Spain; (3) Hospital Clínico San Carlos, Madrid, Spain

Aims: The usual practice in patients taking oral anticoagulation (OAC) undergoing PCI is to withdraw the anticoagulant drug a few days before and, in the majority of cases, a bridge strategy with heparin is used. This strategy favours both ischaemic events and bleeding. We hypothesise that performing procedures without withdrawal of OAC is a safe practice.

Methods and results: We conducted a prospective multicentre registry of PCI in patients under chronic oral anticoagulation with stable disease or acute coronary syndrome, without withdrawal of OAC (vitamin K antagonists [VKA] or direct anticoagulants [DOAC]). Patients included in the registry must have taken the OAC without interruption and must show an INR> 1.8 in case of VKA. Antithrombotic strategy recommended during PCI included the use of 50 IU / Kg of unfractionated heparin in cases of DOAC and when INR <1.8. Safety objectives are evaluated during the procedure and at 24 hours. Between July 2017 – December 2019, 124 patients were included (76, 6% men, 74±9 years, DM 38%, previous stroke 9,7%). The mean CHA2DS2-VASC was 4.25, mean HAS-BLED 2.7, 41.1% received VKA (INR 2.2±0.6) and 58,9% DOAC (22,6% Dabigatran, 11,3% Rivaroxaban, 19,4% Apixaban, 5,6% Edoxaban), mostly (83%) due to atrial fibrillation. 54% of the procedures were performed on an outpatient basis, 94.4% were transradial / ulnar and 95% received some dose of heparin (mean 5,229±2,600 IU). The majority of the procedures were single-vessel PCI (91%) with implantation of 1 DES (84%). Complications during the procedure: 1 stent edge dissection, 4 occlusions of lateral branch, 1 no-reflow, 1 catheter thrombosis and 1 stent thrombosis (these last 2 in a STEMI setting). There were no perforations or need to use antidotes. PCI was considered successful in 97.5% of the cases. Mean time of vascular compression was 203±57 minutes, and vascular complications were minor: 2 prolonged radial bleeding solved with longer compression and 1 wrist haematoma >5 cm. At 24 hours, 1 patient presented a peripheral embolism and other a BARC-2 bleeding. At discharge, 78% of patients received triple therapy.

Conclusions: Performing PCI with the addition of low doses of heparin and without withdrawal of OAC in selected patients receiving VKA or DOAC, is a safe practice, avoiding the ischaemic risk of the withdrawal of OAC and the bleeding risk of the bridge therapy.

Other Coronary interventions - Other

PCI vs conservative management in perioperative myocardial ischaemia following CABG failure: a single-centre experience

BELLAMOLI Michele [(1)], BELLAMOLI Michele [(1)], PIGHI Michele [(1)], SCARSINI Roberto [(1)], DE MANNA Davide [(1)], VENTURI Gabriele [(1)], PESARINI Gabriele [(1)], RIBICHINI Flavio [(1)]

(1) Azienda Ospedaliera Universitaria Integrata Verona, VR, Italy

Aims: Perioperative myocardial ischaemia (PMI) is a major complication of coronary artery bypass graft (CABG) surgery with relevant prognostic implications. The study aimed to review the angiographic findings, the procedural and short-term clinical outcome of bailout percutaneous coronary interventions (PCI) versus conservative management of patients who underwent urgent coronary angiography for suspected acute PMI at our institution.

Methods and results: Between January 2009 and December 2019, 58 patients underwent urgent coronary angiography for suspected PMI within 72 hours from CABG surgery. The angiographic, procedural data and cardiovascular death at 30 days were retrospectively collected and analysed. PMI was suspected in case of new ST-segment changes at ECG or CK-MB levels >4x the standard values (63.8% of the patients), haemodynamic instability with evidence of PMI (15.5%), unexplained haemodynamic deterioration (6.9%) and ventricular tachycardia or fibrillation leading to cardiac arrest (13.8%). Acute graft failure was detected in 37 out of 58 (63.8%) patients and 44 out of 112 (39.2%) examined grafts. The most frequent angiographic finding in this setting was a complete graft occlusion (27 out of 44 grafts, 61.3%). In cases where acute graft failure was not detected, coronary angiography revealed incomplete surgical revascularisation (10 out of 21 patients, 47.6%), diffuse spasm that reverted with high intracoronary doses of nitrates (2/21 patients, 9.5%), or patent grafts and native coronary arteries without any detectable culprit lesion (9/21, 42.8%). PCI was performed in 27 out of 58 (46.5%) patients who underwent urgent coronary angiography, 3 patients (5.2%) underwent redo-CABG, and 28 (48.3%) patients were treated conservatively. Haemodynamic instability at presentation was more frequent in patients treated with PCI compared to the conservative group (40.7% vs 17.9%; p=0.062). PCI was performed on native coronary arteries in most patients (17 out of 27 cases, 63%). PCI failure, defined as post-procedural TIMI 0-1 flow or the occurrence of major complications, was relatively frequent (9/27 patients, 33.3%). Cardiovascular death at 30 days occurred in 14 out of 58 patients (24.1%). Patients who underwent successful PCI and patients treated conservatively presented higher free survival rate at 30 days post-CABG compared with patients in whom PCI failed (log-rank=9.4, p=0.009). Haemodynamic instability at presentation (HR=6.38; CI:2.12-19.14; p=0.001) and PCI failure (HR 12.57; CI:1.39-113.76; p=0.024) were associated with poor outcome.

Conclusions: Perioperative myocardial ischaemia is a very high-risk condition with high short-term mortality. In our series, successful bailout PCI provided non-inferior free survival rate at 30 days compared with conservative treatment despite the higher rate of haemodynamic instability at presentation in the interventional group. Bailout PCI in this setting remains a high-risk procedure with PCI failure being associated with poor short-term clinical outcome.

Stents and scaffolds - Tools, devices and techniques

One-year outcomes of elderly patients treated with bioactive titanium nitride-oxide coated stents in a multicentre registry

CÓRDOBA SORIANO Juan Gabriel [1], CÓRDOBA SORIANO Juan Gabriel [1], GUTIÉRREZ DÍEZ Antonio [1], GARCÍA DEL BLANCO Bruno [2], NÚÑEZ Julio [3], ROMAGUERA Rafael [4], ABELLÁN José [5], BAELLO Pascual [6], AGUAR Pablo [7], OTEO Juan Francisco [8], JIMÉNEZ MAZUECOS Jesús [1]

(1) Complejo Hospitalario Universitario de Albacete, Albacete, Spain; (2) Vall d'Hebron University Hospital, Barcelona, Spain; (3) Hospital clínico de valencia, València, Spain; (4) Bellvitge University Hospital, L'Hospitalet de Llobregat, Spain; (5) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain; (6) Hospital General Universitari de Castelló, Castellón de la Plana, Spain; (7) Hospital Universitario Doctor Peset, Valencia, Spain; (8) Hospital Puerta de Hierro-Majadahonda, Majadahonda, Spain

Aims: Concerns about the higher risk of bleeding and the premature withdrawal of dual antiplatelet therapy, favour the use of BMS rather than DES in elderly patients. The OPTIMAX® stent is a bioactive device having some different properties with respect to other BMS, and results could be comparable with DES in this high-bleeding risk aged group.

Methods and results: We conducted a prospective multicentre registry of patients older than 75-years-old undergoing PCI for stable coronary artery disease or acute coronary syndrome during 2015-2017. One-year follow-up outcomes are presented here with a primary endpoint of MACE (death, non-fatal myocardial infarction [MI], stroke, target vessel revascularisation [TVR] or major bleeding). Overall, 495 patients were included (68.5% male, 82±6 years old, 9.7% nonagenarians, 34% Diabetes Mellitus, 22% chronic kidney disease, 22% atrial fibrillation, 18.6% oral anticoagulation and 30% chronic anaemia). 81% of procedures were performed in the setting of acute coronary syndrome (48% NSTEMI, 33% STEMI) with a median of 1.3 lesions treated with 1.2 stents. At one-year follow-up, only 27% were on dual antiplatelet therapy and 25% were orally anticoagulated. The primary endpoint occurred in 17% of patients (8.8% mortality, 8,6% MI, 1,4% stroke, 3,4% TVR and 1,4% major bleeding). Secondary endpoints were, target lesion revascularisation (2.8%), any BARC bleeding (7%) and stent thrombosis (2.4%; 1.6% definitive).

Conclusions: Elderly patients treated with the OPTIMAX® stent in this registry are very high-risk profile patients with similar one-year outcomes to those previously published using contemporary DES in this age group.

Other Coronary interventions - Other

Impact of renal function on three-year clinical outcome after newer-generation DES implantation for left main coronary artery disease

FUJII Chihiro [(1)], OHYA Masanobu [(1)], MIYAJIMA Keigo [(1)], TAKAMATSU Makoto [(1)], OSAKADA Kohei [(1)], KUWAYAMA Akimune [(2)], TADA Takeshi [(1)], TANAKA Hiroyuki [(1)], FUKU Yasushi [(1)], KADOTA Kazushige [(1)]

(1) Kurashiki Central Hospital, Okayama, Japan; (2) Tsukuba Medical Center Tsukuba Medical Center Hospital, Ibaraki, Japan

Aims: We aimed to assess the impact of renal function on 3-year clinical outcomes after newer-generation DES implantation for left main coronary artery disease.

Methods and results: We retrospectively analysed 553 consecutive patients undergoing newer-generation DES implantation for significant left main coronary artery lesions between 2010 and 2016 and categorised them into three groups according to renal function: 35 patients with haemodialysis (haemodialysis group); 153 patients with serum creatinine >1.0 mg/dl without haemodialysis (renal insufficiency group); and 365 patients with serum creatinine ≤1.0 mg/dl (renal sufficiency group). Newer-generation DES included XIENCE, Nobori, Promus Element, and Resolute stents. The primary outcome measures were defined as all-cause death, cardiac death, and target lesion revascularisation at 3 years. The 3-year cumulative incidences were assessed by Kaplan-Meier methods and were compared by the log-rank test. Cox proportional hazard models were constructed to adjust the potential confounders (a history of hypertension, diabetes mellitus, stroke, peripheral artery disease, and previous PCI). The median follow-up duration was 3.9 (interquartile range, 2.7-5.9) years. The mean age was 73±10 years and the proportion of man was 76%. There were no significant differences in a history of hypertension, diabetes mellitus, stroke, and previous myocardial infarction between the three groups; however, the haemodialysis group was more likely to have a history of peripheral artery disease (34.3% vs 9.8% vs 8.2%, p<0.001). The 3-year cumulative incidences of all-cause death, cardiac death, and target lesion revascularisation were significantly different between the three groups (42.3% vs 31.4% vs 12.4%, log-rank p<0.001; 39.3% vs 18.9% vs 5.6%, log-rank p<0.001; and 36.1% vs 7.5% vs 6.6%, log-rank p<0.001; respectively). The haemodialysis group was associated with worse clinical outcomes than the renal sufficiency group in terms of all-cause death (adjusted hazard ratio [HR] 4.49, 95% confidence interval [CI] 2.20 to 9.20, p<0.001), cardiac death (adjusted HR 8.61, 95% CI: 3.46 to 21.4, p<0.001), and target lesion revascularisation (adjusted HR 6.95, 95% CI: 2.74 to 17.62, p<0.001). On the other hand, the risk in the renal insufficiency group was neutral for target lesion revascularisation (adjusted HR 0.92, 95% CI: 0.39 to 2.17, p=0.848), despite higher risk for all-cause death (adjusted HR 3.16, 95% CI: 2.05 to 4.89, p<0.001) and cardiac death (adjusted HR 3.94, 95% CI: 2.11 to 7.36, p<0.001).

Conclusions: The 3-year mortality in patients treated with newer-generation DES implantation for left main coronary artery disease was dependent on the grade of renal insufficiency. Patients with renal insufficiency without haemodialysis were not associated with higher risk of target lesion revascularisation in comparison with those with renal sufficiency.

Stents and scaffolds - Tools, devices and techniques

Safety and efficacy of sirolimus-eluting stent system in all-comer real-world population with coronary artery stenosis: the Miles-Global study

HUDEC Martin [1], HUDEC Martin [1], IJSSELMUIDEN A.J.J. [2], TRILLO Ramiro [3], GWON Hyeon-Cheol [4], DE COSTA Jose Maques [5], CHAE In Ho [6], MOREU BURGOS Jose [7], HO JEONG Myung [8], MAYURATHAN G K [9], CHARNG Min-Ji [10]

(1) Middle Slovak Institute of Cardiovascular Disease, Banska Bystrica, Slovakia; (2) Albert Schweitzer Ziekenhuis, Dordrecht, the Netherlands; (3) Complexo Hospitalario Universitario de Santiago de Compostela, Santiago de Compostela, Spain; (4) Samsung Medical Center, Seoul, Republic of Korea; (5) Hospital santa maria, Porto, Portugal; (6) Seoul National University, Seoul, Republic of Korea; (7) Hospital Virgen de la Salud, Toledo, Spain; (8) Chonnam National University, Gwangju, Republic of Korea; (9) Teaching General Hospital Kandy, Kandy, Sri Lanka; (10) Taipei Veterans General Hospital, Taipei City, Taiwan

Aims: To evaluate safety and efficacy of ultrathin strut sirolimus-eluting coronary stent in an all-comers real-world patient population with coronary artery stenosis.

Methods and results: The Miles-Global study was a multicentre, prospective, single-arm, open-label study enrolling 520 patients globally. The safety endpoint was the rate of sub-acute stent thrombosis in the presence of dual antiplatelet therapy. The cumulative major adverse cardiac events, composite of cardiac deaths, myocardial infarction, target lesion revascularisation, was the efficacy endpoint. Mean patient age of 520 patients was 64.12±11.14 years; 29% had diabetes, 51.3% had dyslipidaemia, 38.1% had a multivessel disease, 14% had the previous PCI, and 18.3% had a previous myocardial infarction. The mean length of 615 study device treated lesions was 21.99±12.64 mm, and 47.80% were B2/C type. The cumulative major adverse cardiac events up to 12-month (from 410 patients reaching 12-month follow-up) occurred in 9 patients (2.20%), including 1 (0.24%) cardiac death, 3 (0.73%) myocardial infarction and 5 (1.22%) target lesion revascularisation; with zero stent thrombosis up to 12-month.

Conclusions: The outcomes of Miles-Global study demonstrated favourable safety and efficacy of ultrathin strut sirolimus-eluting coronary stent in all-comers real-world patients.

Stents and scaffolds - Tools, devices and techniques

Clinical outcomes from real-world patients treated with biodegradable polymer coated ultrathin-strut sirolimus-eluting coronary stent system

BATRA Vishal [(1)], GUPTA Mohit [(1)], BATRA Vishal [(1)], MP Girish [(1)], BANSAL Ankit [(1)], TYAGI Sanjay [(1)]

(1) GB Pant Hospital, Delhi, India

Aims: Drug-eluting stents have emerged as a potential therapeutic option and have been widely adopted for treating coronary artery lesions. This study aimed to evaluate the safety and performance of biodegradable polymer-coated ultrathin sirolimus-eluting coronary stent systems in real-world patients.

Methods and results: This retrospective study enrolled patients who had been implanted with at least one sirolimus-eluting coronary stent to treat coronary artery disease between November 2017 and April 2018. The clinical endpoint was the incidence of major adverse cardiac events, defined as a composite of cardiac death, myocardial infarction, and target lesion revascularisation, at 24-months follow-up. A total of 1003 patients were included in the study (mean age: 53.51±10.27 years). Among these included patients, 54.8% were smokers, 19.2% had hypertension, and 30% were diabetic. A total of 1132 lesions were successfully intervened with sirolimus-eluting stents (1.13 stent per lesion). The average stent length and diameter were 29.43±9.70 mm and 3.0±0.29 mm, respectively. Approximately 42.7% of the patients had multiple vessel disease and 27.2% had total occlusion. Lesions were mainly located in the right coronary artery (41.3%), followed by the left anterior descending artery (40.3%) and the circumflex artery (17.9%). The cumulative incidence of major adverse cardiac events during a 24-month follow-up was 0.5%. There were three (0.3%) cases of probable stent thrombosis. This study is ongoing.

Conclusions: Low incidences of major adverse cardiac events and stent thrombosis during a 24-month follow-up indicate that ultrathin strut (65 µm) sirolimus-eluting coronary stent systems have encouraging safety and performance in real-world patients with coronary artery disease.

Stents and scaffolds - Tools, devices and techniques

Safety and performance of the biodegradable polymer-coated ultrathin strut sirolimus-eluting coronary stent system for very long lesions: 12-month experience in real-world clinical practice

JINDAL Vivek [(1)], GUPTA Mohit [(1)], BATRA Vishal [(1)], MP Girish [(1)], BANSAL Ankit [(1)], TYAGI Sanjay [(1)], JINDAL Vivek [(1)]

(1) GB Pant Hospital, Delhi, India

Aims: Very long lesions are considered technically difficult and a predictor of worse clinical outcome after percutaneous coronary interventions (PCI). The purpose of this retrospective study was to evaluate the safety and performance of an ultrathin (65 µm) strut biodegradable polymer-coated sirolimus-eluting coronary stent system in real-world patients with very long coronary lesions (≥40 mm).

Methods and results: This was a retrospective, single-centre study that included consecutive patients to treat very long coronary lesion (length ≥40 mm) implanted with at least one study stent. The clinical endpoints were major adverse cardiac events, composite of cardiac death, myocardial infarction, and target lesion revascularisation, at a 24-month follow-up. A total of 216 patients with 236 very long lesions were included (1.09 per patient). Among these patients, 54.6% were active smokers, 21.8% had hypertension, and 30% were diabetics. The indication for PCI was STEMI in 19.9% patients, NSTEMI in 6.9% patients and stable angina in 15.3% patients. The mean lesion length was 41.92±9.03 mm. The average stent length and diameter were 43.75±3.15 mm and 2.96±0.26 mm, respectively. The device success and procedure success rate were achieved in 100% of the patients. The cumulative incidence of major adverse cardiac events at 24-months follow-up was 0.9% in the form of two cardiac deaths. Data collection is underway, and updated results (24-month follow-up) will be available.

Conclusions: This real-world study demonstrated favourable safety and performance of the ultrathin (65µm) strut biodegradable polymer sirolimus-eluting coronary stent system in the treatment of very long lesions, with a very low rate of major adverse cardiac events.

Stents and scaffolds - Tools, devices and techniques

Clinical outcomes of the world's first tapered sirolimus-eluting coronary stent system for long coronary lesions: a real-world experience

DAVIDSON Deepak [1], DAVIDSON Deepak [1], MISRA Mukul [2], CHANDRA Sharad [3], RAGHU T.R [4], CHANANA Bharat Bhushan [5], RAY Shuvanan [6], PARIKH Keyur [7], ROY Sanjeeb [8], JAIN Rajendra [9], SIVAKUMAR R [10]

(1) Caritas Hospital, Kerala, India; (2) Dr. Ram Manohar Lohia Institute of Medical Sciences, Uttar Pradesh, India; (3) Lari Cardiology Centre, Uttar Pradesh, India; (4) Sri Jayadeva Institute of Cardiovascular Sciences and Research, Karnataka, India; (5) Maharaja Agrasen Hospital, Delhi, India; (6) Fortis Medical Centre, West Bengal, India; (7) Care Institute of Medical Sciences, Gujarat, India; (8) Fortis Escorts Hospital, Jaipur, Rajasthan, India; (9) Krishna Institute Of Medical Sciences, Telangana, India; (10) Meenakshi Mission Hospital & Research Centre, Tamil Nadu, India

Aims: To assess the safety and performance of the sirolimus-eluting coronary stent system in real-world patients with very long coronary lesions (≤56 mm) at a 12-month follow-up.

Methods and results: This prospective, single-arm, multicentre, real-world study enrolled 435 patients (453 lesions) at 19 sites across India. The clinical endpoint was freedom from target lesion failure, defined as the aggregate of cardiac death, myocardial infarction, and ischaemia driven-target lesion revascularisation. Mean patient age was 57.94±10.28; 365 (83.91%) were male, 213 (48.97%) had hypertension and 210 (48.28%) had diabetes. A total of 444 coronary lesions were implanted with a sirolimus-eluting coronary stent. The average stent length was 51.18±8.57 mm. Of 444 study stent treated lesions, 256 (57.66%) were type B2/C and 159 (35.81%) were totally occluded. Among these patients, 18.85% presented with stable angina, 47.12% with unstable angina/NSTEMI, 31.95% with STEMI, and 2.07% were asymptomatic. The freedom from target lesion failure was reported in 98.9% at a 12-month follow-up. The cumulative incidence of target lesion failure was 1.1%, in the form of one cardiac death, three myocardial infarction and three ischaemia driven-target lesion revascularisation at a 12-month follow-up. The incidence of definite stent thrombosis was one (0.2%) during the follow-up. This study is ongoing.

Conclusions: The present study ascertains the safety and performance of sirolimus-eluting coronary stent in real-world patients with very long coronary lesions, as demonstrated by low rates of target lesion failure at 12-month follow-up. (CTRI number: CTRI/2016/12/007527).

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Reduced vessel acute recoil and gained vessel area with scoring balloon using a Lacrosse non-slip element in vitro

YAMAMOTO Tadashi [(1)], YAMAMOTO Momoko [(1)], YAMAMOTO Tadashi [(1)]

(1) Hokkaido Cardiovascular Hospital, Sapporo, Japan

Aims: Lesion preparation prior to stent deployment and drug-coated balloon inflation has been recommended. The aim of this study was to investigate *in vitro* the benefit associated with scoring balloon use in lesion preparation that reduced vessel acute recoil and gained vessel area.

Methods and results: Experiment 1: A blood vessel model was created to measure the recoil rate and gain rate. After measuring the lumen area of the blood vessel model by OCT, the scoring balloon (NSE ALPHA 2.5 mm) and the conventional balloon (Powered Lacross2 2.75 mm) were each inflated once at nominal pressure for 15 seconds. After expansion, the lumen area was measured by OCT, and the recoil rate and gain rate were calculated. Similar experiments were performed on five models. Results: The recoil rates of scoring balloons and conventional balloons were 23.6% vs 35.6% (p=0.0003). In addition, the gain rate is 69.2% vs 64.9% (p=0.0003). Compared with the conventional balloon, the scoring balloon has a significantly reduced recoil rate with a quarter-size reduction, and the same gain rate can be obtained. Experiment 2: A blood vessel model with an eccentric plaque model was created to verify the expansion method of the scoring balloon. OCT measures the lumen area of a model of expansion once and a model of expansion for three times with a scoring balloon (NSE ALPHA 3.0 mm) raised by 1 atmosphere per second to 6 atm and a total expansion time of 15 seconds. Then, the gain ratio was calculated from the lumen area before expansion. Similar experiments were performed on five models. Results: The gain ratios for the one-time expansion and the three-time expansions were 42% vs 70% (p=0.00001).

Conclusions: Compared with the conventional balloon, the scoring balloon (NSE ALPHA) achieved the same expansion area with a 0.25 mm size reduction and significantly reduced the vessel recoil rate. And it was proved that the vessel gain area can be obtained more by multiple expansion than by a single expansion.

Stable CAD - Vascular access and bleeding

A single-centre prospective randomised comparison between the distal radial artery approach and the conventional radial artery approach on patient discomfort during procedure or haemostasis in radial artery coronary angiography

LEE Ji Hyun [(1)], SUH Yongsung [(1)], CHO Yoon-Hyeong [(1)]

(1) Myongji Hospital, Gyeonggi-do, Republic of Korea

Aims: We evaluated whether distal radial artery approach (DRA), the so-called snuffbox approach, could reduce patient discomfort during procedure and haemostasis of coronary artery angiography (CAG), comparing it with the conventional radial artery approach (CRA).

Methods and results: We performed non-emergent radial artery CAGs in a total of 205 adults who met inclusion criteria after 1:1 randomisation of DRA group (107 patients) or CRA group (97 patients) in Myongji Hospital, Goyang City, South Korea during Mar. 2019 to Dec. 2019. Immediately after haemostasis, we investigated the character and severity of discomfort during procedure and haemostasis using a simple 0 to 5 scale questionnaire. The puncture success rate in DRA group was lower (DRA vs CRA; 81.9% vs 97.5%, p=0.003) and the lidocaine to sheath time was longer (DRA vs CRA, Median [IQR]; 149 [97~214] sec vs 94 [72~126] sec, p<0.001) comparing with CRA group. There was no statistically significant difference regarding total procedure time, contrast dose, radial artery spasm or dissection. Discomfort scores during procedure (DRA vs CRA; Median [IQR]: 0 (0~2] vs 0 [0~2], p=0.762] or haemostasis (DRA vs CRA, Median [IQR]: 0 [0~2] vs 0 [0~2], p=0.833) were not statistically different between both groups. DRA was no significant predictor for patient discomfort during procedure or haemostasis before and after adjustment of age, gender, BMI, operator, procedure time, sheath size, catheter size.

Conclusions: In this single centre prospective randomised study, we could not find out any significant difference between DRA and CRA in terms of patient discomfort during procedure or haemostasis of CAG.

Stents and scaffolds - Tools, devices and techniques

Safety and efficacy of the biodegradable-polymer everolimus-eluting stent vs durable-polymer DES in high-risk patients undergoing PCI: insights from the TWILIGHT trial

MEHRAN Roxana [1], BABER Usman [1], DANGAS George [1], SHARMA Samin [1], MEHTA Shamir [2], BRIGUORI Carlo [3], ESCANED Javier [4], HUBER Kurt [5], KUNADIAN Vijay [6], OLDROYD Keith [7], MEHRAN Roxana [1]

(1) Icahn School of Medicine at Mount Sinai, NY, USA; (2) McMaster University Medical Centre - Hamilton Health Sciences, ON, Canada; (3) Clinica Mediterranea - Ospedale e Centro Diagnostico, Metropolitan City of Naples, Italy; (4) Hospital Clínico San Carlos, Madrid, Spain; (5) Wilhelminenspital, Vienna, Austria; (6) Freeman Hospital, Newcastle upon Tyne, United Kingdom; (7) Golden Jubilee National Hospital, Clydebank, United Kingdom

Aims: Drug-eluting stents (DES) coated with biodegradable polymers (BP) may confer a safety advantage without compromising efficacy as compared with durable polymer (DP) formulations. Data evaluating the effect of BP-DES versus contemporary DP-DES in high-risk patients treated with ticagrelor are limited. Therefore, we conducted a pre-specified analysis among patients randomised in the TWILIGHT trial treated with the BP everolimus-eluting stent (BP-EES) or a DP-DES, which included cobalt-chromium everolimus-eluting stents, platinum-chromium everolimus-eluting stents and zotarolimus-eluting stents.

Methods and results: Following successful percutaneous coronary intervention (PCI) and 3 months of treatment with ticagrelor plus aspirin, patients were randomised to aspirin or placebo for 1 year; DES choice was at the direction of the treating physician. The primary endpoint was target lesion failure (TLF) (composite of cardiac death, target vessel myocardial infarction [MI], clinically driven target lesion revascularisation [TLR], or definite/probable stent thrombosis [ST]). Event rates were estimated using the Kaplan-Meier method and adjusted hazard ratios (HR) and 95% confidence intervals (CI) were generating using Cox regression. Patients receiving BP-EES (n=577; 10.0%) were more frequently randomised in North America, underwent PCI of the left main and had a lower frequency of prior MI compared to those receiving DP-DES (n=5079; 90.0%). One-year rates of TLF were 6.0% and 4.8% in those receiving BP-EES and DP-DES respectively (p=0.74). Analogous rates of definite/probable ST and TLR were 0.7% vs 0.5% (p=0.51) and 5.1% vs 3.7% (p=0.39), respectively. The effect of ticagrelor monotherapy on ischaemic events was uniform across DES groups (all pint >0.10).

Conclusions: The safety and efficacy profile of the BP-EES is comparable to that of contemporary DP-DES among high-risk patients undergoing PCI. The effect of ticagrelor monotherapy, as compared with ticagrelor plus aspirin, is consistent among patients receiving BP-EES or DP-DES.

STEMI - Adjunctive pharmacotherapy, Stable CAD - Diabetes

Impact of sex on platelet inhibition by aspirin in obese patients with type 2 diabetes: a pooled, patient-level analysis of two randomised clinical trials

KIMMELSTIEL Carey [1], BHATT Deepak [2], ANGIOLILLO Dominick [3], STEG P Gabriel [4], MEHRAN Roxana [5], DANGAS George [5], FAN Weihong [6], PRATS Jayne [7], DELIARGYRIS Efthymios [7]

(1) Tufts Medical Center, MA, USA; (2) Brigham and Women's Hospital, MA, USA; (3) University of Florida, FL, USA; (4) Hopital Bichat, Paris, France; (5) Mount Sinai Medical Center, NY, USA; (6) PLx Pharma Inc., NJ, USA; (7) Elysis LLC, MA, USA

Aims: Aspirin non-responsiveness is more frequent with enteric-coated aspirin (EC-ASA) compared with a novel, pharmaceutical lipid-based formulation of aspirin (PL-ASA), especially among heavier patients. The current analysis explored whether sex had an impact on levels of platelet inhibition achieved with these two aspirin formulations.

Methods and results: Two randomised, crossover studies in obese patients with type 2 diabetes mellitus comparing pharmacologic parameters after 3 days of 325 mg of EC-ASA or PL-ASA were pooled at the patient level. The main objective was to assess the impact of sex on rates of complete aspirin response, defined as percent of patients with ≥99.0% inhibition of serum thromboxane B2 production, and according to aspirin formulation. Logistic regression was used to adjust for body weight. A total of 97 subjects (50 females [mean weight 95.5 kg] and 47 males [mean weight 112.5 kg]) were included and contributed a total of 183 evaluable samples after 3 days of treatment. Overall, females demonstrated higher rates of complete aspirin response compared with males (84/95 [88.4%] vs 56/88 [63.6%], p<0.0001) that persisted following adjustment for body weight (p=0.04). The impact of sex on response to aspirin was less pronounced with PL-ASA (46/48 [95.8%] of females and 36/44 [81.8%] of males, [relative risk 1.171, 95% confidence interval 1.007 to 1363, p=0.04] than with EC-ASA (38/47 [80.9%] of females and 20/44 [45.5%] of males [relative risk 1.779, 95% confidence interval 1.251 to 2.530; p=0.0005). After adjustment for body weight, platelet response to aspirin between females and males was not significantly different for PL-ASA (p=0.483) but did remain significantly different for EC-ASA (p=0.025). Among subjects who did not achieve a complete aspirin response, the degree of serum thromboxane B2 inhibition was still significantly impacted by treatment assignment (median and IQR: PL-ASA 98.2 [96.4, 98.6] vs EC-ASA 96.6 [91.1, 98.2], p=0.004), but not by sex (median and IQR: female 97.1 [94.1, 97.9] vs male 97.4 [93.1, 98.4], p=0.311).

Conclusions: Our data in patients with Type 2 diabetes mellitus show that after EC-ASA treatment, compared with females, males have lower rates of complete aspirin response in large part due to their higher body weight. In contrast, PL-ASA provides comparable rates of complete aspirin response in both females and males

STEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Bioresorbable vascular scaffold: case series with long-term clinical and OCT follow-up

DRNOVSEK Borut [(1)], DRNOVSEK Borut [(1)], BUNC Matjaz [(1)], CERCEK Miha [(1)], TERSEGLAV Simon [(1)]

(1) Klinični centre Ljubljana, Ljubljana, Slovenia

Aims: Bioresorbable vascular scaffolds were launched as a novel and promising treatment option, however, real life experience showed higher rates of stent thrombosis as compared to the latest-generation of DES. Long-term real-life data is still lacking. In this case series we report on a single-centre long-term clinical and OCT follow-up in real-life practice.

Methods and results: In 2012, 2013 and 2014 18 patients were implanted with an ABSORB everolimus-eluting bioresorbable vascular scaffolds, 17% (3) of them due to chronic and 83% (15) due to acute coronary syndrome. Procedural success was achieved in all patients. Clinical, angiographic, and target lesion OCT follow-up was performed at 4,36±0,55 years and clinical follow-up again at 6.36±0.55 years after BRS implantation. OCT study showed complete BRS endothelisation in all lesions. At OCT follow-up, strut remnants were still visible in 33% (6) of patients, probably representing provisional matrix, as shown in previous histological studies. 17% (3) of patients had target lesion failure, 2 of them presented as clinically silent target lesion CTO and 1 as stable angina due to significant in-stent restenosis. In all successful PCI was performed. After long term clinical follow-up at 6.36±0.55 years all 18 patients were alive, and none reported any symptoms suggesting recurrent ischaemia.

Conclusions: In this case series of a small number of real-life cases, predominantly presenting as acute coronary syndrome, long-term follow-up showed comparable rates of target lesion failure to modern DES and a favourable clinical outcome with no cases of very late stent thrombosis.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Pulmonary catheter use and mortality in cardiogenic shock

KAPUR Navin [1], THAYER Katherine [1], GARAN A. Reshad [2], HERNANDEZ-MONFORT Jaime [3], MAHR Claudius [4], WENCKER Detlef [5], SINHA Shashank [6], VOROVICH Esther [7], ABRAHAM Jacobb [8], BURKHOFF Daniel [9], KAPUR Navin [1]

(1) Tufts Medical Center, MA, USA; (2) Beth Israel Deaconess Medical Center (BIDMC), MA, USA; (3) Cleveland Clinic Florida, FL, USA; (4) University of Washington Medical Center, WA, USA; (5) Baylor University Medical Center, part of Baylor Scott & White Health, TX, USA; (6) Inova Heart and Vascular Institute, VA, USA; (7) Northwestern Memorial Hospital, IL, USA; (8) Providence Heart Clinic at Gateway, OR, USA; (9) Cardiovascular Research Foundation, NY, USA

Aims: Mortality in cardiogenic shock (CS) remains prohibitively high despite recent advances in treatment. The extent of clinical benefit of the use of pulmonary artery catheters (PACs) in CS patients is still unclear. We hypothesise that the comprehensive assessment of PAC data is associated with reduced risk of in-hospital mortality in CS patients.

Methods and results: 1,414 all-cause CS patients from the Cardiogenic Shock Working Group Registry, a national multicentre retrospective CS registry, were classified according to the Society for Cardiovascular Angiography and Intervention (SCAI) CS stages and evaluated for PAC usage. PAC use was quantified by the presence of pulmonary artery saturation, pulmonary artery pressures and wedge pressure measurements. We compared patients without any of these measurements (No PAC data), patients with at least one (Incomplete PAC data) and patients with all these parameters in addition to right atrial pressure (Complete PAC data). Complete PAC measurement was analysed for association with in-hospital mortality in a multivariate logistic regression model in the overall cohort and among each SCAI stage. Of the total cohort of 1414 patients, 267 (18.88%) had no recorded PAC data, 549 (38.83%) had partially recorded PAC data, and 598 (42.29%) had complete PAC data. The majority of SCAI stage B (n=43, 93.5%) and C (n=132, 50.19%) had complete PAC data while the majority of SCAI stages D (n=361, 47.63%) and E (n=90, 42.45%) had some PAC data. After adjusting for institution in the total cohort, patients with complete PAC data had almost half the risk of mortality compared to those with no PAC data (OR 95% CI: 0.586, 0.418-0.822) and those with partial PAC data (OR 95% CI: 0.602, 0.467-0.813). There was no significant difference in risk of in-hospital mortality between those with no PAC data and those with partial PAC data. Among stage C patients, the presence of complete or incomplete PAC data were not significantly associated with decreased mortality compared to no PAC data measurement. However, among SCAI D patients, mortality was significantly lower in patients with complete PAC data measurement compared to those with no PAC data measurement (29.31% v. 43.94%, p=0.021). Additionally, among SCAI E patients, the presence of any PAC measurements, whether complete (46.99%, p=0.04) or incomplete (54.44%, p=0.005), was associated with lower in-hospital mortality compared to having no PAC data (74.36%).

Conclusions: These data suggest that using a PAC in CS patients, especially those in more critical condition, may decrease their risk of in-hospital mortality. This benefit could potentially be explained by the information provided by the PAC in developing a more appropriate treatment plan.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Risk stratifying patients with cardiogenic shock: an analysis of the multicentre cardiogenic shock working group registry

NAVIN Kapur [1], KAPUR Navin [1], THAYER Katherine [1], ZWECK Elric [1,2], AYOUTY Mohyee [1], GARAN A. Reshad [3], HERNANDEZ-MONFORT Jaime [4], MAHR Claudius [5], BURKHOFF Daniel [11]

(1) Tufts Medical Center, MA, USA; (2) Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; (3) Beth Israel Deaconess Medical Center (BIDMC), MA, USA; (4) Cleveland Clinic Florida, FL, USA; (5) University of Washington Medical Center, WA, USA; (6) Baylor Scott & White Medical Center - Grapevine, TX, USA; (7) Inova Heart and Vascular Institute, VA, USA; (8) Northwestern Memorial Hospital, IL, USA; (9) Providence Heart Institute, Portland, OR, USA; (10) Henry Ford Hospital, MI, USA; (11) Cardiovascular Research Foundation, NY, USA

Aims: Cardiogenic shock (CS) mortality remains unacceptably high. Risk stratifying CS patients could improve patient management and the design of future trials. We tested whether the Society for Cardiovascular Angiography and Interventions (SCAI) CS Stages, drug and device treatment intensity, and commonly assessed clinical parameters that identify patients with CS at risk of in-hospital mortality.

Methods and results: The Cardiogenic Shock Working Group Registry includes CS patients from 8 medical centres enrolled between 2016 and 2019. Patients with known outcomes were classified into SCAI Stages B-E according to drug and/or device utilisation during hospitalisation. The primary endpoint of in-hospital mortality was evaluated for association with SCAI Stages, treatment intensity, ventricular congestion, pulmonary artery catheter usage, and haemodynamic and lab parameters in univariate and multivariate logistic regression models. Of the 1414 CS patients included, the majority were due to MI (35%) or HF (50%). In-hospital mortality was 31% for the total cohort, but higher among MI patients (41% vs 26%, MI vs HF, p<0.0001). Risk for in-hospital mortality was associated with increasing SCAI stage (OR (95% CI): 3.25 (2.63-4.02), increasing vasopressor/inotrope therapy (OR: 1.68 (1.52-1.85)) and increasing number of devices (OR: 2.27 (1.89-2.71)). Pulmonary artery catheters were used in 71% (n=1116) of patients and was associated with lower mortality in the total CS population and across SCAI stages. Congestion due to elevated right atrial pressure was a significant predictor of mortality and was more common in higher SCAI stages. Additional haemodynamic and metabolic parameters that predicted mortality included increased heart rate and lactate and decreased mean arterial pressure.

Conclusions: Using a contemporary registry of real-world experience, we now provide new data supporting the association between the proposed SCAI staging system for CS and in-hospital mortality. We further identify that pulmonary artery catheter use is associated with lower in-hospital mortality and that venous congestion identifies patients at high risk for in-hospital mortality. Future prospective studies are required to confirm these observations.

Left main and multivessel disease - Tools, devices and techniques

Manual aspiration thrombectomy for acute occlusion of the left main coronary artery

SHIOTA Haruko [1], SHIOTA Haruko [1], KAGAWA Eisuke [1], KATO Masaya [1], ODA Noboru [1], KUNITA Eiji [1], NAGAI Michiaki [1], DOTE Keigo [1]

(1) Hiroshima City Asa Hospital, Hiroshima, Japan

Aims: Routine manual thrombus aspiration is not recommended for patients with acute myocardial infarction. This purpose of this study was to investigate the impact of thrombus aspiration in acute coronary syndrome (ACS) due to left main coronary artery (LMCA) occlusion.

Methods and results: Between November 2000 and January 2020, patients who were complicated with ACS due to LMCA occlusion were enrolled in this study and divided into two groups: those who had undergone thrombus aspiration (aspiration group) and those who had not (non-aspiration group). The one-year survival rate was calculated using the Kaplan-Meier method to evaluate the efficacy of thrombus aspiration. Among the study patients, 20 patients (25%) underwent thrombus aspiration and 60 patients (75%) did not. The aspiration group was younger than the non-aspiration group (median 69 y [interquartile range 57 y – 71 y] vs 73 y [69 y – 83 y], p=0.004). There was no significant difference in sex (male, 65% vs 62%, p=1.00) and location of LMCA occlusion (bifurcation lesion, 30% vs 52%, p=0.12) between the two groups. The prevalence of unstable angina (UA) was lower in the aspiration group than in the non-aspiration group (UA, 5% vs 43%; ST-segment elevation myocardial infarction, 50% vs 13%, p<0.001). The prevalence of cardiogenic shock (80% vs 32%, p<0.001), use of extracorporeal membrane oxygenation (ECMO) (60% vs 17%, p<0.001), and Thrombolysis in Myocardial Infarction (TIMI) flow grade 0/1 (60% vs 18%, p<0.001) were higher in the aspiration group than in the non-aspiration group. The one-year survival rate had the tendency toward lower in the aspiration group than in the non-aspiration group (53% vs 73%, p=0.09); however, the one-year survival rate of the aspiration group had the tendency toward higher than that of the non-aspiration group among the patients with initial TIMI 0/1 and cardiogenic shock (36% vs 14%, p=0.14), those with TIMI 0/1 treated with ECMO (55% vs 16%, p=0.11), and those treated with ECMO (58% vs 10%, p=0.051).

Conclusions: Aspiration thrombectomy may be an effective treatment for patients with LMCA ACS with cardiogenic shock due to total coronary occlusion or supported with mechanical circulation for early reperfusion or reduction of thrombus burden.

Other Coronary interventions - Other

First European experience using a novel contrast reduction system during coronary angiography with automated contrast injection

AMOROSO Giovanni [(1)], AMOROSO Giovanni [(1)], JUNG Christian [(2)], ABELL Christopher [(3)]

(1) Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands; (2) Universitätsklinikum Düsseldorf, Düsseldorf, Germany; (3) Liverpool Heart and Chest Hospital, Liverpool, United Kingdom

Aims: Contrast-induced acute kidney injury (CI-AKI), an iatrogenic effect of coronary angiography, is associated with increased morbidity, mortality, and healthcare costs. While guidelines recommend minimising contrast media volume delivered to the patient, a primary risk factor for CI-AKI, achieving reductions remains challenging and results vary by physician and procedure [1,2]. Contrast-sparing devices may assist in preventing CI-AKI. We report the first European experience using a novel contrast reduction device during coronary angiography with automated contrast injection.

Methods and results: We performed a multicentre, post-market, retrospective product performance study of the new DyeVert Power XT Contrast Reduction System for real-time contrast media monitoring and volume minimisation during coronary angiography procedures performed with automated contrast injectors. The DyeVert System includes a diversion line and 2 valves that adjust fluid pathway resistance to divert excess contrast media into a reservoir when injection pressure exceeds a threshold thereby reducing contrast volume to the patient. All patient care and automated contrast injector system settings were completed per standard of care and there were no study-induced procedures. The primary objective was to assess contrast media volume savings and the secondary objective was to evaluate user satisfaction with the DyeVert System. For each procedure, data were collected regarding the physician, procedure type, access site, contrast type, catheters, contrast injector settings, contrast media volume to the patient and volume saved. A physician satisfaction survey completed acceptability of the DyeVert System regarding set-up, priming, intraprocedural usability (including image quality), and overall satisfaction. 26 coronary angiography procedures were performed September - November 2018 using the DyeVert System with the ACIST CVi Contrast Delivery System at 3 hospitals by 9 physicians. 54% were diagnostic only and 46% were interventional. 85% were performed using radial access. Mean contrast media volume delivered was 87.9±51.5 mL (range 30.6 – 211.9 mL) and mean contrast media volume savings was 34.4±6.2% (range 24.1– 47.0%) per procedure. Physicians described DyeVert System set-up, priming, and intraprocedural usability (including overall satisfaction) as acceptable in all (100%) cases. Physicians characterised image quality as acceptable for 25 cases (96%). In one case, the physician noted while placing a stent in the obtuse margin of the circumflex one image was not as opacified as desired around the stent pre-dilation.

Conclusions: Data collected in this project suggest DyeVert Power XT System use with automated contrast injectors during coronary angiography enables meaningful contrast media volume savings without diminishing image quality or disrupting clinical practices thereby providing a feasible procedure-based strategy to reduce CI-AKI risk through reduction of a known risk factor, contrast media volume. Further research is needed to assess the impact of risk factor reduction on real-world patient outcomes.

STEMI - Tools, devices and techniques

The oculostenotic reflex improves survival in patients with AMI and multivessel disease treated with primary angioplasty

PIRAINO Ruben Aldo [(1)], KIRSCHMANN Diego [(1)], ROMERO Lucas Matias [(1)], CAMBIASO Ivan [(1)], PIRAINO Ruben Aldo [(1)]

(1) SANATORIO DELTA, ROSARIO, Argentina

Aims: Determine the best strategy for patients (p) with acute myocardial infarction (AMI) and multivessel disease (MVD) treated with primary angioplasty (PPCI). Comparing survival of p with PPCI at the infarct related artery only (IRA ONLY) versus complete systematic revascularisation (CSR) PPCI at the IRA and other vessel, during the hospitalisation period (HP) and 6-month follow-up (6-mFU).

Methods and results: From 06/14 to 06/19 344 PPCI were performed in p with AMI, 155 suffered from MVD. The p was divided into 2 groups(G): G1 (2014-2017): p treated with PPCI at the IRA ONLY (113 p – 72.9%). G2 (2018-2019): p treated with PPCI at the IRA and a new PCI at another artery during the HP(CSR) (42 p – 27.1%). Clinical, angiographic, and therapeutic variables, events during the HP and the 6-month FU were analysed. Primary endpoints of death and re-AMI were determined in the HP. Death, AMI and need for a revascularisation due to coronary artery bypass grafting (CABG) or PCI were determined at the 6-month FU. Statistics: compare two proportions. Primer of biostatistics (by Stanton A. Glantz). Previous coronary disease was higher in G1 (24.78% vs 4.76% p: <0.001), and hypertension in G2 (39.8% vs 76.2 % p: <0.001). There were no significant differences at the Killip and Kimball at entrance between both G. The left anterior descending artery was the more frequent IRA (50.4% vs 47.6% p:ns). No significant difference was found in the angiographic TIMI in the IRA previous to PPCI (TIMI 0: 84.07% vs 76.16%). There were no significant differences in the use of GP IIB-IIIA (13.2% vs 19.04%). During the HP the primary endpoint was 28,3 % of the G1 vs 9,52 % of the G2 (p=0.003). There were no significant differences in the primary endpoint at 6-month FU (5,87% vs 5%, p=ns).

Conclusions: Survival of p with AMI and MVD was higher in the G2 (CSR). The benefit was obtained during the HP. The best strategy was the CSR performed during the HP. These results must be validated by a prospective and randomised study.

STEMI - Invasive imaging and functional assessment

Comparison of stent expansion between XIENCE and Orsiro stents using cadaveric heavily calcified coronary arteries

JINNOUCHI Hiroyuki [(1)], JINNOUCHI Hiroyuki [(1)], SATO Yu [(1)], SAKAMOTO Atsushi [(1)], CORNELISSEN Anne [(1)], MORI Masayuki [(1)], KAWAKAMI Rika [(1)], PERKINS Laura [(2)], VIRMANI Renu [(1)], FINN Aloke [(1)]

(1) Cvpath Institute Inc, MD, USA; (2) Abbott Vascular Inc, CA, USA

Aims: New-generation drug-eluting stents (DES) offer good clinical results, yet stent underexpansion is still an important cause of DES failure. The extent of coronary calcification is considered to be an important contributing factor in stent underexpansion. However, the relative impact of stent design including strut thickness on stent expansion in calcified arteries still remains unknown. Therefore, in this study, we assessed stent expansion of both XIENCE and Orsiro stents in calcified human autopsy coronary arteries.

Methods and results: Three human hearts with six calcified arteries were included in this study, and the type of stent (XIENCE or Orsiro) was randomly assigned. Stent size and length was determined by the results of angiography and optical coherence tomography of autopsy hearts. The area stented was approximately matched for area and density of calcification. Micro computed tomography was performed following the stenting procedure, and every 1 mm image was analysed to assess area loss [expected stent area – actual stent area] and asymmetry index [(shortest diameter/longest diameter)-1]. A total of 50 sections from 3 XIENCE and 46 sections from 3 Orsiro stents were evaluated in 3 human hearts. Calcium area was numerically higher in the stented segment in XIENCE (1.61±1.44 mm^2) relative to Orsiro (1.30±1.09 mm^2). Area loss was significantly less in XIENCE as compared to Orsiro (XIENCE 1.40±0.80 mm^2 vs 2.96±1.74 mm^2, $p<0.001$). Asymmetry index showed significantly lower score for XIENCE versus Orsiro suggesting XIENCE was closer to a ideal circular shape relative to Orsiro in calcified arteries.

Conclusions: XIENCE showed less area loss and more symmetrical shape in calcified arteries as compared to Orsiro. Thinner struts are likely to have poorer stent expansion in heavily calcified arteries. Therefore, adequate strut thickness may be an important factor required for ideal stent expansion in complex calcified lesions undergoing PCI.

Stable CAD - Vascular access and bleeding

Using a mother-in-child technique to overcome severe radial artery spasm

KHOKHAR Arif [(1)], KHOKHAR Arif [(1)], MANGIERI Antonio [(1)], LARICCHIA Alessandra [(1)], RUGGIERO Rossella [(1)], STICCHI Alessandro [(1)], SBARZAGLIA Paolo [(1)], OSHOALA Kareem [(1)], GIANNINI Francesco [(1)], COLOMBO Antonio [(1)]

(1) Maria Cecilia Hospital, Province of Ravenna, Italy

Aims: Severe radial artery spasm (RAS) can limit the use and effectiveness of the preferred transradial access (TRA) route during PCI. We describe and report our preliminary findings using a novel technique designed to facilitate guide catheter advancement and manipulation in the setting of severe RAS.

Methods and results: All patients with severe RAS hindering guide catheter advancement, were prospectively enrolled from October 2019 till January 2020. In all cases, TRA was secured in a conventional manner using a short 6 Fr hydrophilic sheath. Diagnostic angiography was performed with the choice and number of catheters left to the operators' discretion, including guide catheter selection. If severe RAS, defined as significant pain and discomfort experienced by the patient and significant friction encountered by the operator, prevented guide catheter advancement, we employed the following technique. A 125 cm, 4 Fr multipurpose (MP) diagnostic catheter was inserted inside a 6 Fr guiding catheter in a mother-in-child-like setup. Care was taken to ensure that the distal end of the 4 Fr MP catheter protruded past the distal tip of the guiding catheter. This system was then advanced as one over a 0.035" guidewire into the aortic root. The MP catheter was partially retracted back into the guiding catheter to maintain guide catheter stability and facilitate coronary cannulation. Baseline clinical, procedural and follow-up data were prospectively collected in all patients in whom this technique was employed. Procedural success was defined as completion of the intended procedure without needing to switch to an alternative access site. In our preliminary study, we utilised this technique in eight patients (6 females, mean age 74 years, mean BMI 27kg/m^2). Risk factors included hypertension (6/8), dyslipidaemia (4/8), previous smoking history (3/8), diabetes (1/8) and chronic kidney disease (1/8). All patients developed severe RAS refractory to intra-arterial vasodilators and sedatives following at least two (maximum 4) diagnostic catheter exchanges. With this technique, a range of 6 Fr (outer diameter 2.1 mm) guiding catheters (Boston Scientific, MA, USA) were successfully advanced: Judkins left 3.5, Judkins right 4, extra backup 3.5, Amplatzer 1, Voda leftTM 3. There was a 100% procedural success rate (4/8 underwent PCI and 4/8 had intracoronary assessments) with all procedures completed from the intended transradial access site. No additional pharmacological therapy was required in any of the cases. There were no access site complications noted during the procedure or at time of hospital discharge.

Conclusions: Severe RAS limiting guide catheter advancement can be overcome using a mother-in-child-like system with a long 4 Fr multipurpose catheter inside of a 6 Fr guiding catheter. In our preliminary study, this technique achieved a 100% procedural success rate with no access site complications noted.

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Posters

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Treatment of stenosis in coronary artery ectasia and coronary artery aneurysm with a self-apposing stent: 12-month clinical results

HUYNH Vi-Phong [(1)], ANGIOI Louis [(1)], COLES Thomas [(1)]

(1) Stentys, Paris, France

Aims: The literature available on the treatment of lesions located in vessels with important diameter variations such as coronary artery ectasia and coronary artery aneurysms is scarce. We decided to validate the use of a self-apposing stent in these specific vessels with a sub-analysis of two observational registries.

Methods and results: Sizing and Win registries were designed to assess the safety and efficacy of self-apposing stents in various lesion subsets. Both registries were prospective, multicentre and observational studies. Combining both registries, 1483 patients were treated with the self-apposing Xposition-S stent, which includes 396 patients (26.7%) with target lesion located in aneurysmal or ectatic vessels. All patients were clinically followed 12 months after the index procedure. In the subgroup of patients with lesion located in aneurysmal or ectatic vessels, 71.7% of the patients had acute coronary syndrome, including 33.6% of ST-segment elevation myocardial infarction. Most of the lesions treated were *de novo* lesions with 73.6% of class B2/C lesions. The mean reference vessel diameter was 4.28±0.77 mm and the mean lesion length was 21.78±11.95 mm. The target lesion diameter stenosis was 87.5±13.9% pre-procedure. Predilatation was performed in 84.6% of procedure and post-dilatation in 87.9%. The mean residual stenosis was 2.8±9.7% post-procedure. The procedural success was 96.9% of cases. The major adverse cardiac event rate at a mean follow-up duration of 373±42 days was 4.0%, which included 0.9% of cardiac death, 2.3% of target vessel related myocardial infarction and 1.4% of target lesion revascularisation. Definite or probable stent thrombosis was reported in only two patients (0.6%). Interestingly, the major adverse cardiac event rate reported in ST-segment elevation myocardial infarction or non-ST-segment elevation myocardial infarction patients was very low (1.8%).

Conclusions: In this largest data analysis available on the treatment of lesions in aneurysmal or ectatic coronary vessels, we observed very low rates of clinical events at 12 months post-procedure. Compared to previous data reported in the literature, the procedural success rate was good, the rate of stent thrombosis was very low as well as the major adverse cardiac event rate in ST-segment elevation myocardial infarction or non-ST-segment elevation myocardial infarction patients. These results confirm the interest of the self-apposing Xposition-S stent for the treatment of lesions in aneurysmal or ectatic coronary vessels.

Other Coronary interventions - Other

Burden of CVD in very young patients admitted in a tertiary care hospital, Bangladesh: a unique subset

KABIR C.M. Shaheen [1]

(1) Ibrahim Cardiac Hospital & Research Institute, Dhaka, Bangladesh

Aims: Coronary heart disease (CHD) remains a major cause of death in Bangladesh. CHD in younger age is not, simply a problem of sufferers but a huge emotional & economical loss to the family. This study looked at the demographic data and risk profile of very young patients presenting to a busy tertiary PCI centre in Dhaka, Bangladesh.

Methods and results: Prospective data was collected on patients who underwent coronary angiography over a 6-month period from January – June 2018. "Young" was defined as ≤35 years of age. Young patients comprised of 15.4% (n=60) of all patients during this period. Mean age was 32.1±3.1 years and only 15% (n=9) were obese. Male sex (70%), hypertension (41.7%), dyslipidaemia (30%) and smoking (23.5%) were the major conventional risk factors followed by diabetes mellitus (23.3%). Family history of premature CHD was seen in 12.9%. Mean ejection fraction was 52.4± 12.3%. Clinical presentation was STEMI in 24 (40%) patients, NSTEMI in 5 (8.3%) & UA in 9 (15%) patients. 8.3% (n=5) received thrombolytic therapy. Angiography was performed via the right radial access in 90% and via left radial access in 10% patients. SVD was seen in 20 (33.3%) young patients while 12 (20%) & 2 (3.3%) patients had double vessel and triple vessel disease, respectively. Normal coronaries were noted in 18 (30%) patients while 4 (6.7%) had recanalised IRA and 1 (1.6%) had pure ectasia. LAD was main artery involved in 28 (46.6%) patients while LCx and RCA were involved in 11 (18.3%) and 15 (25%) patients, respectively. 27 of the young patients required coronary revascularisation. 24 (33.3%) were performed percutaneously with DES and 3 (5.0%) had surgical revascularisation. Of the PCI cohort, 3 (12.5%) patients underwent primary PCI & 1 (4.1%) underwent POBA. 19 (79.2%) patients required 1 stent while 5 (20.8%) patients required 2 stents during PCI. Mean stent diameter and length were 2.7±0.2 and 21.0±8.4 mm respectively. There were no in-hospital deaths, MI or cerebrovascular events.

Conclusions: Very young adults had significant CAD which warrants extremes of preventive steps and also revascularisation to prevent reoccurrence of fatalities due to CAD.

CTO - Tools, devices and techniques

Slender CTO PCI

KABIR C.M. Shaheen [1]

(1) Ibrahim Cardiac Hospital & Research Institute, Dhaka, Bangladesh

Aims: Treating CTOs by the antegrade approach needs skill and appropriate devices. The guide catheter is an important factor for success. 5 Fr guide catheters for treating CTOs are an alternate choice for the diabetic population with narrow calibre radial arteries.

Methods and results: In an absolute radial centre like ours, PCI to CTO lesions the last 1 year period from July 2017 to June 2018 were evaluated retrospectively by the antegrade approach through transradial access. A total of 147 CTO lesions were attempted during this period of time. Using 5 Fr or 6 Fr guide catheter was the operator's choice. Out of 147 CTOs in diabetic patients, 66 (45%) were made using a 5 Fr guide catheter and 81 (55%) by a 6 Fr guide catheter. Success rates in both group were almost similar (63.6% vs 65.4%, p=0.82). Smaller profile balloon support was needed in both groups in similar numbers (66.7% vs 69.1%, p=0.75). Workhorse CTO guidewires in our lab were thin hydrophilic PT2 (Boston Scientific) and used in similar percentages (94% vs 89%, p=0.28). Only in 5 cases for each group, was a microcatheter was used. CTO of LAD was greater in the 5 Fr group (45.5% vs 34.6%). CTO lesion of RCA were 35% vs 40%. Contrast volume is lower in 5 Fr group, though not statistically significant (152 vs 165 ml, p=0.26). Fluoroscopy time was similar in both groups.

Conclusions: Backup support of the guide catheter is an important prerequisite for PCI to CTO. "Active back-up support" by a 5 Fr guide catheter is better in our experience, especially for a left system. Other than using bulky devices like an IVUS catheter and rotablation, a 5 Fr guide catheter can be a feasible and comfortable choice for CTO PCI.

Stents and scaffolds - Tools, devices and techniques

Predictors of clinical outcomes after novel sirolimus-eluting stent

DANI Sameer [1], DESAI Devang [2], PANDYA Rashmit [3], PARIKH Pritesh [4], BHALANI Nirav [5], SHARMA Arvind [5], SHETH Chirag [5], TESTA Luca [6], SHAH Dinesh [7]

(1) Apollo Hospitals & Apollo CVHF Heart Institute, Ahmedabad, India; (2) Mahavir Hospital, Surat, India; (3) Life care Institute of Medical Sciences & Research, Ahmedabad, India; (4) Care Hospitals, Surat, India; (5) Rhythm Heart Institute, Baroda, India; (6) IRCCS Pol. S. Donato, Milan, Italy; (7) William Beaumont Hospital, Michigan, USA

Aims: We sought to assess the safety and efficacy of novel ABLUMINUS DES+, sirolimus eluting stent (Concept Medical) based on complex group of patients.

Methods and results: en-ABL e-Registry is a multicentre, prospective, all-comers clinical registry conducted in 31 cardiology centres across India. The primary endpoint was MACE, a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target vessel/lesion revascularisation (TVR/TLR) at 1-year. We performed multivariable analyses in order to assess the impact of predictors on the primary endpoint. With a mean age of 57.0±12.6 years, 2,500 patients had been treated with 3,287 ABLUMINUS DES+ (1.31 stent/patient) Among them, 34.4%, 42.2% and 66.8% patients presented with diabetes mellitus, hypertension and acute coronary syndrome (ACS) respectively. 47.1 % had small vessel (SV) disease and 55.2% were had long lesions (LL). At 1 year, 1.0% cardiac death, 0.4% TV-MI, 1.4% TLR/TVR were reported, and combined MACE occurred in 2.8% patients. In the present sub-analysis, we performed multivariable analyses in order to assess the presence and the impact of predictors on the primary endpoint. The multivariable analysis identified small vessel disease 3.6 % (HR 1.89 95% CI: 1.07;3.33, p=0.027), Multivessel disease 4.6 % (HR 3.095, 95% CI: 1.11;8.58, p=0.030) and overlapping DES 7.5 % (HR 3.981, 95% CI: 1.58;10.04, p=0.003) were independent predictors of MACE at 1 year.

Conclusions: The use of ABLUMINUS DES+ proved to have good safety and efficacy in real-world scenarios. In addition, this study also identified factors such as small vessel size, multivessel disease and overlapping DES which are associated with poor clinical outcomes. These clinical variables are worthy of further investigation to improve outcomes.

Stable CAD - Tools, devices and techniques

MyocaRdial brIdge evALuation Towards persOnalised medicine: the RIALTO registry

D'AMARIO Domenico [(1)], D'AMARIO Domenico [(1)], CASAMASSIMA Fabio [(1)], RESTIVO Attilio [(1)], MIGLIARO Stefano [(1)], VERGALLO Rocco [(1)], MONTONE Rocco Antonio [(1)], GALLI Mattia [(1)], LEONE Antonio Maria [(1)], MERLINO Biagio [(1)], TRANI Carlo [(1)], CREA Filippo [(1)]

(1) Fondazione Policlinico Universitario A. Gemelli, Metropolitan City of Rome, Italy

Aims: A myocardial bridge (MB) is defined as a muscle overlying the intramyocardial segment of an epicardial coronary artery (tunnelled artery), mainly the left anterior descending artery. These congenital coronary anomalies have long been recognised anatomically and traditionally considered a benign condition; however, the presence of an MB when associated with evidence of myocardial ischaemia and symptoms (i.e. angina) increases their clinical relevance.

Methods and results: In our tertiary centre, the coronary angiography records from May 2015 to November 2019 were evaluated and centrally analysed by three experts. All patients were referred to our centre due to evidence of stress induced myocardial ischaemia. Patients who had more than 70% narrowing during systole were eligible for the present study. Medical and procedural notes were recorded together with data regarding the physical examination, echocardiography, and treadmill exercise testing. CT scan images were centrally reviewed. Medical treatment on admission, at the time of follow-up, and during experienced events (recurrence of angina, death, myocardial infarction and/or revascularisation) were recorded. The study included 11,925 patients. The non-MB group comprised 11,703 patients (98.1%; women, 38.01%), while the MB group included 222 patients (1.9%; women, 39.98%). The most frequent location of MB was the left anterior descending artery (97.1% of patients with MB). The MB group less often had diabetes (11.3% vs 18.63%), previous stroke (1.61% vs 2.96%), previous myocardial infarction (3% vs 21.97%), kidney disease (0.8% vs 5.04%), previous coronary artery bypass graft (1.03% vs 8.64%), previous percutaneous coronary intervention (1.20% vs 25.86%) than the non-MB group ($p<0.01$). The incidence of acute coronary syndromes was lower in the MB group ($p<0.01$). According to interventional cardiologists performing the procedure, when considering the MB group, 23 (10.4%) patients underwent physiological assessment with either FFR and/or iFR. Provocative tests with acetylcholine was performed in 31 patients (13.9%) in the MB group, while invasive imaging techniques were utilised in only 5 patients (2.2%) in the MB group. Analysis of the single subgroups in terms of MACE has been performed.

Conclusions: There is no accepted anatomic or functional classification of MBs. Moreover, the variability in clinical symptoms, results of noninvasive tests, and the concomitant presence of other conditions, such as coronary artery disease, hypertrophic cardiomyopathy, or valvular heart disease, may independently influence treatment options and outcomes of patients with MB. Our registry demonstrated that there is a huge variability in the assessment and evaluation of myocardial bridges in the cath lab, mainly dependent on the personal skills of the operator involved. At this moment, there is no evidence to support any specific strategy to better stratify the risk of MACE in patients with MB. However, a personalised approach to test the different mechanisms involved in the occurrence of symptoms in patients with myocardial bridge might help in tailoring the best pharmacological and non-pharmacological treatment in each individual case.

Stents and scaffolds - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Comparison of overexpansion capabilities and thrombogenicity at the side branch ostia after implantation of four different DES: insights from an in vitro model

GASIOR Pawel [1], GASIOR Pawel [1], LU Shengjie [2], NG Jaryl [2,3], TOONG WAI YEE Daniel [4], WONG EN HOU Philip [2,5], FOIN Nicolas [2,5], KEDHI Elvin [6], WOJAKOWSKI Wojciech [1], ANG Hui Ying [2,3]

(1) Division of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland; (2) National Heart Research Institute Singapore, National Heart Centre Singapore, Singapore, Singapore; (3) Department of Biomedical Engineering, National University of Singapore, Singapore, Singapore; (4) School of Material Science & Engineering, Nanyang Technological University, Singapore, Singapore; (5) Duke-NUS Medical School, Singapore, Singapore; (6) AZ Sint-Jan Brugge, Oostende AV, Belgium

Aims: Despite recent technological advancements in stent platforms, bifurcation lesion PCI remains challenging. Currently provisional stenting technique is the gold standard approach. It often requires aggressive overexpansion of stent diameter in the setting of acute vessel tapering. In this study we aimed to evaluate and compare the overexpansion capabilities and thrombogenicity at the side branch (SB) ostia after implantation four latest-generation DES in an *in vitro* bifurcation model.

Methods and results: We compared four clinically available modern drug-eluting stents (DES): one bifurcation dedicated DES (Bioss LIM C, Balton, Poland) and three conventional DES (Ultimaster, Terumo, Japan; XIENCE Sierra, Abbott, USA; Biomime, Meril Life Sciences, India).*In vitro* biomechanical testing was performed under static condition in bifurcation silicone vessel models (proximal=5.5 mm, distal=3.5 mm and SB=3.5 mm). All the devices were implanted with proximal optimisation with 5.5 semi-compliant balloon at 14 atm ensuring expansion (visually confirmed from OCT pullback) and then perfused with porcine blood at a rate of 200 ml/min up to 60 minutes. Subsequently, immunofluorescence analysis and scanning electron microscope analysis of polymer coating integrity at the over-expanded part of the stents were performed. OCT and immunofluorescence analysis demonstrated lowest thrombus area at SB ostia in bifurcation dedicated DES together with favourable biomechanical properties when compared to conventional DES.

Conclusions: This model demonstrated numerical differences in terms of mechanical properties and acute thrombogenicity at SB ostia between tested devices. Furthermore, the bifurcation dedicated Bioss LIM C demonstrated improved coating integrity and lower acute thrombogenicity compared to conventional DES when over-expanded.

NSTEMI - Vascular access and bleeding, Stable CAD - Vascular access and bleeding

A randomised trial comparing distal vs conventional radial access for angiography and intervention: DISCO-RADIAL study rationale and study design

AMINIAN Adel [(1)], AMINIAN Adel [(1)], SHIGERU Saito [(2)]

(1) centre hospitalier universitaire, Charleroi, Belgium; (2) Shonan Kamakura General Hospital, Kanagawa, Japan

Aims: The objective of DISCO-RADIAL study is to demonstrate the superiority of distal transradial access (DTRA) over conventional transradial access (CTRA) regarding forearm radial artery occlusion (RAO).

Methods and results: The distal radial artery is a novel vascular access approach with potential advantages of improved operator/patient comfort, easier and shorter haemostasis, and reduction in bleeding and vascular access site complications. An important feature of this technique is a puncture distal to the superficial palmar arch, with the potential to maintain antegrade flow in the forearm radial artery during haemostatic compression, reducing thereby the risk of retrograde thrombus formation and forearm RAO. However, clinical evidence supporting its use is limited to small to moderate sized observational studies looking primarily at the feasibility and success rates of DTRA. DISCO-RADIAL is a prospective, multicentre, randomised controlled trial with the plan to include approximately 1,300 patients who will undergo transradial coronary angiography and/or intervention. Patients will be randomised in 1:1 ratio to either DTRA or CTRA arm. The primary endpoint is to compare forearm RAO rates before discharge between the two groups. Secondary endpoints will include: rate of successful sheath insertion, time to sheath insertion, puncture-site related bleeding, vascular access-site complication, rate of radial artery spasm, rate of distal radial artery occlusion, haemostasis time, and pain score associated with the procedure. Eligible patients are those undergoing diagnostic coronary angiography and/or PCI and suitable for both DTRA and CTRA. Patients on chronic haemodialysis, presenting with ST-elevated myocardial infarction, or planned to be treated for chronic total occlusion lesions will be excluded. Patients will be followed up until hospital discharge. The study enrolment is ongoing and is expected to be completed within one year.

Conclusions: DISCO-RADIAL is a large scale multicentre randomised trial comparing DTRA with CTRA for coronary angiography and/or interventions. The results of this trial will provide important insights about the safety and efficacy of this new vascular approach, with a potential impact on daily practice.

Stents and scaffolds - Tools, devices and techniques

Safety and efficacy of sirolimus-coated balloons with nanolute technology in real-world coronary artery disease patients: angiographic and clinical outcomes

PARIKH Keyur [(1)], BHATT Parloop [(1)], CHAG Milan [(1)], BAXI Hemang [(1)], SHAH Urmil [(1)], PATEL Tejas [(1)]

(1) Care Institute of Medical Sciences and Research, Ahmedabad, India

Aims: Drug-coated balloon has emerged as a new treatment modality for coronary artery disease specifically in patients with complexity such as in-stent restenosis, small vessel and bifurcation stenosis. We aim to evaluate safety and efficacy of the MagicTouch sirolimus coated balloon (Concept Medical) for the treatment of both *de novo* and in-stent restenotic coronary lesions.

Methods and results: A prospective, single-arm, single centre, real-world study which included 131 all-comer patients who underwent sirolimus-coated balloon angioplasty from July 2013 to September 2017 was conducted. The study endpoint comprised of major adverse cardiac event (MACE) at 6-months and 1-year. The components of MACE were target lesion/vessel revascularisation (TLR/TVR), target vessel myocardial infarction (TV-MI) and cardiac death. Quantitative coronary angiography (QCA) was performed and post-procedural outcomes are presented. Reference vessel diameter (RVD), minimal lumen diameter (MLD), and % diameter stenosis (DS) were measured at baseline and post-procedure. Mean age of the 131 enrolled patients enrolled was 60.1±10.1 years with male predominance (83.2%); encompassing 139 lesions treated by sirolimus-coated balloon. Diabetes mellitus was present in 31.3% patients while 40.5 % patients were hypertensive. Half of the patients presented with acute coronary syndrome (50.4%). Amongst the 139 treated lesions, 77% lesions were *de novo* while 23% were in-stent restenotic lesions. SCB alone treatment strategy was employed in majority of the patients (91.6%) while additional treatment was required in 8.4% of patients. The mean sirolimus-coated balloon size and length were 2.6±0.5 mm and 25.2±7.2 mm respectively. Procedural success was 100% with no flow-limiting dissection reported. Angiographic outcomes were available for 112 patients with 128 lesions. MLDs were reported as 0.39±0.30 mm and 1.57±0.55 mm pre-procedure and post procedure respectively. The results depict increased lumen diameter and acute gain post procedure. Increased lumen diameter post procedure with acute gain of 1.18 depicts that SCB is associated with good immediate outcomes with well flowing coronaries after the treatment. At 1-year, all patients completed clinical follow-up and the incidence of MACE was reported as 3.8%. MACE rate was mainly driven by TLR/TVR (3.1%) followed by cardiac death (0.8%). There was not TV-MI reported at 1-year.

Conclusions: In real-world, high-risk patients with complex coronary artery lesions, MagicTouch Sirolimus coated balloons are a safe and efficacious treatment strategy as evidenced by angiographic assessment and clinical outcomes.

Stents and scaffolds - Tools, devices and techniques

Outcomes with sirolimus-coated balloons and novel sirolimus-eluting stents in PCI in diabetic patients

TESTA Luca [1], DANI Sameer [2]

(1) IRCCS Pol. S. Donato, Milan, Italy; (2) Apollo Hospitals & Apollo CVHF Heart Institute, Ahmedabad, India

Aims: Despite impressive improvements in drug eluting stents (DES) technology, diabetic patients still represent one of the main unsolved issue for percutaneous coronary intervention (PCI). The outcomes with drug-coated balloons (DCBs) in diabetic patients have received limited study. We performed comparison analysis of a sirolimus coated balloon – the SCB (Magic Touch SCB, Concept Medical) vs a novel sirolimus eluting stent (SES) which have unique coating technology (ABLUMINUS DES+, Concept Medical) for the treatment of diabetic patients.

Methods and results: We performed comparison analysis of 204 DM patients treated with MagicTouch SCB, and 859 DM patients treated with ABLUMINUS DES+. Outcome of interest were major adverse cardiac events (MACE), composite of cardiac death, target vessel myocardial infarction (TV-MI), and target vessel/lesion revascularisation (TVR/TLR) at 1-year. During a follow-up of 12 months, MagicTouch SCB was associated with a similar risk of MACE (4.9% vs 3.7%, HR= 1.40, 95% CI= 0.68–2.87; p=0.351) compared with ABLUMINUS DES+. There was also a trend toward a lower risk of cardiac death (0.98 % vs 1.4%, HR= 0.763, 95% CI= 0.16–3.44; p=0.725) and TLR (3.9 % vs 1.8%, HR= 2.115, 95% CI= 0.90–4.94; p=0.084) with MagicTouch SCB compared with ABLUMINUS DES+ without achieving statistical significance.

Conclusions: In diabetic patients with coronary lesions undergoing PCI, treatment using SCB is associated with similar outcomes compared with the new-generation drug-eluting stent ABLUMINUS DES+. Further studies are needed to better depict the role of SCB in the context of PCI for diabetic patients.

Stents and scaffolds - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Overview of first experience using the new stent positioning assistance system

OSIEV Alexander [1], OSIEV Alexandr [1], SEMISYNOV Ilya [2], KOMKOV Artem [1], MONOSOV Dmitriy [2]

(1) Moscow State University, Moscow, Russian Federation; (2) Saint Petersburg State University, Saint Petersburg, Russian Federation

Aims: The main objective of the new stent positioning assistance system (SPAS) was to increase the accuracy of stent positioning in complex lesions. In this registry, we checked positioning accuracy using OCT and IVUS control in some cases.

Methods and results: We performed 102 different cases of stent implantation using stent positioning assistance system (including complex bifurcation, ostial, left main lesions and edge to edge several stent placement). 20 cases with OCT control, 3 case with IVUS control before and after PCI also were performed to selective patients. In OCT and IVUS pullbacks before PCI we suggested the site of stent implantation and other parameters (vessel diameter, size of the stent). In all patients, preparation of the stent implantation site was performed. After predilatation new stent assistant positioning system (SPAS) was mounted on stent delivery system before introducing on the guidewire. Assistance device was fixed on stent delivery system very close to the Y-connector when the stent was delivered to the lesion site. The stent was moved into the correct position by rotation of the device back handle. The final result was checked by angiography and post-PCI OCT pullback. In 3 cases we also used IVUS before and after PCI to evaluate lesion site and implanted stent. Patients were 60,2±9,6 years old. 81% of them were male, 19% - female. 82 patients had stable coronary artery disease and 20 had AMI. Distance error of stent placement from the defined site of implantation based on OCT data was 0,5±0,4 mm in cases that operators used the device first/second time and 0,2±0,2 mm in cases of experienced operator.

Conclusions: Angio and OCT results showed effective and precise stent positioning with SPAS assistance

STEMI - Tools, devices and techniques

Validation of the Zwolle score for in-hospital mortality assessment of STEMI patients treated with primary PCI

CORDERO Alberto [1,2], CORDERO Alberto [1,2], ESCRIBANO David [1], FREITES Alfonso [1], POMARES Antonia [1], MARTÍNEZ REY-RAÑAL Elías [1], ZUAZOLA Pilar [1]

(1) Hospital Universitario San Juan de Alicante, Sant Joan d'Alacant, Spain; (2) CIBER - Centro de Investigación Biomédica en Red, Madrid, Spain

Aims: The Zwolle risk score was designed to stratify the actual in-hospital mortality risk of ST-elevation myocardial infarction (STEMI) patients treated with primary percutaneous coronary intervention (PCI). It was also designed for decision-making related to whether a patient should be located to an intensive care unit or not. Patients with Zwolle risk score <3 would quality as "low risk", 3-5 as "intermediate risk" and ≥6 as "high risk. Since the GRACE score continues being the gold-standard for individual risk assessment in STEMI in most institutions we assessed the specificity of both scores for in-hospital mortality.

Methods and results: We assessed the accuracy of Zwolle risk score for in-hospital mortality estimation as compared to the GRACE score in all patients admitted for STEMI in a single centre. Zwolle risk score ≥6 and GRACE score >140 were considered as high-risk. Specificity, sensitivity, and classification were assessed by ROC curves. We included 1,105 patients, mean age 65.8 (13.8), 24.6% women, 38.3% anterior STEMI, 6.3% had out-of-hospital cardiac arrest and median time to PCI was 139 (0-250). Mean GRACE score was 166.5 (46.2) and Zwolle score 3.4 (3.9); 64.5% had GRACE score >140 but only 23.64% had Zwolle score ≥6. In-hospital mortality was 10.1% (111 patients) and it increased statistically in patients with Zwolle risk score <3 (0.28%), 3-5 (3.85%) or ≥6 (36.86%). No patient with GRACE score <140 died. The threshold of 140 for the GRACE score had a very low specificity (35.1%) and only 41.6% of the patients were accurately classified; the 200 limit increased specificity to 88.0% being 88.3% of the patients were accurately classified. The cut-off Zwolle risk score ≥6 had 83.7% specificity and 84.6% were accurately classified.

Conclusions: The specificity of the Zwolle score for in-hospital mortality risk assessment was higher than the GRACE score. Patients with a Zwolle risk score ≥6 are actually at high-risk of in-hospital mortality rather than patients with GRACE score >140. Patients with Zwolle score <3 could reasonably be managed outside an intensive care unit.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

The distal transradial approach for primary PCI in patients with AMI: a multicentre study

YAMADA Takeshi [(1)], YAMADA Takeshi [(1)], IZUMIKAWA Takuya [(2)], MIZUGUCHI Yukio [(1)], TANIGUCHI Norimasa [(1)], NAKAJIMA Shunsuke [(1)], HATA Tetsuya [(1)], TAKAHASHI Akihiko [(1)]

(1) Sakurakai Takahashi Hospital, Kobe, Japan; (2) Izumikawa Hospital, Minamishimabara, Japan

Aims: The distal transradial approach (dTRA) for percutaneous coronary intervention (PCI) is expected to have a lower incidence of vascular complication, including haemorrhagic complications and radial artery occlusion, than a more conventional transradial approach. This study investigated the feasibility and safety of application of this technique for primary percutaneous coronary intervention (PCI) in patients with acute myocardial infarction (AMI).

Methods and results: This study included patients with AMI who underwent primary PCI via the distal radial artery across 2 Japanese hospitals between January 2018 and December 2019. Patients' background, procedural characteristics, and clinical outcomes including the incidence of haemorrhagic complications were analysed. Consecutive 208 patients with AMI in whom distal radial artery puncture was attempted for primary PCI were enrolled in this study. They included 152 patients (73.1%) with ST-segment elevation myocardial infarction (STEMI), and the mean age was 71.6±12.8 years. Eighteen patients with cardiac arrest on arrival (8.7%) and 11 patients with shock on arrival (5.2%) were included. The haemodynamic support with extracorporeal membrane oxygenator (ECMO) and intraaortic balloon pumping (IABP) were performed in 11 (5.3%) and 40 patients (19.2%), respectively. Among these patients, cannulation was successfully performed in 200 patients (96.2%), and conventional transradial approach or brachial approach was selected in patients in whom dTRA failed. A 5, 6, or 7 Fr sheath (conventional or slender) was used in this study. PCI was successfully performed in all patients. The mean time to achieve haemostasis was 5.5±4.2 hours, and major bleeding was observed in 1 patient (0.5%). Based on The Early Discharge After Transradial Stenting of Coronary Arteries trial haematoma scale, grade III subcutaneous haemorrhages were observed in 1 patient (0.5%), and no patient developed a haematoma > grade IV. In patients with STEMI, the mean door-to-balloon time was 37.6±27.9 min, and the mean puncture-to-balloon time was 18.5±14.8 min.

Conclusions: The distal radial approach is feasible and safe for primary PCI in selected patients with AMI. The application of the dTRA may reduce the haemorrhagic complication in these patients.

STEMI - Invasive imaging and functional assessment, NSTEMI - Invasive imaging and functional assessment

Routine coronary angiography in cardiopulmonary resuscitation using veno-arterial ECMO

KAGAWA Eisuke [(1)], KAGAWA Eisuke [(1)], KATO Masaya [(1)], ODA Noboru [(1)], KUNITA Eiji [(1)], NAGAI Michiaki [(1)], SHIOTA Haruko [(1)], DOTE Keigo [(1)]

(1) Hiroshima City Asa Hospital, Hiroshima, Japan

Aims: Routine coronary angiography (CAG) in patients without ST-segment elevation was reported to have no association with improved outcomes. This study investigated whether routine CAG is beneficial for patients treated with cardiopulmonary resuscitation (ECPR) using venoarterial extracorporeal membrane oxygenation (ECMO) and whose electrocardiograms are often difficult to assess owing to chest compression.

Methods and results: Patients treated with ECPR were enrolled in this retrospective study. During the study period, percutaneous initiation of ECMO was encouraged by interventional cardiologists in the catheter laboratory, and immediate CAG was also encouraged after ECMO initiation. ECMO initiation, performance of immediate CAG after ECMO initiation, and subsequent percutaneous coronary intervention (PCI) were based on the attending physician's discretion. The patients were divided into non-CAG, CAG-alone group, and PCI groups. The non-CAG group included 52 patients (22%); the CAG-alone group, 78 patients (33%); and the PCI group, 104 patients (44%). Among the study patients, 5 (10%), 17 (22%), and 100 (96%) were finally diagnosed as having acute coronary syndrome (ACS) in the non-CAG, CAG-alone, and PCI groups, respectively. The ages of the study patients were similar (median [interquartile range], 66 years [54 – 72 years], 65 years [53 – 72 years], and 65 years [56 – 71 years], respectively; p=0.80). Significant differences in male sex (56%, 31%, and 22%, respectively; p<0.001), initial shockable rhythms (15%, 36%, and 48%, respectively; p<0.001), no-flow time (1 min [0 – 2 min], 2 min [0 – 10 min], and 1 min [0 – 4 min], respectively; p=0.007), and low-flow time (32 min [22 – 49 min], 51 min [40 – 67 min], and 35 min [20 – 57 min], respectively; p<0.001) were found. Among the study patients, 117 (64%) were diagnosed as having ACS by CAG. Among the patients in the non-CAG group, 5 (10%) were diagnosed as having ACS, and the reasons for not undergoing CAG were failure of ECMO initiation (2 patients), acute ECMO failure (accidental removal of cannulation [1] and cannula occlusion with thrombus), and treatment withdrawal due to a neurological injury. The 1-year survival rate obtained using the Kaplan-Meier method was similar between the non-CAG (29%) and PCI groups (26%) and was significantly lower in the CAG-alone group (12%; p=0.044). After adjusting for low-flow time, performance of CAG (risk ratio, 1.02 [95% confidence interval, 0.68 – 1.56]; p=0.93) was not independently associated with 1-year survival.

Conclusions: The CAG-alone group had than did the other groups; however, this may be caused by other reasons such as the severity of the ischaemic injury and the heterogeneity of the cardiac arrest. Further studies are necessary to investigate the usefulness of routine CAG after ECPR.

STEMI - Tools, devices and techniques

Identification of predictors of no-reflow phenomenon after PCI in patients with STEMI: a novel score

ORDOÑEZ Santiago [(1)], ORDOÑEZ Santiago [(1)], SPALETRA Pablo [(1)], PEDERNERA Gustavo [(1)], ABUD Marcelo [(1)], PADILLA Lucio [(1)], CURA Fernando [(1)]

(1) ICBA Instituto Cardiovascular, Buenos Aires, Argentina

Aims: No-reflow is a phenomenon that affects between 2 and 44% of primary PCI in patients with STEMI. The current evidence shows that it has prognostic implications. Although many treatments have been tried, the prevention of this phenomenon appears to be the most effective strategy. Unfortunately, there is no tool that can be used to predict the problem of No-Reflow. In this study we propose to identify predictors of this phenomenon and to develop a simple tool to predict it effectively.

Methods and results: A retrospective analysis was performed on patients admitted to a referral centre in Buenos Aires, Argentina, with diagnosis of STEMI who received primary PCI between 2009 and 2018. The different variables related to the no reflow phenomenon were evaluated using a univariate and multivariate analysis. With the identified variables, a score was built. The power to predict the phenomenon of no reflow was assessed using the area under the ROC curve. 1065 patients with STEMI were included. The rate of no reflow was 9.5% (102 patients). 4 independent predictors of this phenomenon were identified: culprit vessel diameter > 3 mm, large intracoronary thrombus (> 2 times vessel diameter), prolonged ischaemia time (> 6 hours) and initial TIMI flow < 1. The score created with these 4 variables (1 point to each variable) presented an area under the ROC curve to predict no reflow of 0.84 (95% CI: 0.79-0.88). A score > 3 presented a sensitivity and specificity of 89.2% and 93% respectively.

Conclusions: The presence of culprit vessel diameter > 3 mm, large intracoronary thrombus, prolonged ischaemia time and initial TIMI flow < 1 behaved as independent predictors of the no reflow phenomenon. A score developed from these variables presented good performance to predict this phenomenon.

STEMI - Vascular access and bleeding, Stable CAD - Vascular access and bleeding

Effectiveness and safety of PCI in patients with blood malignancy

GITELZON Ekaterina [(1)], FAIBUSHEVICH Alexander [(1)], VERETNIK Galina [(1)], MAXIMKIN Daniil [(1)], BARANOVICH Vladislav [(1)], GITELSON Daniil [(1)]

(1) RUDN University, Moscow, Russian Federation

Aims: There are still many questions about myocardial revascularisation in certain groups of patients with a high risk of complications. So, the goal of our study is to analyse the effectiveness and safety of PCI in patients with blood malignancy.

Methods and results: The study included 90 patients with a combination of blood malignancy and CHD. Patients were divided into 2 groups: I (n=48)-PCI with implantation of BMS, II (n=42) - PCI with implantation of DES. 84 patients after PCI had polychemotherapy and 6 patients received radiation therapy. In I group there were 37 (77.1%) men, in II group - 23 (54.8%) men. The average age in I group was 64.6±11.9 years, in II group - 61.1±10.9 years. Anaemia was observed in 80% of patients. The haemoglobin level was on average below normal in both groups, and also statistically significantly distinguishable between groups (p=0.004). In I group the platelet content in the blood was on average lower than normal and amounted to 173.4±17.4x109 /µl, in contrast to II group - 182±29.7x109 /µl. The groups statistically differed in the number of patients with LMCA (in 4 (9.5%) patients of I group) (p=0.022198). Prior to the coronary angiography all patients underwent platelet aggregation analysis. According to the platelet aggregation analysis with ADP 15 patients needed to change the scheme of the earlier prescribed antiplatelet therapy. TIMI II flow due to coronary artery spasm was observed in 1 patient of I group. In 2 patients of II group the postoperative period was complicated by the bleeding from the puncture site of the femoral artery with anaemic syndrome and significant decrease of the haemoglobin level. Long-term treatment results were tracked for 18 months after PCI. 1 patient of I group 4 months after PCI with BMS implantation underwent a partial resection of cerebellar lymphoma of the left hemisphere, after 2 months the patient died due to progressive blood malignancy. 3 patients of II group at different times from the moment of PCI (after 10.15 and 17 months) also died due to hematologic disease. 2 patients of II group had splenectomy 4 and 9 months after PCI. In II group the incidence of late stent thrombosis was statistically significantly higher than in I group. Thus, stent thrombosis was observed in 12 patients during the 3,4,5 and 6 months of observation (p=0,02509). Restenosis was diagnosed only in 6 (12.5%) patients of I group (p=0,01913). MACE (cardiac death, thrombosis, and restenosis) in the study groups was 18.7% and 38%, respectively (p=0.012).

Conclusions: Despite the burdened comorbid background and risk factors for the development and progression of cardiovascular pathology, PCI in patients with blood malignancy is an effective and safe method for the treatment of coronary artery disease.

Bifurcation lesion - Tools, devices and techniques

Procedural and intrahospital outcomes after true bifurcation stenting

LADUSS Arnis [1,3], LADUSS Arnis [1,3], CAMANE Evija [1,3], PODOLSKY Ilya [1], ERGLIS Andrejs [1,3], TRUSINSKIS Karlis [2,3], LATKOVSKIS Gustavs [1,3], NARBUTE Inga [1,3], BRIEDE Ieva [1,3], JEGERE Sanda [1,3], KUMSARS Indulis [1,3]

(1) University of Latvia, Riga, Latvia; (2) Riga Stradins University, Riga, Latvia; (3) Pauls Stradiņš Clinical University Hospital, Riga, Latvia

Aims: The aim of this study was to evaluate procedural and intrahospital outcomes of patients who underwent PCI for bifurcation lesions involving both main vessel and side branch with diameters of more or equal to 2.5 mm.

Methods and results: A retrospective analysis of the ongoing Coronary Bifurcation Treatment registry (PCI performed from 01/01/2017 to 31/12/2019). In total 12,414 PCI procedures performed during this period were screened. Patients with STEMI within the last 24 hours and lesions involving the Left Main were excluded. A total of 407 patients with true bifurcations were included in this study. Study population was divided into two groups: provisional single-stenting and systematic double-stenting. Procedural and intrahospital complication rates were compared between groups. 340 (83.5%) patients were treated using provisional single-stenting technique (1 stent) and 67 (16.5%) with systematic double-stenting technique (2 stent). Procedural complications were perforation (total 0.2% [n=1]; 1 stent 0% [n=0] vs 2 stent 1.5% [n=1], p=0.165), side branch occlusion (total 2.0% [n=8]; 1 stent 2.1 % [n=7] vs 2 stent 1.5 % [n=1], p=0.758), no reflow phenomenon (total 0.2% [n=1]; 1 stent 0% [n=0] vs 2 stent 1.5% [n=1], p=0.165). We observed periprocedural myocardial infarction (total 4.4% [n=18]; 1 stent 4.1 % [n=14] vs 2 stent 6.0 % [n=4], p=0.425), all cases, except one, were non-Q myocardial infarctions. There was one acute stent thrombosis case in 1 stent group, but no intrahospital deaths in either group. Creatine kinase-MB levels 24 hours after PCI were measured in 159 patients (1 stent in 134 and 2 stents in 25). Creatine kinase-MB levels more than 3 times above upper normal limit (total 4.2% [n=17]; 1 stent 4.1 % [n=14] vs 2 stent 4.5 % [n=3], p=0.733).

Conclusions: Procedural and intrahospital complication rates in the treatment of true coronary bifurcation lesions was low and there was no significant difference between the one or two stent strategy groups.

Stable CAD - Invasive imaging and functional assessment

Association between circulating micro-ribonucleic acids and lipid core burden index in patients with prediabetes

MAZULE Mairita [1,3], TRUSINSKIS Karlis [1,2], MAZULE Mairita [1,3], KNOKA Evija [1,2], CAUNITE Laima [1,2], JEGERE Sanda [1,3], KUMSARS Indulis [1,3], NARBUTE Inga [1], BRIEDE Ieva [1], STRENGE Karlis [1,3], ERGLIS Andrejs [1,3,4]

(1) Pauls Stradins Clinical University Hospital, Riga, Latvia; (2) Riga Stradins University, Riga, Latvia; (3) University of Latvia, Riga, Latvia; (4) Latvian Research Institute of Cardiology, Riga, Latvia

Aims: Circulating micro-ribonucleic acids (miRNAs) -126, -145 and -155 have been shown to be associated with atherosclerotic lesion development and formation of complex vulnerable plaques. Near-infrared spectroscopy (NIRS) is able to quantify lipids within coronary arteries by the lipid core burden index (LCBI). The aim of this study was to indicate the association between atherosclerosis-related miRNAs and LCBI in patients with pre-diabetes.

Methods and results: Patients with impaired glucose regulation (HbA1c 5.7 – 6.4%) and stable CAD were enrolled. Anthropometric and clinical parameters were evaluated. Total RNA was isolated from plasma to evaluate the expression of circulating miRNA-126, miRNA-145 and miRNA-155. NIRS was done on culprit artery after successful angioplasty with stent implantation distally beyond the target lesion. An automated mechanical pullback (0.5 mm/s; 240 rotations) was performed back to the vessel ostia. A total of 16 patients (mean age 57.50±7.52 and 81.30% men) were enrolled. In patient group with a maxLCBI4mm more than 200 expression of miR-145 was statistically significantly lower than in group of patients with maxLCBI4mm less than 200 (p=0.025). A similar tendency was observed about miR-155 (p=0.084), but not with miR-126 expression (p=0.484). In multivariate logistic regression analysis a correlation remained between miR-145 and LCBI (p=0.056).

Conclusions: Altered expression of miR-145 was associated with higher LCBI in patients with prediabetes. Future research is needed to investigate the potential role of miRNAs in pathogenesis of atherosclerosis.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Long-term outcomes after PCI using DEB in ACS

OSTOJIC Zvonimir [1], OSTOJIC Zvonimir [1], KLARA Klaric [1], MARIC BESIC Kristina [1], STROZZI Maja [1], SKORAK Ivan [1], JURIN Hrvoje [1], SKORIC Bosko [1], MARGETIC Eduard [1], BULUM Josko [1]

(1) KBC Zagreb, Zagreb, Croatia

Aims: Utilisation of drug-coated balloons (DCB) in the treatment of native coronary artery disease is controversial as opposed to treatment of in-stent restenosis (ISR). Aim of the study was to compare angiographic and clinical outcomes after percutaneous coronary interventions (PCI) using DCB in patients treated for ISR or *de novo* coronary artery lesions, in acute coronary syndrome (ACS).

Methods and results: Study included 128 ASC patients treated with DCB between January 2012 and June 2019. All baseline procedures and consecutive coronary angiographies were reviewed to determine indication, lesion complexity, vessel size and procedural success. Baseline and follow up clinical data were extracted from hospital digital database. Patients were stratified in two groups – those treated for ISR or native coronary artery disease (non-ISR). Mean patient age was 63.8 years, with the majority being men (75.8 %, N=97). In total, 24 (18.75 %) patients were treated for ISR. Patients in the ISR group more often had previous myocardial infarction (83.3 % vs 15.4 %, p<0.001) while patients in the non-ISR group were more often active smokers (38.5 % vs 12.5 %, p=0.01). There was no other significant difference between groups in the prevalence of arterial hypertension, hyperlipidaemia, diabetes mellitus, chronic renal insufficiency and atrial fibrillation, nor in medical therapy at discharge including duration of dual antiplatelet therapy (total mean 14.3±10.1 months). Regarding procedural characteristics, there was no difference in mean procedure and fluoroscopy duration, nor in contrast volume administered. Patients in the non-ISR group had more often multivessel disease (56.7 % vs 25 %, p=0.005), bifurcation PCI (45 % vs 20.8 %, p=0.042) and more DCB used in the index event (1.1±0.3 vs 1.0±0, p=0.004). Furthermore, they had more concomitant PCI with stent implantation in other lesions (75.9 % vs 33.3 %, p<0.001) with consequent higher number of stents implanted per person (1.2 vs 0.5, p=0.002). Both mean DCB diameter and length were larger in the ISR group (2.85±0.59 mm vs 2.48±0.49 mm, p=0.007 and 23.38±3.23 mm vs 21.24±5.24 mm, p=0.012, respectively). In the non-ISR group 8 (7.7 %) patients had "bail out" stent implantation, while none was done in ISR group. Mean angiographic (ISR vs non-ISR; 1.59±1.45 years vs 0.87±1.38 years, p=0.22) and clinical (ISR vs non-ISR; 2.51±2.02 years vs 2.52±2.36 years, p=0.98) follow-up was not significantly different between groups. Altogether 75 (58.6 %) patients underwent repeated coronary angiography, more often in the non-ISR group (64.4 % vs 33.3 %, p=0.005), but most of those were elective (73.1%). There was no significant difference in the composite endpoint consisted of death, unplanned rehospitalisation, target vessel revascularisation and target lesion failure (ISR vs non-ISR; 29.2 % vs 26.9 %, p=0.82), nor in any of its components. There was numerically more target lesion failure in ISR group (16.7 % vs 9.6 %, p=0.32).

Conclusions: In conclusion, DCB in treatment of native coronary arteries provides similar angiographic and clinical outcomes compared to DCB for ISR in patients presenting with ACS in real-world settings. Furthermore, the prevalence of target lesion failure after DCB treatment was smaller in native coronary arteries compared to ISR. However, in 7.7 % of cases in native coronary artery PCI "bail out" stent implantation was performed. Further research is needed to confirm these results.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Factors associated with optimal IVUS results and their impact on functional PCI results in treating long coronary artery lesions

BUDRYS Povilas [1,2], BUDRYS Povilas [1,2], BARANAUSKAS Arvydas [1,2], BAJORAS Vilhelmas [1,2], ABRAITIS Vytautas [1,2], DAVIDAVICIUS Giedrius [1,2]

(1) Vilnius University, Faculty of Medicine, Clinic of Cardiac and Vascular Diseases, Vilnius, Lithuania; (2) Vilnius university hospital Santaros klinikos, Vilnius, Lithuania

Aims: To identify preprocedural factors associated with optimal IVUS results and to evaluate whether optimal IVUS results improve functional PCI results in treating long (≥30 mm) coronary artery lesions.

Methods and results: Twenty-three patients suffering from stable angina or NSTE-ACS with a functionally significant coronary artery lesion (FFR ≤0.8), requiring stent length ≥ 30 mm, were enrolled in the study. FFR was measured before and after PCI in all target lesions using standard techniques. All patients underwent IVUS guided PCI. IVUS was performed before PCI and was used to select stent implantation sites (optimally with a plaque burden <50%) and stent diameter (distal external elastic membrane diameter – 0.25 mm). IVUS was repeated after PCI. Optimal IVUS result was achieved if all criteria were met: (1) good stent apposition; (2) good stent expansion (minimal stent area (MSA) >90% of distal reference lumen area and/or MSA ≥5.5 mm^2); (3) plaque burden 5 mm proximal and distal to the stent <50%); (4) no stent edge dissection. According to IVUS results patients were divided into two groups: optimal IVUS result (OIR) group (n=13 (56.5%)) and non-optimal IVUS result (NOIR) group (n=10 (43.5%)). There was no statistically significant difference between OIR and NOIR groups in respect of patients age, gender, diabetes mellitus, hypertension, dyslipidaemia and presence of previous MI. Target vessel in the majority of cases was LAD (10 (76.9%) vs 8 (80.0%), p=0.92). Total stent length (62.6±18.8 mm vs 69.8±22.0 mm, p=0.42) did not differ between OIR and NOIR groups, respectively. Post-dilation with NC balloons was performed in all patients with no significant difference of maximal balloon size (4.1±0.45 mm vs 4.2±0.54 mm, p=0.72). IVUS analysis revealed that calcium arc of ≥180° was more often found in NOIR group (8 (80.0%) vs 5 (38.5%), p=0.04). OIR group patients had larger proximal reference lumen area (10.9±2.2 mm^2 vs 8.7±1.9 mm^2, p=0.04) and smaller proximal plaque burden (39.4±7.5% vs 48.3±7.6%, p=0.02), while distal reference lumen area and plaque burden did not differ significantly. Minimal stent diameter (2.6±0.46 mm vs 2.4±0.50 mm, p=0.14) and minimal stent area (6.1±1.9 mm^2 vs 5.1±2.3 mm^2, p=0.26) did not reach statistically significant difference between OIR and NOIR groups, respectively. Baseline FFR value was 0.67±0.10 in OIR group and 0.69±0.07 in NOIR group, p=0.97. Post PCI FFR value in the distal segment of coronary artery (0.90±0.05 vs 0.87±0.04, p=0.15) and gradient along stented segment (0.065±0.04 vs 0.074±0.03, p=0.52) did not differ significantly among OIR and NOIR groups, respectively.

Conclusions: A calcium arc of ≤180°, larger proximal reference lumen area and smaller proximal plaque burden were associated with optimal IVUS results. However, optimal PCI results according to IVUS did not translate into better functional results after treating long coronary artery lesions.

Stable CAD - Invasive imaging and functional assessment

The role of exercise stress test in detecting functionally significant coronary artery disease: are there any predictors of a false negative result?

BUDRYS Povilas [1,2], BUDRYS Povilas [1,2], RODEVIC Greta [3], KRUPENINAITE Laura [3], PETRYLAITE Marija [1,2], SATRAUSKIENE Agne [1,2], BARANAUSKAS Arvydas [1,2], DAVIDAVICIUS Giedrius [1,2]

(1) Vilnius University, Faculty of Medicine, Clinic of Cardiac and Vascular Diseases, Vilnius, Lithuania; (2) Vilnius university hospital Santaros klinikos, Vilnius, Lithuania; (3) Vilnius University, Faculty of Medicine, Vilnius, Lithuania

Aims: To identify the sensitivity and specificity of exercise ECG stress tests to detect functionally significant coronary artery disease and to determine clinical predictors of a false negative result.

Methods and results: Data of 361 consecutive patients, who underwent coronary angiography with FFR measurement during a one-year period, were analysed. Only patients with prior exercise test were included. Patients, who had inconclusive stress tests were rejected. Thus, the final study population consisted of 72 patients. FFR was measured using a standard technique. Exercise ECG stress test was considered to be positive when there was at least 1 mm horizontal or down-sloping ST segment depression in two or more contiguous leads. According to FFR and exercise ECG tests, patients were divided into two groups: false negatives (FFR $\leq$ 0.8 and negative stress test; n=16 [22.2%]) and true positives (FFR $\leq$ 0.8 and positive stress test, n=13 [18.1%]). Various demographic and clinical characteristics were compared between two groups. The sensitivity of exercise ECG stress test to identify functionally significant CAD was 44.8%, while specificity was 72.1%. There was no statistically significant difference between true positives and false negatives groups in respect of patients age, gender, smoking status, diabetes mellitus, stable angina as an indication for stress test, previous CABG, presence of CTO, ischaemia in LAD territory, and mean FFR value. False negatives group patients had more previous myocardial infarctions (10 [62.5%] vs 3 [23.1%], p=0.03) and more previous PCI (12 [75.0%] vs 5 [38.5%], p=0.05) compared to true positives group patients. 23.1% of true positives group patients were found to have triple vessel disease with left main involvement, while there were no such patients in false negatives group, p<0.05. However, frequency of triple vessel disease without left main involvement did not differ between two groups (4 [30.8%] vs 3 [18.8%], p>0.05, true positives and false negatives, respectively). Univariate logistic regression analysis revealed that previous MI (OR 5.6 [95% confidence interval 1.1-28.6], p=0.04) and previous PCI (OR 4.8 [95% confidence interval 1.0-23.5], p=0.05) were predictors of a false negative ECG stress test. There was no correlation between ischaemic territory (according to FFR) and ischaemic changes on ECG during stress test.

Conclusions: Exercise ECG testing has poor sensitivity and moderate specificity in detecting functionally significant coronary artery disease. Previous MI and previous PCI predicts false negative ECG stress test results, thus should be used cautiously in this group of patients.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

The use of IVUS is associated with a longer stented segment, but it does not improve functional PCI results in treating very long coronary artery lesions

BUDRYS Povilas [1,2], BUDRYS Povilas [1,2], BARANAUSKAS Arvydas [1,2], BAJORAS Vilhelmas [1,2], ABRAITIS Vytautas [1,2], DAVIDAVICIUS Giedrius [1,2]

(1) Vilnius University, Faculty of Medicine, Clinic of Cardiac and Vascular Diseases, Vilnius, Lithuania; (2) Vilnius university hospital Santaros klinikos, Vilnius, Lithuania

Aims: We sought to investigate whether the use of IVUS has an impact on the stent length and functional PCI results in treating very long (≥50 mm) coronary artery lesions.

Methods and results: Fifty-six patients suffering from stable angina or NSTE-ACS with a functionally significant coronary artery lesion (FFR ≤0.8), requiring stent length ≥ 50 mm, were enrolled in the study. FFR was measured before and after PCI in all target lesions using a standard technique: at the distal part of the vessel, at the distal stent edge and at the proximal stent edge. 37 patients underwent angiography guided PCI (angiography group) and in 19 patients PCI was guided using IVUS (IVUS group). IVUS was performed before PCI and was used to select stent implantation sites (optimally with a plaque burden <50%) and stent diameter (distal external elastic membrane diameter – 0.25 mm). Operators were trying to reach optimal PCI result according to IVUS: (1) good stent apposition; (2) good stent expansion (minimal stent area [MSA] >90% of distal reference lumen area and/or MSA ≥5.5 mm^2); (3) plaque burden 5 mm proximal and distal to the stent <50%); (4) no stent edge dissection. There was no statistically significant difference between Angiography and IVUS groups in respect of patients age, gender, diabetes mellitus, hypertension, dyslipidaemia, presence of previous MI or multivessel disease and LV ejection fraction. Total stent length was longer in IVUS group compared to angiography group (72.3 mm±15.9 vs 62.4 mm±10.7, p=0.02, respectively), while average stent diameter did not differ significantly between the two groups. The target vessel in the majority of cases was LAD (15 [78.9%] vs 35 [94.6%], p=0.22). Post-dilation with NC balloons was performed in 86.5% of patients in the angiography group and in all IVUS group patients, p<0.11. Bigger diameter NC balloons were used to post-dilate stents in IVUS group (4.1 mm±0.43) compared to angiography group (3.51 mm±0.28), p=0.01. Baseline FFR value was 0.57±0.11 in the angiography group and 0.65±0.10 in the IVUS group, p=0.006. Post-PCI FFR value in the distal segment of coronary artery (0.86±0.04 vs 0.89±0.04, p=0.35) and gradient along stented segment (0.070±0.031 vs 0.074±0.032) was similar in Angiography and IVUS groups, respectively. However, the gradient between distal parts of the vessel and the distal stent edge was smaller in the IVUS group (0.02±0.02 vs 0.05±0.03, p=0.001, respectively). 3 patients (8.3%) in the angiography group remained ischaemic (FFR≤0.8) after PCI, while in all IVUS group patients FFR post-PCI was >0.8. Only one patient (2.8%) in the angiography group demonstrated post-PCI FFR value >0.9, whilst there were 5 (26.3%) patients with post-PCI FFR value >0.9 in IVUS group, p=0.01.

Conclusions: The use of IVUS in treating very long coronary artery lesions does not increase mean post-PCI FFR value, however, there were no patients with ischaemic FFR value and more patients with optimal functional post-PCI result in IVUS group. The use of IVUS is associated with a longer stented segment.

STEMI - Tools, devices and techniques

Contrast-induced acute kidney injury outcomes in patients with STEMI and multivessel disease undergoing staged complete revascularisation: a call for standardisation

MILLUZZO Rocco Paolo [(1)], MILLUZZO Rocco Paolo [(1)], POLLICINO Tatiana [(1)], ARCIDIACONO Francesco [(1)], SPAGNOLO Marco [(1)], GRECO Antonio [(1)], INGALA Salvatore [(1)], FRANChina Antonio Gabriele [(1)], D'ARRIGO Paolo [(1)], CAPODANNO Davide [(1)], TAMBURINO Corrado [(1)]

(1) University of Catania, Province of Catania, Italy

Aims: In patients with STEMI and multivessel disease (MD) from the COMPLETE trial, complete revascularisation (CR) reduced the composite of cardiovascular death or myocardial infarction compared to PCI of the infarct-related-artery (IRA) only. However, the timing and trade-off of CR remains unclear in these patients. In particular, patients undergoing earlier CR might experience higher rates of contrast-induced acute kidney injury (CI-AKI). The aim of this study was to evaluate the incidence of CI-AKI in contemporary patients with STEMI and MD undergoing staged CR at different timings after IRA-PCI.

Methods and results: Among 700 consecutive patients with STEMI undergoing primary PCI from January 2017 to March 2019, we selected those with MD, defined as the presence of a non-IRA stenosis ≥70%, and excluded those who underwent IRA-only PCI. Demographic characteristics, cardiovascular risk factors, and PCI data were collected using a web-based case report form. Creatinine values were serially collected immediately after primary PCI and daily thereafter until discharge. CI-AKI was defined as an absolute increase in serum creatinine by 0.5 mg/dl or ≥ 25% within 5 days from PCI in the absence of an alternative aetiology. A total of 98 patients qualified for the study, of which 16 (16%) had CR during the primary PCI procedure, 77 (79%) during the index hospitalisation, and 5 (5%) during a staged hospitalisation. The mean age was 63.7±11 years, 23.5% of patients had diabetes mellitus, and 15.2% had pre-existing chronic kidney disease. Based on median timing from primary PCI to CR (79.5 hours) the study population was stratified into 2 groups (i.e., short- and long- staging groups). There were no statistically significant differences in baseline, angiographic and procedural characteristics between the two groups, with the exception of length of hospital stay that was longer in long-staging group (5.05±1.65 vs 7.43±4.9 days, p=0.003). An increase in serum creatinine was observed from baseline to post-PCI in both the short-staging (0.92±0.44 vs 1.06±0.68 mg/dL vs, p=0.001) and long-staging (1.01±0.74 vs 1.33±1.17, p<0.001) groups. Overall, the incidence of CI-AKI was 37.5%. CI-AKI was less frequent in the long-staging group as compared with the short-staging group (22.9% vs 41.7%, p=0.049), possibly as the result of ascertainment bias with more creatine collections in patients who were discharged later due to in-hospital staged CR. After adjusting for length of stay, this difference was not found to be statistically significant at multivariable analysis (OR 0.42; 95% CI: 0.25-1.75; p=0.41).

Conclusions: In patients with STEMI and MD who had CR after primary PCI, those undergoing earlier CR did not experience higher rates of CI-AKI compared with those undergoing later CR. However, this finding may be confounded by the current definition of CI-AKI, which is sensitive to the length of stay, time from primary PCI and the number of creatinine collections during hospitalisation. Collection of CI-AKI outcomes in studies of CR in STEMI and MD warrants more standardisation.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Safety and efficacy of the treatment of in-stent restenosis and de novo complex lesions with the novel paclitaxel-coated scoring balloon (AngioSculpt X)

AGIP FUSTAMANTE Dante Paul [1], AGIP FUSTAMANTE Dante Paul [1], ORTIZ CRUCES Samuel [1], CAMACHO FREIRE Santiago Jesús [1], GUTIÉRREZ BARRIOS Alejandro [2], GÓMEZ MENCHERO Antonio [1], CAÑADAS PRUAÑO Dolores [2], ROA GARRIDO Jessica [1], CALLE PÉREZ Germán [2], CARDENAL PIRIS Rosa [1], DÍAZ FERNÁNDEZ José Francisco [1]

(1) Hospital Juan Ramón Jiménez - Huelva, Huelva, Spain; (2) Puerta Del Mar, Cádiz, Spain

Aims: To assess the safety and efficacy of real-world patients with in-stent restenosis (ISR) or *de novo* complex lesions (vessels < 2.5 mm, calcified lesions, bifurcation lesions…) treated with a novel paclitaxel-coated scoring balloon.

Methods and results: A "real-world", prospective registry from two centres was performed including consecutive patients presenting with ISR or *de novo* complex lesions and treated with AngioSculpt®X. Their clinical data were prospectively registered. Major adverse cardiac events (MACE) were defined as a composite of cardiac death, stent thrombosis, nonfatal myocardial infarction, target lesion revascularisation (TLR) and target vessel revascularisation (TVR). Overall, 87 real-world patients and 93 lesions (73% male, 68±10 years, 46% smoker, 83% hypertensive, 62% diabetic, 71% hyperlipidaemic, 35% LVEF <60% impairment) were enrolled in the study. Clinical presentation was stable angina in 19%, unstable angina in 33%, NSTEMI in 29% and STEMI in 5%. Radial access account 84%. The median fluoroscopy time was 17 (IQ range 10,0-37.5) min. *De novo* complex lesions were treated in 35% (n=32) while ISR in 63% (n=57), (prior BMS 7%; sirolimus DES 5%; everolimus DES 15%; biolimus/anfilimus DES 12%; zotarolimus DES 15%) with a median time to ISR of 3.6 (IQ range 1.1-10.7) years. Total stent length was 28±18 mm, with an overlap spot affected in 18%, and 27% had >1 treatment for ISR. The most frequent artery treated was left anterior descending (41%) followed by left circumflex (35%) and right coronary artery (17%). Quantitative coronary angiography reference diameter of lesions was 2.7±0.5 mm and length 9.0±4.8 mm, with a % stenosis of 75±20. Predilatation/post-dilatation was performed in 60/24% respectively. Device diameter was 2.9±0.4 mm and length 13.6±3.9 mm, deployed at 16±3 atmospheres, with an inflation time of 33±16 seconds. The balloon/artery ratio was 0.99±0.03. Crossover was decided on 18 cases (19%) due to remaining intimal flap, but the success rate (residual stenosis <30%) was 100%. Intracoronary imaging technique was performed in 12% (OCT=7, IVUS=4). At 7±6-month follow-up, there were 10 MACE (cardiac death=1, nonfatal myocardial infarction =4, TLR=4 and TVR=1).

Conclusions: Paclitaxel-coated scoring balloon offers a safe and valuable treatment option for ISR and *de novo* complex lesions.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

The role of plaque preparation and the type of balloon used before DEB in the treatment of de novo coronary lesions

AGIP FUSTAMANTE Dante Paul [(1)], AGIP FUSTAMANTE Dante Paul [(1)], SAMUEL Ortiz Cruces [(1)], CAMACHO FREIRE Santiago Jesús [(1)], ROA GARRIDO Jessica [(1)], GÓMEZ MENCHERO Antonio [(1)], CARDENAL PIRIS Rosa [(1)], DÍAZ FERNÁNDEZ José Francisco [(1)]

(1) Hospital Juan Ramón Jiménez - Huelva, Huelva, Spain

Aims: Plaque preparation prior to the use of a drug-coated-balloon (DCB) has been suggested as a mandatory step to achieve the best outcomes; however, there is a lack of evidence regarding the effect of the type of balloon used in predilatation. Our purpose was to assess the role of lesion preparation before drug-coated balloon use.

Methods and results: This is a single-centre, all-comers registry, from May 2009 – Dec 2019 including all patients in whom a DCB was used for *de novo* coronary lesions. Clinical data, angiographic characteristics, indications, and outcomes were collected. The primary endpoint was target lesion restenosis (TLR), secondary endpoints were target lesion failure (TLF), vessel thrombosis, all-cause mortality, and technical success of PCI. Results: overall, 227 patients (246 lesions) were included. Mean age was 66±11 years-old, 81% were male, 85% hypertensive, 45% diabetic and 66% dyslipidaemic, 23% smoker (former smoker 35%), 10% chronic kidney disease, 9% peripheral artery disease, 34% had LVEF <60%, 27% had prior myocardial infarction and 36% prior PCI. The patients presented most commonly with NSTEMI (35.4%), followed by stable coronary artery disease (28.9%) as clinical presentation. Angiographically, the left anterior descending was the most common vessel involved (40%). 39% were calcified lesions. Baseline quantitative coronary angiography analysis showed a minimal lumen diameter (MLD) of 0.7±0.4 mm and a diameter stenosis predilatation of 83.1±10.8%. Predilatation was performed in 186 lesions (76% semi-compliant balloon, 4%, non-compliant balloon [NC] and 15% scoring balloon). Predilatation balloon diameter was 2.3±0.4 mm and length 13.0±3.8 mm, deployed at 13.9±2.0 atmospheres resulting in a residual stenosis <20% after predilatation in 94.6% of cases. The type of DCB used were 71% SeQuent Please, 11% AngioSculpt X and 18% Impact Falcon (all paclitaxel). Device diameter was 2.7±1.8 mm and length 18.7±6.1 mm, deployed at 13.2±2.4 atmospheres, with a mean inflation time of 30±1.4 seconds. A second drug-coated balloon was used in 5 cases, all of them in long lesions where a unique balloon did not cover the entire lesion. Post-dilatation was only performed in 38 lesions. Complications during the procedure accounted for 7.7% (N=19) (16 flow-limiting vessel dissections, 1 vessel rupture and 2 residual stenosis >30%), all of them solved with a stent implantation. A stent was implanted in 35.4% (N=87) (BMS 67, DES 19, BVS 1). Procedural success was achieved in all cases (100%). At 3.7±3.0 years follow-up the TLR rate was 6.5% without differences depending on plaque preparation or not (6.5 vs 6.7%, p=0.96) but changed with the type of predilatation done (3.5% semi-compliant / 25% NC balloon / 13.9% scoring, p=0.008) however this could be a selection bias (NC or scoring balloon were usually used in more complex lesions when semi-compliant balloons did not open the target lesions), 1% vessel thrombosis, 6.9% all-cause death (1.6% cardiovascular death).

Conclusions: The use of DCB for *de novo* coronary lesions is an effective and safe option in many cases with a very low TLR rate in a long-term follow up. There were no significant differences in outcomes depending on predilatation or not, however the type of balloon used could be important (more TLR with NC or scoring balloons).

STEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Correlation of the severity of coronary artery disease with the metabolomic profile of patients: rationale, design and baseline patient characteristics of the CORLIPID trial

KARAGIANNIDIS efstratios [1,2,3], KARAGIANNIDIS Efstratios [1,3], SOFIDIS Georgios [1], KONSTANTINIDIS Nikolaos [1], STALIKAS Nikolaos [2], DEDA Olga [2], PANTERIS Eleftherios [2], GIKA Helen [2], THEODORIDIS Georgios [2], SIANOS Georgios [2]

(1) AHEPA hospital, Thessaloniki, Greece; (2) AHEPA hospital, Thessaloniki, Greece; (3) Aristotle University of Thessaloniki, Thessaloniki, Greece

Aims: Coronary artery disease (CAD) remains one of the leading causes of mortality and morbidity worldwide. As oxygen and nutrient supply to the myocardium significantly decreases during ischaemic periods, important changes occur regarding myocardial intermediary energy metabolism. Metabolomics is an emerging field in systems biology, which quantifies metabolic changes in response to disease progression. This study aims to evaluate the diagnostic utility of plasma metabolomics-based biomarkers for determination of the complexity and the severity of CAD, as it is assessed using SYNTAX score.

Methods and results: A total of 1,000 adult patients, admitted to the Department of Cardiology in AHEPA University Hospital of Thessaloniki, Greece who underwent coronary angiography for clinical purposes were enrolled in the study. Patients with a previous history of coronary artery disease (previous coronary artery bypass graft or previous percutaneous coronary intervention) are excluded, as it is not possible to calculate the SYNTAX score for these patients. Based on their SYNTAX score, patients were classified into three groups, consistent with prior published reports: low SYNTAX score (0-22), mid SYNTAX score (23-32) and high SYNTAX score >32. Furthermore, patients were categorised into those with chronic coronary syndrome and those with acute coronary syndrome (unstable angina, NSTEMI, STEMI). Collected samples were analysed using a targeted HILIC-UPLC-MS/MS method for the determination of 101 small polar metabolites, including sugars, amino acids, organic acids and amines. From February 2019 till November 2019, a total of 602 patients were enrolled in the study. Mean age was 63.71 (SD ±12.68) years. 271 patients (45.01%) presented with acute coronary syndrome, of whom 106 patients were diagnosed with STEMI, 99 patients were diagnosed with NSTEMI and 66 patients suffered from unstable angina. 331 patients presented with chronic coronary syndromes. Hypertension was found in 56.0% of patients. About 28.7% were diabetics, while dyslipidaemia was observed in 38.4%. Smoking was reported by 41.5% of patients. Completion of enrolment is expected in April 2020. Preliminary statistical analysis (Kruskal-Wallis test with Bonferroni correction, [SPSS v.26]) showed high-sensitivity troponin (ng/mL) to be significantly higher for STEMI patients (mean 2,251.04, SD ±2,600.11) compared to all other groups, NSTEMI (Mean 450.21, SD ±691.44,), unstable angina (mean 158.41, SD ±558.12) and chronic coronary syndromes (mean 85.97, SD ±393.07). Furthermore, patients with STEMI had lower left ventricular ejection fraction (LVEF) at discharge (mean 46.74, SD ±11.02, 95% CI: 44.32-49.17), compared to patients with unstable angina (mean 55.47, SD ±8.01, 95% CI: 53.12-57.82) and patients with chronic coronary syndromes (mean 51.49, SD ±11.86, 95% CI: 49.95-53.03). Results of the metabolomics analysis will be available.

Conclusions: Deciphering the details of plasma metabolome has the potential to identify novel cardiovascular disease biomarkers, which can accurately predict the risk for coronary artery disease and subsequent cardiovascular events, and to significantly alter the management of coronary artery disease.

Stable CAD - Vascular access and bleeding

Ultrasound-assisted distal radial access for coronary and peripheral procedures

RUZSA Zoltán [1,3], RUZSA Zoltán [1,3], TÓTH Julia [3], CSAVAJDA Ádám [3], MOLNÁR Levente [1], BECKER Dávid [1], MERKELY Béla [1], ISTVÁN F Édes [1], KOMÓCSI András [2]

(1) Semmelweis University, Cardiac and Vascular Center, Várnmajor str 68, Hungary; (2) Medical School University of Pécs, Dept. of Invasive Cardiology, Heart Centre, Pécs, Hungary; (3) Bács-Kiskun County Hospital, Invasive Cardiology Department, Kecskemét, Hungary

Aims: The transradial approach can be considered as the default technique for arterial access and is widely used for coronary but also increasingly for peripheral angiographies. Distal radial access has been reported to be feasible as an alternative puncture site. Data are scarce regarding the feasibility of distal radial as a first-choice access.

Methods and results: From January 2015 to March, data of 605 consecutive patients scheduled for coronary or peripheral angiography were analysed. Right arm was the preferred choice. After disinfection and lidocaine infiltration the puncture site was selected after positioning a sterile sleeved ultrasound head. Vessel diameter and Doppler characteristics were measured. Distal radial access was deferred in case of any of the following: monophasic or missing Doppler signal suggesting radial occlusion, diameter <1 mm, planned intervention requiring a sheath size >6 Fr. Determinants of radial artery diameter were assessed in forward stepwise linear modelling. 429 cases underwent coronary (group C) 147 peripheral procedures (group P). 29 cases with both were excluded from the comparison. Patients in group P had lower weight and BMI (mean difference 4.7±1.6 kg and 1.3±0.5, respectively, $p<0.001$). With similar peak velocities (43±24 vs 48±26) the distal radial artery was wider in group C (MD 0.1±0.04 mm, $p<0.01$). Procedural time and contrast use were higher, but the dose area product was lower in the group C (MD: 6.1±1.8 min, 12.5±4.5 ml, 11.9±2.6, respectively $p<0.01$). Following sex (56%), peripheral artery disease was the second most important predictor (16%) of distal radial artery diameter. BMI and diabetes but not age prevailed in the model (importance ≤7%).

Conclusions: Peripheral artery disease is an important predictor of the distal radial diameter, however, ultrasound assisted puncture is a feasible method for both coronary and peripheral interventions.

Left main and multivessel disease - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Real-world outcomes for unprotected left main stem PCI

HUNTER George [(1)], HUNTER George [(1)], VARMA Chetan [(1)], ALI Nawshard [(1)]

(1) Birmingham City Hospital, Birmingham, United Kingdom

Aims: To retrospectively assess outcome data for 114 real-world, all-comer, non-selected cases of unprotected LMS Percutaneous Coronary Intervention (PCI) performed between January 2017 and June 2019 at Birmingham City Hospital, a large non-surgical PCI centre in a deprived urban area in the West Midlands. The outcomes assessed are to include death, repeat revascularisation and myocardial infarction at 6 and 12 months following on from the index procedure date and up to the study date (15th of December 2019).

Methods and results: Unprotected LMS procedural cases between January 2017 and June 2019 were obtained from the Birmingham City Hospital BCIS data. Case and procedure notes were obtained using Unity, CSS and Medcon IT systems at Birmingham City Hospital. Information was obtained from the UK death registry regarding cause of death if not present on the previously listed systems. SYNTAX scores were calculated using the online calculator. The average SYNTAX score calculated for the 114 cases was 28 and the average left ventricular ejection fraction was 48%. There were 24 females and 90 males in the cohort with 31 diabetics, 14 current (and 7 ex-) smokers, 61 with hypertension, 17 with peripheral vascular disease and 8 with prior cerebrovascular disease. The LMS lesion characteristics within the treated population included 2 ostial lesions, 9 body stenoses and 103 distal bifurcation stenoses. The distal bifurcation stenoses included 75 lesions treated provisionally with a stent from the LMS into the left anterior descending artery (LAD) and 13 lesions treated provisionally with a stent from the LMS into the left circumflex (LCx). There were 15 cases of distal LMS bifurcation stenosis treated with an upfront 2 stent strategy into the LAD and LCx with 8 T-stent and protrusion (TAP), 3 T-stent, 2 Culotte, 1 reverse crush and 1 DKCRUSH being performed. The mean follow-up period was 597 days with a median of 579 days. With regards to outcomes there were 5 cases of periprocedural or post-procedural deaths (4%) during the index admission, all of which were primary PCI activations in the context of cardiogenic shock including 1 case of cardiac arrest due to ventricular tachycardia and 1 with complete heart block requiring pacing. There was 1 further death in the 12-month period post-PCI and 1 further death at 13 months post-PCI that were not due to cardiac causes. In the first 6 months from the index procedure there were 2 cases of repeat LMS intervention (1.7%) and 4 cases of CABG (3.5%). There were a total of 12 non-target vessel PCI procedures in the follow up period. There were a total of 7 clinical diagnoses of myocardial infarction events (6%) within the follow up period with 5 of these occurring within the first 6 months of follow up. None of these events were peri - procedural. Out of this group 2 underwent further revascularisation with 1 patient undergoing CABG and 1 undergoing PCI to the proximal LCx.

Conclusions: This real-world analysis of all patients undergoing LMS PCI at our centre, including both elective and acute cases has demonstrated that LMS PCI is safe and effective in a range of lesion and patient groups with short term outcome data consistent with other contemporary data sets.

Stable CAD - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Post-market study of the Fantom sirolimus-eluting bioresorbable coronary scaffold: 30-day clinical outcomes on first 50 patients

PUJDAK Krzysztof [1], PUJDAK Krzysztof [1], OTTO Sylvia [2], NEF Holger [3], GEPPERT Alexander [4], LEIBUNDGUT Gregor [5], LUTZ Matthias [6]

(1) Klinikum Herford, Herford, Germany; (2) Jena University Hospital, Jena, Germany; (3) Justus-Liebig-Universität Gießen, Giessen, Germany; (4) Wilhelminenspital, Vienna, Austria; (5) Kantonsspital Baselland, Liestal, Switzerland; (6) Universitätsklinikum Schleswig-Holstein, Campus Kiel Notaufnahme, Kiel, Germany

Aims: The primary objective of the FANTOM post-market study was to evaluate the continued safety and performance of native coronary artery stenting with the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold in every-day clinical practice. Fantom encore is a fully resorbable scaffold, manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogues. Fantom encore is completely radiopaque and is comprised of thin struts (95-115 micron) that facilitate device delivery and precise target lesion treatment.

Methods and results: The FANTOM post-market study is a prospective, multicentre trial which plans to enrol up to 1,500 patients with *de novo* coronary stenosis with reference vessel diameters between 2.5 to 3.75 mm in diameter and lesion lengths less than or equal to 20 mm. In this study all lesions were to be pre-dilated using a 1:1 NC balloon and then subsequently assessed to determine vessel diameter and lesion length. Once sizing was complete, the Fantom Encore scaffold was implanted using standard stent implantation techniques. Post-dilation was then recommended in all cases to a minimum of 16 atm. Optimal implantation was then determined using standard angiographic techniques with the highly recommended option of using OCT at the physician's discretion. All patients in this trial will be followed for 5 years post-implant. This initial presentation will provide the current ongoing analysis of the clinical results from the first 50 patients enrolled through 30 days of follow-up. The presented results will include acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol. In addition, clinical outcomes such as MACE, TLF and scaffold thrombosis will be available.

Conclusions: As in the Fantom II Trial which was used as a basis for obtaining CE mark, the Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favourable initial acute safety in this post-market study of every-day clinical use. The study is continuing to enrol patients and future results will be reported as they become available.

STEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Four-year clinical outcomes after implantation of an everolimus-eluting bioresorbable scaffold in patients with stable angina and ACS. Single-centre real-life registry data for N=225 patients

BRIEDE Ieva [1,2], BRIEDE Ieva [1,2], SONDORE Dace [1], KUMSARS Indulis [1,2], NARBUTE Inga [1], TRUSINSKIS Karlis [1,3], LATKOVSKIS Gustavs [1,2], DOMBROVSKIS Andis [1], JEGERE Sanda [1,2], STRENGE Karlis [1], ERGLIS Andrejs [1,2]

(1) Pauls Stradins Clinical University Hospital, Riga, Latvia; (2) University of Latvia, Riga, Latvia; (3) Riga Stradins University, Riga, Latvia

Aims: The aim of this long-term registry data was to evaluate four-year clinical and angiographic outcomes after implantation of everolimus-eluting bioresorbable scaffolds. In total from N= 431 registry patient, N=225 reached four-year follow-up.

Methods and results: All patients n=225 had successful PCI following bioresorbable scaffold implantation. First analysed hospital outcomes as hospital death, hospital myocardial infarction and hospital scaffold thrombosis. At four years, clinical parameters and outcomes were analysed; all-cause death, cardiovascular death, myocardial infarction, target lesion revascularisation, target vessel revascularisation, scaffold thrombosis, cerebral infarction, repeat PCI. Clinical follow-up at four years reached 93.3% (n=210). 1.3% (n=3) of patients were missing for follow-up. 5.3% (n=12) death occurred. Male population was 77.4% (n=174) and female 22.6% (n=51). Mean patient age 58.0±12.0 years. Hypertension was in 81.7% (n=170), dyslipidaemia in 72.3% (n=209) and diabetes in 18.2% (n=40) of patients. Previous myocardial infarction was in 35% (n=78) of patients, previous PCI 44.7% (n=99). Stable angina was in 79.1% (n=177), NSTEMI 3.1% (n=7) and STEMI 8,9% (n=20) and unstable angina in 12% (n=27) of patients. Multivessel disease by coronary angiography was diagnosed in 72.8% (n=158) of patients. The left anterior descending artery was stented in 45.7% (n=103) of cases, right coronary artery in 25.3% (n=57) of cases and left circumflex in 18.6% (n=42) of cases. Mostly stented area was located in middle part of the artery - 63% (142), proximal part was stented in 63% (142) of cases. Elective PCI was done in 84.5% of cases. Radial approach used in 73.5%. IVUS guidance use in 15.1% (n=34) of cases and optical coherent tomography was used in 13.7% (n=31). Lesion predilatation was done in 92.4% (n=208). Mean scaffold length was 20,3±5.7 mm. Mean scaffold diameter used 3,3±0.2 mm, mean post-dilatation balloon diameter was 3,5±0.6 mm. Post-dilatation was done in 92.4% (n=208) of cases. In-hospital death occurred in 0,9% (n=2) patients, one patient had in-hospital myocardial infarction - 0.4%. At four years, the rate of all-cause death was 4,4% (n=10), cardiovascular death in 0.9% (n=2), myocardial infarction at four-year follow-up was in 5.2% (n=11) of patients. Target vessel revascularisation 12.4 % (n=26), target lesion revascularisation 6.2% (n=13). Repeated PCI was done in 33.2 % (n=71) but mainly due to staged second PCI. Cerebral infarction in four years occurred in 2,3% (n=5). Between hospital discharge and four-year follow up scaffold thrombosis occurred in 1.4% (n=3). In-hospital scaffold thrombosis occurred in 0.4% (n=1) due to clopidogrel resistance.

Conclusions: Everolimus-eluting bioresorbable scaffolds showed acceptable efficacy (target lesion revascularisation) and safety (cardiac death, myocardial infarction, and scaffold thrombosis) results at long-term follow-up in stable angina and acute coronary syndrome patients.

Other Coronary interventions - Other

The usefulness of the myocardial performance index in assessing the impaction of isolated coronary ectasia on left ventricular function

HUSSEIN Shady [1]

(1) Mansoura University, Mansoura, Egypt

Aims: We aimed to assess the left ventricular function in patients with isolated coronary artery ectasia (CAE) by the left ventricular myocardial performance index (MPI) using tissue Doppler imaging (TDI) and alterations in mitral valve inflow parameters using conventional Doppler imaging.

Methods and results: A prospective study was conducted including 40 patients (age, 45–68 years) presenting with typical angina chest pain who were admitted at our hospital from January 2018 to January 2019. All patients were subject to conventional coronary angiography during their in hospital stay, Patients were divided into two groups: I) patients with isolated coronary ectasia and no significant coronary stenosis (test group, 20 patients) and II) patients with normal coronary angiography who are age and sex matched (comparative group, 20 patients), left ventricular function of the patients in the two groups was assessed by conventional echo Doppler and TDI, Median follow-up duration was 6 (4–9) days. Results: regarding alterations in mitral inflow parameters, there was significant increase in late mitral inflow velocity (A wave) and decrease in E/A ratio (p=0.007 and 0.004, respectively) in group I and no significant difference in early mitral inflow velocity (E wave) (p=0.465) whereas regarding TDI, using pulsed wave Doppler at lateral side of mitral annulus, there was significant increase of isovolumic relaxation time (IVRT), MPI and late myocardial relaxation velocity (Aa wave) (p=0.003, 0.000 and 0.000, respectively) and significant decrease of early myocardial relaxation velocity (Ea wave) and Ea/Aa ratio (p=0.000 and 0.000, respectively) in group I, using pulsed wave Doppler at septal side of mitral annulus there was significant increase of isovolumic contraction time (IVCT), IVRT, ejection time (ET), MPI and Aa wave (p=0.009, 0.000, 0.025, 0.000 and 0.000, respectively) and significant decrease of Ea wave and Ea/Aa ratio (p=0.000 and 0.000, respectively) in group I.

Conclusions: Pulsed wave TDI is useful complement to standard echo Doppler examination and a helpful tool in diagnosis and prognosis of coronary artery disease (CAD), TDI is relatively independent from the volume loading conditions and enables us to assess subclinical long-axis myocardial dysfunction that cannot be detected by conventional left ventricular systolic function measurements. TDI- MPI is considered a reliable parameter for evaluation of global left ventricular function.

STEMI - Tools, devices and techniques

Impact of early successful primary PCI on global left ventricular systolic function in STEMI patients

HUSSEIN Shady (1)

(1) Mansoura University, Mansoura, Egypt

Aims: We aimed to assess the impact of time to treatment on myocardial function and perfusion after primary percutaneous coronary intervention (PPCI) in patients with ST-elevation myocardial infarction (STEMI).

Methods and results: A prospective study was conducted including 30 patients (age, 22–82 years) with acute STEMI who underwent successful PPCI within 24 hours of presentation at our hospital from February 2018 to May 2019. Patients were divided into two groups: I) Early presenters treated with PPCI within 6 hours of presentation (test group, 19 patients) and II) Late presenters treated with PPCI after 6 hours up to 24 hours of presentation (comparative group, 11 patients). Transthoracic echo (TTE) with assessment of left ventricle EF (LVEF), wall motion score (WMS) and wall motion score index (WMSI) was performed to all patients in the first day of presentation, and at 1 month and 2 month intervals. Median follow-up duration was 2 months. Regarding TTE follow-up (at presentation, 1 month and 2 months) of LVEF, WMS and WMSI, there was statistically significant difference between the two groups, The early group showed improved EF (at presentation 44.74% vs 38.54%; p=0.005, 1 month follow-up 59.89% vs 45.63%; p 0.001 and 2 months follow-up 60.16% vs 47.73%; p 0.001), improved WMS (at presentation 24.26% vs 29.27%; p=0.003, 1 month follow-up 17.21% vs 25.18%; p 0.001 and 2 months follow-up 17.05% vs 24.36%; p 0.001) and improved WMSI (at presentation 1.52% vs 1.83%; p=0.002, 1 month follow-up 1.07% vs 1.57%; p 0.001 and 2 months follow-up 1.06% vs 1.52%; p 0.001) than the late group.

Conclusions: In patients with STEMI treated by PPCI, prolonged ischaemic time is associated with impaired myocardial function and perfusion and larger infarct size even after opening of epicardial artery due to distal embolisation and impaired myocardial perfusion. Therefore, all efforts should be made to shorten the delay to reperfusion in order to achieve better myocardial perfusion.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Prognostic impact of coronary artery calcification as detected by a novel automatic quantification tool based on IVUS

NELEMAN Tara [1], NELEMAN Tara [1], LIU Shengnan [1], TOVAR FORERO Maria [1], HARTMAN Eline [1], LIGTHART Jurgen [1], WITBERG Karen [1], CUMMINS Paul [1], VAN SOEST Gijs [1], BOERSMA Eric [1], DAEMEN Joost [1]

(1) Erasmus MC, Rotterdam, the Netherlands

Aims: We recently developed, trained and validated a novel algorithm to automatically detect and quantify coronary artery calcium on intravascular ultrasound (IVUS) using machine learning techniques. The objective of the present study is to assess the clinical applicability of this algorithm to determine patient outcome in a large local PCI and IVUS registry.

Methods and results: In this retrospective cohort study, we enrolled 408 patients who underwent coronary angiography plus pre-procedural IVUS imaging (Boston Scientific OptiCross or Atlantis 40 MHz at 0.5 mm/sec) between January 2008 and January 2018. Inclusion criteria included motorized IVUS pullbacks over a length >40 mm in a native coronary artery. Exclusion criteria were presence of stent struts, severe quality issues and catheter in false lumen. For each patient, only one vessel was included in the analysis, in case of multiple suitable vessels the longest pullback was included. An automatic calcium detection algorithm computed the presence of calcium per A-line based on A-line intensity. The IVUS calcium score (ICS) was defined as the number of calcium-positive A-lines divided by the total number of A-lines times 1000. The primary endpoint was Patient-Oriented Cardiovascular Endpoint (POCE), a composite of all-cause mortality, any myocardial infarction and any revascularisation. Median age of the patient cohort was 66 (interquartile range (IQR) 57 – 72) years, 72.5% was male and 56.4% presented with stable angina, 36.8% had a history of coronary artery disease and 18.4% had renal impairment (estimated glomeral filtration rate (eGFR) < 60 ml/min). A total of 75.5% of vessels visualised with IVUS were subsequently revascularised. Median ICS was 85 (IQR 25 – 169) and ranged from 0 to 503. To meet assumptions for linear regression a square root transformation was applied to the ICS. Multiple linear regression for √ ICS showed that a history of cerebrovascular accident (CVA) and age were independent predictors of ICS. Prior CVA was associated with a 2.60 increase in √ ICS (p=0.025) and a one year increase in age was associated with a 0.074 increase in √ ICS (p<0.001). R2 of the multiple linear regression model was 0.12. Median follow-up was 5.9 years. During median follow-up time POCE occurred in 146 patients. The cumulative incidence of POCE for patients with an ICS ≥ 85 was 48.4% versus 36.4% for the patients with ICS < 85 (p=0.022, log-rank test). An ICS ≥ 85 was significantly associated with POCE (hazard ratio (HR) 1.44; 95% CI: 1.00 – 2.05, p=0.045, adjusted for age, eGFR, history of CABG, smoking habits, presentation with ACS and PCI or CABG at index, stratified for diabetes). A subanalysis of the non-revascularised vessels (n=100) revealed similar results: cumulative incidence of POCE for patients with a ICS ≥ 85 was 56% versus 28% for the patients with ICS < 85 (p=0.011, log-rank test). An ICS ≥ 85 remained significant associated with POCE (HR 3.09, 95% CI: 1.46 – 6.55, p=0.003, adjusted for smoking habits). In revascularised vessels (n=308) no difference was observed in the cumulative incidence of POCE (ICS ≥ 85 46.8% versus ICS < 85 39.6%, p=0.22, log-rank test).

Conclusions: Coronary calcium as detected by a novel automated calcium detection algorithm on IVUS is correlated to prior CVA and age. The ICS, used as a patient-based risk factor, proved to independently predict long-term clinical outcome.

STEMI - Tools, devices and techniques

Prediction of contrast-induced nephropathy in patients undergoing primary PCI by Mehran risk score

MALIK Fazila [(1)], MALIK Fazila [(1)], KALIMUDDIN Md [(1)]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Contrast-induced nephropathy (CIN) developing after primary percutaneous coronary intervention (pPCI) may lead to worse clinical outcomes, including prolonged hospitalisation, increased costs, repeat revascularisation, and short- and long-term mortality. The Mehran risk score (MRS) predicts CIN in patients undergoing elective PCI. The aim of this study was to predict CIN in patients with ST-segment Elevation Myocardial Infarction (STEMI) undergoing pPCI by MRS.

Methods and results: This prospective observational study was conducted from January 2018 to December 2019 in our hospital which included 533 patients with STEMI who underwent pPCI. Patients, who did not survive beyond 48 hours were excluded from the study. The Mehran CIN risk score was calculated for each patient from the corresponding scores for the 8 prognostic variables (age >75 years, hypotension, congestive heart failure, intra-aortic balloon pump, serum creatinine, diabetes, anaemia, and volume of contrast) it involves. CIN was defined as a 0.5 mg/dL increase in serum creatinine or 25% increase compared with baseline values within 48 hours of the procedure. Four categories of risk of CIN were established as follows: low (<5 points); medium (6 to 10); high (11 to 16); and very high (>16). The effectiveness of Mehran's score was analysed using logistic regression model and receiver operating characteristic (ROC) curve. Results: CIN developed in 11.1% patients. Of them 2.1% patients developed CIN in low risk group; 4.1% in medium risk group; 3.5% in high risk group and 1.3% patients in high risk group. But risk of developing CIN is 4.2% in low risk group; 12.5% in medium risk group; 24.1% in high risk group and 41.2% in very high risk group which correlates with risk for CIN reported by Mehran et al (7.5%, 14% 26.1% and 57.3% respectively). Logistic regression analysis showed that MRS was highly significant for predicting CIN (P value <0.001). According to the ROC curve, as area under the curve (AUC) is 0.72 (95% CI: 0.65-0.79) and it is statistically highly significant (p<0.001). At the cutoff value of 7.5 Mehran score can detect 66.1% of positive cases and false positive detection rate is 29.3%.

Conclusions: Mehran risk score can predict CIN in patients with STEMI who underwent PPCI as in patients with elective PCI.

Stable CAD - Invasive imaging and functional assessment

Correlation between quantitative flow ratio and iFR

LOO Jia Jing Fernando [1], LI Ki Fung Cliff [1], LOO Jia Jing Fernando [1], CHUANG Ting Hsuan [1], GALAPON Richard Rex [1], ONG Paul [1]

(1) Tan Tock Seng Hospital, Tan Tock Seng Hospital, Singapore

Aims: Haemodynamic assessment tools are essential in assessment of angiographically intermediate coronary lesions (CL), helping to determine the need for further coronary intervention. Quantitative flow ratio assessment (QFR) is a novel modality which allows non-invasive physiological assessment of CL based on 3-dimensional vessel reconstruction and computational flow dynamics. We conducted this study to assess the correlation of QFR with instantaneous wave-free ratio (iFR).

Methods and results: Our centre conducted a retrospective analysis of patients who underwent iFR in 2018-2019, including 50 patients (mean age 60±11, 66% male, 74% hypertensive, 78% hyperlipidaemia, 40% diabetic, 20% smoker) with 65 CL (64% LAD, 12% LCx, 24% RCA). Offline QFR analysis of the anonymised lesions was then conducted by a blinded operator. Analysis with Pearson bivariate correlation shows good correlation of 0.667 with statistical significance. Results displayed on a simple scatter plot shows a general linear trend between QFR and iFR. When using a cut-off of ≤0.80 for QFR, there were multiple data points with positive iFR results <0.90, indicating false negative for QFR. This was minimised when the cut-off was increased to ≤0.85, with only 1 data point being false negative instead. This indicates a good agreement between QFR and iFR, and also suggest that the sensitivity of QFR to identify a haemodynamically significant lesion is much higher when a cut-off 0.85 instead of 0.80.

Conclusions: The authors suggest a hybrid approach to angiographically intermediate CL, using QFR as the initial non-invasive assessment, and proceeding with iFR for further confirmation of physiological significance only if QFR is ≤0.85. This will minimise the need for invasive coronary wires and associated complications, yet still allow proper functional assessment. The hybrid approach may potentially be a cost-saving strategy to both the patient and the healthcare system. Further studies may be needed in the future to validate this strategy and for long term clinical outcomes assessment.

Other Coronary interventions - Other

Anomalous right coronary artery originating from left sinus: risk stratification using IVUS and FFR techniques

BELTRAME Mirko [1], BELTRAME Mirko [1], ANGELOZZI Andrea [1], MAOLO Alessandro [2], NICOLINI Elisa [1], TERRACCIANO Francesco [1], GIUSTI Giuliano [1], BIANCO Francesco [1], POZZI Marco [1], PIVA Tommaso [1]

(1) Ospedali Riuniti Torrette Di Ancona, Province of Ancona, Italy; (2) Ospedale Di Macerata, Province of Macerata, Italy

Aims: To assess the clinical and pathophysiological relevance of the anomalous origin of the right coronary artery from the left sinus (R-ACAOS) in the Cath Lab.

Methods and results: We report on 5 cases of anomalous origin of the right coronary artery from the left sinus. All the patients presented with typical or atypical angina or arrhythmias. In all the cases there were an intramural course of the abnormal coronary artery at the multislice computed tomography. They underwent to coronary angiography, intravascular ultrasound (IVUS), baseline FFR (intracoronary adenosine infusion of 200-300 mcg) and Dobutamine stress FFR beginning at 5-10 µg/kg/min and raising the dosage by 5 µg/kg/min at 3 min intervals, for a maximal dose of 20-40 µg/kg/min. Dobutamine stress FFR was significant (≤0.8) in two patients one of whom were surgical treated with unroofing technique. (the other refused surgical treatment). Dobutamine stress FFR was not significant (0,85) in the only paediatric patient (7 years old) but with a reduction compared baseline values (1). In view of clinical presentation, coronary anatomy and estimated ischaemic and arrhythmic risk, this patient underwent surgery after Heart Team discussion. IVUS confirmed intramural course and showed a slit-like origin in 4 patients with variable degrees of systolic compression. At follow-up (max 20 months) all the patients are alive and asymptomatic.

Conclusions: IVUS and Dobutamine stress FFR are safe techniques. They offer anatomical and functional information in patients with symptomatic R-ACAOS and inconclusive non-invasive tests. The evidence of ischaemia inducible from invasive tests is likely to indicate an increased risk of sudden cardiac death, although this has not been proven.

Other Coronary interventions - Other

Nonagenarians with AMI; invasive vs conservative strategy

LEE Jooho [1]

(1) Seoul Medical Center, Seoul, Republic of Korea

Aims: There is limited data supporting invasive strategy in nonagenarians with acute myocardial infarction (AMI). We aimed to investigate performing percutaneous coronary intervention (PCI) is beneficial in this frail population.

Methods and results: We analysed retrospectively 41 nonagenarians admitted with AMI between 2006 and 2015 in single centre. We assessed 30-day, 1-year mortality in PCI group and medical treatment group. Among 41 nonagenarian AMI patients, 24(59%) were treated with PCI and 17(41%) were received medical treatment upon clinician's discretion. Mean follow-up duration was 34 months (95% CI: 23-45). Age, sex, smoking, diabetes, dyslipidaemia, history of coronary artery disease were not significantly different between the two groups except body mass index (BMI). 30-day mortality was 17% in PCI group and 65% in medical treatment group ($p<0.001$). 1-year mortality was 21% and 76%, respectively($p<0.001$). Cox proportional hazard regression analysis was performed to adjust age, sex, BMI, ejection fraction, renal insufficiency, Killip class (adjusted HR: 6.36, ;95% CI: 2.19-18.47, $p<0.001$). In subgroup analysis except Killip class 4(5), 30-day mortality was 13% in PCI group and 54% in medical treatment group($p<0.001$). 1-year mortality was 17% and 69%, respectively($p<0.001$) (adjusted HR: 6.62, ;95% CI: 2.19-20.02, $p<0.001$). After 30-day survivals, there was no significant difference in cumulative mortality rate between the two groups.

Conclusions: Mortality after AMI was decreased in invasive strategy compared with medical strategy, even in nonagenarians. Regardless of age, PCI should be considered in AMI.

STEMI - Tools, devices and techniques, Other Coronary interventions - Other

Benefit of a staged, in-hospital revascularisation strategy in haemodynamically stable patients with STEMI and multivessel disease: analysis by risk stratification

KIM Min Chul [(1)], KIM Min Chul [(1)], AHN Youngkeun [(1)], AHN Jun Ho [(1)], HYUN Dae Young [(1)], CHO Kyung Hoon [(1)], SIM Doo Sun [(1)], HONG Young Joon [(1)], KIM Ju Han [(1)], JEONG Myung Ho [(1)], AHN Tae Hoon [(2)], CHAE Shung Chul [(3)]

(1) Chonnam National University Hospital, Gwangju, Republic of Korea; (2) Gacheon University Medical Campus, Incheon, Republic of Korea; (3) Kyungpook National University Hospital, Daegu, Republic of Korea

Aims: The proper timing and indication for revascularisation of a non-culprit artery in patients with STEMI and MVD without cardiogenic shock remains controversial. We investigated the long-term outcomes of various interventional strategies in patients with ST-segment elevation myocardial infarction (STEMI) and multivessel disease (MVD) without cardiogenic shock.

Methods and results: This multicentre study included patients with STEMI and MVD without cardiogenic shock. Data were analysed at 3 years according to a percutaneous coronary intervention (PCI) strategy: immediate multivessel revascularisation (MVR), stepwise MVR, and culprit-only PCI. The primary outcome was all-cause mortality. The stepwise MVR group had a lower risk of all-cause death (culprit-only vs stepwise MVR, hazard ratio [HR]: 0.46, 95% confidence interval [CI]: 0.29 to 0.75, p=0.002; immediate vs stepwise MVR, HR: 0.43, 95% CI: 0.24 to 0.75, p=0.003) and major adverse cardiac events (MACE: a composite of all-cause mortality, recurrent myocardial infarction, and any repeat revascularisation). The results were consistent after multivariate regression, propensity-score matching, inverse probability weighting, and Bayesian proportional hazards modelling. In subgroup analyses stratified by the Global Registry of Acute Coronary Events score, stepwise MVR also lowered the risk of all-cause death compared to culprit-only PCI and immediate MVR in high risk patients but not in patients at low to intermediate risk.

Conclusions: In patients with STEMI and MVD without cardiogenic shock, in-hospital stepwise MVR was associated with a lower risk of all-cause death and MACE than culprit-only PCI or immediate MVR, particularly in the high-risk subgroup.

NSTEMI - Tools, devices and techniques, Other Coronary interventions - Other

Optimal revascularisation strategy in NSTEMI with multivessel coronary artery disease: culprit-only vs one-stage vs multi-stage revascularisation

KIM Min Chul [1], KIM Min Chul [1], AHN Youngkeun [1], AHN Jun Ho [1], HYUN Dae Young [1], CHO Kyung Hoon [1], SIM Doo Sun [1], HONG Young Joon [1], KIM Ju Han [1], JEONG Myung Ho [1], AHN Tae Hoon [2], CHAE Shung Chul [3]

(1) Chonnam National University Hospital, Gwangju, Republic of Korea; (2) Gacheon University Medical Campus, Incheon, Republic of Korea; (3) Kyungpook National University Hospital, Daegu, Republic of Korea

Aims: Few studies have investigated optimal revascularisation strategies in NSTEMI with MVD. We investigated 3-year clinical outcomes according to revascularisation strategy in patients with non-ST-segment elevation myocardial infarction (NSTEMI) and multivessel disease (MVD).

Methods and results: This multicentre study included patients with NSTEMI and MVD without cardiogenic shock. Data were analysed at 3 years according to the percutaneous coronary intervention (PCI) strategy: culprit-only revascularisation (COR), one-stage multivessel revascularisation (MVR), and multi-stage MVR. The primary outcome was major adverse cardiac events (MACE: a composite of all-cause death, non-fatal spontaneous myocardial infarction, or any repeat revascularisation). The COR group had a higher risk of MACE than other strategies (COR vs one-stage MVR, hazard ratio [HR]: 0.65, 95% confidence interval [CI]: 0.54–0.77, p<0.001; COR vs multi-stage MVR, HR: 0.74, 95% CI: 0.57–0.97, p=0.027). There was no significant difference in the incidence of MACE between one-stage and multi-stage MVR (HR: 1.14, 95% CI: 0.86–1.51, p=0.355). The results were consistent after multivariate regression, propensity score matching, inverse probability weighting, and Bayesian proportional hazards modelling. In subgroup analyses stratified by the Global Registry of Acute Coronary Events score, one-stage MVR lowered the risk of MACE compared to multi-stage MVR in low-to-intermediate risk patients but not in patients at high risk.

Conclusions: MVR reduced 3-year MACE in patients with NSTEMI and MVD compared to COR. However, one-stage MVR was not superior to multi-stage MVR for reducing MACE except in low-to-intermediate risk patients.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Poor prognosis of contrast-induced nephropathy observed during long-term clinical follow-up

SANG-ROK Lee [(1)], LEE Sang-Rok [(1)], TALI Liu [(1)]

(1) Chonbuk National University Hospital, Jeollabuk-do, Republic of Korea

Aims: The development of contrast-induced nephropathy (CIN) was related to short-term poor prognosis. The aim of our study was to evaluate the long-term outcome of CIN during 10-year follow up.

Methods and results: We enrolled 544 patients (mean follow up 75±56 months) who received coronary intervention in Chonbuk National University Hospital (South Korea, Jeonju) from January 2005 to December 2006. The primary study endpoints were the all-cause death at 1, 5, and 10-years. The secondary study endpoints were major adverse cardiac events (MACE) including cardiac death, non-fatal myocardial infarction (MI), and target vessel revascularisation (TVR) at 1, 5, and 10-years. Study population was divided into two groups: group I (No CIN, n= 496, 62±11 years, male 63.9%) and group II (CIN, n=48, 64±12 years, male 64.6%). Baseline clinical characteristics and cardiovascular risk factors were not significantly different between the two groups except the baseline creatinine level (1.21 mg/dL vs 1.95 mg/dL, p=0.001). All-cause death at 1-year (3.6% vs 14.5%, log-rank, p=0.001), 5-year (17.7% vs 33.3%, log-rank, p=0.004), and 10-year (25.2% vs 45.8%, log-rank, p=0.001) were higher in group II. MACE at 1-year (4.2% vs 10.4%, log-rank, p=0.069), 5-year (7% vs 19.2%, log-rank, p=0.044), and 10-year (13.5% vs 25%, log-rank, p=0.049) were higher in group II. Multivariate Cox regression analysis showed CIN (HR 2.367, 95% CI: 1.46-3.83, p 0.0001) was an independent predictor for 10-year MACE.

Conclusions: The poor prognosis of CIN was persistently observed even after 10-year clinical follow-up.

NSTEMI - Adjunctive pharmacotherapy

Atorvastatin reload dose in patients with NSTE-ACS undergoing PCI

PERE FUENTES Pedro Ramon [(1)], PÉREZ FUENTES Pedro Ramon [(1)], REYES ROCHA Miguel [(1)], MIRANDA Gustavo [(1)], ALARCON Javier [(1)], SABATE Manel [(2)]

(1) Hospital Rebagliati, Jesús María, PERU; (2) Hospital Clínic i Provincial de Barcelona, Barcelona, Spain

Aims: The aim of this study is to show if an acute reload dose of atorvastatin in patients undergoing percutaneous coronary intervention for non-ST segment elevation acute coronary syndrome is effective to reduce mayor adverse cardiovascular events.

Methods and results: Patients on chronic statin therapy, presenting with non-ST segment elevation acute coronary syndrome undergoing percutaneous coronary intervention were randomised (1-1) to receive atorvastatin 80 mg reload dose up to 6 hours previous to the procedure or to the standard statin therapy regimen. Primary endpoints were the presence of major cardiovascular adverse events defined by a composite of death by cardiac cause, type 4 myocardial infarction and clinically driven target vessel revascularisation at 30 days of follow up. Secondary endpoints were the individual components of the composite primary endpoint, variation of 20% or more of basal values of troponin, variation on inflammation serum biomarkers, creatinine levels and liver enzymes elevation, hospitalisations and time to discharge. Between January 2016 and January 2017, a total of 100 patients were included in the Study (50 to atorvastatin reload and 50 to standard statin therapy). Patients had 66.7±8 years old and were 21% women without differences in subgroups regarding baseline, clinical nor procedural characteristics. The primary endpoint was found in 40% of the standard statin therapy group and in 10% of the atorvastatin reload group (OR: 0.169, p=0.005), been this mainly driven by a reduction in type 4 myocardial infarction (34% on the control group vs 10% on the intervention group). Patients undergoing atorvastatin reload had a significant reduction in the incidence of troponin plus 20% elevation (54% on the control group vs 32% on the atorvastatin group, p=0.026). Creatinine and C reactive protein levels were lower on the atorvastatin group (p=0.0037 and p=0.001 respectively). No changes were found on time to discharge but a significate reduction in hospitalisations were found (8% in control group vs 0% on atorvastatin group, p=0.041). Finally, a numerical but statistically non-significant elevation of liver enzymes was found on the atorvastatin group (p=0.250).

Conclusions: Atorvastatin acute reload dose in patients undergoing percutaneous coronary intervention for non-ST segment elevation coronary syndrome is effective to prevent the incidence of mayor adverse cardiovascular events. This effect is mainly driven by a reduction of type 4 myocardial infarction.

Left main and multivessel disease - Tools, devices and techniques

PCI for unprotected left main coronary artery disease when CABG is not an option

OIKONOMOU Dimitrios [1], OIKONOMOU Dimitrios [1], BENIA Dimitra [1], KYPARISSI Antigoni [1], FERENTINOS Georgios [1], KALOGERA Vasiliki [1], TRIANTAFYLLOU Konstantinos [1]

(1) Evaggelismos General Hospital, Athens, Greece

Aims: Treatment of left main (LM) lesions with percutaneous coronary intervention (PCI) is recommended as an acceptable alternative to surgery in low-risk patients with low or intermediate anatomic complexity. We sought to examine outcomes of LM PCI in high-risk patients deemed ineligible for surgical treatment.

Methods and results: We included 20 consecutive patients from a single-centre cohort that underwent unprotected LM PCI after rejection for coronary artery bypass grafting (CABG). Primary outcome was the composite endpoint of cardiovascular death, acute myocardial infraction, stroke and clinically driven target lesion revascularisation. Mean age was 75±9 years. Previous revascularisation with PCI or CABG had been performed in 7 patients. Most patients presented with acute coronary syndrome (70%) including ST segment elevation myocardial infraction (STEMI) in 5 cases (25%). The documented reason for surgical rejection was high surgical risk in 12 patients (60%), poor surgical targets in 3 patients (15%) and ongoing ischaemia with clinical instability while in the catheterisation laboratory in 5 patients (25%). Left main and two- or three-vessel disease was present in most patients (75%). Median SYNTAX score, median EuroSCORE II and median STS mortality score were 28 (24.5-33.4), 4.5% (2.9-8%), 2.9% (2.1-3.8) respectively. A single procedure or staged revascularisation was performed aiming at complete revascularisation when technically possible. Complete revascularisation was achieved in most cases (80%). In the majority of procedures (90%) LM PCI with provisional side branch stenting was the selected strategy. Intravascular ultrasound (IVUS) was utilised to guide revascularisation in 5 cases (25%) and scoring balloons and/or rotablator were used in 8 procedures (40%). Thirty-day follow-up was available for all patients, while 15 patients (75%) completed 1-year follow-up. During the follow-up period one patient that had presented with STEMI with cardiogenic shock died 24 hours post-procedure. The primary outcome was not met regarding the remaining patients.

Conclusions: In high-risk patients with significant LM disease deemed ineligible for CABG, PCI using current interventional strategies aiming to complete revascularisation seems to be a reasonable and safe option with acceptable short- and mid- term outcomes.

NSTEMI - Vascular access and bleeding, Stable CAD - Vascular access and bleeding

Percutaneous artErial closure devices and ultrasound-guided Trans-femoRal puncture ObservatioNal InvestigatiOn: insights from the PETRONIO registry

IANNOPOLLO Gianmarco [1], IANNOPOLLO Gianmarco [1], NOBILE Giampiero [1], CAPECCHI Alessandro [1], LANZILOTTI Valerio [1], BRUNO Matteo [1], RUBBOLI Andrea [1,2], CASELLA Gianni [1]

(1) Maggiore, Metropolitan City of Bologna, Italy; (2) Ospedale "Santa Maria delle Croci", Ravenna, Italy

Aims: Previous data have shown that ultrasound-guided femoral puncture (U) and the use of percutaneous arterial closure devices (P), taken individually, have reduced vascular access complications (VAC) in femoral arterial access compared to traditional techniques. The aim of this study was to compare the VAC of a single and combined use of U and P techniques with standard fluoroscopic guidance and manual compression.

Methods and results: the PETRONIO (Percutaneous artErial closure devices and ultrasound-guided Trans-femoRal puncture ObservatioNal InvestigatiOn) observational registry included all the femoral artery procedures performed between July 2017 and December 2018 divided into three phases: 1) between July-2017-January 2018 fluoroscopic guided femoral puncture and manual haemostasis were mainly performed; 2) between January 2018-June 2018 U and P with ProGlide techniques were introduced; 3) between June 2018 and December 2018 U and P were performed with the expertise acquired in the second phase. We identified different subgroups according to the presence (+)/absence (-) of U and P technique: U-/P- (reference group), U+,P+,U-P+, U+P-,U+P+. The primary endpoint was VAC at 30 days that included haematoma >3 cm, pseudoaneurysm, AV fistula and retroperitoneal bleeding. Results: 418 procedures (14%) out of 3,025 were performed via femoral arterial access. Vascular access complications (7.2%) occurred in 30 cases: 24 haematomas >3 cm (5.7%), 2 AV fistulas (0.5%), 2 pseudoaneurysms (0.5%) and 2 retroperitoneal bleeding (0.5%). The rate of complications was reduced progressively during the three study periods (I phase: n=16 [10.9%]; II phase: n=8 [5.8%]; III phase: n=2 [2.7%]; I vs II: p=0.11; I vs III: p=0.036). The reference group (U-/P-) complication rate was 12.2% (n=18). The introduction of the U and P technique both individually and combined reduced the rate of VAC compared to the reference group (group U+: n=8, 4.3%; p=0.008- group P+: n=9, 4.6%;p=0.010) (group U+/P-:n=4.4%;p=0.040) (group U-/P+: n=4, 4.8%;p=0.060) (group U+/P+: n=5, 4.5%; p=0.035).

Conclusions: In a high volume radial centre the introduction of the U and P techniques for femoral artery puncture and haemostasis has reduced the rate of VAC compared to the traditional techniques, with a trend of progressive improvement after the first 6 months of the learning period.

STEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Sirolimus-eluting, TyroCore Fantom BRS implantation in patients with STEMI: six-month outcomes – FANTOM STEMI pilot study

KOLTOWSKI Lukasz [(1)], KOLTOWSKI Lukasz [(1)], KOCHMAN Janusz [(1)], ANDERSON Jeffrey [(2)]

(1) Warszawskim Uniwersytetem Medycznym, Warsaw, Poland; (2) Reva Medical, CA, USA

Aims: This study is evaluating the safety and performance of the Fantom bioresorbable scaffold in the acute setting of myocardial infarction with unstable lesions and thrombogenic milieu. Fantom is manufactured from TyroCore, and is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogues. Fantom is completely radiopaque with thin struts (125 microns) in the 2nd generation device and as low as 95 micron struts in the 3rd generation Fantom Encore version. This presentation represents the first report on the 6-month results from the full STEMI study population.

Methods and results: Twenty STEMI patients were enrolled into a prospective, observational study utilising optical coherence tomography guided primary PCI with the sirolimus-eluting Fantom BRS implantation. The scaffold sizing, positioning and optimisation was performed based on OCT to achieve full lesion coverage, proper stent expansion (>80%) and strut apposition. Dual antiplatelet therapy was administered according to the current guidelines. Patient follow-up is ongoing through 36 months. Reported outcomes will include acute technical success, acute procedural success, and clinical procedural success. In addition, the incidences of major cardiac adverse events (MACE), scaffold thrombosis imaging outcomes through 6-months follow-up will be presented.

Conclusions: This is the first pilot study evaluating performance of second-generation Fantom BRS in STEMI patients undergoing primary PCI. Full conclusions will be completed after all data has been analysed.

Stents and scaffolds - Tools, devices and techniques

FANTOM I: pilot study of the Fantom sirolimus-eluting bioresorbable coronary scaffold. First report: five-year outcomes

KOLTOWSKI Lukasz [(1)], KOLTWOSKI Lukasz [(1)], KOCHMAN Janusz [(1)], ABIZAID Alexandre [(2)]

(1) Oddział Kardiologii Inwazyjnej, Warsaw, Poland; (2) Dante Pazzanese, State of São Paulo, Brazil

Aims: The primary objective of the FANTOM I pilot study was to evaluate the initial safety of a unique bioresorbable scaffold platform in native coronary arteries that includes incorporation a new scaffold material TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogues. Fantom is completely radiopaque and is comprised of thin struts (125 micron) that facilitate device delivery and precise target lesion treatment.

Methods and results: The FANTOM I pilot study is a prospective, multicentre trial which enrolled 7 patients with *de novo* coronary stenosis with reference vessel diameters between 2.7 to 3.3 mm in diameter and lesion lengths ≤14 mm. The primary endpoint of the study which was MACE through 6 months of follow-up was 0%. Through 4 years of follow-up only a single MACE event occurred in this study, which was a TLR at the 13-month timepoint. Clinical results through complete degradation of the scaffold at 5 years of follow-up will be presented at the conference. Acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol were 100% (7/7) in all cases. Angiographic follow-up was performed at 4 months (n=7) in all patients. The angiographic in-stent percent diameter stenosis at 4 months was 7.6±11.9%, and the in-stent late loss had a median value of 0.22 mm. The OCT analysis showed that at 4 months 99% of the struts had been covered by tissue.

Conclusions: The Fantom I pilot study has demonstrated favourable safety and effectiveness performance through 5 years of follow-up and complete scaffold degradation. This study was used as a basis to launch the FANTOM II trial in a larger patient population and continues to demonstrate the sustainability of the early safety results.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

ACS in the elderly; a clinical-epidemiological study

HUSSEIN Shady [1]

(1) Mansoura University, Mansoura, Egypt

Aims: We aimed to demonstrate the current status of the epidemiology and clinical profile of elderly patients, who suffer from acute coronary syndrome (ACS), and its impactions on the management and in hospital outcome.

Methods and results: A prospective study was conducted including 150 patients (age, 40–81 years) with ACS who were admitted at our hospital from January 2018 to June 2018. Patients were divided into two groups: A) elderly patients ≥65-years-old (test group, 100 patients) and B) patients <65-years-old (comparative group, 50 patients). All patients in both groups A and B were subjected to: I) Full history taking including demographic data, a detailed medical and cardiac history, II) Clinical examination including vital signs, signs of heart failure/ haemodynamic instability, Signs of comorbidities and local cardiac examination, III) Venous sampling for laboratory data including complete blood count, lipid profile, cardiac biomarkers, blood sugar profile and kidney function test, IV) Twelve lead surface ECG, V) Echocardiography and VI) Conventional coronary angiography, The two risk scores (RSs) (TIMI and GRACE) were calculated from the initial clinical history, electrocardiogram, and laboratory values collected and recorded on admission. Median follow-up duration was 6 (4–9) days. Results: TIMI and GRACE risk scores were significantly higher in "group A" (p-value: 0.003 and 0.001, respectively), whereas there was statistically significant positive correlation between TIMI score and severity of angina, systolic blood pressure, diastolic blood pressure, Killip classification, serum creatinine and GRACE score in group A (p-value <0.001). While a significant negative correlation was found between TIMI score and ejection fraction (p-value <0.023), Also there was statistically significant positive correlation between GRACE score and severity of angina, systolic blood pressure, diastolic blood pressure, Killip classification, neutrophils, lymphocytes, serum creatinine and TIMI score in group A (p-value <0.001). While a significant negative correlation was found between GRACE score and high-density lipoprotein and ejection fraction (p-value <0.001).

Conclusions: In conclusion, ACS risk score (GRACE, TIMI) is more predictive of high risk in ACS patients ≥65 years old, risk stratification should be done in all cases whatever the age and more in the elderly. Elderly patients should be evaluated and treated in the same way as young patients.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Infarct size and long-term clinical outcomes of prasugrel vs clopidogrel in patients with ACS undergoing coronary artery stenting: a prospective randomised study

YABE Takayuki [(1)], AIKAWA Hiroto [(1)], MATSUMOTO Shingo [(1)], NOIKE Ryota [(1)], OKUBO Ryo [(1)], AMANO Hideo [(1)], IKEDA Takanori [(1)]

(1) Toho University Medical Center Omori Hospital, Tokyo, Japan

Aims: The antiplatelet drug, prasugrel, can demonstrate inhibition of platelet aggregation early after oral administration. It has also been reported that there is an association between platelet aggregation and ischaemic events. In this study, we examined whether prasugrel is effective in inhibiting infarct size and can reduce the incidence of cardiovascular events in patients with acute coronary syndrome (ACS) undergoing coronary artery stenting.

Methods and results: This study was a single-centre, prospective randomised study. Of a total of 80 ACS patients who presented at our institution from July 2014 to September 2015, 76 ACS patients undergoing stenting and getting final achievement of TIMI flow grade 3 were assigned to aspirin plus prasugrel (prasugrel group; n=37) or aspirin plus clopidogrel (clopidogrel group; n=39) using the sealed envelope method. The primary endpoint was survival free of major adverse cardiovascular events (MACE), including cardiovascular death, non-fatal myocardial infarction, heart failure, and target vessel revascularisation. The secondary endpoint was the evaluation of the infarct size defined as the area under the curve (AUC) of troponin-I, calculated by the linear trapezoidal method. During a mean follow-up of 1262.4±599.6 days, 14 patients experienced MACE. There were no significant differences in patient or lesion characteristics, and the CYP2C19 genotype between 2 groups. Median level of maximal troponin-I was significantly lower in the prasugrel group than the clopidogrel group (prasugrel group 73.9±90.6 ng/ml vs clopidogrel group 130.1±151.8 ng/ml, p=0.05), and AUC of troponin-I up to 72 hours after intervention tended to be smaller in the prasugrel group (2073.3±2330.6 ng/ml vs 3417.8±4006.0 ng/ml, p=0.07). The cumulative incidence of MACE was significantly higher in the clopidogrel group (log-rank test; p=0.02).

Conclusions: As compared to clopidogrel, prasugrel was associated with a reduction in infarct size and long-term adverse outcomes in ACS patients undergoing stenting.

CTO - Tools, devices and techniques

Long-term results after recanalisation of coronary CTO

STELMASHOK Valeriy [1], STELMACHOK Valeriy [1], MROCHEK Alexander [1], POLONETSKY Oleg [1], STRYGO Nikolai [1]

(1) Republican Scientific and Practical Centre «Cardiology», Minsk, Belarus

Aims: To evaluate the long-term results after coronary artery chronic total occlusion recanalisation in a single centre study.

Methods and results: From 2009 to 2013 an attempted coronary artery chronic total occlusion (CTO) recanalisation by the antegrade approach was performed in 217 patients. In our analysis, we established two groups of patients: group 1 with successful CTO recanalisation – 158 patients and group 2 with unsuccessful attempt - 59 patients. Recanalisation rate was 72.8%. Groups 1 and 2 did not differ in terms of demographic and clinical data. Over the longer term period, we evaluated such endpoints as death (all-cases mortality and cardiac mortality), the necessity for repeated revascularisation in target lesion zone, as well as the combined endpoint: any cases of death + acute myocardial infarction + necessity for target lesion repeated revascularisation. The average follow-up period after recanalisation/attempted of CTO recanalisation was 82.6 months (interquartile range: 74.0-101.0 months). Maximal observational period for both groups was 120 months (10 years). All-cases mortality was registered in 10.1% patients after successful CTO recanalisation (group 1) and 18.6% after failed procedure (group 2). At the end of observation period, prognostic cumulative proportion of survivors in group 1 was 83.0±5.1%, in group 2 it was 64.8±9.3% ($p>0.05$). Cardiac mortality occurred in 5.1% of patients in group 1 and 16.9% of individuals in group 2, prognostic cumulative proportion of survivors in group 1 was 87.5±5.1%, in group 2 - 67.4±9.4% respectively ($p<0.01$). There was significantly lower rate of cardiac mortality in group with successful CTO recanalisation (Breslow test: $\chi2=7.092$, $p=0.008$; log-rank test: $\chi2=9.054$, $p=0.003$; Taron-Ware test: $\chi2=8.136$, $p=0.004$).The necessity for repeated revascularisation due to target lesion failure was 24.7% in group 1 and 55.9% in group 2, prognostic cumulative proportion of patients without these outcomes was 67.9±5.8% in group 1 and 26.6±8.9% in group 2 ($p<0.001$). The achievement of the combined endpoint was recorded in 34.2% of patients in group 1 and 71.2% in group 2, prognostic cumulative proportion of people without these events at the end of observational period was 56.4±5.9% in group 1 and 15.6±6.4% in group 2 respectively ($p<0.001$).

Conclusions: The obtained data revealed statistically higher cardiac mortality rates in the long term after unsuccessful coronary CTO revascularisation ($p<0.01$). Cumulative endpoints of all death cases, acute myocardial infarctions and the necessity of revascularisation due to target lesion failure also was statistically higher in the group with unsuccessful CTO recanalisation attempts ($p<0.001$). Unsuccessful coronary CTO recanalisation is a strong negative predictor in terms of survival and clinical outcomes for patients with coronary CTO.

NSTEMI - Tools, devices and techniques

Credibility of risk scores in predicting coronary artery disease severity in NSTE-ACS patients

HUSSEIN Shady [1]

(1) Mansoura University, Mansoura, Egypt

Aims: We aimed to assess the value of Global Registry of Acute Coronary Events (GRACE) and Thrombolysis in Myocardial Infarction (TIMI) risk scores (RSs) for predicting coronary artery disease (CAD) severity and prognosis in patients with non-ST segment elevation acute coronary syndrome (NSTE-ACS).

Methods and results: A prospective study was conducted including 100 patients (age, 45–68 years) with NSTE-ACS who were admitted at our hospital from January 2018 to January 2019. The two RSs (TIMI& GRACE) were calculated from the initial clinical history, electrocardiogram, and laboratory values collected and recorded on admission. All patients were subjected to conventional coronary angiography during admission, Patients were divided into two groups: 1) patients with SYNTAX score ≤ 32 (comparative group, 80 patients) and 2) patients with SYNTAX score > 32 (test group, 20 patients). Median follow-up duration was 6 (4–9) days. Results: Regarding correlation between coronary angiographic severity based on SYNTAX score and the clinical profile based on the two RSs (TIMI&GRACE) in NSTE-ACS patients, statistically significant correlation were found between GRACE score and SYNTAX score ($r = 0.789$; $p=0.001$) with GRACE score accuracy: 94% and negative predictive value (NPV): 98.7%, whereas no statistically significant correlation were found between TIMI score and SYNTAX score ($r = 0.087$; $p=0.388$) with TIMI score accuracy: 32% and NPV: 73.1%.

Conclusions: In conclusion, the GRACE score provides a quick and reliable prediction of CAD severity in NSTE-ACS patients, It allows accurate risk estimation, categorises patients and consequently can help in making accurate therapeutic decisions either with the use of invasive strategies in high risk selected patients or the use of conservative strategies in low risk patients in presence of limited resources.

STEMI - Invasive imaging and functional assessment

A comparison between the ADDED index and the visually-estimated diameter of residual coronary artery stenosis to predict long-term clinical outcome in STEMI patients with multivessel disease

DI SERAFINO Luigi [(1)], DI SERAFINO Luigi [(1)], MAGLIULO Fabio [(1)], CIRILLO Plinio [(1)], BARBATO Emanuele [(1)], ESPOSITO Mafalda [(1)], FRANZONE Anna [(1)], PICCOLO Raffaele [(1)], MORISCO Carmine [(1)], ESPOSITO Giovanni [(1)]

(1) University of Naples Federico II, Metropolitan City of Naples, Italy

Aims: We compared the prognostic value of the ADDED index with visually estimated percentage diameter stenosis (DS) of residual coronary artery stenosis (RS) in STEMI patients after successful PCI of the culprit stenosis.

Methods and results: We retrospectively included 596 patients grouped on the basis of either the ADDED index value (ADDED negative [< 2.23, n=153] vs ADDED positive [≥ 2.23, n=129]) or the DS of the RS (RS negative [< 50%, n=177] vs RS positive [≥ 50%, n=105]). Patients without any RS served as control (n=314). Primary endpoints were: 1) major adverse cardiac events (MACE), composite of all-cause death, non-fatal myocardial infarction (MI), clinically driven revascularisations (CDR); 2) non-culprit vessel oriented clinical events (VOCE), composite of all-cause death, deferred non-culprit vessel related MI and deferred non-culprit vessel related CDR. At 24 months the rate of both MACE and VOCE was significantly higher in both the ADDED positive and RS positive groups. However, patients' clinical outcome was comparable between the ADDED negative and control groups.

Conclusions: In STEMI patients with MVD, after PCI of the culprit stenosis, deferring treatment of RS on the basis of the ADDED index, rather than the DS, is associated with a favourable clinical outcome.

Stable CAD - Vascular access and bleeding

The effect of left distal transradial access on compression times post-angiography

COUGHLAN JJ [(1)], KIERNAN Thomas [(1)], ARNOUS Samer [(1)], ZEBRAUSKAITE Aiste [(1)]

(1) Limerick Regional Hospital, County Limerick, Ireland

Aims: In 2017, Kiemeneij published a paper on distal transradial artery access for coronary angiography in 62 patients. This paper proposed several advantages to this method. In this study, we performed a nonrandomised control study of left distal transradial access in patients undergoing coronary angiography in our centre.

Methods and results: We prospectively identified patients presenting for coronary angiography to our centre for enrolment in this study. We recruited 94 patients (47 ldTRA, 47 age and sex matched controls). Pre-defined endpoints for the study were as follows: Time until radial compression device (RCD) removal, procedural time, radiation dose, fluoroscopy time and contrast dose. For our primary endpoint, we estimated a mean time until RCD removal of 240 minutes in the control group and 180 minutes in the left distal radial access group. This estimate was based on an audit of our pre-existing RCD removal protocol times and the mean time until RCD removal in the Kiemeneij paper. In order to provide power of 95% to detect a difference of this magnitude (60 mins) between the groups at a significance level of 0.05, we determined that we would need to recruit 64 patients in a 1:1 ratio (32 distal radial access cases and 32 controls). Analysis was performed using SPSS. Categorical variables were compared across both groups using Fischer's exact test or the Chi-Square test where appropriate. We calculated the means (±SD) for continuous variables in each of the two groups and compared them using Student's t-test or Wilcoxon Rank test where appropriate. A p value of < 0.05 was considered statistically significant. We recruited 94 patients (47 ldTRA, 47 age and sex matched controls). The majority of patients in both groups were male (83% vs 79.2%, p=0.31). The mean age did not differ between groups (61±10.17 vs 61.8±10.9 years, p=0.71). The most common indication for angiography in both cohorts was stable angina (91% vs 85%, p=0.33). The majority of diagnostic angiograms were performed with 5 Fr sheaths as per our normal practice (89.4% vs 82.9%, p=0.37). Patient and procedural characteristics are detailed in Table 1 below and did not differ significantly between the two groups. Successful left distal radial access was obtained in 100% of patients enrolled in our study group. Similarly, successful access was obtained in 100% of patients in our control conventional radial access group. We attribute our high success rate with left distal radial access to stringently ensuring patients had an easily palpable artery in the snuffbox prior to enrolment in the study. With regard to our primary endpoint, patients undergoing ldTRA required, on average, 69 minutes less time until removal of the RCD (167.8±30 mins vs 236.6±63.9 mins, p<0.0001). Procedural length did not vary between groups (28.95±5.89 mins vs 29.76±8.16 mins, p=0.5824). Similarly, there was no statistically significant difference in radiation dose area product (5032.66±2740Gy/cm^2 vs 4826±2796Gy/cm^2, p=0.7191), contrast dose (82.93±23 mls vs 92.1±33 mls, p=0.1215). and fluoroscopy time between the two groups (5.41±3.42 mins vs 4.82±2.97 mins, p=0.3742).

Conclusions: Our study confirms that ldTRA is a feasible technique for diagnostic coronary angiography in a modern cardiac catheterisation laboratory. It results in decreased post-procedure radial artery compression time without increasing procedural time or radiation dose.

STEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

DCB use in the real-world setting of a single large tertiary centre

THIRUNAVUKARASU Sharmaine [1], THIRUNAVUKARASU Sharmaine [1], TIONG Denise [2], CONTRACTOR Hussain [1]

(1) Wythenshawe Hospital, Manchester, United Kingdom; (2) Manchester Royal Infirmary, Manchester, United Kingdom

Aims: Drug-coated balloons (DCBs) have rapidly entered into clinical practice as an adjunctive device in PCI, often being utilised in situations beyond their recognised licensed indications. Recently, safety concerns have been raised in peripheral arterial disease with a single study suggesting increased mortality with paclitaxel-coated balloons and its use in coronary disease is now under scrutiny. Here, we assess the use of DCBs in a real-world setting of a single large tertiary centre providing services for more than 3 million patients and describe their indications for use, efficacy and safety.

Methods and results: Prospectively gathered data on all PCIs between January 2018 to November 2019 was analysed including demographic characteristics, procedural and clinical outcome data. 317 patients were included in the final analysis. Mean age was 63±0.7 years, 74% male, 70% hypertensive, 58% hyperlipidaemic, 36% diabetic and 30% current smokers. 4% had previous cerebrovascular events, 20% of patients had CKD III-V. and 17% were anaemic. 68% of patients were being treated for ACS (26% STEMI, 42% NSTEMI/unstable angina) and 32% with stable angina. Paclitaxel DCB (Inpact Falcon 28% and SeQuent Please 65%) was used in 297 patients and sirolimus-DCB in 20 patients (Magic Touch 7%). 66% of patients had *de novo* lesions of which a DCB was deployed. Mean DCB diameter was 2.8 mm and mean DCB length was 23 mm with 45% of DCBs deployed in vessels of 2.5 mm diameter or less. There were no flow compromising dissections requiring bailout DES, and no other significant periprocedural complications following DCB. At 12-month follow-up there were no emergency re-admissions for non-fatal MI, or non-urgent revascularisation for TLR or TLF. All cause mortality at 1 year was 2% which is comparable to current published data with DES.

Conclusions: Our real-world study demonstrates DCB as a safe and effective treatment option for a broad range of patient groups in a variety of settings including STEMIs, NSTEMIs, and stable angina with extensive utilisation in *de novo* lesions as well as ISR. Both periprocedurally and at 12-month follow-up, DCB demonstrated stent-like outcomes in both safety and efficacy.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Endovascular implant malapposition persists in diffuse hard lesions but not in pristine coronary arteries

TZAFRIRI Rami [1], RIKHTEGAR Farhad [2], ATHANASIOU Lambros S. [3], O'BRIEN Caroline [2], BAILEY Lynn [1], MA Elaine [2], LOPES Augusto C. [4], TZAFRIRI Rami [1], EDELMAN Elazer R. [2,3]

(1) CBSET, Inc, MA, USA; (2) M.I.T, MA, USA; (3) Brigham and Women's Hospital, MA, USA; (4) Interventional cardiology centre, Monte Klinikum Hospital, Fortaleza, Brazil

Aims: Stents are placed in complex environments, where strut malapposition is observed acutely in 80% of cases, and persists frequently (30% of cases), with a higher rate of late stent malapposition for drug-eluting stents. While usually subclinical, when the malapposition manifests clinical events are often catastrophic. The present study developed an innovative animal model with controlled lesion stiffness and acute stent malapposition to investigate the determinants of persistent malapposition.

Methods and results: Animal experiments were performed at an AAALAC-accredited, GLP-adherent laboratory (CBSET Inc., Lexington, MA). We created hard lesions by placing well-apposed metal stents 28 days prior to intervention in 4 healthy Yorkshire Swine (35-45 kg). 7 vessels in these 4 animals (1.75±0.95 stented vessels/animals) were re-stented, including 3 fully apposed, and 4 malapposed stents with programmed under-expansion to induce strut malapposition. This controlled and reproducible acute strut malapposition was achieved using specially modified hour-glass shaped balloons to inflate stents *in situ*. In a parallel arm, 5 healthy animals were considered as a control, wherein 5 malapposed and 3 apposed stents were implanted in 8 arteries (1.60±0.55 stented vessels/animals). Angiographic imaging and optical coherence tomography (OCT) were conducted at baseline as well as 5 and 28 days after stent implantation. Strut malapposition of 40 % and 31 % post-implantation were confirmed in diseased and pristine arteries by OCT. Images were recorded both at baseline and follow-ups, and post processed to extract geometrical features and assess the apposition level (e.g. the reference lumen cross-sectional area, maximum, minimum and mean values of stent cross-sectional area, wall distance, and number of malapposed struts, among others). OCT frames were also fused with angiographic images to produce realistic three-dimensional models of stented arteries. This validated approach was not only applied to measure multiple architectural parameters, but also utilised for computational haemodynamics to highlight the effect of compensatory/persistent vascular response on blood flow patterns. Endovascular imaging at follow-up confirmed elastic recoil of pristine arteries obliterating malapposition in acute and long-term follow-up, but no such effect in vessels with pre-existing disease even a month after implantation. Malapposition was only retained in vessels with pre-existing disease, highlighting the limitations of using naïve animal models to represent clinical scenarios.

Conclusions: Insight into the determinants of persistent malapposition has been hampered by the complexity of the various factors (flow, recoil, intimal hyperplasia etc.) involved in luminal obstruction of human atherosclerosed vessels, but not in healthy animals. The current data illustrate that the compensatory elastic response of the treated artery is the key determinant of persistence, and that its disruption by mechanical means results in a disease-like human response. These findings may explain the historical discrepancies between preclinical experiments and clinical trial outcomes, while providing a more predictive animal model.

Stable CAD - Tools, devices and techniques

Same day discharge after coronary angioplasty in a low-income sub-Saharan country

MBOUP Mouhamed Cherif [1], MBOUP Mouhamed [1]

(1) Hopital Principal de Dakar, Dakar, SENEGAL

Aims: Coronary angioplasty is little practiced in sub-Saharan Africa in general and Senegal in particular. The objective of this work is to describe the indications, techniques, results of ambulatory coronary angioplasty in Senegal.

Methods and results: We prospectively included all patients who underwent coronary angioplasty between July 2019 and December 2019. We evaluated the clinicals characteristics, technical, and periprocedural complications and follow-up. Forty-three coronary angioplasties were performed at the haemodynamic unit of the principal hospital in Dakar. The average age of patients was 60.41 + 10.93 years. A male predominance was noted with a sex ratio of 2.3. Hypertension was found in 57% of patients. The indications of coronary angioplasty procedures were exclusively the management of coronary chronic syndrome in all patients. We performed our procedures by the transradial artery in all patients. The lesions treated were type A / B1 or B2 in 30 and 13 cases, respectively. The success rates of coronary angioplasties and 30-day mortality were 100% and 0.0% respectively.

Conclusions: In sub-Saharan Africa and especially in Senegal, activity of coronary angioplasty is low. Nerveless, same day discharge after coronary angioplasty is feasible in a low-income sub-Saharan country with high success rate and no complications.

Left main and multivessel disease - Tools, devices and techniques

Outcome of left main PCI in a single-centre registry

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Detection of left main coronary artery (LMCA) stenosis during coronary angiography or within the 1st few hours thereafter is a high risk for adverse cardiac events. As immediate management is crucial for this patient, left main percutaneous coronary intervention (PCI) has become an attractive option for interventional cardiologists. The aim of this study was to assess outcome of left main PCI.

Methods and results: Method: This prospective observational study was carried out from 2007 to October-2019 in our hospital. A total of 2,038 patients who underwent left main PCI during this period were included in the study. They were studied for clinical characteristics and angiographic profile, procedural characteristics, management strategy and outcome. Results: Mean age of the patients was 56.29±11.4 years (range 24-95 years). Most patients were male (79.1%), female were 20.9%. Hypertension (74.8%) was the most common risk factor followed by dyslipidaemia (69.2%), diabetes mellitus (51.3%) and smoking (48.5%). Patients with chronic coronary syndrome were 65.7% and 34.3% patients were with acute coronary syndrome. Good left ventricular systolic function was present in 63.4% patients and 21.6% patients had mild, 13.4% patients moderate and 1.6% patients had severe left ventricular systolic dysfunction. Isolated LM disease was in 21.4% patients, LM with single vessel disease in 26.4% patients, LM with double vessel disease in 33.7% patients and LM with triple vessel disease in 18.5% patients. Right dominant circulation was 84.3%, left dominant circulation was 15.3% and co-dominant circulation was 0.4%. Most patients had unprotected left main disease (92%). Distal left main disease was present in 78% patients, ostial left main in 19% patients and shaft involvement in 3% patients. In distal left main disease, 75.6% patients were treated by single stent strategy and 24.4% patients were treated by double stent strategy. The T and protrusion (TAP) technique was used in 44.85% patients, Culotte technique in 28.1%, DK (double kissing) crush technique in 13.65% and mini crush technique in 13.4% patients, in cases of double stent strategy. Mean duration of follow-up was 42.28±34.67 months. Symptom driven check CAG (coronary angiogram) was done in 164 patients and in-stent restenosis was 12% cases. Long-term mortality was 7.8% (in-hospital death 0.76% and follow-up death 7.04% due to cardiac and non-cardiac causes).

Conclusions: Left main PCI is an alternative to CABG in appropriately selected patients with favourable anatomy and/or high surgical risk.

Euro2OA-POS515
Posters

Stents and scaffolds - Tools, devices and techniques

Safety and clinical performance of biodegradable polymer-coated sirolimus-eluting coronary stent in real-world patients

JARIWALA Pankaj [(1)], JARIWALA Pankaj [(1)], REDDY Rohith [(1)], A. GURU Prakash [(1)], JADHAV Kartik [(1)], KULKARNI Anil [(1)], KADIYALA Sriramulu [(1)], MADIREDDY Jagadesh [(1)], KUCHULAKANTI Pramod Kumar [(1)], RAJU Narasa [(1)]

(1) Yashoda Hospitals - Somajiguda, Telangana, India

Aims: To evaluate the safety and clinical performance of the sirolimus-eluting coronary stent system in real-world patients with coronary artery disease in a one-year follow-up.

Methods and results: This was an observational, single-centre, post-marketing and retrospective study. All real-world patients who had received sirolimus-eluting coronary stent between January 2016 and February 2017 at our centre were analysed. Patients treated with at least one sirolimus-eluting coronary stent for native coronary artery lesions were included in the study. The endpoint of the study was the rate of major adverse cardiac events, which includes cardiac death, myocardial ischaemia, and target lesion revascularisation at a one-year follow-up. Among 141 patients, the mean patient age was 54.01±12.69 years, and 105 (74.5%) were male. The comorbidities, i.e., hypertension and diabetes mellitus, were presented in 80 (56.7%) and 57 (40.4%) patients, respectively. A total of 187 lesions were treated with sirolimus-eluting coronary stent. The average stent length and diameter were 24.75±9.50 mm and 2.93±0.38 mm, respectively. At a one-year follow-up, the cumulative incidence of major adverse cardiac events was 2 (1.42%) attributed by two cardiac deaths and no incidence of stent thrombosis.

Conclusions: The present study suggests that the sirolimus-eluting coronary stent shown favourable safety and performance in real-world patients, indicating a low rate of major adverse cardiac events and the absence of stent thrombosis at a one-year clinical follow-up.

Euro2OA-POS518
Posters

Stents and scaffolds - CT / MRI imaging

Longitudinal stent deformation detected on coronary CT in the novel BioMime 60 mm long sirolimus-eluting tapered stent

HOMS Silvia [1], HOMS Silvia [1], FERNANDEZ-LOPEZ Leticia [1], TOLEDANO Beatriz [1], CALABUIG Alvaro [1], MUÑOZ Juan Francisco [1], PADILLA Ferran [1]

(1) Mútua Terrassa University Hospital, Terrassa, Spain

Aims: The BioMimeTM Morph 60 mm-long sirolimus-eluting stent (SES) has been commercialised as an interesting tool for patients with long coronary lesions. However, the complexity of the procedures, the lesions characteristics, and the modern stent design, submitted the BioMime Morph to a high risk of longitudinal stent deformation (LSD).

Methods and results: This is a prospective single-centre study with the aim to analyse the LSD of the stent BioMime Morph by multislice computed tomography (MSCT). Inclusion criteria: long lesions (> 48 mm) treated with BioMime Morph as well as follow-up with MSCT after 6-9 month. LSD was defined as uneven stent distortion or shortening in the longitudinal axis assessed by MSCT. Primary endpoint was the ratio stent length by MSCT divided by nominal stent length (60 mm). Secondary endpoint was the relative deformation. In order to define the extent of individual variation, the longitudinal deformation was examined by two experts. From July 2018 to November 2019, twenty patients were included. The post-dilation was the procedural-related factor with major degree of stent stretching deformation (median [IQR] ratio MSCT stent length / nominal stent length in the non-post-dilation group, 1.013 [1.011-1.038]; median [IQR] ratio MSCT stent length / nominal stent length in the post-dilation group 1,041 [1.021-1.050]). Any case of stent shortening was identified.

Conclusions: In conclusion, the SES BioMime Morph 60 mm-long shows a promising profile as an option for the treatment of long and complex lesions.

NSTEMI - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

The impact of bifurcation lesions in infarct-related arteries of NSTEMI patients: two-year outcomes

BOUKERCHE Farouk [1]

(1) CHU d'Oran, Oran, Algeria

Aims: The aim of this study was to determine the prognostic impact of bifurcation lesions on two-year outcomes in a prospective cohort of NSTEMI patients. Bifurcation lesions (BFLs) remain a challenging lesion subset, often associated with lower success rates than less complex lesions. There are few data regarding the impact of BFLs in the setting of NSTEMI.

Methods and results: Patients admitted for NSTEMI and indication for coronary angiography were prospectively evaluated. Patients were divided into 2 groups according to whether infarct-related-artery lesions were vs were not a bifurcation lesion. Major outcomes were assessed at 2 years. A total of 296 patients were evaluated: mean age was 62±12 years and 58% were male. The two-year mortality was 8.4% (25 patients) and the two-year MACCE was 19.9% (59 patients). The bifurcation lesion group included 62 patients (20.9%). The two-year mortality and MACCE in the patients of the bifurcation lesion group was significantly higher (14.5% vs 6.8%; p=0.05) and (33.9% vs 16.2%; p=0.02) respectively.

Conclusions: In NSTEMI, bifurcation lesions portend worse prognosis. This may guide prognostication and decision making in treatment.

Stable CAD - Invasive imaging and functional assessment, Stents and scaffolds - Invasive imaging and functional assessment

Interpreting intracoronary imaging: insights from eye tracking

SIBBALD Matthew [(1)], SIBBALD Matt [(1)], PINILLA Natalia [(1)], SHETH Tej [(1)]

(1) McMaster University, ON, Canada

Aims: Interpreting intracoronary imaging is a complex task that requires the user to evaluate multiple data inputs. The aim of this study was to compare eye-tracking patterns of novice optical coherence tomography (OCT) users with experienced users to understand how each group approaches the task's complexity.

Methods and results: Static OCT images were prepared for each of three tasks: interpreting ambiguous lesions, planning intervention and assessing stent results. Key areas within the standard OCT image presentation template were pre-specified for each task: longitudinal view, cross sectional view and co-registered angiographic view. For the tasks of planning intervention and assessing stent results two addition areas were specified: automated measurements and lumen profile. The time to eye fixation on key areas and total interpretation time was compared between novice and experts using ANOVA testing. Graphical representations of eye fixations and histograms of eye movements in and out of key information areas were qualitatively analysed. Six readers (three novice and three expert) reviewed 24 static OCT images resulting a total of 144 evaluations with concurrent eye tracking. Novice interpretation time was substantially greater than experts (34 vs 16 for interpreting ambiguous lesions, 29 vs 12 for planning intervention, and 54 vs 18 seconds for assessing stents results, all $p<0.001$). With ambiguous lesions, novices' time to first eye fixation in the longitudinal view was longer than experts (6.0 vs 3.2 seconds $p=0.006$), whereas time to first fixation within the co-registered angiographic view was shorter (1.2 vs 3.3 $p=0.04$). With planning intervention, there were no significant differences between novices and experts in time to first fixation into key areas. When assessing stent results, novices' time to first fixation within the longitudinal view and automated measurements were slower (7.6 vs 1.0 and 21.8 vs 2.1 seconds respectively, both $p<0.01$), but faster than experts in viewing the angiographic representation (1.3 vs 10 $p=0.006$). Qualitative review of eye tracking patterns revealed evidence of both top-down and bottom-up visual processing

Conclusions: Systematic differences in viewing patterns are present between experienced and novice OCT users, with novice spending substantial time on areas of the OCT presentation template with low information content. Focusing novice users attention on task relevant areas holds promise for improving speed of intracoronary imaging interpretation.

NSTEMI - Tools, devices and techniques, CTO - Tools, devices and techniques

Prognostic impact of CTO lesions in non-infarct-related arteries of NSTEMI patients: two-year outcomes

BOUKERCHE Farouk [1]

(1) CHU d'Oran, Oran, Algeria

Aims: The aim of this study was to determine the prognostic impact of chronic total occlusion (CTO) on two-year outcomes in a prospective cohort of NSTEMI patients. CTO is present in many patients with NSTEMI and is difficult to treat with percutaneous coronary interventions.

Methods and results: Patients admitted for NSTEMI and with an indication for coronary angiography were prospectively evaluated. Patients were divided into 2 groups according to whether CTO lesions were present or not. Major outcomes were assessed at 2 years. A total of 296 patients were evaluated: mean age was 62±12 years and 58% were male. The two-year mortality was 8.4% (25 patients) and the two-year MACCE was 19.9% (59 patients). The CTO group included 18 patients (6.1%).The two-year mortality and MACCE in the patients of CTO group was significantly higher (22.2% vs 7.6%; p=0.05) and (44.4% vs 18.3%; p=0.02), respectively.

Conclusions: In this prospective observational study of patients with NSTEMI, CTO was associated with a worse two-year outcome.

NSTEMI - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Prognostic impact of calcified infarct-related arterial lesions in NSTEMI patients: two-year outcomes

BOUKERCHE Farouk [1]

(1) CHU d'Oran, Oran, Algeria

Aims: Little is known about the impact of coronary calcification on outcomes in patients presenting in the setting of acute coronary syndromes.

Methods and results: Patients admitted for NSTEMI with an indication for coronary angiography were prospectively evaluated. Patients were divided into 2 groups according to whether infarct-related-arterial lesions were or were not moderately/severely calcified. Major outcomes were assessed at 2 years. A total of 296 patients were evaluated: mean age was 62±12 years and 58% were male. The two-year mortality was 8.4% (25 patients) and the two-year MACCE was 19.9% (59 patients). The calcified group included 125 patients (42.2%). The two-year mortality and MACCE in the patients of calcified group was significantly higher (15.2% vs 3.5%; p<10-3) and (32.0% vs 13.5%; p=0.001), respectively.

Conclusions: In patients with NSTEMI, the calcified infarct-related-arterial lesion is a characteristic which is strongly predictive of worst outcome. Novel approaches are needed to improve the prognosis in this high–risk lesion subset.

NSTEMI - Adjunctive pharmacotherapy, Stable CAD - Adjunctive pharmacotherapy

Very short vs long DAPT after second-generation DES in 35,785 patients undergoing PCI: a meta-analysis of randomised controlled trials

BENENATI Stefano [1], BENENATI Stefano [1], GALLI Mattia [3], DE MARZO Vincenzo [1], PESCETELLI Fabio [1], ANDREOTTI Felicita [3,4], CANEPA Marco [1,2], AMERI Pietro [1,2], CREA Filippo [3,4], PORTO Italo [1,2]

(1) IRCCS Ospedale Policlinico San Martino, Genoa, Italy, Metropolitan City of Genoa, Italy; (2) University of Genoa, Metropolitan City of Genoa, Italy; (3) Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico A. Gemelli IRCCS, Rome, Italy, Metropolitan City of Rome, Italy; (4) Catholic University of the Sacred Heart, Metropolitan City of Rome, Italy

Aims: To provide an updated assessment of the efficacy-safety profile of very short (1 or 3 months) dual antiplatelet therapy (DAPT) compared to long (12 months) DAPT in patients undergoing percutaneous coronary interventions (PCI).

Methods and results: Seven randomised controlled trials (RCTs) comparing very short versus long DAPT in 35,785 patients undergoing PCI were selected. The primary efficacy endpoint was major adverse cardiovascular events (MACE) and the primary safety endpoint trial-defined major bleeding through at least 1 year. Compared to longer duration, very short DAPT yielded comparable rates of MACE (OR - odds ratio - 0.93, 95% CI: - confidence interval - 0.84-1.03, p=0.19), all-cause mortality (OR 0.92, 95% CI: 0.80-1.06, p=0.25), myocardial infarction (OR 1.01, 95% CI: 0.88-1.15, p=0.91), stroke (OR 1.04, 95% CI: 0.72-1.50, p=0.83), stent thrombosis (OR 1.05, 95% CI: 0.80-1.37, p=0.73) and target vessel revascularisation (OR 0.99, 95% CI: 0.82-1.18, p=0.89), and comparable net clinical benefit (OR 0.92, 95% CI: 0.84-1.01, p=0.08). Very short DAPT was associated with reduced rates of major bleeding (OR 0.61, 95% CI: 0.40-0.94, p=0.03) or any bleeding (OR 0.65, 95% CI: 0.47-0.90, p=0.009). Subgroup analyses showed consistent results for 1 versus 3-month DAPT and for aspirin versus $P2Y_{12}$ inhibitor monotherapy following very short DAPT.

Conclusions: Compared to long DAPT, very short DAPT did not increase the odds of ischaemic complications, while reducing the odds of major or any bleeding by over 30%.

Stents and scaffolds - Tools, devices and techniques

Comparison of long-term clinical outcomes of polyurethane-covered cobalt-chromium stents in coronary perforations or aneurysms

JURADO Alfonso [8,9], JURADO Alfonso [8,9], AMAT Ignacio [1], GARCÍA TUCHARD Arturo [2], FERNANDEZ CISNAL Agustin [3], SUBINAS Asier [4], NUÑEZ Ivan [5], BAYON Jeremias [6], GARCÍA TEJADA Julio [7], MORENO Raul [8], LOPEZ SENDON Jose Luis [8]

(1) Hospital Clinico Valladolid, Valladolid, Spain; (2) Hospital Puerta de Hierro-Majadahonda, Majadahonda, Spain; (3) Hospital clínico de valencia, València, Spain; (4) Hospital Universitario de Galdakao, Galdakao, Spain; (5) Hospital Clínico San Carlos, Madrid, Spain; (6) Hospital Lucus Augusti, Lugo, Spain; (7) University Hospital 12 de Octubre, Madrid, Spain; (8) University Hospital La Paz, Madrid, Spain; (9) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: The main indication of covered stents (CS) is coronary perforation (P), however, their use has been increasingly extended to seal coronary aneurysms (CA). The results of CS have been worse than those with DES. However, these outcomes have not been analysed regarding the indication for CS implantation and may not be extrapolated to the latest-generation polyurethane-covered cobalt-chromium stents with only one metal layer. Aim: to compare the long-term results of these CS implanted in P or CA.

Methods and results: A national multicentre retrospective registry was performed with polyurethane CS implanted in 15 centres. 109 stents were implanted in 91 patients (68.3±14 years; 83.5% male), 72 in P and 37 in CA. The clinical presentation was stable coronary disease in 29%, NSTEMI in 44% and STEMI in 27%. The number of CS per patient were 1.2±0.5 (1-3) with a mean diameter of 3.3±0.7 mm and a mean length of 18.3±3.6 mm. They were implanted over a previous stent in 48.4% and overlapped with another stent in 49.5%. Angiographic success (stenosis <20%, TIMI 3) was achieved in 98.3% of cases. There were only two complications secondary to stent implantation: an occlusion of an atrial branch and an acute thrombosis. Intracoronary imaging techniques were used during stent implantation in 23% of patients. There were differences between the two groups in terms of the most frequent treated vessel (P: LAD vs CA: RCA; p=0.011), with a higher frequency of stent overlap in the group of CA (P: 41% vs CA: 62.1%; p=0.046). The CS had a larger diameter and length in the CA group (P: 3.1±0.6 mm vs CA: 3.6±0.9 mm; p=0.003) and (17.6±2.9 mm vs 19.6±4.4 mm; p=0.016) respectively. Intracoronary imaging techniques were more frequently used in CA group (P: 5.3% vs CA: 43.2%; p<0.0001). Angiographic follow-up was more frequent in patients with CA (P: 12% vs CA: 29.4%; p=0.039). There were 8 cardiac deaths, of which 6 were during the procedure or hospitalisation secondary to coronary perforations that could not be resolved. There were 3 stent thrombosis (ST), one acute, one at 11 months of the implant and another 2 years later. There were 6 myocardial infarctions related to the treated lesion, 3 periprocedural and 3 in the follow-up. There were 5 patients who underwent target lesion revascularisation (TLR), 2 for ST and another 3 for restenosis. The 3 cases of ST were in patients with CA, admitted for ACS. None of these patients received prasugrel or ticagrelor. Intracoronary imaging techniques were not used in any of these cases. The mean follow-up of patients who were discharged was 22.4±15.8 months [median: 21.1 (0.2-70.4) months)]. At the end of follow-up there were no significant differences between both groups in the rate of major cardiovascular adverse events (MACE) (cardiac death, ST or TLR): P: 7.7% vs CA: 6.7%; p=0.86. There were also no significant differences in the rate of cardiac death: (P: 4.4% vs CA: 0%; p=0.23), or TLR (P: 4.1% vs CA: 9.7%; p=0.32). There was a tendency for a higher ST rate in the CA group (P: 0% vs CA: 9.6%; p=0.079).

Conclusions: After hospital discharge, long-term clinical outcomes of polyurethane-covered cobalt-chromium stents with a single metal layer were favourable with similar MACE rate in CA and P. However, there was a tendency to a higher rate of ST in the CA group, probably due to the haemodynamic characteristics of these vessels. This fact, suggests the need to be more careful in the implantation and follow-up when CS are used in CA.

Left main and multivessel disease - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Rotational atherectomy and coronary aneurysms: a safe tool or interventional madness? Results from a multicentre case series

BARBIERI Lucia [1], BARBIERI Lucia [1], TUMMINELLO Gabriele [1,2], LUCREZIOTTI Stefano [1], RAMETTA Francesco [2], CARUGO Stefano [1]

(1) ASST Santi Paolo e Carlo, Metropolitan City of Milan, Italy; (2) Ospedale S. Andrea di Vercelli, Province of Vercelli, Italy

Aims: Several techniques in the last decades have been developed to facilitate PCI in the setting of heavily calcified coronary lesions (CCL) and one of the most diffused and effective is rotational atherectomy (RA). Coronary aneurysms (CA) are detected in 1.2-4.9% of patients undergoing coronary angiography. The co-presence of CA and CCL is an infrequent but not rare condition where the use of RA may be mandatory but at very high risk of complications. The aim of the present study was to evaluate efficacy and safety of RA in patients presenting CA and severe CCL.

Methods and results: We performed a multicentre retrospective analysis of patients treated with RA from January 2015 to January 2018. From a total of 174 procedures we identified 6 patients (3.4%) with concomitant CA involving the target lesion. All demographic, clinical and procedural characteristics were collected in a dedicated database protected by password. Long-term follow-up and data collection about serious adverse events such as all-cause death, cardiovascular death, re-hospitalisation for myocardial infarction (MI) and target lesion failure were conducted by phone call. Our population was represented by six patients, 67% males, aged 71.7±5.8 with a mean ejection fraction of 53±5.1%. Diabetes and active smoking were present in 17% of patients, 67% showed hypertension, 50% dyslipidaemia and 33% family history of CAD. Renal function was normal or mild reduced (eGFR 82±33 ml/min/m^2) and a mild anaemia (haemoglobin 12.3±1.8) was present at baseline. In 50% of cases the indication to angiography was an acute coronary syndrome and RA was performed during a staged procedure. All patients underwent 7 Fr femoral approach with mean time fluoroscopy 27+/11 min and mean contrast volume 210±124 ml. In 83% left anterior descending was the target vessel and only in one case left circumflex was involved. Mean lesion length was 29.8±17.5 mm, proximal and distal reference diameter (PRD-DRD) were 3.4±0.6 mm and 2.4±0.5 mm respectively. Mean aneurism diameter was 4.4±1.1 mm and in 50% of cases the calcific lesion involved a bifurcation. A floppy rotawire was used in 66% and ratio burr 1/DRD was 0.56±0.17. Mean stent length was 53.0±23.8 mm and in 66% of patients the procedure was IVUS guided. All the procedures showed final TIMI flow 3 and the absence of major complications such as no-reflow or coronary perforation. Residual stenosis was poor (2.5±4.2%) with a good stent expansion. Mean time for the duration of dual antiplatelet therapy was 232±153 days and two patients were in therapy with direct oral anticoagulant and one with Vit k antagonist. The mean follow-up was 252±152 days and no severe adverse events such as all-cause death, cardiovascular death, re-hospitalisation for MI and target lesion failure were reported.

Conclusions: Our case series showed safety and efficacy of PTRA among high risk patients with CCL involving CA. Future large studies are certainly needed to confirm our findings and to validate the use of PTRA in this particular setting.

Stable CAD - Invasive imaging and functional assessment, CTO - Invasive imaging and functional assessment

Predictors for target vessel failure after PCI for CTO in patients undergoing routine follow-up coronary angiography

GEYER Martin [(1)], GEYER Martin [(1)], WILD Johannes [(1)], HIRSCHMANN Marc [(1)], DIMITRIADIS Zisis [(1)], MÜNZEL Thomas [(1)], GORI Tommaso [(1)], WENZEL Philip [(1)]

(1) University Medical Center Mainz, Mainz, Germany

Aims: Evidence on predictors influencing long-term patency after interventional recanalisation of chronic total coronary occlusions (CTO) as well as data regarding invasive follow-up is scarce. J-CTO score was developed and validated to predict successful guidewire crossing; furthermore, a potential impact on the incidence of future adverse events has been postulated based on registry data.

Methods and results: We aimed to investigate on predictors for target vessel failure (TVF) in patients undergoing routine invasive follow-up after percutaneous recanalisation of a CTO in a monocentric retrospective cohort. 93 consecutive patients (15.1% female) with routine angiographic follow-up after successful PCI for CTO-lesion from 10/13 – 05/18 in our centre were enrolled (median time to follow-up 185 days [IQR 127-237]). The incidence of the primary combined endpoint of TVF was 15.1%, consisting of re-stenosis (11.8%) including re-occlusion (7.5%), and target vessel revascularisation (5.4%). Reduced TIMI-flow immediately after recanalisation (OR for TVR: 11.0 [95% CI:2.7-45.5], p=0.001) as well as female gender (OR for TVR: 11.0 [95% CI:2.1-58.5], p=0.005) were found to be predictive for a higher rate of adverse angiographic findings at follow-up. Higher blood values of high-sensitive troponin after successful revascularisation could be associated with a higher incidence of all endpoints. Neither the pre-interventional J-CTO score nor the presence of symptoms at the time of follow-up visit be correlated to adverse angiographic results.

Conclusions: In this medium sized retrospective observational study, we were able to identify a reduced TIMI-flow at the end of the index-procedure as well as female gender as strongest predictors for future TVF. Based on our analysis, surveillance coronary after recanalisation of a CTO seems to be justified and should rather be driven by the presence of risk factors than symptoms (in the absence of acute coronary syndrome).

STEMI - Tools, devices and techniques

Predictors of mortality and long-term outcome in patients with anterior STEMI: results from a single-centre study

BARBIERI Lucia [(1)], BARBIERI Lucia [(1)], FERRANTE Giulia [(1)], SPONZILLI Carlo [(1)], LUCREZIOTTI Stefano [(1)], CARUGO Stefano [(1)]

(1) ASST Santi Paolo e Carlo, Metropolitan City of Milan, Italy

Aims: Anterior ST segment elevation myocardial infarction (A-STEMI) carries the worst prognosis among all infarct sites, especially in the setting of acute cardiogenic shock (CS). Primary percutaneous coronary intervention (p-PCI) of the infarct-related artery (IRA) is the standard of care, but up to 65% of cases presents multivessel coronary artery disease. Aim of our study was to evaluate main predictors of short and long-term mortality in a selected cohort of patients affected by A-STEMI with particular attention on those presenting with cardiogenic shock and with multivessel disease.

Methods and results: We retrospectively analysed 584 consecutive A-STEMI patients undergoing percutaneous intervention from October 2008 to April 2019. Follow-up was assessed at clinic visits or during phone call. Data from the "Registro regionale Lombardia" were also used for long-term mortality evaluation. The median follow-up time was 1,774 days (range 931 to 2,715) and a minimum of 1-year follow-up was available for 498 patients. In-hospital mortality was 8.6% while long-term all-cause mortality and 1-year mortality were 18.8% and 6.8% respectively. At Cox regression analysis we found that the main predictors for mortality were age, CAD extension and ejection fraction (EF). In particular, about in-hospital mortality, EF, baseline eGFR, female gender and CS at admission were the main significant predictors, while at 1-year, age and Killip class ≥ 3. In our population a total of 38 patients (6.5%) presented with CS. The mortality rate, as expected, was extremely higher in this setting: 68.4% in-hospital, 41.7% long-term. In this subgroup, multivessel disease was detected in 55.2% and 23.7% showed three vessels disease. Mean EF was 28.4±12.2% and IABP was positioned in 55.2%. Complete revascularisation (CR) during index procedure was performed in 42.8% and also in this case mortality rate was extremely high (44.4% in-hospital, 40% at follow-up). The concomitant approach with IABP support and CR was applied in 15.8%. At logistic regression analysis, we didn't find any significant impact of IABP support and CR on in-hospital mortality. Focusing on patients with multivessel disease (n=245), 42%, we divided our population in two groups according to the PCI strategy (CR n=47 vs culprit only-CO n=198). Patients treated with CR were more often in CS at admission (19.1% vs 6.1%, p=0.008), and showed a higher rate of two vessels disease (80.9% vs 51.5%) while a lower incidence of three vessels disease (19.1% vs 48.5%) (p=0.001). In-hospital mortality was 18.6% and was not significantly influenced by the PCI strategy (8.5% vs 10.1%, p=0.99) (HR [95% CI]=1.31 [0.71-2.44], p=0.39). Similar results were found regarding long term mortality (31% vs 24.6%, p=0.43) and 1-year mortality (10% vs 7.8%, p=0.65). The main predictors for mortality were age, lower EF and Killip class ≥ 3 at admission.

Conclusions: Our study confirmed the high mortality rate of A-STEMI patients both at short- and long-term follow-up, especially in case of AMI complicated by CS. Left ventricular EF is a powerful predictor of poor outcome and should therefore be a part of the routine evaluation both for in-hospital risk stratification and for a closer long-term follow-up. In multivessel CAD, CR during primary PCI did not show any advantage in terms of reduction of in-hospital, short-term and long-term mortality compared to culprit-only PCI strategy.

STEMI - Invasive imaging and functional assessment

Primary PCI in a small hospital in a provincial town in India with no on-site surgical facility, a study of 175 cases over two years

NISTY Niranjan [(1)], MARGOL Siddappa [(1)], VEEREDDY Sanjeevkumar [(1)], NISTY Nidhish [(1)]

(1) Nishty Heart Centre, Karnataka, India

Aims: To study the outcome of primary PCI patients in small volume centre in a provincial town without onsite surgical facilities.

Methods and results: This is a study of 175 patients over two years from a small volume hospital which had no surgical back up in Kalaburagi, Karnataka in India. All the patients were diagnosed with STEMI according to ESC/AHA guidelines and all cases presented within 6 to 12 hours of onset of chest pain, all underwent primary PCI. Door-to-balloon time was less than 90 minutes. All patients received drug-eluting stents. All patients are being followed up. Out of 175 patients, 108 patients (61.2%) were anterior wall AMI and 67 patients (38.8%) were inferior wall AMI. 5 patients with inferior wall AMI had occlusions in the left circumflex artery. 7 patients (4%) did not require stenting. Of these, 3 patients were inferior wall AMI, the vessels were patent. Another 2 patients were deferred for stenting because of slow flow following balloon Dottering, these were anterior wall AMI. The remaining 2 patients were also anterior wall AMI where the lesions couldn't be crossed and they died about 24 hours after procedure following cardiogenic shock, one patient developed ventricular septal rupture. In-hospital mortality was 7 patients which accounts for 4%. All patients died of cardiogenic shock and one case died during the procedure. All these patients were anterior wall AMI. Complications occurred in were 11 patients which accounts for 6.2%. 10 patients had transient congestive cardiac failure and responded to noninvasive ventilation, intravenous nitroglycerin and diuretics. Another patient had renal segmental artery perforation and was treated by coil embolisation. All these patients were anterior wall AMI. 15 patients (8.5%) anterior wall AMI and 3 patients (1.7%) anterior wall AMI were in hypotension at the time of presentation. 7 patients (4%) lost to follow-up and rest patients are being followed up and are doing well. Most of the procedures were performed during day hours and 14 patients (8%) were performed between 12 am to 6 am.

Conclusions: Primary PCI is a very effective therapy and feasible in small places without surgical back-up showing good results. The success rate in this study is 96%. Lack of surgical back-up should not dissuade small centres performing primary PCI

CTO - Invasive imaging and functional assessment

Long-term outcomes of CTO treatment in patients with coronary artery disease

BARANAUSKAS Arvydas [1,2], BAJORAS Vilhelmas [1,2], SAULE Ieva Marija [1]

(1) Vilnius University, Faculty of Medicine, Vilnius, Lithuania; (2) Vilnius university hospital Santaros klinikos, Vilnius, Lithuania

Aims: Long-term outcomes of chronic total occlusion (CTO) treatment in patients with coronary artery disease are poorly investigated. The benefit of revascularisation versus optimal medical therapy (OMT) is not established in these patients. We sought to assess long term all-cause mortality in patients with CTO who were revascularised or received OMT alone.

Methods and results: 1,005 patients who had a CTO in one of the major coronary arteries were retrospectively selected from a single centre registry. All patients with acute coronary syndromes were excluded and 470 patients who had coronary angiography due to stable coronary artery disease were further investigated. According to the treatment received, patients were divided into four groups: successful PCI on CTO (n=143); failed attempt to open a CTO (n=20); CABG performed (n=92); OMT alone (n=215). The primary endpoint was all-cause mortality at follow-up. A mean follow-up period was 3.5±0.97 years and was similar in all four groups. In all study cohort baseline clinical characteristics were: 75.2 % male, 24.1 % diabetes, 90.8 % hypertension, 59.5 % previous MI, 38.1 % multivessel disease. There was significantly more patients with previous MI in PCI group, multivessel disease patients in CABG group and significantly less female patients treated by CABG. All-cause mortality at follow-up was 10.5 % (15/143), 10.0 % (2/20), 9.8 % (9/92) and 19.8 % (41/215) in the groups of PCI, unsuccessful PCI, CABG and OMT, respectively. On regression analysis, there was a significant all-cause mortality difference between PCI and OMT groups in favour of PCI (OR 2.011, 95% CI: 1.067-3.790, p=0.031). There was no difference in all-cause mortality between CABG and PCI groups (OR 0.861, 95% CI: 0.387-2.212, p=0.861).

Conclusions: Revascularisation of patients with stable coronary artery disease and CTO is associated with reduced risk of all-cause mortality at long-term follow-up.

Other Coronary interventions - Other

Targeted septal branch microcirculatory embolisation with tris-acryl gelatine microspheres in hypertrophic obstructive cardiomyopathy

OKUTUCU Sercan [(1)], AKSOY Hakan [(1)], YETIS SAYIN Begum [(1)], OTO Ali [(1)]

(1) Memorial Ankara Hastanesi, Ankara, Turkey

Aims: Alcohol septal ablation (ASA) has been shown to be an effective treatment in patients with hypertrophic obstructive cardiomyopathy (HOCM) who are refractory to medical treatment. ASA may cause some life-threatening complications including conduction disturbances, haemodynamic compromise, ventricular arrhythmias, distant and massive myocardial necrosis. Tris-acryl gelatine microspheres provides consistent and predictable results for effective targeted microcirculatory embolisation. Herein, we aimed to report our initial experience in tris-acryl gelatine microspheres for septal ablation in HOCM.

Methods and results: Microspheres (Embosphere, Merit Medical) are biocompatible, hydrophilic, non-resorbable microspheres which are available in a range of calibrated sphere sizes. In our method, after the cannulation of left anterior descending by 6 Fr-7 Fr guiding catheter, a 0.014-inch guide wire is introduced through the catheter, and advanced into the septal branch. This septal artery is selectively cannulated with a 4 Fr catheter over the guide wire. Selective angiography of the septal artery is performed to show the anatomy and collateral branches to other coronary arteries. Contrast echocardiography is performed to make sure that the pertinent septal artery is the target vessel supplying the hypertrophied septum. A microcatheter is then advanced deep enough into the septal artery through the 4 Fr catheter. Microspheres/ contrast solution infused slowly under fluoroscopic guidance into the targeted septal branches initially using coronary arteriolar sized small particles (diameter 100-300 µm); then the particle size was stepped up to larger particles (diameter 300-500 µm) until complete block of the arteriolar flow is achieved. Septal ablation with tris-acryl gelatine microspheres was performed in 6 patients (mean age = 47.8±11.5; 5 males). Immediately after the procedure peak left ventricular outflow (LVOT) gradient reduced significantly both in direct catheter (69.0±13.8 vs 8.2±3.7 mmHg, p<0.001) and Doppler echocardiographic measurements (78.8±19.9 vs 12.0±5.1 mmHg, p<0.001). Post procedure peak serum CK- MB fraction concentration was 82±22 ng/ml (normal reference range is 0 - 4.9 ng/mL) and peak serum troponin T concentration was 1.2 ng/ml [(interquartile range, 0.4–1.4), (normal reference range <0.017 ng/mL)]. LVOT tract gradient reduction persisted after 6 months follow-up. There was no significant complication during the procedure and within 6 months follow-up period.

Conclusions: The novel strategy by targeted septal branch microcirculatory embolisation with tris-acryl gelatine microspheres seems to be an efficient and safe approach to HOCM. Further experience is needed in order to assess the long-term efficacy and safety of this technique.

Stable CAD - Diabetes

The impact of the history of diabetes on clinical outcomes after PCI with special attention to stent size

ZIBAEENEZHAD Javad [(1)], ZIBAEENEZHAD Javad [(1)], RAZEGHIAN-JAHROMI Iman [(1)], SAYADI Mehrab [(1)], MOHAMMADI Seyyed Saeed [(1)], KHORSHIDI Soorena [(1)], HADIYAN Ehsan [(1)]

(1) Cardiovascular Research Center, Shiraz University of Medical Sciences, Shiraz, Islamic Republic of Iran

Aims: Reports on the incidence of clinical outcomes in diabetic patients after PCI are conflicting. The present study investigated the occurrence of such outcomes in patients with a history of diabetes (hDM) after PCI (index PCI).

Methods and results: Among patients with stable coronary artery disease (CAD) who underwent PCI with drug-eluting stents (DES), 1,630 subjects were entered from 2003 till 2019. hDM was considered as participants with a history of DM. DM was defined as fasting plasma glucose of ≥ 126 mg/dL (7.0 mmol/L) or 2-h plasma glucose of ≥200 mg/dL (11.1 mmol/L) during oral glucose tolerance test or A1C of ≥6.5% (48 mmol/mol) or in a patient with classic symptoms of hyperglycaemia or hyperglycaemic crisis, a random plasma glucose of ≥200 mg/dL (11.1 mmol/L) or those who were under antidiabetic medications. Outcomes including revascularisation, myocardial infarction, and death, totally defined as major adverse cardiac events (MACE), were sought in follow-up phase. Time from index PCI to the earliest MACE was considered as time-to-event. Age was considered as the age of the participants at the time of index PCI. T test and Chi-square tests were used for continues and categorical variables, respectively. Cox proportional-hazards regression with two sided tests at the 5% level of significance was done. All the analyses were performed using the statistical Package for Social Sciences version 16 (SPSS Inc., Chicago, IL, USA). Of the total, 29% of the patients who referred for PCI had hDM and among those who experienced MACE, 37.8% had hDM. About 70% of MACEs happened in more than 6 months post-PCI. Unlike age and time-to-event, significant difference was seen in gender between hDM and non-hDM patients with majority of hDM patients were female. Also, there is no significant difference between hDM and non-hDM patients neither with respect to the length and diameter of the stents, nor to the MACE incidence.

Conclusions: In our population, hDM and stent size did not statistically affect MACE incidence. This may be due to the use of DES supplemented by two years dual antiplatelet therapy and tight control of diabetic status.

Other Coronary interventions - Calcified lesions

Intravascular lithotripsy for the treatment of severely calcified coronary lesions in high-risk patients

GIANNONE Sara [1], GIANNONE Sara [1], MANGIACAPRA Fabio [1], NUSCA Annunziata [1], MELFI Rosetta [1], MIGLIONICO Marco [1], RICOTTINI Elisabetta [1], GALLO Paolo [1], GRIGIONI Francesco [1], USSIA Gian Paolo [1]

(1) Campus Biomedico Trigoria, Metropolitan City of Rome, Italy

Aims: Severely calcified coronary lesions represent a challenge for successful percutaneous coronary intervention (PCI), especially in patients with either clinical or angiographic high-risk features. Recently, a novel tool for modification of heavily calcified coronary plaques based on intravascular lithotripsy (IVL) through a balloon catheter that uses pulsatile mechanical energy to disrupt calcified lesions has been introduced. We present our early experience with IVL-assisted PCI in high-risk patients with severely calcified coronary lesions.

Methods and results: This prospective, observational, single-centre study enrolled patients with severely calcified coronary lesions undergoing PCI and treated with IVL between January 2019 and May 2019. All patients presented at least one of the following high-risk features: left ventricle ejection fraction (LVEF) <40%, chronic kidney disease (CKD), severe valvular disease, multivessel PCI, aorto-ostial lesion, left main stem lesion. In-hospital and 30-day clinical outcomes were monitored. We enrolled a total of 33 patients (66.6% male; age, 74±8,6 years). Indication for PCI was acute coronary syndrome in two patients (6%). Three patients (9%) underwent transcatheter aortic valve implantation during the same procedure. Left main stem was treated in 6 patients (18.2%). Ten patients (30.3%) underwent multivessel IVL-assisted PCI. IVL use was planned upfront in 8 patients (24%), whereas it was used as a bailout strategy in the remaining cases (n=25, 76%). Angiographic success (residual stenosis >30%) was obtained in all cases. No procedural complications were recorded, although in 20 cases (60.6%) premature ventricular contractions were observed during IVL without clinical consequences. No adverse events were recorded in-hospital and at 30-day follow-up.

Conclusions: Our early experience suggests that IVL-assisted PCI is effective and safe in treating high-risk patients with severely calcified coronary lesions. This technology is feasible in most clinical and procedural scenarios, allowing efficient plaque modification without increasing procedural time and complexity.

Stable CAD - Bypass surgery, Left main and multivessel disease - Bypass surgery

Predictive performance of the SYNTAX score II in patients with complex coronary artery disease undergoing CABG: multicentre analysis with population from countries in transition and high-income countries

STANETIC Bojan [1,2], STANETIC Bojan [1], OSTOJIC Miodrag [1,2,3], HUBER Kurt [4]

(1) University Clinical Centre of the Republic Srpska, Banja Luka, BOSNIA AND HERZEGOVINA; (2) Medical Faculty, University of Banja Luka, Banja Luka, BOSNIA AND HERZEGOVINA; (3) Institute for Cardiovascular Diseases Dedinje, Belgrade, Serbia; (4) Wilhelminenspital, Vienna, Austria

Aims: Recently, the SYNTAX score II (SSII) failed to predict all-cause mortality in patients following coronary artery bypass grafting (CABG). We aimed to assess the performance of SSII in a multicentre real-life population undergoing CABG.

Methods and results: From January 2008 to December 2010, 414 consecutive patients with angiographically proven three-vessel coronary disease (≥50% diameter stenosis) and/or unprotected left main coronary disease (≥50% diameter stenosis) without major haemodynamic instability, who were referred for CABG (three centres from Austria, Bosnia an Herzegovina and Serbia), were analysed. All-cause mortality at four years was ascertained by telephone contacts and/or from mortality registries. The median age was 64.1 years (IQR 59-71), 315/414 (76.1%) were male, 171/414 (41.3%) were smoker, 165/414 (39.9%) had diabetes, and the median left ventricular ejection fraction was 55% (IQR 42-60%). Left main disease was present in 188/414 (45.4%) patients. The median SYNTAX score was 30 (IQR 24.0-39.0). Out of 414 included patients, 13 were lost to follow-up (3.1%). After four years of follow-up, the rate of all-cause death in the studied population was 10.9%. The SSII was able to separate low-, medium-, and high-risk tertiles (log-rank p=0.03), surpassing the SYNTAX score tertiles (log-rank p=0.32). In the low-risk group, where the predicted probability of death was 0.6% to 4.0%, 5 patients died (5/138=3.6%). In the high-risk group, however, where the predicted probability of death ranged from 9.1% to 85.5%, 25/138 patients (18.5%) died within 4 years of CABG. The prognostic accuracy of the SSII was 0.09 by Brier score. There was a good agreement between the predicted and the observed mortality (Hosmer and Lemeshow Test p=0.91). The calibration of the SSII tested in the present analysis was as follows: r=0.83; p<0.01.

Conclusions: For patients with complex coronary artery disease treated by CABG, the combination of clinical and angiographic factors provided by SSII demonstrated strong discriminatory accuracy for long-term mortality in a real-life multicentre population.

Left main and multivessel disease - Invasive imaging and functional assessment

Association between angiographic outcomes and stent underexpansion detected by IVUS in patients undergoing Ultimaster sirolimus-eluting stent implantation for left main coronary artery disease

OHYA Masanobu [(1)], OHYA Masanobu [(1)], MIURA Katsuya [(1)], SHIMADA Takenobu [(1)], AMANO Hidewo [(1)], KUBO Shunsuke [(1)], TADA Takeshi [(1)], TANAKA Hiroyuki [(1)], FUKU Yasushi [(1)], KADOTA Kazushige [(1)]

(1) Kurashiki Central Hospital, Okayama, Japan

Aims: We aimed to perform IVUS assessment of the association between the angiographic outcomes and stent underexpansion in patients undergoing Ultimaster sirolimus-eluting stent implantation for left main coronary artery disease (LMCA).

Methods and results: We retrospectively examined 42 consecutive patients undergoing IVUS-guided Ultimaster sirolimus-eluting stent implantation for LMCA between 2017 and 2018. The underexpansion cutoff values were defined as 5.0 mm^2 (ostial left circumflex), 6.0 mm^2 (ostial left anterior descending), 7.0 mm^2 (confluence of left anterior descending and left circumflex), and 8.0 mm^2 (within the left main above the confluence), based on the 5-6-7-8 criteria. The cutoff value in the left circumflex was not included in patients with 1-stent strategy from LMCA to left anterior descending artery. The primary outcome measure was defined as angiographic late lumen loss within one year after stent implantation. According to our institutional protocol, follow-up coronary angiography is scheduled 8 months after percutaneous coronary intervention. The mean age was 75 years, and 74% were men. Thirty-two patients (76%) had stable coronary artery disease, and the rate of 1-stent strategy was 92.8% (39 lesions). Follow-up angiography within one year was performed on 73.8% (31/42 patients). Restenosis within one year was observed in 1 main branch (3.2%) and 2 side branches (6.5%). The incidence of underexpansion in least one segment was 38.7% (12/31 lesions). Late lumen loss within one year was not significantly different between the underexpansion (n=12) and non-underexpansion (n=19) groups in both main and side branches (0.56 mm vs 0.52 mm, p=0.84; 0.20 mm vs 0.17 mm, p=0.89; respectively). Current smokers and diabetic patients had significantly progressed late lumen loss in the side branch (0.41 mm vs –0.07 mm, p=0.01 and 0.40 mm vs 0.02 mm, p=0.045, respectively). The incidence of target lesion revascularisation within 1 year was only 2 cases in this cohort. Those of myocardial infarction and definite or probable stent thrombosis were none.

Conclusions: Some patient characteristics were associated with angiographic late lumen loss within one year in patients treated with Ultimaster sirolimus-eluting stent for LMCA, but IVUS results based on the 5-6-7-8 criteria were not.

Other Coronary interventions - Other

Preliminary experience on the use of 30-40 mm DEB in the treatment of de novo diffuse coronary disease

CHUA Jia Min [(1)], LEE Jin Hyun [(1)], HO Hee Hwa [(1)]

(1) Tan Tock Seng Hospital, Tan Tock Seng Hospital, Singapore

Aims: The role of the drug-eluting balloon (DEB) is still being defined. To date, DEB has growing evidence for in-stent restenosis and atherosclerosis in small coronary artery disease. For long diffuse coronary artery lesions, the role of DEB has yet to be evaluated. We sought to investigate the role of DEB in the treatment of diffuse *de novo* coronary artery disease (>25 mm).

Methods and results: We retrospectively evaluated all patients treated with 30-40 mm SeQuent Please DEB (B. Braun, Vascular, Germany) for diffuse coronary artery disease from August 2016 to January 2019. Endpoints analysed were major adverse cardiac events (MACE) defined as a composite of all-cause mortality, myocardial infarction, and target lesion revascularisation. The clinical outcomes were evaluated at 1 year. A total of 126 patients (163 lesions) were treated with DEB±drug-eluting stent (DES). Majority of patients (38%) presented with non-ST-elevation myocardial infarction with the left anterior descending artery being the most common target vessel (53.6%) followed by right coronary artery (28.5%). 61% of patients were diabetic. Of the DEB-treated lesions, 64.2% were treated with DEB alone, 4.7% with DEB and DES as bailout, and 31% with DES and DEB as part of hybrid approach for very long disease. Mean lesion length was 37.5±4.7 mm and mean vessel diameter 2.5±0.5 mm. An average of 1.2±0.4 mm DEB was used per patient, with mean DEB diameter of 2.5±0.5 mm and mean DEB length of 39.3±4.5 mm. Intra-coronary imaging (IVUS or OCT) were used in 11% of cases. At 1-year follow-up, there were 7 cases (5%) of major adverse cardiac events including 2 cases of mortality, 2 cases of myocardial infarction and 3 cases of target lesion revascularisation.

Conclusions: Our preliminary experience showed that the use of SeQuent Please DEB in diffuse *de novo* coronary artery disease, either alone or in combination with DES in very long disease was feasible with regard to 1-year clinical outcome.

STEMI - Adjunctive pharmacotherapy

Risk factors for acute ventricular fibrillation in patients with STEMI

WATANABE Shingo [(1)], USUI Michio [(1)], KUJIRAOKA HIrofumi [(1)]

(1) Tokyo Yamate Medical Center, Tokyo, Japan

Aims: As a result of primary PCI becoming the standard of care, the mortality rate of STEMI patients is decreasing. On the other hand, there are still many patients who die of ventricular arrhythmia during the acute phase of STEMI. It is important to know the risk factors for ventricular arrhythmias. The purpose of this study is to investigate the risk factors of patients for ventricular fibrillation during acute phase of STEMI.

Methods and results: We investigated 504 consecutive STEMI patients who were admitted to our hospital and successfully revascularised with PCI. We divided patients into those who developed ventricular fibrillation requiring cardioversion during hospitalisation for STEMI treatment (VF group) and those who did not develop ventricular fibrillation (non-VF group). We compared the two groups for patient background and lesion location. There were 27 VF groups and 477 non-VF groups. HDL cholesterol at admission was significantly lower in the VF group (43.7 mg/dl vs 46.9 mg/dl p=0.03), and UA was significantly higher in the VF group(6.8 mg/dl vs 5.6 mg/dl p=0.003). There were no significant differences between the two groups in terms of other patient characteristics. Regarding the lesion site, the ratio of LAD, RCA, Cx was not significantly different between the two groups. max CK was significantly higher in the VF group (5422 mg/dl vs 2994 mg/dl p=0.002).

Conclusions: Hyperuricemia and hypo-HDL cholesterol are risk factors for acute ventricular fibrillation in STEMI patients.

Stents and scaffolds - Tools, devices and techniques

Long-term outcomes of patients with polyurethane-covered cobalt-chromium stent implantation

JURADO Alfonso [1,9], RODRIGUEZ Oriol [2], ROMANI Sebastian [3], CRUZ Ignacio [4], CORDOBA Juan G [5], HERNANDEZ ANTOLIN Rosana [6], SALINAS Pablo [7], CORTES Carlos [8], MORENO Raul [1], LOPEZ SENDON Jose Luis [1]

(1) University Hospital La Paz, Madrid, Spain; (2) Hospital Germans Trias i Pujol, Badalona, Spain; (3) Hospital San Pedro de Alcantara, Cáceres, Spain; (4) Hospital Universitario de Salamanca, Salamanca, Spain; (5) Complejo Hospitalario Universitario de Albacete, Albacete, Spain; (6) Hospital Ramón y Cajal, Madrid, Spain; (7) Hospital Clínico San Carlos, Madrid, Spain; (8) Hospital San Pedro, Logroño, Spain; (9) Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Aims: Classically, covered stents have had worse results compared to drug-eluting stents. However, this may be due to the design of the first-generation covered stents with greater thickness and several metal layers. There is insufficient data on the long-term follow-up of the new polyurethane-covered cobalt-chromium stents and a single metal layer. Aim: to present long-term results with this type of covered stent.

Methods and results: A national multicentre retrospective registry was performed with polyurethane-covered stents implanted in 15 centres. 118 stents were implanted in 99 patients (68.4±14 years; 81.8% male). 35.4% were diabetic and the mean LVEF was 54±11%. The indications were: 56.8% coronary perforation, 34.7% coronary aneurysms, 2.1% radial artery perforation, 0.9% femoral artery perforation, 2.1% coronary fistula closure, 1.1% SVG PCI, sealing of capillaries with paraganglioma irrigation (0.9%) and dissection of Valsalva sinus (0.9%). The clinical presentation was stable coronary disease in 29%, NSTEMI in 44% and STEMI in 27%. The treated vessel was the left main in 3.1%, left anterior descending in 41.8%, circumflex 15.3%, right coronary artery 32.7%, SVG 3.1% and left internal mammary artery 1.7%. The number of covered stents per patient were 1.23±0.5 (1-3) with a mean diameter of 3.3±0.7 mm and a mean length of 18.5±3.7 mm. They were implanted over a previous stent in 44.6% and overlapped with another stent in 50%. Angiographic success (stenosis <20%, TIMI 3) was achieved in 98.3%. There were only 2 complications secondary to covered stent implantation: an occlusion of an atrial branch and an acute thrombosis. Intracoronary imaging techniques were used during stent implantation in 31% of patients. 18% of the patients had angiographic follow-up and 12.3% with intracoronary imaging techniques. There were 8 cardiac deaths, 6 of which were during the procedure or initial hospitalisation secondary to coronary perforations that could not be solved. There were 3 stent thrombosis (ST), one acute, one 11 months after the stent implantation and another 20 months later. There were 6 myocardial infarctions related to the treated lesion, 3 periprocedural and 3 during the follow-up. There were 5 patients with new target lesion revascularisation (TLR), 2 due to a ST and other 3 for restenosis. The mean follow-up of patients who were discharged was 22.9±16.6 months (median: 21.3 [0.2-70.4] months]). The rate of major cardiovascular adverse events (cardiac death, ST or TLR) at the end of the follow-up was 6.7% (cardiac death: 2.2%, TLR: 5.5% and ST: 2.2%). To the best of our knowledge this is the largest series of polyurethane-covered cobalt-chromium stents with a long-term follow-up.

Conclusions: Taking into account the clinical and anatomical features of patients, after hospital discharge, long-term clinical outcomes of polyurethane-covered cobalt-chromium stents with a single metal layer were favourable and similar to those described in contemporary series of drug-eluting stents.

Stable CAD - Adjunctive pharmacotherapy

Androgenic alopecia, premature greying, and hair thinning as independent predictors of coronary artery disease in young Asian males

HUMANE Dhammdeep [1], SHARMA Kamal [2], TIRMALE Rakesh [1], RANE Sandip [1]

(1) Mumbai Heart Clinic, Maharashtra, India; (2) U N Mehta Institute of Cardiology & Research Centre, Gujarat, India

Aims: Biological age is an established risk factor of coronary artery disease (CAD) and is often associated with various dermatological changes like premature greying and alopecia apart from genetics. Aim of this study was to study the overall prevalence and association of premature greying, androgenic alopecia, and hair thinning with coronary artery disease in young Asian male patients and their predictability for coronary artery disease.

Methods and results: In this prospective case–control study, we recruited 1,380 individuals in 2:1 ratio- of which cases n=468 were patients with coronary artery disease (< 40 years of age) who were admitted for ACS. The diagnosis of coronary artery disease was performed using angiography, and stenosis of at least 70% diameter was considered as significant. Controls- were age matched young males (n= 912), not having any major history of cardiovascular disease with normal coronary angiograms, were included as healthy control. Overall prevalence of hair thinning, premature greying, and androgenic alopecia in coronary artery disease cases were 36.3, 49, and 50%, respectively, which was significantly higher as compared with control population (hair thinning – 14.6%, premature greying – 25.8%, and AGA – 27.4%). SYNTAX score – an index of coronary artery disease complexity – was also found to be an independently associated with premature greying ($p<0.0001$) and androgenic alopecia ($p<0.0001$), but not of hair thinning ($p=0.737$). Multiple logistic regression analysis showed that androgenic alopecia (5.619, $p<0.0001$) is the strongest predictor of coronary artery disease among young Asian males, closely followed by premature greying (5.267, $p<0.0001$), obesity (4.133, 95% CI: 2.839–6.018, $p<0.0001$), and hair thinning (3.36, 95% CI: 2.452–4.621, $p<0.0001$). Multiple logistic regression analysis showed that androgenic alopecia (5.619, $p<0.0001$) is the strongest predictor of coronary artery disease among young Asian males, closely followed by premature greying (5.267, $p<0.0001$), obesity (4.133, 95% CI: 2.839–6.018, $p<0.0001$), and hair thinning (3.36, 95% CI: 2.452–4.621, $p<0.0001$). LVEF as assessed by Simpson's method on echocardiography and degree of severity were also associated with these cutaneous markers.

Conclusions: Androgenic alopecia and premature greying of hairs correlated with the complexity of the coronary artery disease as assessed by the SYNTAX score. Hair thinning correlated with coronary artery disease, but not with the SYNTAX Score (complexity of coronary artery disease). In light of our study and recent publications, we would propose that young men (<40) with premature greying and androgenic alopecia should receive extra monitoring for coronary artery disease and primary prevention measures like lifestyle modifications, diet modifications, exercise and psychosocial stress management.

Stents and scaffolds - Invasive imaging and functional assessment

Impact of residual plaque burden and plaque composition on early neointimal coverage of stent struts after second- and third-generation DES implantation: a very short-term OCT analysis

ITAGAKI Tadashi [(1)], ITAGAKI Tadashi [(1)], OTAGIRI Kyuhachi [(1)], YUI Hisanori [(1)], MACHIDA Keisuke [(1)], TAKEUCHI Takahiro [(1)], KITABAYASHI Hiroshi [(1)]

(1) Ina central hospital, Ina, Japan

Aims: We aimed to assess the impact of residual plaque burden (RPB) and residual plaque composition (RPC) behind stent struts on the early neointimal coverage (NC) of stent struts after new-generation drug-eluting stent (DES) implantation.

Methods and results: We evaluated 726 frames, including 7,730 struts obtained from 17 new-generation DESs (six sirolimus-eluting cobalt chromium stents [CoCr-SES], six everolimus-eluting platinum chromium stents [PtCr-EES], and five everolimus-eluting cobalt chromium stents [CoCr-EES]), using optical coherence tomography (OCT) for a very short-term follow-up period (21.7±5.3 days). Cross-sectional OCT images were analysed at 0.4 mm intervals to evaluate the NC rate, RPB, and calcification (CA) or lipid (LP) scores stratified by grading the measured angle as 0–4 (0°, <90°, 90°–180°, 180°–270°, and >270°). All evaluated frames were classified into significant RPB (≥5.83 mm^2) and mild RPB (<5.83 mm^2) groups based on the average value and high (≥3) and low (≤2) score groups according to CA and LP scores in each frame. The associations of odds ratios (ORs) for poor NC rate (<85%) with significant RPB, high CA score, and high LP score were assessed. In all stents analysis, lower NC rates were observed in the significant RPB, high CA score, and high LP score groups than in the mild RPB, low CA score, and low LP score groups (85.4%±16.6% vs 91.5%±10.8%, p<0.01; 83.1%±15.4% vs 88.9%±14.2%, p<0.01; 88.0%±14.6% vs 93.1%±9.8%, p<0.01, respectively). The significant RPB, high CA score, and high LP score groups demonstrated high ORs for poor NC rate (OR 2.20, 95% confidence interval [CI] 1.59–3.03, p<0.01; OR 2.66, 95% CI: 1.49–4.74, p<0.01; OR 1.94, 95% CI: 1.06–3.53, p=0.03, respectively). In each DES-based analysis, CoCr-SES demonstrated lower NC rates in the significant RPB, high CA score, and high LP score groups than in the mild RPB, low CA score, and low LP score groups (84.7%±16.0% vs 91.3%±10.0%, p<0.01; 76.1%±19.7% vs 88.2%±13.6%, p<0.01; 87.1%±14.4% vs 93.6%±8.5%, p=0.03, respectively). In PtCr-EES, although lower NC rates were observed in the significant RPB and high LP score groups than in the mild RPB and low LP score groups (82.5%±17.1% vs 93.1%±10.7%, p<0.01; 89.0%±14.4% vs 96.1%±6.3%, p=0.02, respectively), there was no difference in the NC rate between the high and low CA score groups (87.2%±12.5% vs 90.1%±14.1%, p=0.34). Meanwhile, there were no differences in the NC rates between the significant and mild RPB and the high and low CA/LP score groups in CoCr-EES (87.8%±17.0% vs 89.5%±11.7%, p=0.41; 83.1%±13.0% vs 88.8%±15.0%, p=0.21; 88.3%±15.2% vs 90.0%±12.4%, p=0.60, respectively). High ORs for poor NC rates were observed in the significant RPB and high CA score groups in CoCr-SES, the significant RPB and high LP score groups in PtCr-EES, and the high CA score group in CoCr-EES (OR 2.14, 95% CI: 1.29–3.54, p<0.01; OR 4.00, 95% CI: 1.37–11.72, p<0.01; OR 5.05, 95% CI: 2.64–9.64, p<0.01; OR 4.52, 95% CI: 1.13–17.93, p=0.03; OR 3.97, 95% CI: 1.19–13.13, p=0.02, respectively).

Conclusions: Poor early NC appears to be affected by RPB and RPC. Moreover, the effect of RPB and RPC on early NC appears to be different depending on the type of DES. To achieve a suitable early in-stent endothelialisation, appropriate DES selection should be made based on the lesion characteristics despite the use of new-generation DESs.

Stable CAD - Vascular access and bleeding

Coronary interventions in the radial lounge: a novel model of care focused on operational efficiency and patient experience

CURA Fernando [1], CURA Fernando [1], ABUD Marcelo Angel [1], PADILLA Lucio Tiburcio [1], SPALETRA Pablo [1], PEDERNERA Gustavo [1], LAMELAS Pablo [1], MASCOLO Pablo [1], CANDIELO Alfonsina [1], CIGALINI Ignacio [1], BELARDI Jorge [1]

(1) Instituto Cardiovascular de Buenos Aires, Buenos Aires, Argentina

Aims: The aim of this study was to assess the procedural safety, operational efficiency and patient experience of a novel model of care in the radial lounge for patients undergoing an elective coronary intervention.

Methods and results: Patients undergoing an elective coronary intervention between January 2016 and July 2019 who were planned to be discharged the same day were included in the analysis. The cohort was divided according to the model of care (radial lounge vs standard hospital care). Radial lounge is an outpatient facility adjacent to the hospital with a comfortable environment and with less hospital feeling. The decision of the attention model was upon availability of cath lab. Patients in the radial lounge could wear their own clothes during the procedure and had no restrictions during their pre- and post-procedural stay. Systematic fasting was not indicated. Among 9,591 patients, 1,850 were treated in the radial lounge (19%) and 7,741 (81%) in the standard hospital care. Patients were excluded if they had ACS, clinical instability, oxygen-dependent COPD, severe renal failure, LVEF <30% or CTO interventions. To reduce selection bias, a propensity score was generated by logistic regression model. Then, statistical analyses were weighted by the inverse probability of the attention in the radial lounge (inverse probability-weighted analysis). There were differences between groups in basal characteristics that were minimised in the weighted population. Radial lounge patients had higher rates of same-day-discharge (86.2% vs 55.8%, p<0.0001) and achieved better operational efficiency profile with shorter length-of-stay (-4.48 hrs. [95% CI: -4.77 – -4.21]), even among same-day-discharge patients (-1,65 hrs. (95% CI: -1,75 – -1.55; p 0.001). The start time and the occupancy rates were similar, however, patient turn-over was shorter in the radial lounge (23.5 min [IQR 18.2 – 30.5] vs 33.5 min [IQR 30.2 – 38.7], p<0.0001). Regarding hospitalisation cost, the radial lounge saw a 44% reduction in the entire cohort and 55% reduction among same-day-discharge patients. There were no difference in in-hospital and 30-day MACE. No patient had a procedure-related infection 30-days after the procedure. Patient experience was assessed by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) score which is a standardised measure of a patient's hospital experience. It should be noted that while both models were perceived as high standards of care the radial lounge obtained higher values of patient satisfaction measured in a 1-10 scale (9.56±0.76 vs 9.36±0.98, p 0.001).

Conclusions: The radial lounge is a novel model of care for elective coronary interventions with similar safety levels compared to standard hospital care and enhances patient experience. This working model improves cath lab workflow, reduces length-of-stay and hospital bed occupation. In addition, the radial lounge significantly reduces hospital costs and may positively impact a health system's cost burden.

Stable CAD - Adjunctive pharmacotherapy

Ticagrelor monotherapy in patients with concomitant diabetes mellitus and chronic kidney disease: insights from the GLOBAL LEADERS trial

CHAO Gao [1,2,3], GAO Chao [1,2,3], MARIUSZ Tomaniak [3], KUNIAKI Takahashi [4], HIDEYUKI Kawashima [3], RUTAO Wang [1,2,3], HIRONORI Hara [3,4], ONUMA Yoshinobu [3], DOMINICK Angiolillo [5], SERRUYS Patrick W. [3]

(1) Xijing Hospital, Shaanxi, China; (2) Radboudumc, Nijmegen, the Netherlands; (3) National University of Ireland Galway, Galway, Ireland; (4) Amsterdam UMC - Locatie AMC, Amsterdam, the Netherlands; (5) University of Florida College of Medicine – Jacksonville, FL, USA

Aims: Both DM and CKD are independently associated with an increased risk of cardiovascular ischaemic events. These two risk factors of coronary heart disease have also been shown to synergistically amplify the hazards once they co-exist. The growing prevalence of CKD in patients with DM underscores the need to investigate the effects of different antiplatelet strategies in this specific patient cohort.

Methods and results: In this *post hoc* analysis of the GLOBAL LEADERS trial, patients were divided into subgroups according to DM and CKD status. The treatment effects of the experimental regimen (one-month dual antiplatelet therapy [DAPT] followed by ticagrelor monotherapy for 23 months) versus the reference regimen (12-month DAPT followed by aspirin alone for 12 months) were analysed in each subgroup. The primary endpoint was a composite endpoint of all-cause death or new Q-wave myocardial infarction and the key secondary safety endpoint was Bleeding Academic Research Consortium (BARC) type 3 or 5 bleeding at two-years. Compared with DM-/CKD- patients, DM+/CKD+ patients had a higher incidence of the primary endpoint (3.1% vs 9.5%, adjusted HR 2.16; 95% CI: [1.66-2.80]) and key safety secondary endpoint (1.8% vs 4.4%, adjusted HR 1.74; 95% CI: [1.20-2.53]). Patients with DM+/CKD- or DM-/CKD+ had intermediate ischaemic and bleeding risk profiles. There were no significant differences in the primary or secondary endpoints between the reference and experimental regimen in DM+/CKD+ patients. In DM+/CKD+ patients, the experimental regimen was associated with lower rates of any revascularisation (11.5% vs 15.6%, HR 0.67; 95% CI: [0.45-0.99]) and target vessel revascularisation (6.1% vs 10.0%, HR 0.56; 95% CI: [0.33-0.93]), compared with the reference regimen.

Conclusions: Patients with both DM and CKD are characterised by high ischaemic and bleeding event rates. Ticagrelor monotherapy did not lower rates of all-cause death or new Q-wave or reduce major bleeding complications, however it did decrease repeat revascularisations. These findings should be interpreted as hypothesis-generating.

Stable CAD - Diabetes

Impact of diabetes mellitus in patients undergoing PCI

ABUD Marcelo [1], ABUD Marcelo [1], PADILLA Lucio [1], PEDERNERA Gustavo [1], SPALETRA Pablo [1], LAMELAS Pablo [1], CANDIELLO Alfonsina [1], ORDOÑEZ Santiago [1], MASCOLO Pablo [1], BELARDI Jorge Atilio [1], CURA Fernando [1]

(1) ICBA Instituto Cardiovascular, Buenos Aires, Argentina

Aims: Diabetes mellitus (DM) has been associated with increased adverse outcomes in patients treated with percutaneous coronary intervention (PCI) compared with non-diabetic patients. The aim of this study was to evaluate in a population of unselected patients treated with PCI, the risk of major adverse cardiac events (MACE) in diabetic patients stratified according to treatment (non-insulin dependent or insulin-dependent).

Methods and results: A retrospective, single centre registry of patients with coronary artery heart disease treated with PCI was analysed from March 2009 to June 2018 according to the presence of DM stratified into insulin-dependent DM (ID-DM) and non-insulin dependent DM (NID-DM). An adjusted Cox regression model was applied to evaluate the relationship between the diabetic status and the risk of MACE. A total of 6,313 patients with mean follow-up of 4.1±1.8 years and a global prevalence of DM of 22.8% (NID-DM 19.1%, IDDM 3.8%) were included in the study. Diabetic patients showed a higher risk profile, particularly those with ID-DM. At mean follow-up time, the adjusted risk of MACE was similar between Non-DM and NID-DM patients (HR 1.02 [0.81–1.27], p=0.85). A higher risk of MACE was reported in ID-DM compared with Non-DM (HR 1.73 [1.20–2.49], p=0.003) and NID-DM (HR 1.65 [1.10–2.48], p=0.015) patients. A significant interaction was observed between the diabetic status and the risk of cardiovascular events according to the indication of PCI at admission (pint 0.045).

Conclusions: In our registry of patients undergoing PCI and with a long-term follow-up, diabetic patients presented a high risk of MACE. This risk was particularly increased in ID-DM patients. However, there were no significant differences in the risk of MACE between NID-DM and non-DM patients.

Other Coronary interventions - Other

Management and outcomes of patients with in-stent restenosis of a second-generation DES according to restenosis pattern

ABUD Marcelo Angel [1], ABUD Marcelo [1], CIGALINI Ignacio Manuel [1], PADILLA Lucio Tiburcio [1], LAMELAS Pablo Manuel [1], SPALETRA Pablo Marcelo [1], PEDERNERA Gustavo [1], MASCOLO Pablo [1], CANDIELLO Alfonsina [1], BELARDI Jorge Atilio [1], CURA Fernando Adrián [1]

(1) ICBA Instituto Cardiovascular, Buenos Aires, Argentina

Aims: Although the in-stent restenosis (ISR) pattern has prognostic implications after new percutaneous coronary intervention (PCI), this information mainly involves studies with bare-metal stents or first-generation drug-eluting stents (DES). Our aim is to assess patients outcomes after PCI of clinically relevant ISR of a second-generation DES (2G-DES) according to its angiographic pattern and treatment received.

Methods and results: Patients initially treated with a 2G-DES for a *de novo* coronary lesion and had clinically significant ISR requiring new PCI were included. ISR pattern was classified as focal or diffuse. The cohort was divided into 3 groups according to treatment received: Hetero-DES (PCI with a different DES), Homo-DES (PCI with same DES) or drug-eluting balloon (DEB). A total of 264 patients with an average follow-up of 3.4±2.1 years were included, representing a prevalence of 2G-DES ISR of 4.7%. Of those, 111 (42%) presented with diffuse ISR. The overall MACE rate was 25.8%, higher in patients with diffuse ISR, mainly driven by higher TLR rates (plog-rank <0.0001). Patients with diffuse ISR treated with Hetero-DES had the lowest TLR rate compared to Homo-DES (plog-rank 0.001) and DEB (plog-rank 0.036). Those with with focal ISR had similar TLR rates despite of treatment (plog-rank 0.632). An adjusted interaction term was applied between ISR pattern and treatment which resulted significant (p=0.045).

Conclusions: Diffuse ISR of a 2G-DES presented with higher rates of MACE compared with focal ISR. Treatment with hetero-DES strategy resulted in lower overall TLR rates, especially in patients with diffuse ISR. These findings should be confirmed in randomised trials.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Comparison of three contemporary thin-strut DES implanted in severely calcified coronary lesions of participants in a randomised all-comer trial

BUITEN Rosaly [1], BUITEN Rosaly [1], PLOUMEN Eline [1], ZOCCA Paolo [1], DOGGEN Carine [2], DANSE Peter [3], SCHOTBORGH Carl [4], STOEL Martin [1], SCHOLTE Martijn [5], LINSSEN Gerard [6], VON BIRGELEN Clemens [1]

(1) Medisch Spectrum Twente, Enschede, the Netherlands; (2) University of Twente / Universiteit Twente, Enschede, the Netherlands; (3) Rijnstate Arnhem, Arnhem, the Netherlands; (4) Haga ziekenhuis, The Hague, the Netherlands; (5) Albert Schweitzer Ziekenhuis, Dordrecht, the Netherlands; (6) ZGT Almelo, Almelo, the Netherlands

Aims: Severe lesion calcification increases cardiovascular event risk after coronary stenting, but there is a lack of data on the performance of more recently introduced drug-eluting stents. The objective was to assess the 2-year clinical outcome of all-comer patients with severely calcified lesions, who were treated with three contemporary thin-strut drug-eluting stents.

Methods and results: The investigator-initiated, patient-blinded BIO-RESORT trial (NCT01674803) randomly assigned 3,514 all-comer patients to very-thin-strut biodegradable polymer everolimus-eluting Synergy or sirolimus-eluting Orsiro stents, versus thin-strut durable polymer zotarolimus-eluting Resolute Integrity stents. Patients were enrolled from December 2012 to August 2015, in 4 Dutch centres for cardiac intervention. In a post-hoc analysis, we assessed 783 patients (22.3%) with at least one severely calcified target lesion. The main outcome was target vessel failure at 2-year follow-up, a composite of cardiac death, target-vessel related myocardial infarction or target vessel revascularisation and was analysed by Kaplan-Meier methods. At 2-year follow-up (available in 99% of patients), the main composite endpoint target vessel failure occurred in 19/252 (7.6%) patients treated with everolimus-eluting and in 33/265 (12.6%) of patients treated with zotarolimus-eluting stents (HR 0.59, 95% CI: 0.34-1.04, p-logrank=0.07). Target vessel failure occurred in 24/266 (9.1%) of patients treated with sirolimus-eluting stents (vs zotarolimus-eluting: HR 0.72, 95% CI: 0.42-1.21, p-logrank=0.21). There was a difference in target vessel revascularisation between everolimus-eluting and zotarolimus-eluting stents, which was required in 6/252 (2.4%) and 20/265 (7.7%) patients respectively (HR 0.31, 95% CI: 0.12-0.76, p-logrank=0.01); the target vessel revascularisation rate in patients treated with sirolimus-eluting stents was 9/266 (3.4%, vs zotarolimus-eluting stents: HR 0.44, 95% CI: 0.20-0.97, p-logrank=0.04). Multivariate analysis showed that implantation of everolimus-eluting stents was independently associated with lower target vessel revascularisation rates than in zotarolimus-eluting stents (p=0.02). Multivariate analysis of the same endpoint for the sirolimus-eluting stents versus the zotarolimus-eluting stents lost statistical significance with a p-value of 0.06.

Conclusions: In BIO-RESORT participants with severely calcified target lesions, treatment with the everolimus-eluting stent was independently associated with a lower 2-year target vessel revascularisation rate than treatment with the zotarolimus-eluting stent.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Bifurcation lesions: sex-specific differences in patients with ACS

SIKIC Jozica [1]

(1) Sveti Duh, Zagreb, Croatia

Aims: To study the impact of age and sex-related differences to type and manage of bifurcation lesions (BIF) in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI).

Methods and results: From March 2017 to November 2019, 9106 patients (2,797 men and 6,309 women) with ACS from 11 PCI centres were enrolled in this study. 17.4% have had BIF. The incidence of BIF was the opposite in men and women due to age. 26% of men vs 10% of women ($p<0.001$) younger than 55-years and have had BIF, and 7% vs 20% older than 80-years ($p<0.001$). Smoking were stronger predictor for BIF in women than in single vessel ACS (20.94% vs 33.11%) Men have had a higher prevalence of previous myocardial infarction (11.26% vs 3.33% p 3,2% of women and 2.03 % of men were on triple anticoagulation therapy but without differences in blood complications. Ticagrelor was drug of choice in 49%. There was not differences in mortality rate between gender and age.

Conclusions: BIF in ACS is a technically challenging lesion, but there were no differences between BIF and single vessel ACS in achieving TIMI 3 flow. Although provisional technique with single stent implantation was more commonly used, the rate of restenosis in BIF lesions was significantly higher than in single-vessel ACS, especially in men.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

ACS: differences in men and women

SIKIC Jozica [(1)], SIKIC Jozica [(1)], PLANINIC Zrinka [(1)]

(1) Sveti Duh, Zagreb, Croatia

Aims: To study the impact of age and sex-related differences in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI)

Methods and results: From March 2017 to November 2019, 9,106 patients (2,797 men and 6,309 women) with ACS from 11 PCI centres were enrolled in this study. Among enrolled patients, men (69%) were younger than women (63 y vs 68 y, p=0.001), with a higher prevalence of previous myocardial infarction (15% vs 9.5% p<0.001), previous PCI (15.9 vs 9.7%, p=0.003), and similar frequency of previous cerebrovascular insult and peripheral artery disease (PAD). The most affected coronary artery was proximal and mid left anterior descending (LAD) in both gender and all ages. PCI on CABG was performed in 0.3% (0.33% in men vs 0.18% in women, p=0.2). In patients under age 55, 25% of men vs 11% of women (p<0.001) have had ACS. The radial approach was used in 81%, and in 89% (87.7% in men and 88.9% in women) a stent has been implanted. Average stent length was 22.01×2.99 mm in men vs 20.7×3.17 mm in women. Women had 3% of the unsuccessful procedures, in comparison to 2.3% in men. The restenosis rate was 3.9% and seen more often in men (4.8% vs 2.7%, p<0.001). The highest restenosis rate was between 55-80 y in men, and between 66-80 y in women. Clopidogrel was the drug of choice in 56.49%. There was no difference in blood complications. The in-hospital mortality rate for STEMI patients was 5.2%, without gender differences.

Conclusions: Although there were no differences between men and women in management and in-hospital outcomes, gender was shown to be predictor of earlier occurrence of ACS, higher restenosis, and re-ACS rate.

Stents and scaffolds - Tools, devices and techniques

New-generation DES in octogenarians: patient-level pooled analysis of 9,204 TWENTE I–IV trial participants

PLOUMEN Eline [1,2], PLOUMEN Eline [1,2], BUITEN Rosaly [1,2], DOGGEN Carine [2], SCHOTBORGH Carl [3], JESSURUN Gillian [4], ROGUIN Ariel [5], DANSE Peter [6], BENIT Edouard [7], AMINIAN Adel [8], VON BIRGELEN Clemens [1,2]

(1) Medisch Spectrum Twente, Enschede, the Netherlands; (2) Universiteit Twente, Enschede, the Netherlands; (3) Haga ziekenhuis, The Hague, the Netherlands; (4) Treant Zorggroep, Scheper Hospital, Emmen, the Netherlands; (5) Rambam Hospital, Haifa, Israel; (6) Rijnstate Arnhem, Arnhem, the Netherlands; (7) Jessa Ziekenhuis, Hasselt, Belgium; (8) centre hospitalier universitaire, Charleroi, Belgium

Aims: Patients aged ≥80 years are often treated with new-generation drug-eluting stents (DES), but data from randomised studies are scarce due to underrepresentation in most trials. In this study, we aimed to assess the 1-year clinical outcome of octogenarian participants in all-comer randomised controlled trials, treated with new-generation DES, versus younger trial participants.

Methods and results: We pooled patient-level data of 9,204 participants in the TWENTE (NCT01066650), DUTCH PEERS (NCT01331707), BIO-RESORT (NCT01674803), and BIONYX (NCT02508714), also known as the TWENTE I-IV randomised clinical trials. A total of 671 (7.3%) patients were octogenarian. Life expectancy of <1 year was an exclusion criterion in all trials. The main clinical endpoint was target vessel failure (TVF), a composite of cardiac death, target vessel-related myocardial infarction, or target vessel revascularisation. It was analysed using Kaplan-Meier methods. The 671 octogenarian trial participants had significantly more comorbidities than the 8,533 younger patients. The TVF rate in octogenarians was higher than in patients <80 years (7.3% vs 5.3%, HR 1.36, 95%-CI:1.0-1.83, p-logrank=0.04). This difference was driven by a higher cardiac death rate in octogenarians (3.9% vs 0.8%, p-logrank<0.001), while cardiac mortality ≤48 hours was similar (0.15% vs 0.04%, p-logrank=0.38). There was no significant between-group difference in target vessel myocardial infarction (2.3% vs 2.3%; p-logrank=0.88) and target vessel revascularisation (1.9% vs 2.8%; p-logrank=0.16). Multivariate analysis revealed that age ≥80 years was not independently associated with TVF (adjusted HR:1.04, 95%-CI:0.76-1.42), and risk of repeat target vessel revascularisation was even lower in octogenarians (adjusted HR:0.50, 95%-CI:0.27-0.92). The standardised mortality ratio for Dutch octogenarian study participants was 0.81 (95%-CI:0.57-1.10). There was no between-group difference in the incidence of definite or probable stent thrombosis (0.6% vs 0.5%, HR:1.05, 95%-CI:0.38 to 2.90; p-logrank=0.93).

Conclusions: Octogenarian participants in 4 large randomised DES trials had more comorbidities and a higher incidence of the main endpoint TVF, driven by cardiac death only. However, age ≥80 years was not independently associated with TVF, and octogenarians had an myocardial infarction rate similar to younger patients and even a lower risk of undergoing repeat revascularisation. In addition, the 1-year mortality rate of Dutch octogenarian trial participants was comparable to that of all Dutch octogenarian citizens. Thus, treatment of octogenarians with new-generation DES appears to be safe and effective.

Stable CAD - Adjunctive pharmacotherapy

Bleeding risk associated with one-month DAPT after DEB angioplasty

CORBALLIS Natasha [1,2], CORBALLIS Natasha [1,2], MERINOPOULOS Ioannis [1,2], GUNAWARDENA Tharusha [1,2], WICKRAMARACHCHI Upul [1], ECCLESHALL Simon [1], VASSILIOU Vassilios [1,2]

(1) Norfolk & Norwich University Hospital NHS Foundation Trust, Norwich, United Kingdom; (2) Norwich Medical School, UEA, Norwich, United Kingdom

Aims: There is increasing evidence supporting the safety of one-month duration of dual antiplatelet therapy (DAPT) after drug-coated balloon (DCB) therapy for stable coronary disease. As such, this makes DCB angioplasty an attractive option for patients with higher bleeding risk as it avoids the need for prolonged DAPT. Twelve months of DAPT is associated with higher all-cause mortality and bleeding rates than shorter duration DAPT. We sought to determine the bleeding risk associated with one-month DAPT in our DCB cohort.

Methods and results: We retrospectively interrogated our registry database from a tertiary UK PCI centre. We analysed all consecutive patients who received one-month duration of DAPT after PCI with DCB for stable coronary disease from 13/06/2011 to 14/12/2018. Follow-up data was determined from local procedural records and clinical notes and supplemented with NHS Digital Mortality Data. Our primary outcome was bleeding as defined by the Bleeding Academic Research Consortium (BARC) at one-month. Our secondary outcome was bleeding at six months. We identified 453 patients, with a total of 553 lesions treated. 76.7% were male with 28% of patients over the age of 75. The average age of the patients was 67.7. A total of 436 patients received aspirin and clopidogrel, 13 ticagrelor and aspirin and 4 received prasugrel and aspirin. Patients on triple therapy were excluded. Only two patients (one was over the age of 75) (0.4%) required hospital admission at one-month for type 3A bleeding as defined by BARC. Eight patients (1.8%) required hospitalisation for type 3A bleeding at six-months. There were no deaths at one-month and no deaths at six months attributed to bleeding.

Conclusions: This low number of patients with significant bleeding whilst on one-month DAPT after DCB angioplasty strengthens the role of DCB angioplasty for stable coronary disease, particularly for patients at high risk of bleeding.

Bifurcation lesion - Tools, devices and techniques, CTO - Tools, devices and techniques

The fate of the side branch in coronary CTOs: Which bifurcation type should we take care of?

ADACHI Yuya [(1)], ADACHI Yuya [(1)], KINOSHITA Yoshihisa [(1)], HABARA Maoto [(1)], NASU Kenya [(1)], KOSHIDA Ryouji [(1)], TSUCHIKANE Etsuo [(1)], TERASHIMA Mitsuyasu [(1)], MATSUBARA Tetsuo [(1)], SUZUKI Takahiko [(1)]

(1) Toyohashi heart centre, Toyohashi, Japan

Aims: There is little evidence on the optimal strategy for bifurcation lesions in the context of a coronary chronic total occlusion (CTO). The aim of this study was to investigate the fate of the side branch (SB) and evaluate predictors of SB loss in CTO interventions.

Methods and results: We retrospectively reviewed consecutive 1,149 patients who underwent CTO percutaneous coronary intervention (PCI) from March 2010 to June 2018. From them, 206 patients with bifurcation (SB ≥ 2.5 mm) involved in CTO lesions were evaluated. We divided patients into 2 groups based on the SB loss and non-SB loss groups. Side branch loss was defined as a final Thrombolysis in Myocardial Infarction (TIMI) flow < grade 3 in the side branch. The baseline characteristics, procedural outcomes, and clinical outcomes were compared between patients in the SB loss and non-SB loss groups. We also evaluated predictors of side branch loss. Mean age was 68±10 years and 42% were men. Concerning the distribution of the target vessel, the right coronary artery was 27.2%, left circumflex artery was 28.2%, left anterior descending artery was 43.6%, and left main trunk was 1.0%. Concerning the location of bifurcation lesions, 91 lesions (44%) were at the proximal part of occlusion, 52 lesions (25%) were located within the occluded segment and 63 lesions (31%) were at the end of occlusion. Side branch loss occurred in 33 cases (16.0%). Bifurcations located within the occluded segment (39.3 % vs 22.5%; p<0.001) and subintimal tracking at SB ostium (45.4 % vs 26.6%; p<0.001) were more frequently observed in SB loss group. In a Cox regression multivariate analysis, subintimal tracking was an independent predictor of SB loss risk (hazard ratio, 4.30; 95% CI: 1.78–10.68; p<0.001). The cumulative incidence of SB restenosis for 1 year showed significant differences between the SB loss and non-SB loss groups (16.2% vs 9.3%; p<0.001). In patients with bifurcations located within the occluded segment, usage of two stent technique was also significantly lower in SB loss group (7.7% vs 35.9%; p<0.001).

Conclusions: Predictors of SB loss was subintimal tracking at SB ostium and bifurcation lesions located within the occluded segment. In bifurcation lesions located within the occluded segment, use of a two stent strategy may be desirable for preserving the side branch.

Stable CAD - Invasive imaging and functional assessment, Stents and scaffolds - Invasive imaging and functional assessment

Clinical significance of intra-plaque dissection in the coronary in-stent restenosis lesion

MURASATO Yoshinobu [(1)], MURASATO Yoshinobu [(1)], MENO Kyohei [(1)], OMURA Soichiro [(1)], MORI Takahiro [(1)], TAKENAKA Katsuhiko [(1)]

(1) National Hospital Organisation Kyushu Medical Center, Fukuoka, Japan

Aims: Intimal rupture of the in-stent restenosis (ISR) lesion has been considered to occur at the surface of thin-cap fibroatheroma of the neo-atherosclerosis; however, intra-plaque dissection (IPD) in the deep layer of the ISR lesion is sometimes encountered in optical coherence tomography (OCT) observation. We sought to investigate tissue and clinical characteristics of the IPD and impact on clinical event in the comparison between non-IPD ISR lesions.

Methods and results: This is a single centre retrospective observational study. In 73 consecutive ISR lesions in 70 patients that OCT observations were completely performed from 2013 to 2018, we found 12 lesions in 12 patients with unusual IPD at the deeper layer of ISR plaque. The dissected lumen was located beside the struts with surrounding low-intensity tissue. Thick intima overlaid and no connection to the vessel lumen was observed in 7 cases. In the comparison between the non-IPD group (61 lesions in 58 patients), both groups presented similar patient characteristics especially in higher prevalence of male gender, hypertension and dyslipidaemia (>90%); however, the IPD group included more elderly patients (76.4±7.5 years vs 71.0±8.5 years, $p<0.05$). The lesion was located at left main in 0-2%, LAD in 50-60%, LCX in 15-20% and RCA in 25-30%. The underlying tissue characteristic in the ISR lesion was also similar; calcification in 30-35%, bending in 0-15%, bifurcation 25-35% and 2 times recurrence of ISR in 25%. Numerical predominance of more implantations of bare metal stent and 1st DES were present in the IPD group (75% vs 46%). The period of the ISR documentation was likely to be longer in the IPD group (median [1st-3rd quartile]; 2,401 [2,129-3,584] days vs 1082 [288-3,235] days, $p=0.076$). Although the non-IPD group had two peaks at <700 days and 3,000 days, the IPD group has only one peak at 3000 days. The lesions were treated similarly (drug-coating balloon 75-82%, plain ballooning 8%, DES deployment 10-17%). Clinical outcome at 1-year follow-up was not significantly different between the groups; target lesion revascularisation, stent thrombosis / myocardial infarction, cardiac death and these composite endpoints were 8%, 0%, 0% and 8% in the IPD group and 18%, 2%, 3% and 21% in the non-IPD group.

Conclusions: The IPD around the peri-strut in the ISR lesion was frequently observed in 17%, which was one of the causes of very late ischaemic events with a peak at 3,000 days after DES implantation. Peri-strut persistent inflammation might lead to a proliferation of unmatured loose tissue with different responses to vascular motion from fibrous tissue at the surface, which resulted in intimal dissection in the deeper layer.

Bifurcation lesion - Tools, devices and techniques

Efficacy of stentless strategy by directional coronary atherectomy plus DEB for de novo lesions

HONDA Yasuhiro [(1)], KOIWAYA Hiroshi [(1)], NISHIHIRA Kensaku [(1)], KURIYAMA Nehiro [(1)], SHIBATA Yoshisato [(1)]

(1) Miyazakishigun Medical Association Hospital, Miyazaki, Japan

Aims: Percutaneous coronary intervention (PCI) for bifurcation lesions is still challenging due to the carina or plaque shift which occurs even in the current drug-eluting stent (DES) era. We sought to evaluate the efficacy of a novel strategy by the combination of directional coronary atherectomy (DCA) plus drug-coated balloon (DCB) (DCA-DCB) for *de novo* lesions, comparing with that of DCA plus DES (DCA-DES).

Methods and results: This single centre, retrospective, observational study was examined in our institute. From January 2016 to February 2019, we had performed DCA-DCB (n=36) or DCA-DES(n=35) to consecutive 71 *de novo* lesions. There was no significant difference in patient characteristics between two groups. The lesion characteristics was similar in DCA-DCB group and DCA-DES group. Almost all of the lesions were the LMT bifurcation lesions (DCA-DCB: 97.2%, DCA-DCS: 85.7%). All procedures were successfully performed under the guidance of intravascular ultrasound (IVUS) findings without major complications. In quantitative coronary angiography (QCA) analysis before the procedure, there was no significant difference in percent diameter stenosis and minimal lumen diameter between two groups. In quantitative coronary IVUS (QCU) before the procedure, there was no significant difference in vessel cross-sectional area (CSA), lumen CSA and plaque area (PA) between two groups. After DCA, PA was significantly smaller in DCA-DCB group than DCA-DES group (40.0±10.1% vs 50.0±12.1%, p<0.001). After the procedure, minimal lumen diameter and acute gain were significantly smaller in DCA-DCB group than DCA-DES group (2.94±0.65 mm vs 3.43±0.41 mm, p=0.01; 2.46±0.66 mm vs 2.87±0.47 mm, p=0.01, respectively). The primary outcome was the incidence of 6-month major adverse cardiac event (MACE) after PCI. MACE was defined as a composite outcome; all-cause death, myocardial infarction (MI) and target lesion revascularisation (TLR). All cause death and MI did not occur in any patients during the follow-up period. Consequently, the incidence of MACE was comparable between two groups (2.8% vs 5.7%, p=0.54).

Conclusions: A stentless strategy by the combination of DCA plus DCB would be an effective strategy for the *de novo* bifurcation lesion during the short-term follow-up.

Stents and scaffolds - Tools, devices and techniques

Stent length as predictor of target vessel revascularisation in patients treated with DES

CODNER Pablo [1], CODNER Pablo [1], PERL Leor [1], BENTAL Tamir [1], ORVIN Katia [1], TALMOR Yeela [1], SAMARA Abed [1], GABRIEL Greenberg [1], RAN Kornowski [1], VAKNIN-ASSA Hana [1]

(1) Beilinson, Petah Tikva, Israel

Aims: While several factors have been shown to increase the risk of stent thrombosis, most cases of target vessel revascularisation (TVR) are due to in-stent restenosis (ISR) and have not been fully evaluated. Our aims were to identify predictors of early and late TVR after drug-eluting stents (DES) implantation in a large prospective registry, focusing on stent length.

Methods and results: We analysed rates of TVR according to stent length in a prospective registry of 14,447 all-comers treated with angioplasty and DES implantation in our institution. Patients were divided into quartiles according to stent length – mean 21 mm – percentile 25 (Q1) 15 mm, 50 (Q2) 18 mm, 75 (Q3) 26 mm and 100 (Q4) 32 mm. At baseline patients had similar rates of diabetes mellitus, congestive heart failure and left ventricular ejection fraction. Patients in the first quartile tend to be older, more commonly of female gender, with higher rates of GFR<60, anaemia and unprotected LM angioplasty. At 4 years follow-up, rates of TVR and MACE were higher in patients with longer stents; 8.5%, 9.8%, 10.4% and 16.1% ($p<0.001$) and 25.3%, 26.6%, 27% and 28.4% ($p=0.031$); for TVR and MACE in Q1, Q2, Q3 and Q4 groups of patients; respectively. There were no significant differences in the rates of all-cause death amongst patients in different quartiles. Furthermore, at multivariate Cox-regression analysis length of stent was found to be a significant independent predictor for TVR (OR 1.25 95.0% CI 1.11 – 1.42; $p<0.001$).

Conclusions: From the analysis of a large cohort of all-comer angioplasty patients who were treated with DES, stent length emerged as an independent predictor of TVR and MACE.

Stable CAD - Tools, devices and techniques

Long-term outcome of DEB in patients with stent edge restenosis

NAGASAKA Takashi [1]

(1) Gunma University, Gunma, Japan

Aims: Drug-eluting stent (DES) implantation reduced dramatically the occurrence of in-stent restenosis (ISR). Recently, many studies show that use of drug-coated balloon (DCB) is effective treatment of ISR. However, there are only few data on the efficacy of DCB treatment for stent edge restenosis (SER). The aim of this study was to investigate the clinical outcomes associated with DCB use for the treatment of SER compared with new-generation DES implantation.

Methods and results: Between April 2014 and May 2017, a total of 92 lesions with SER (edge restenosis; if located within the 5 mm segment proximal or distal to the stent edge margins) were enrolled. We divided into two groups: 37 lesions treated with DCB (DCB group) and 55 patients treated with new-generation DES (DES group). We assessed the differences with respect to cardiac death, myocardial infarction (MI) and target lesion revascularisation (TLR) between two groups. Baseline clinical and angiographic parameters were similar between the two groups at baseline. No significant difference was shown with respect to cardiac death and MI during follow-up (mean 18.2±9.1 months). In addition, survival rate free showed that there was no significant difference in TLR between the two groups (DCB group: 82.9% vs DES group: 83.3%, log rank p=0.717).

Conclusions: There were no significant differences in the clinical outcomes between DCB and new-generation DES in the treatment of SER. This study revealed that DCB was useful option to treat SER.

Stents and scaffolds - Tools, devices and techniques

A new-generation polymer-free amphilimus eluting stent efficiency in complex PCI lesions: a single-centre experience

ZEBRAUSKAITE Aiste [(1)], ZEBRAUSKAITE Aiste [(1)], FAIRLEY Sarah [(1)], RANCHORD Anil [(1)], HARDING Scott [(1)]

(1) Wellington Hospital, New Zealand, Wellington, New Zealand

Aims: The Cre8 polymer-free amphilimus eluting stent has shown efficacy especially in the diabetic subgroup. The new-generation Cre8 EVO amphilimus drug-eluting stent (DES) has an improved architecture and design which is favourable for complex percutaneous coronary intervention (PCI). However, there is lack of data for this new-generation DES in complex lesions. Our single centre study was designed to assess Cre8 EVO DES efficacy in complex lesions PCI.

Methods and results: This study is a physician-initiated, single centre, prospective, observational study. Consecutive patients undergoing complex PCI with implantation of a Cre8 Evo DES were enrolled between January and November 2019. Complex PCI was defined as PCI for chronic total occlusions, long (>28 mm) lesions, heavily calcified lesions, aorto-ostial lesions, in-stent restenosis or bifurcation lesions with a side branch >2 mm. Use of intravascular imaging was at the physician's discretion. Data was collected from clinical records, the cardiac catheterisation database and national admissions database. In-hospital and 30-day outcomes were collected. The primary endpoint was major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction or target lesion revascularisation at 30 days. The study enrolled 67 patients with 76 lesions being stented with the Cre8 Evo DES. The mean age was 67.5±9.6 years with 72.6% being male. Diabetes was present in 20.9% and 22.4% were current smokers. The majority (70.1%) presented with an acute coronary syndrome. Radial access was used in 88.1%. Lesions location were the left main (5.3%), left anterior descending (36.8%), circumflex (22.4%) and right coronary artery (35.5%). Of the lesions treated had the following characteristics: chronic total occlusions (18.4%), long lesions (65.8%), heavily calcified lesions (36.8%), aorto-ostial lesions (17.1%), in-stent restenosis (5.2%) or bifurcation lesions with a side branch >2 mm (34.2%). Intravascular imaging was used in 69.3% of lesions and rotational atherectomy in 9.3% of lesions. The mean number of stents per lesion was 1.4±0.6, mean stent diameter was 3.6±0.5 mm and mean stent length was 38.1±22.5 mm. Stent delivery and angiographic success was achieved in all cases. In-hospital there were no deaths, spontaneous myocardial infarction, or target vessel failure. There were 2 (3%) periprocedural myocardial infarctions. At 30 days MACE was 3% with the only adverse events being the 2 periprocedural myocardial infarctions.

Conclusions: We found the Cre8 Evo stent to be highly deliverable with good short-term outcomes in very complex lesions. One-year outcomes are awaited.

Stents and scaffolds - Tools, devices and techniques

Is it safe to deploy a 3.5 mm long XIENCE Sierra stent in vessels with reference diameters between 3.0 mm distally and beyond 4.5 mm proximally?

LEE JinHyun [(1)], ONG Paul Jau Lueng [(1)], LI Cliff Ki Fung [(1)]

(1) Tan Tock Seng Hospital, Tan Tock Seng Hospital, Singapore

Aims: Inserting a long stent to cover tapered left anterior descending artery (LAD), at times extending to the left main, is common. The size discrepancy between the proximal and distal vessel reference diameter often stretches beyond the expansion limit of modern stents. While the 3.0 mm stent size is frequently used, the expansion limit is often no more than 4.0 mm. The 3.5 mm XIENCE Sierra stent (EES) has an expansion limit of 5.5 mm can be useful in such cases. We explored the use of 3.5 mm EES to achieve stent expansion and apposition in long tapered vessels with distal reference diameter 3.0 mm.

Methods and results: We present 4 cases of optical coherent tomography (OCT) guided percutaneous coronary intervention (PCI) in naturally tapered vessels involving left main or ostial LAD extending to mid LAD. The 3.5 mm EES of either 38 mm were used to achieve adequate stent expansion and apposition. The distal and proximal references were selected by identification of the largest lumen area both distal and proximal to the minimal lumen area region. The mean maximum lumen diameter (LD) in distal was 3.0±0.5 mm and maximum LD in proximal was 4.3±0.6 mm. The DES was initially deployed below nominal pressure at 6 atm, to avoid injury to distal vessel reference. The stent balloon was then pulled back 5 mm and inflated at its nominal pressure. Post-dilatation was made using appropriately sized noncompliant (NC) balloons guided by OCT findings. On average 1.5 number of NC balloons of incremental sizes (3.0 mm to 4.5 mm) were used to optimise these long stents. Post stenting OCT in all 4 cases showed achievement of adequate stent expansion and apposition, with a progressive increase in stent dimensions from distal to proximal, respecting the natural vessel tapering. The distal stent diameters of all the 4 stents were good match to the vessel reference size and there was no exit dissection.

Conclusions: It appears safe to under deploy a long 3.5 mm EES followed by sequential post dilatation to treat long lesions with reference diameters between 3.0 mm distally and beyond 4.5 mm proximally.

Other Coronary interventions - Other

Giant coronary artery aneurysm following implantation of everolimus DES presenting with fever

TYAGI Hariom [1]

(1) Lokpriya Hospital - Best Dental Center in Meerut, Best Implantologist Meerut, Rct Center, Endodontist Meerut, Uttar Pradesh, India

Aims: Development of coronary aneurysms following drug-eluting stent (DES) implantation has been increasingly reported in the past few years. We report a case of a giant aneurysm formation following implantation of a everolimus DES. This patient presented with systemic inflammatory manifestations along with chest pain and was discovered to be having a giant aneurysm at the stent implantation site.

Methods and results: A 69-year-old male patient presented with complaints of severe chest pain with massive sweating associated with ghabrahat (editor's note: a severe anxiety attack) since the last 30 min during trade mill test in Lokpriya Hospital prior to admission. H/O T2DM/HTN for last 15-20 years. Coronary angiography (10/8/2016) revealed TVD. Primary PTCA to RCA done in same sitting. Percutaneous coronary intervention (PCI) to right coronary artery (RCA). The patient had a prior history of myocardial infarction. Recently, the patient was having worsening angina despite full medical therapy. His two-dimensional (2D) echocardiography showed no RWMA. Adequate LV systolic function (LVEF =60%). Mild MR His coronary angiography showed a right coronary artery (RCA) proximal total occlusion, and an ostioproximal LAD 80% lesion. After informed consent, a decision for revascularisation of the RCA with a DES was taken. A floppy wire was passed towards the lesion and thrombo-suction was performed with an export catheter 6 Fr. Predilatation was then done with a 2.0 mm × 10 mm SPRINTER Balloon (Medtronic, Minneapolis, MN, USA), inflated at 12 atm and subsequently a 3.5 mm × 28 mm XIENCE Prime stent (Abbott vascular, Minneapolis, MN, USA) was deployed at 16 atm pressure with good thrombolysis in myocardial infarction (TIMI) 3 flow. The patient received standard care in terms of anticoagulant and antiplatelet medication and standard preprocedural guidelines were followed. He was discharged on the 2nd day on dual antiplatelet therapy along with atorvastatin 80 mg, metoprolol 100 mg, along with oral anti-hyperglycaemic drugs. One months later, the patient had an episode of high-grade fever with chills and pyrexia lasting for 7 days. He was prescribed oral antibiotics by his local physician. However, the fever continued, and no cause could be ascertained. He also started experiencing left precordial pain, which was a constant dull ache and had a dragging character. On occasions, the pain was relieved with sublingual nitrates for which he was again sent to us for evaluation.

Conclusions: Coronary artery aneurysms after PCI are rare, with a reported incidence of 0.3–6.0%, and most 'aneurysms' are in fact pseudoaneurysms rather than true aneurysms. Aneurysms after PCI are more commonly reported after ablative techniques, particularly excisional atherectomy, residual dissection and deep arterial wall injury caused by oversized balloons or stents, high-pressure balloon inflations, and laser angioplasty have all been associated. Dissection of the coronary artery during the time of balloon angioplasty has long been known as the major factor related to the occurrence of coronary artery aneurysms. As stents were used for the management of dissection, they also lead to restenosis which leads to the development of DES for the prevention of restenosis.

STEMI - Invasive imaging and functional assessment, Other Coronary interventions - Other

Near simultaneous presentation of coronary artery disease in identical twins

TYAGI Hariom [1]

(1) Lokpriya Hospital - Best Dental Center in Meerut, Best Implantologist Meerut, Rct Center, Endodontist Meerut, Uttar Pradesh, India

Aims: Cardiovascular diseases, in particular coronary artery disease (CAD), remain the leading cause of morbidity and mortality in the world. The development of coronary artery disease has a strong genetic component. In our presentation, a pair of monozygotic identical twins presenting near simultaneously with coronary heart disease and identical atherosclerotic lesions. To date there are only 10 cases series of CAD in identical twins.

Methods and results: CASE-I: A 70-year-old male (CS) presented with C/O heaviness in chest, sweating, associated with generalised weakness since 1 day prior to admission. At the time of admission, ECG revealed Q-wave & ST-T changes in inferolateral leads and ECHO suggestive of adequate LV systolic function, LVEF =55%, Mild MR. The patient was diagnosed as a case of CAD/ACS/ACUTE IWMI (LP). Patient was taken for CAG which revealed LAD: Type III vessel, mid 40-50% disease, LCX: Co-dominant, ostioproximal minimal disease, OM2: Proximal 80-90% disease, L-PDA: 90% disease, RCA: Co-dominant, mid 100% occlusion. In same sitting taken for PTCA to RCA (culprit vessel) by radial route and in second sitting, PTCA to OM done. Post-PTCA period was uneventful and the patient was discharged in satisfactory condition. CASE-II: A 70-year-old male (editor's note: the first patient's identical twin: AS) presented here with C/O angina on exertion, dyspnoea on exertion, uneasiness, associated with generalised weakness since 10-15 day prior to admission. At the time of admission, ECG revealed non-specific changes and ECHO suggestive of Adequate LV systolic function, LVEF=55%, Mild MR. H/o TMT +ve. Patient was diagnosed as a case of CAD/AOE-II/DOE-II/TMT+ve. Patient was taken for CAG which revealed LAD: Type III vessel, proximal 40-50% disease, distal 70% disease, LCX: Co-dominant, proximal 40-50% disease, mid 50-60% disease, OM1: ostioproximal 90% disease, L-PDA: Proximal 80% disease, RCA: Co-dominant, proximal to mid-60-70% disease, distal 90% calcified. Patient was taken for PTCA to RCA by radial route. Post-PTCA period was uneventful and the patient was discharged in satisfactory condition.

Conclusions: The genetics of CAD are complex and while some Mendelian disorders contribute to CAD, most manifestations result from a multifactorial interplay between genetic factors. Similarities between the twins are fascinating, near simultaneous onset, and similar coronary lesions. There is the suggested predominance of genetic risk factors. This risk is about 20 time higher that of representative individual in the general public. The result of this study shows that the genetic effect is greater than environmental factors. The other features observed here have also been reported and a high index of suspicion of CAD should exist even in asymptomatic twins if a coronary event has occurred in one or the other.

Stents and scaffolds - Tools, devices and techniques

Clinical outcome at 6-months between paclitaxel coated balloon versus sirolimus coated balloon in de novo coronary lesions

ATHUKORALA Sampath [1], MOHAMMED Ishaq [1], KALOGERAS Konstantinos [2], ABID Husnain Ali [1], LEE Kaeng [1], WATKIN Richard [1], FREESTONE Bethan [1], PITT Michael [1], PULIKAL George [1], BHATIA Gurbir [1], BASAVARAJAIAH Sandeep [1]

(1) Heartlands Hospital, Birmingham, United Kingdom; (2) Harefield Hospital, London, United Kingdom

Aims: Drug-coated balloons (DCB) are being increasingly used in *de novo* coronary lesions especially in small vessel disease. However, all the available data are from Paclitaxel coated balloons (PCB) with no published data on Sirolimus coated balloons (SCB), which is relatively a new concept. We embarked on SCB in our practice since April 2018 and in this study, we compare short-term clinical outcomes in patients treated with PCB versus SCB for *de novo* coronary lesions.

Methods and results: We included all patients treated with PCB (Sequent Please, B Braun, Germany and In-pact Falcon, Medtronic, USA) between August 2016-January 2018 and those treated with SCB (MagicTouch, Concept Medical Limited, India) between April 2018-December 2018. Since SCB is a relatively new concept and we were comparing the two groups from different years, we obtained follow-up for all patients including PCB for 9-months and events occurring after 9-months were censored for both the groups. Endpoints included cardiac death, target-vessel myocardial infarction (TVMI), target lesion revascularisation, target vessel revascularisation and MACE (combination of cardiac death, target vessel MI and target vessel revascularisation). During the study period, 223 patients (303 lesions) were treated with PCB and 124 patients (153 lesions) with SCB. There were no significant differences in the demographic characteristics between the two group. In regards to procedural characteristics, mean diameter of DCB was smaller in SCB compared to PCB (2.51 vs 2.46 mm; p=0.2) and mean length was longer in SCB compared to PCB (23.5 mm vs 26 mm; p=0.001). Clinical outcomes at 9-months between PCB and SCB were; cardiac death (n=10; 4.5% vs 2; 2%: p=1.6), TVMI (n=3; 1% vs 3; 2.4%: p=0.7), TLR (n=10; 3.3% vs 10; 6.5%: p=0.12), TVR (n=14; 4.6% vs 11; 7.2%: p=0.3) and MACE (n=17; 7.6% vs 11; 8.9%: p=1).

Conclusions: In this study of a relatively small number of patients treated with SCB when compared with those treated with PCB, the short-term follow-up at 9-months seems encouraging for SCB as the outcomes are comparable with PCB group. We certainly need more patients with longer follow-up to confirm this and we will be able to provide this at the meeting.

Stents and scaffolds - Tools, devices and techniques

Clinical outcomes following bailout stenting in patients treated with paclitaxel-coated balloon vs sirolimus-coated balloon, synergy or toxicity?

BASAVARAJAIAH Sandeep [1], ATHUKORALA Sampath [1], MOHAMMED Ishaq [1], KALOGERAS Konstantinos [2], PANOULAS Vasileios [2], LOKU WADUGE Bhagya Harindi [1], WATKIN Richard [1], ABID Husnain Ali [1], LEE Kaeng [1], PULIKAL George [1], MENT Jerome [1], FREESTONE Bethan [1], BHATIA Gurbir [1], PITT Michael [1]

(1) Heartlands Hospital, Birmingham, United Kingdom; (2) Harefield Hospital, London, United Kingdom

Aims: The bailout stenting post-drug-coated balloon (DCB) is performed with second-generation drug-eluting stents (DES). For paclitaxel DCBs (PCB), it will result in delivery of 2 different drugs to the vessel wall (Paclitaxel from DCB + limus from DES), on the contrary for sirolimus DCBs (SCB) it will result in double dose of a same drug (limus from DCB + limus from DES). In this study, we study the differences in the clinical outcomes between the two groups (PCB + limus stent vs SCB + limus stent) assessing for either a synergistic or a toxic-effects.

Methods and results: We evaluated patients treated with DCB between January 2016 and June 2019 at our centre. Results are reported as death, cardiac death, target vessel myocardial infarction (TVMI), target lesion revascularisation (TLR) and MACE (combination of cardiac death, TVMI and TLR). During the study period, 890 lesions (766 patients) were treated with DCB. Of these; 433 were treated with PCB and 477 with SCB. A total of 81-lesions (9%) needed bailout stenting for either dissection and/or recoil of >50%. This included 42 lesions in PCB group and 39 lesions in the SCB group. There were no significant differences in the baseline characteristics between the two groups. During the median follow-up period of 18 months, the clinical outcomes between PCB and SCB group were; death: 3 (7%) vs 0; p=0.3, cardiac death: 2 (5%) vs 0; p=0.5, TVMI: 0 vs 1 (2.6%); p=0.4, TLR: 1 (2.4%) vs 3 (7.7%); p=0.5, MACE: 3 (7%) vs 3 (7.7%); p=0.7. There were no reported cases of stent thrombosis in either group.

Conclusions: The bailout stenting was relatively low in our group (9%) as compared to previously published studies. No significant differences were observed between the two-bailout stenting group, although numerically PCB + limus stent group had lower rates of TLR, but had higher mortality rates as compared to SCB + limus stent implying potential synergistic effect, but maybe at the cost of toxicity? This needs to be confirmed with larger patient group with multicentre experience.

Stents and scaffolds - Tools, devices and techniques

Incidence and outcomes of bailout stenting following use of sirolimus-DEB

ATHUKORALA Sampath [1], LOKU WADUGE Bhagya Harindi [1], KALOGERAS Konstantinos [1], PANOULAS Vasileios [2], WATKIN Richard [1], LEE Kaeng [1], PULIKAL George [1], MENT Jerome [1], BHATIA Gurbir [1], FREESTONE Bethan [1], BASAVARAJAIAH Sandeep [1]

(1) Heartlands Hospital, Birmingham, United Kingdom; (2) Harefield Hospital, London, United Kingdom

Aims: Bailout stenting post-paclitaxel drug-coated balloon use (DCB) is done with limus eluting stent as we don't use paclitaxel eluting stent anymore. However, when using sirolimus DCB, bailout stenting is done with limus eluting stent, but this raises the issue of drug toxicity with double dose of limus to the vessel wall. In this study, we evaluate all patients treated with limus DCB that required bailout stenting for safety and clinical outcomes.

Methods and results: We evaluated all patients who were treated with MagicTouch sirolimus-eluting DCB (Concept Medical limited, India) March 2018-June 2019. Bailout stenting per lesion were identified and studied for endpoints which included cardiac death, target vessel MI, stent thrombosis, target lesion revascularisation and MACE. Between the study period; 406 patients (477 lesions) with a mean age of 66±11.2 years (range; 37-90) were treated with MagicTouch DCB. Bailout stenting was required in 39 lesions (8%) and of which 22 were due to dissections and 17 were due to >50% recoil following DCB use. During a median follow-up of 302 days; there were no cases of cardiac death, 1 case of target vessel MI (2.6%) and 3-cases (7%) of TLR. The MACE rate was 7%. There were no cases of stent thrombosis as per the ARC definition.

Conclusions: One of the highlighting features of our study are the low rates of bailout stenting (9%). This may be due to our criteria of not stenting mild dissections (unless they are flow limiting) and not to expect stent like results. The outcomes in the bailout stenting group is excellent with very low hard clinical endpoints indicating there may not be any toxic effect from double dose of limus drug (DCB + DES).

Stents and scaffolds - Adjunctive pharmacotherapy

The impact of antithrombotic therapy on the 10-year clinical outcomes of the first sirolimus-eluting coronary stent

KURIHARA Ken [1], KURIHARA Ken [1], KIMURA Ayaka [1], TSUCHIYA Ken [1], HIDETSUGU Nomoto [1], MIYAZAKI Toru [1], SUZUKI Asami [1], ONO Yuichi [1], OTOMO Kenichiro [1]

(1) Ome Municipal General Hospital, Tokyo, Japan

Aims: This study aimed to evaluate the impact of antithrombotic therapy on long-term outcomes like target lesion revascularisation (TLR), stent thrombosis (ST), and bleeding risk in cases treated with the first sirolimus-eluting coronary stent (Cypher™).

Methods and results: Between June 2004 and December 2009, 1,021 patients underwent Cypher™ implantation at our institute. Of the original 1,021 patients, 433 were reviewed since data regarding 5 years of antithrombotic therapy was available for these patients. We investigated the patient characteristics, lesion and procedure characteristics, and antithrombotic therapy at 5 years following the initial procedure. Adverse events occurring at postoperative 5–10 years were also analysed. The median follow-up period was 3,600 days (interquartile range: 3145–3600 days), and the mean age of the patients was 67.0±9.9 years. When comparing dual antiplatelet therapy (DAPT) to single antiplatelet therapy at postoperative 5 years, the incidence of major bleeding was high (6.7% vs 3.9%; hazard ratio [HR] = 1.73, p=0.30). However, the incidence of definite/probable ST was low (1.4% vs 5.2%; HR = 0.27, p=0.070) in the DAPT group at postoperative 10 years. While on the one hand, the use of anticoagulant agents significantly increased the incidence of major bleeding events (17.7% vs 5.9%; HR=3.00, p=0.035), no ST or TLR occurred between postoperative 5 and 10 years in this group.

Conclusions: According to our study, there is a possibility that patients implanted with Cypher™ might need a stricter DAPT regimen compared to those with new era drug-eluting stents (DES), to avoid the long-term risk of ST. Furthermore, no TLR or ST was observed in patients undergoing anticoagulant therapy, which demonstrates the excellent effectiveness of anticoagulant agents against Cypher stent failure. However, since the superiority of DAPT and anticoagulant therapy are traded-off against a higher risk of bleeding, the final decision should be made only after risk stratification of patients has been performed.

Other Coronary interventions - Other

Preventive effect of pre-treatment with pitavastatin on contrast-induced nephropathy in patients with renal dysfunction undergoing coronary procedures: PRINCIPLE-II randomised clinical trial

KANG Woong [(1)], KANG Woong [(1)], JANG Albert Y [(1)], OH Pyung Chun [(1)], MOON Jeonggeun [(1)]

(1) Gachon University Gil Medical Center, Incheon, Republic of Korea

Aims: This study aimed to evaluate the efficacy of pitavastatin pre-treatment on CIN in patients with chronic kidney disease (CKD) after the coronary procedure.

Methods and results: This was a prospective, randomised, double-blinded, placebo-controlled, multicentre clinical trial. All consecutive 70 patients with CKD (eGFR <60 mL/min/1.73 m^2) were enrolled and randomised into two groups. Group I consisted of patients who were treated with statins (pitavastatin 4 mg/day) for 7 days before and 3 days after the procedure (n=37, 52.9%), and group II consisted of patients who were treated with placebo (n=33, 47.1%). The primary endpoint was the incidence of CIN, and the secondary endpoints were the change in serum creatinine (sCr) level and estimated glomerular filtration rate (eGFR) after the procedure. The mean age of the patients (males, 74%) was 70.4±9.0 years. After the coronary procedure, the incidence of CIN was lower in group I than in group II, but the difference was not significant (5.4% vs 9.1%, p=0.661). The maximal sCr was lower and the maximal eGFR was higher in group I than in group II, but the difference was not significant (−0.11±0.53 mg/dL and −0.04±0.33 mg/dL, p=0.678; 4.3±11.2 mL/min/1.73 m^2 and −2.9±20.4 mL/min/1.73 m^2, p=0.161, respectively).

Conclusions: This study showed the possibility of a clinical benefit of pre-treatment with high dose pitavastatin for prevention of CIN in patients with CKD after coronary procedure.

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Posters

STEMI - Vascular access and bleeding

Distal transradial approach in patients with STEMI undergoing primary PCI: the RADIM 34 registry

ROMO PEREZ Miguel Angel [1], JAUREGUI RUIZ Oddir [1], ALEJOS MARES Edson Levir [1], GALVAN GARCIA Jose Eduardo [1], PALACIOS RODRIGUEZ Juan Manuel [1]

(1) UMAE Hospital de Cardiologia No. 34, Nuevo Leon, Mexico

Aims: To compare the safety and feasibility of distal transradial access (DTRA) versus conventional transradial access in patients with STEMI who underwent primary PCI in the real-world.

Methods and results: From the RADIM 34 registry, all patients undergoing primary PCI with the diagnosis of STEMI were included. The success rate in arterial cannulation and the completion of the procedure between DTRA and conventional radial access were recorded and compared. Door-to-balloon time, door to arterial cannulation time and intrahospital complications related to vascular access, including the conversion of the first vascular access to a different one were recorded and compared. Between November 2018 to September 2019, a total of 710 STEMI patients underwent primary PCIs; 25% DRA, 66% conventional radial access and 9% femoral access. In DTRA, the success rate of arterial cannulation was 95% and the success rate of completing the procedure was 85.8%. For the comparative analysis, only 458 patients were included. The logistic regression analysis showed no differences in vascular access complications (OR 1.27; 95% CI: 0.67-2.43; p=0.45) or delay of reperfusion therapy (>60 minutes door-to-balloon) (OR 0.59; 95% CI: 0.26-1.37; p=0.22) in DTRA versus other vascular access.

Conclusions: The use of DTRA as the primary vascular access in primary PCI in patients with STEMI did not represent a delay in reperfusion therapy. No differences were found in the rate of vascular complications or in successfully completing the procedure compared to conventional radial or femoral access. A tendency to conversion to alternative arterial access was found in the DTRA group. This is the first study that evaluates and compares DTRA in STEMI patients undergoing to primary PCI of our knowledge. More studies are needed to confirm these findings.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Deferred treatment of intermediate coronary lesion outcomes based on fractional flow reserve measurement

CHIRIATTI Niccolò [1], MAIOLI Mauro [1], CHIRIATTI Niccolò [1], TOSO Anna [1], GRIPPO Gabriele [1], MUSILLI Nicola [1], NIERI Massimiliano [1], LEONCINI Mario [1], BELLANDI Francesco [1]

(1) S. Stefano Hospital, Prato, Italy

Aims: Fractional flow reserve (FFR) value ≤0.80 is a well-established discriminant value for treating patients with coronary artery disease. It is considered safe to defer treatment of lesions with FFR >0.80. However, the risk of adverse outcome in this broad group of patients has not been widely evaluated. We have investigated outcomes in revascularisation-naïve patients with intermediate lesions stratified according to two different ranges of FFR values.

Methods and results: Between January 2002 and December 2018, 527 coronary lesions (527 patients) classified as intermediate at angiographic imaging were functionally evaluated by FFR analysis at our institution. In 280 patients FFR value was >0.80 and they were treated conservatively (i.e., no revascularisation). Of these, 156 had undergone prior coronary revascularisation and 124 patients were revascularisation-naïve. The "naive" patients were divided into two sub-groups based on FFR value: Group A with FFR >0.80 to ≤0.90 and Group B with FFR >0.90. The primary composite endpoint was cardiac death, acute coronary syndrome (ACS) or revascularisation. The secondary endpoint was ACS or revascularisation. Follow-up was evaluated at 5 and 10 years; 2 patients were lost to follow-up. Overall, adverse events were: 16 deaths (13 cardiac deaths); 10 ACS (1 STEMI); 11 revascularisations. Kaplan-Meier analysis showed a significantly lower incidence of both primary and secondary endpoints in Group B than in group A at follow-up (primary endpoint at 5 years: log rank 5.1, p=0.023; 10 years log rank 7.9, p=0.005; secondary endpoint at 5 years: log rank 5.1, p=0.023; at 10 years log rank 6.71, p=0.01).

Conclusions: Revascularisation-naïve patients with FFR >0.80 to ≤0.90 experienced a significantly higher incidence of adverse clinical events than those with FFR >0.90. Even in the case of intermediate lesions specification of different ranges of FFR values leads to better definition of long-term clinical prognosis.

Stents and scaffolds - Invasive imaging and functional assessment

Clinical outcomes after deferral according to FFR grade

PELLEGRINI Denise [1], PELLEGRINI Denise [1], LASEVITCH Ricardo [1], GOMES Vitor [1], CARAMORI Paulo [1], PINHEIRO Diego [1], SOCCOL Ricardo [1], AGOSTINI Gustavo [1]

(1) Hospital São Lucas da PUCRS, RS, Brazil

Aims: There is limited data on clinical outcome of deferred coronary lesions according to their functional severity. This study aimed to evaluate the 5-year clinical outcomes of patients with non-deferred lesions with FFR <0.8 and deferred lesions patients with FFR > 0.8.

Methods and results: From 2013 to 2018 FFR was performed in 227 consecutive patients included in a single centre registry. Participants were categorised on the basis of FFR in ischaemic FFR group (≤ 0.8, intervention group, n=55), low-normal FFR group (> 0.81-0.9, deferred, n=99) and high-normal FFR group (> 0.9, deferred n=73). The primary endpoint was major adverse cardiac events (MACE), a composite of all-cause mortality, myocardial infarction, and target vessel revascularisation. Additional secondary endpoints were new coronary angiography, hospital admission, and stroke. The mean follow-up period was 3.5 years. The baseline characteristics were similar among groups. The median age was 63.5 years, 64% were male and diabetes was present 32.5%. By coronary angiography, stenosis severity was 62%, 56% and 53% in groups ischaemic, low-, and high-normal FFR, respectively (p>0.05). The incidence of MACE was 14.5%, 9.1% and 8.5% respectively (p=0.28). The cumulative rate of MACE by Kaplan-Meier analysis was not different between ischaemic and normal FFR patients. New angiography occurred more frequently in ischaemic group (27.3%) as compared to low-normal (7.1%) and high-normal (14.1%) FFR patients (p=0.04). Similarly, new hospital admission occurred in 23.6% in ischaemic FFR patients as compared to low-normal 6.1% and high-normal 8.1% FFR patients (p=0.03). Acute myocardial infarction occurred in 1.8%, 3.0% and 1.4% in groups ischaemic, low-, and high-normal FFR, respectively (p=0.82) and stroke occurred in 1.8%, 0,0% and 1.4% in groups ischaemic, low-, and high-normal FFR, respectively (p=0.89).

Conclusions: The major findings of this long-term follow-up study is that the outcome of patients with deferred lesions with low-normal and high-normal FFR was favourable and comparable. Patients with FFR 0.81-0.9 have similar incidence of MACE as compared to patients with FFR >0.91.

Stable CAD - Invasive imaging and functional assessment

OCT and optical frequency domain imaging predictors for recurrent restenosis after paclitaxel-coated balloon angioplasty for DES restenosis

IIDAKA Kazunobu[1]

(1) Edogawa Hospital, Tokyo, Japan

Aims: Little is known of the relationship between OCT or optical frequency domain imaging findings and recurrent restenosis after paclitaxel-coated balloon angioplasty for drug-eluting stent in-stent restenosis. To identify the predictors of recurrent restenosis after paclitaxel-coated balloon angioplasty, we investigated quantitative and qualitative OCT or optical frequency domain imaging findings during paclitaxel-coated balloon angioplasty for drug-eluting stent in-stent restenosis.

Methods and results: In all, 55 drug-eluting stent in-stent restenosis lesions treated by paclitaxel-coated balloon angioplasty with OCT or optical frequency domain imaging assessment and followed-up angiographically were divided into restenotic and non-restenotic lesions on the basis of the presence or absence of restenosis at follow-up. OCT or optical frequency domain imaging was performed before and after PCI. The restenotic tissue pattern before PCI were classified into three types: homogeneous pattern, heterogeneous pattern, layered pattern. Before and after successful PCI, minimum lumen area, stent area, intima area were measured. Differences in minimum lumen area, stent area, and intima area before and after PCI were defined as Δminimum lumen area, Δstent area, and Δintima area. Restenotic lesion was documented in 16 lesions (34%). The restenotic tissue pattern was similar in both groups (p=0.19). The oct or optical frequency domain imaging-derived post-procedural minimum lumen area, stent area, and intima area was similar in both groups. Δminimum lumen area was significantly smaller in restenotic lesions (1.73±1.64 mm² vs 2.72±1.65 mm² p=0.02).

Conclusions: Δminimum lumen area, rather than the restenotic tissue pattern before PCI, was associated with restenosis after paclitaxel-coated balloon angioplasty for drug-eluting stent in-stent restenosis.

Stable CAD - Vascular access and bleeding

The impact of the use of a dominant forearm artery on complications after PCI with transradial or transulnar access: a randomised controlled trial with preprocedural ultrasound examination

LEWANDOWSKI Pawel [1,2], LEWANDOWSKI Pawel [1,2], ZUK Anna [1,2], MACIEJEWSKI Pawel [1,2], SLOMOSKI Tomasz [1], RAMOTOWSKI Bogumil [1,2], BUDAJ Andrzej [1,2]

(1) Grochowski Hospital Admissions, Warsaw, Poland; (2) Medical Centre of Postgraduate Education, Warsaw, Poland

Aims: The impact of dominant vs recessive forearm artery access in interventional cardiology has yet to be studied. This study aimed to assess the impact of the selection of the dominant forearm artery based on pre-procedural ultrasound examination on the incidence of vascular complications at 24-hour and 30-day observation.

Methods and results: This prospective, single-centre, randomised trial included patients undergoing coronary angiography or percutaneous coronary intervention. The dominant artery was identified with ultrasound examination, and patients were randomised into either a dominant artery group or recessive artery group. The primary endpoints were: an incidence of total artery occlusion or composite endpoint (total artery occlusion, large haematoma, stroke or major bleeding). The secondary endpoint was an incidence of any minor vascular complication (iatrogenic pseudoaneurysm, arteriovenous fistula, small haematoma, or bleeding). Between 2016 and 2019, 200 patients (107 men, mean age 68±8 years) were enrolled in this study. Due to crossover events between the transradial access and transulnar access, the dominant artery group and recessive artery group consisted of 115 (57%) and 85 (43%) patients, respectively. Dominant artery access was superior in terms of total artery occlusion and composite endpoint at 24-hour: odds ratio (OR) 0.07; 95% confidence interval (CI) 0.09-0.61; p<0.016 and OR 0.26; 95% CI: 0.08-0.86; p<0.028, respectively; and at 30-day: OR 0.25; 95% CI: 0.05-0.12; p<0.001 and OR 0.17; 95% CI: 0.05-0.57; p=0.004, respectively. There were no statistically significant differences in the frequency of minor complications. The visual analogue scale scores for procedure pain were greater in the recessive artery group than in the dominant artery group (3.08±1.8 vs 2.63±1.6, p<0.05).

Conclusions: Dominant artery access was associated with a lower incidence of total artery occlusion and clinic complications. It is suggested to apply the preprocedural ultrasound examination to identify the dominant forearm artery for vascular access.

Stents and scaffolds - Tools, devices and techniques

Midterm clinical outcomes post-sirolimus-coated balloon angioplasty in patients with coronary artery disease

ATHUKORALA Sampath [1], LOKU WADUGE Bhagya Harindi [1], KALOGERAS Konstantinos [2], PANOULAS Vasileios [2], WATKIN Richard [1], LEE Kaeng [1], PULIKAL George [1], MENT Jerome [1], BHATIA Gurbir [1], FREESTONE Bethan [1], BASAVARAJAIAH Sandeep [1]

(1) Heartlands Hospital, Birmingham, United Kingdom; (2) Harefield Hospital, London, United Kingdom

Aims: Use of drug-coated balloons (DCBs) in coronary intervention is escalating. Most available DCBs elute paclitaxel and there is plethora of data on them. However, when it comes of stents, we prefer limus over paclitaxel eluting stents. There is very limited data on sirolimus-eluting DCBs. MagicTouch (Concept Medical limited, India) a CE marked DCB elutes sirolimus via nanotechnology. We report a midterm follow-up with this relatively new technology from 2 high volume centres in the UK.

Methods and results: We included all patients treated with MagicTouch DCB between March 2018 and June 2019 at Heartlands hospital, Birmingham and Harefield hospital. London, UK. Results are reported as cardiac death, target vessel myocardial infarction (TVMI), target lesion revascularisation (TLR), target vessel revascularisation (TVR) and MACE (combination of cardiac death, target vessel MI and TLR). 406 patients (477 lesions) with a mean age of 66±11.2 years (range; 37-90) were treated with MagicTouch DCB. 77% (n=314) were male, 210 (52%) were in the setting of acute coronary syndrome, 37% (n=152) had diabetes and 60% (n=285) had DCB in *de novo* lesions. Small vessels accounted for 64% of cases (n=305). Predilatation was performed in 93% (n=445) of cases. Bailout stenting (with DES) was required in 8% lesions (n=39) and of which 22 were due to dissections and 17 were due to >50% recoil following DCB use. The mean diameter and length of DCBs were 2.69 mm and 25 mm, respectively. During a median follow-up of 302 days; cardiac death occurred in 6 patients (1.5%). Target vessel MI was in 2.2%; n=9, TLR per lesion was 13%. The MACE rate was 9%. There were no documented cases of acute vessel closure.

Conclusions: The results from midterm follow-up with this relatively new technology DCB is encouraging with a low-rates of hard endpoints and acceptable rates of TLR and MACE despite complex group of patients (50% ACS and 37% diabetics) and complex lesion subsets (40% restenotic lesions and 64% small vessels). The results are comparable to Paclitaxel DCB, although we need more long-term data. We will aim to provide even longer follow-up in the future.

Stents and scaffolds - Tools, devices and techniques

Does the use of scoring balloons prior to DEB improve clinical outcomes in de novo coronary lesions?

ATHUKORALA Sampath [1], LOKU WADUGE Bhagya Harindi [1], KALOGERAS Konstantinos [2], PANOULAS Vasileios [2], WATKIN Richard [1], LEE Kaeng [1], PULIKAL George [1], MENT Jerome [1], BHATIA Gurbir [1], FREESTONE Bethan [1], BASAVARAJAIAH Sandeep [1]

(1) Heartlands hospital, Birmingham, United Kingdom; (2) Harefield Hospital, London, United Kingdom

Aims: The use of scoring balloons prior to drug-coated balloon has been proven to be effective in restenotic lesions. However, their effect in *de novo* lesions has not been tested although logic tells that use of scoring balloons should enhance the drug uptake into the vessel wall. In this study, we evaluated this concept of scoring balloon prior to DCB in *de novo* lesions and compared to those who were treated with conventional approach (semi-compliant and/or non-compliant balloons).

Methods and results: We evaluated all *de novo* lesions treated with DCBs between January 2018 and June 2019 at two high-volume centres in the UK. Results are reported as cardiac death, target vessel myocardial infarction, target lesion revascularisation and MACE (combination of cardiac death, target vessel MI and TLR). During the study period 299 *de novo* lesions (263-patients) were treated with DCB. Of these; 28 lesions (25 patients) were predilated with scoring balloon prior to use of DCB and remaining 271 lesions (238 patients) were predilated with non-scoring balloons (semi-compliant and/or noncompliant). There were no significant differences in the baseline characteristics between the two groups except mean diameter of the lesions were larger in the scoring balloon group: 2.6±0.5 vs 2.41±0.4; p=0.02 and mean length of lesions longer in the non-scoring balloon group: 24.5±8.6 vs 20.3±7.7; p=0.01. During the median follow-up of 309 days clinical outcomes between the scoring and non-scoring balloons were; cardiac death: 0 vs 3 (1.3%); p=1, TVMI: 0 vs 3 (1.3%); p=1, TLR: 0 vs 19 (7%); p=0.7, MACE: 0 vs 13 (5.5%).

Conclusions: Clinical outcomes were numerically better in the scoring balloon group as there were no recorded events as compared to the non-scoring balloon group, but numbers were too small to demonstrate any significant differences between the group. Nevertheless, the study gives some signal that scoring balloon prior to DCB may give better clinical outcomes, although this needs to be tested in larger patient group.

STEMI - Tools, devices and techniques

Prognostic factors for survival after immediate multivessel PCI in cardiogenic shock AMI patients without a concomitant CTO

YAMANE Masahisa [1], ARAMAKI Kazuhiko [1]

(1) Saitama Sekishinkai Hospital, Saitama, Japan

Aims: The further beneficial advantage of PCI for CTO immediately after PCI for AMI culprit lesions is controversial. This is seen even in haemodynamically unstable multivessel AMI-patients, because the complex PCI such as CTO often requires higher doses of contrast material and longer procedural time which might have led to adverse outcomes. However, it is unclear whether the immediate PCI for non-CTO is also hazardous or not. The aim of this study is to clarify the clinical predictors for survival after immediate multivessel PCI in cardiogenic shock AMI patients not involving CTO.

Methods and results: This retrospective study included 42 multivessel AMI patients with cardiogenic shock who were treated with PCI for not only culprit lesion but non-culprit lesions immediately following culprit. Cardiogenic shock was defined as a systolic blood pressure of less than 90 mm Hg (including the use of catecholamine therapy to maintain a systolic pressure of at least 90 mm Hg) or clinical signs of pulmonary congestion. AMI patients with a concomitant CTO in the non-culprit artery were excluded. In-hospital death occurred in 15 patients (D-group) and non in-hospital death did in 27 (ND-group). A comparative analysis of clinical characteristics between D- and ND-group was performed to determine the predictive factors for survival. The proportion of cardiovascular risk factors were comparable between D- versus ND-group (hypertension: 60 vs 48%, diabetes mellitus: 73 vs 44%, dyslipidaemia: 40 vs 41%, and smoking: 6.7 vs 37%, p=ns, respectively). Culprit lesion locations of AMI were also not different (RCA: 33 vs 41%, LAD: 33 vs 44%, and LCX: 0 vs 11%, p=ns, respectively) except for LMT (33 vs 3.7%, p<0.03). No significant differences were seen in contrast volume (167.2±44.6 vs 200.3±79.4ml, p=ns), Air Kerma (1138 [515, 1886] vs 1039 [609, 1557] mGy, p=ns), and procedural time (36.16 [26.5, 57.8] vs 34.9 [24.7, 41.5] minutes, p=ns) between 2 groups.

Conclusions: Non-LMT culprit lesions predict survival in cardiogenic shock AMI patients not involving CTO after immediate multivessel PCI.

STEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Integrated backscatter-intravascular ultrasound and modification of plaque during excimer laser coronary angioplasty

SASAKI Satoru [(1)], NAKAJIMA Kenji [(1)], TAKAOKA Hideyuki [(1)]

(1) Department of Cardiology Takatsuki General Hospital, Osaka, Japan

Aims: No reflow or slow flow phenomenon is a serious complication of percutaneous coronary intervention (PCI). Excimer laser coronary angioplasty (ELCA) has been shown in several reports to be associated with the reduction of these phenomenon after PCI, but the mechanism behind this is unclear. We hypothesise that ELCA modifies coronary plaque in addition to debulking it, which may lead to this reduction. To test this hypothesis, we evaluate tissue characteristics of coronary plaque after ELCA using integrated backscatter-intravascular ultrasound (IB-IVUS).

Methods and results: This is a retrospective study of patients who required angioplasty and who underwent ELCA at our hospital between August 2018 and October 2019. We focused on patients who underwent PCI using ELCA and IB-IVUS to treat *de novo* lesions. In total, 34 patients, each with one lesion met this inclusion criteria. We observed the culprit lesions with IB-IVUS before and after ELCA. Mean laser catheter size was 1.3±0.3 (range: 0.9-1.7 mm) and a mean of 51±5 mJ/mm^2 at 29±4 hertz were required for lesion modification. Parameters were improved in minimum lumen diameter (from 1.73±0.58 to 2.26±1.13 mm, p=0.004), lumen volume (from 42.6±28.9 to 50.7±28.6 mm^3, p<0.01), and plaque volume (from 155±98.5 to 151±95.0 mm^3, p=0.02). Analysis of IB signals revealed that the ratio of lipid-rich plaque (IB value ranges from 0 to 69: purple-coloured area) decreases from 37.7% to 32.5% (p<0.001). Whereas, the ratio of yellow-coloured (IB value ranges from 146 to 170) and green-coloured (IB value ranges from 99 to 146) areas which mean dense-fibrous plaque and fibrous plaque increase from 3.78% to 4.73% (p=0.008), and from 32.5% to 36.6% (p<0.001) respectively.

Conclusions: ELCA seems to effectively contribute to modification of coronary plaque composition in addition to debulking it. This may explain the reported reduction of no reflow or slow flow phenomenon during PCI.

NSTEMI - Invasive imaging and functional assessment

Angiographic interpretation of Wellen's syndrome

MOHAMED JUNAIDEEN Mohamed Nawshad [(1)], MOHAMED JUNAIDEEN Mohamed Nawshad [(1)], WEERAKOON Gamini [(1)], JAYASEKARA Thilina [(1)], BANDARA Lakshman [(1)], SOORIYAGODA Hansa [(1)], WICKRAMATUNGA Indika [(1)], AMARASINGHE Manjula [(1)], JAYAWICKREME Subhashini [(1)], MAYURATHAN Gnamoorthi [(1)], KULARATHNE Ajith [(1)]

(1) National Hospital Kandy, Kandy, Sri Lanka

Aims: Diagnosis of Wellen's syndrome is a stressful situation for clinicians as well as patients in developing countries as they need early angiograms. We wanted to assess the correlation between the electrocardiogram and angiographic findings in patients who were labelled as having Wellen's syndrome in the cardiology unit of the National hospital, Kandy, Sri Lanka.

Methods and results: We performed a descriptive cross-sectional studies on patients clinically diagnosed to be have Wellen's syndrome (type 1 and 2) and admitted to the cardiology unit, National hospital, Kandy, Sri Lanka from January 2018 up to now. All the patients who were admitted to the ward fulfilling the Wellen's diagnostic criteria were included in the study. Detailed history and investigations including 2D echocardiograms were taken and managed in the coronary care unit. The patients underwent coronary angiogram at the same time as their hospital admission. The patients who had critical lesions were treated with angioplasty and stenting. Total number of patients is 27 (mean age= 55.19±8.89 years) with n=21 (77.78%) males. Type 1 n=08 (29.63%) and type 2 n=19 (70.37%). There were n=23 (85.19%) of them were troponin negative. Hypertension and diabetes were the common risk factor with 44.44% (n=12) and 40.74% (n=11), respectively. Most of the patients were non-smokers n=19, (70.37%). Only n=8 (29.63%) had significant family histories of heart disease. The majority of the patients were within normal BMI n=15 (55.56%) and only one patient (3.70%) is obese. 2D echocardiogram show normal LVEF in n=17 (62.96%). None had significant wall motion abnormalities. Angiogram interpretation showing critical left anterior descending artery (LAD) lesion as defined as more than 90% stenosis were found in n=17 (62.96%) out of which n=9 (33.33%) had 99% LAD stenosis. Out of type 1 Wellen's n=2 (25.00%) had 99% stenosis and in type 2 Wellen's n=7 (36.84%) had 99% stenosis. Out of the total number of patients n=13 (48.15%) had single vessel disease, n=4 (14.81%) had double vessel disease, n=8 (29.63%) had triple vessel disease and n=2 (7.41%) had normal epicardial coronaries. The PCI was performed in n=18 (66.67%) and n=7(25.93%) referred to CABG and n=2 (7.41%) were managed medically.

Conclusions: Most of the patients who were diagnosed as having Wellen's syndrome had critical (>90% stenosis) LAD stenosis (n=17 [62.96%]) and type 2 Wellen's patients had more severe (>99% stenosis) disease (36.84%) compared to type 1 patients (25.00%). To assess the significance of this difference between type 1 and type 2 we need more samples for this study. It is important to increase awareness and open proper channels to refer patients for early angiograms for Wellen's syndrome in order prevent future anterior STEMI. This is something that will be much cost effective in a developing country like Sri Lanka.

Stents and scaffolds - Tools, devices and techniques

One-year clinical outcomes of patients undergoing PCI in very small vessel(s) with bioresorbable polymer sirolimus-eluting stents: insights from an all-comer, worldwide registry

MICHAEL Angioi [(1)], ANGIOI Michael [(1)]

(1) Clinique Louis Pasteur, Essey-lès-Nancy, France

Aims: Stenting to lesions in very small vessels is associated with a higher risk of adverse events. Although a new-generation thin-strut bioresorbable polymer drug-eluting stents (DES) may reduce the risk, data is limited to date. This study aimed to evaluate the impact of stenting to very small-vessel lesions with a thin-strut Ultimaster sirolimus-eluting stent (SES) with a bioresorbable polymer coating on one-year clinical outcomes.

Methods and results: The present analysis was a prespecified sub-study of the e-Ultimaster registry (NCT02188355), which was a prospective, multicentre, large-scale, all-comers registry enrolling 36,916 patients from 348 sites in 50 countries (4 continents). So far, 34,538 patients who reached one-year follow-up or died were included in this analysis. Among them, 2,982 patients underwent PCI for treatment of lesions in very small vessels (defined as treated with at least one stent with diameter ≤ 2.25 mm). The primary endpoint was target lesion failure (TLF) at 1 year defined as a composite of cardiac death, target-vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent Clinical Event Committee adjudicated all endpoint-related events. Patients with very small-vessel stenting were older and more frequently female, and had a higher prevalence of comorbidities (diabetes, hypertension, hypercholesterolaemia, history of MI and revascularisation [PCI or CABG]), compared to those without very small-vessel stenting (n= 31,556) ($p<0.05$ for each). Patients with stenting to very small-vessel lesions were more likely to have chronic total occlusion (CTO), bifurcation, long lesion, greater number of stents and longer total stent length implanted. The crude rate of the primary endpoint of TLF was significantly higher in patients receiving stenting in very small-vessel lesions compared to those who did not (4.1% vs 3.0%, $p<0.01$). In terms of individual components of the primary endpoint, stenting to very small-vessel lesions had a numerically higher risk of cardiac death (1.5% vs 1.1%, $p=0.06$) and a significantly higher risk of TV-MI (1.2% vs 0.7%; $p=0.01$) and CD-TLR (2.2% vs 1.6%; $p=0.02$), as compared with stenting to non-very small-vessel lesions. The crude rate of definite or probable stent thrombosis was numerically higher in very small-vessel group (0.9% vs 0.6%; $p=0.07$). After a propensity-score matching for baseline and procedural characteristics, these significant differences became non-significant; the TLF was similar between the two groups (3.8% vs 3.7%; $p=0.84$). For individual endpoints of TLF, the rate was similar in the very small-vessel group compared to the non-small-vessel group in terms of cardiac death (1.6% vs 1.4%; $p=0.37$), TV-MI (1.3% vs 1.1%; $p=0.38$), and CD-TLR (2.0% vs 2.0%; $p=0.91$). The risk of definite or probable stent thrombosis was also comparable between the two groups (0.8% vs 0.7%; $p=0.37$).

Conclusions: Using a contemporary thin-strut bioresorbable polymer SES, patients treated with stenting to very small-vessel lesions were associated with a similar risk of ischaemic events at one year to those without very small-vessel stenting.

STEMI - Invasive imaging and functional assessment, Other Coronary interventions - Other

Close link between right ventricular branches compromise post-PCI and future adverse cardiac event in patients with right coronary artery ST-elevation myocardial infarction

SETOYAMA Koshi [1], SONODA Shinjo [1], NAKA Yutaro [1], OKABE Hiroki [1], INOUE Konosuke [1], MIURA Toshiya [1], REO Anai [1], TSUDA Yuki [1], ARAKI Masaru [1], YUTAKA Otsuji [1]

(1) Hospital of University of Occupational and Environmental Health, Fukuoka, Japan

Aims: Past studies revealed that right ventricular dysfunction (RVD) is the important predictor of poor prognosis. We often experience that largely right ventricular branches (RVB) were compromised post-PCI in patient with right coronary artery (RCA) ST-elevation myocardial infarction (STEMI). However, little is known about future prognosis in these patients. The aim of this study is to evaluate the relationship between RVB compromised post-PCI and sustained RVD and future adverse cardiac event.

Methods and results: We retrospectively analysed 87 consecutive patients with inferior STEMI patients who underwent PCI from August 2009 to January 2019. After we measured Thrombolysis in Myocardial Infarction frame counts (TFC) on RVB by post-PCI angiography, we divided all study population into 2 groups (RVB-SF, non RVB-SF). As a result, 10 patients were excluded due to no follow-up data. We measured RV fractional area change (RVFAC, %) using 2D-echocardiography at baseline and mid-term follow-up (8±5 months). We defined sustained RVD as less than 30% RVFAC. We also investigated future prognosis (43±31 months) by their outpatient clinic data or by telephone interview. We focused on future adverse cardiac events (MACE) including cardiac death, heart failure requiring hospitalisation, threatening arrhythmia, non-fatal MI. Patients characteristics including medication, onset to balloon time and left ventricular stroke volume were no significantly difference in both groups. (RVB-SF: 46 patients, RVB non-SF: 31 patients). Baseline RVFAC and follow-up RVFAC was significantly smaller in RVB-SF than in RVB non-SF, respectively (26.1±9.4 % vs 35.4±9.9 %, 31.2±6.0 % vs 46.7±6.6 %, p<.0001). Furthermore, ΔRVFAC (follow-up RVFAC – baseline RVFAC) was significantly smaller in RVB-SF group (5.2±9.9 % vs 11.3±10.8 %). Follow-up echocardiography data showed sustained RVD occurred 45% in RVB-SF, and there are no sustained RVD patients in non RVB-SF group. Multivariate analysis showed RVB-SF is the only predictor of follow-up RVD (p<.0001). In total, 15 MACEs including cardiac deaths (N=9) occurred. The event-free survival analysis showed significantly higher MACE rate in RVB-SF than in non RVB-SF (Log-rank p<.001,). Multivariate analysis showed RVB-SF is the independent predictor of poor prognosis (p=0.006). Sustained RVD with RVB-SF showed significantly higher MACE rate than the others (Log-rank p=0.01).

Conclusions: RVB-SF after PCI for RCA-STEMI mostly caused could predict sustained RVD at midterm follow-up, which may lead to poor future. RVB-SF, sustained RVD, and poor prognosis might have a close relationship.

STEMI - Tools, devices and techniques

12-month clinical outcomes of an ultrathin strut (60 µm), biodegradable polymer coated, sirolimus-eluting coronary stent in STEMI patients: a real-world, multicentre experience

POTHINENI Ramesh [1], POTHINENI Ramesh [1], VIJAN Vikrant [2], POTDAR Anil [3], INAMDAR Manohar K [4], PATHAK Abhijit [5], MANTRAVADI Sai Sudhakar [6], AJMERA Prakash [7], CHAWLA Kamal Kumar [7], JARIWALA Pankaj Vinod [8], VIJAN Vinod [2]

(1) Dr. Ramesh Cardiac and Multispeciality Hospital, Vijayawada, India; (2) Vijan Cardiac & Critical Care, Maharashtra, India; (3) Parisoha Foundation Pvt. Ltd., Mumbai, India; (4) Ashwini Hospital, Akluj, India; (5) Swasthya Hospital and Medical Research Center, Ahmednagar, India; (6) Gleneagles Global Hospitals, Telangana, India; (7) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (8) Yashoda Hospitals - Somajiguda, Telangana, India

Aims: Acute ST-segment elevation myocardial infarction (STEMI) is a lethal presentation of coronary artery disease with very high mortality rates. Management of STEMI poses particular challenges in percutaneous coronary intervention (PCI) due to its pro-thrombotic and inflammatory background. Here, we evaluated the safety and clinical performance of Supraflex Cruz (Sahajanand Medical Technology, Pvt. Ltd.), a biodegradable polymer-coated, ultrathin (60 µm) strut, sirolimus-eluting coronary stent in STEMI patients.

Methods and results: From two multicentre, real-world and retrospective registries of the Supraflex Cruz (n=2472), we identified and analysed 689 patients with STEMI who underwent PCI with only Supraflex Cruz from August 2016 to May 2018. At 12-months, target lesion failure (TLR), defined as a combination cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularisation (TLR), was considered as primary endpoint. Stent thrombosis (ST) was considered as a safety endpoint. Mean age of the patients was 55.3±11.5 years. Among all, 509 (73.9%) patients were male, 194 (28.2%) were diabetic and 144 (20.9%) were smokers. A total 893 Supraflex Cruz stents were implanted to treat 784 lesions, among which 172 (21.9%) lesions were totally occluded. Twelve-month follow-up was received in 660 (95.79%) patients with 6.2% (n=41) TLF which included 1.4% (n=9) cardiac death, 2.1% (n=14) TV-MI and 2.7% (n=18) TLR. Stent thrombosis was observed in 8 (1.2%) patients.

Conclusions: From the present analysis, it can be concluded that Supraflex Cruz is a safe and effective coronary stent in STEMI patients, as it has presented favourable clinical outcomes at 12-month follow-up.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

One-year clinical outcomes of an ultrathin strut (60 µm) biodegradable polymer coated sirolimus-eluting coronary stents in diabetic patients

POTHINENI Ramesh [1], POTHINENI Ramesh [1], VIJAN Vikrant [2], POTDAR Anil [3], INAMDAR Manohar K [4], PATHAK Abhijit [5], MANTRAVADI Sai Sudhakar [6], AJMERA Prakash [7], CHAWLA Kamal Kumar [7], JARIWALA Pankaj Vinod [8], VIJAN Vinod [2]

(1) Dr. Ramesh Cardiac and Multispeciality Hospital, Vijaywada, India; (2) Vijan Cardiac & Critical Care, Maharashtra, India; (3) Parisoha Foundation Pvt. Ltd., Mumbai, India; (4) Ashwini Hospital, Akluj, India; (5) Swasthya Hospital and Medical Research Center, Ahmednagar, India; (6) Gleneagles Global Hospitals, Telangana, India; (7) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (8) Yashoda Hospitals - Somajiguda, Telangana, India

Aims: Diabetes mellitus is highly associated with the occurrence of coronary artery disease. Despite of extensive technological advances in drug-eluting stents, patients with diabetes mellitus are affected by higher rates of adverse events after percutaneous coronary intervention (PCI). The present analysis evaluates one-year clinical outcomes of Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India), an ultrathin strut (60 µm) biodegradable polymer-coated sirolimus-eluting stent, in patients with diabetes mellitus.

Methods and results: We analysed 852 patients with self-reported diabetes mellitus (diet controlled, on oral hypoglycaemic agents, or on insulin therapy), from two multicentre retrospective registries, who underwent PCI with only Supraflex Cruz coronary stents between May 2016, and March 2018. The incidence of target lesion failure (TLF), a composite of cardiac death, target vessel myocardial infarction (TV-MI) and TLR, was considered as a primary outcome at one-year follow-up. Stent thrombosis, defined as per Academic Research Consortium, was considered as a safety endpoint. Mean age of the patients was 55.6±9.8 years. Among all patients, 575 (67.5%) were male, 566 (66.4%) were hypertensive, 123 (14.4%) were smokers, 308 (36.2%) had hypercholesterolaemia, and 516 (60.6%) presented with acute coronary syndrome. Total 1024 lesions were treated with 1158 Supraflex Cruz coronary stents. The majority of treated lesions were type B2/C (79.6%) lesions and 136 (13.3%) were totally occluded. At one-year, follow-up was obtained for 807 (94.7%) patients. The TLF was observed in 56 (6.9%) patients, comprising of 6 (0.7%) cardiac death; 19 (2.4%) TV-MI; and 31 (3.8%) TLR. At one-year follow-up, definite/probable stent thrombosis was observed in 8 (1.0%) patients.

Conclusions: Supraflex Cruz, an ultrathin strut biodegradable polymer-coated sirolimus-eluting coronary stent, performed well in diabetic patients up to one year of implantation with favourable safety and clinical performance.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Cilostazol based triple vs potent $P2Y_{12}$ inhibitor based DAPT in patients with AMI undergoing PCI

KIM Woohyeun [(1)], KIM Woohyeun [(1)], RHA Seung-Woon [(1)], CHOI Byoung Geol [(1)]

(1) Korea University Guro Hospital, Seoul, Republic of Korea

Aims: Although potent $P2Y_{12}$ inhibitor based dual antiplatelet therapy has become the standard treatment in acute myocardial infarction (AMI) patients instead of clopidogrel based therapy, there is a concern about bleeding risk in East Asian patients. We investigated the efficacy and safety of cilostazol based triple antiplatelet therapy compared to potent $P2Y_{12}$ inhibitor based dual antiplatelet therapy.

Methods and results: A total of 4,152 AMI patients underwent percutaneous coronary intervention (PCI) in the Korea Acute Myocardial Infarction Registry (KAMIR) were analysed retrospectively. Patients were divided into two groups (triple antiplatelet group [TAT]; aspirin + clopidogrel + cilostazol [n=3,161] and potent DAPT group; aspirin + potent $P2Y_{12}$ inhibitors [ticagrelor or prasugrel, n=991]). Major clinical outcomes at 30 days and 2 years were compared between the two groups using propensity score matching (PSM) analysis. After PSM (869 pairs), there were no significant differences between the two groups in the incidence of total death, cardiac death, myocardial infarction (MI), target vessel revascularisation, stent thrombosis, and stroke at 30 days and 2 years. But Thrombolysis in MI (TIMI) major or minor bleeding rates were significantly lower with the TAT group compare with the potent DAPT group at 2 years (5.8% vs 2.9%, p=0.004).

Conclusions: In Korean AMI patients undergoing PCI, the TAT including cilostazol seems to be associated with lower bleeding without increased ischaemic risk than the potent $P2Y_{12}$ inhibitor based DAPT. These results could provide a rationale for the use of triple antiplatelet therapy in East Asian AMI patients.

Stents and scaffolds - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Modified jailed balloon technique does not raise proximal incomplete stent apposition and proximal optimisation technique demand but is shown to be very useful to prevent side branch occlusion

TAGASHIRA Toru [(1)], TAGASHIRA Toru [(1)], YAMADA Shinichiro [(1)], NANIWA Shota [(1)], TERASHITA Daisuke [(1)], TSUDA Shigeyasu [(1)], TAKAMI Kaoru [(1)], YOSHIDA Akihiro [(1)], AWANO Kojiro [(1)]

(1) Kita-Harima Medical Center, Ono, Japan

Aims: A major complication of bifurcation PCI is side branch (SB) occlusion after main vessel (MV) stenting that may cause periprocedural myocardial infarction or haemodynamic compromise, even if in small branch. In case two-stenting is not suitable, strategies to reduce the risk of SB occlusion during MV stenting are preferable.

Methods and results: Recently, the modified jailed balloon technique (MJBT) has become recognised as one of the strategies to reduce SB occlusion during MV stenting; but there are some problems such as increase of balloons, POT demand due to proximal incomplete stent apposition (ISA) and jailed balloon entrapment in traditional MJBT. In our institution, we perform an improved method of MJBT in two points. First, we set the SB balloon only a little protruded into the MV. Second, the stent is inflated three times. The first two stent inflations are performed simultaneously with those of SB balloon. Then, the stent balloon is inflated alone with a higher pressure. These "tips and tricks" can reduce ISA and POT demand. We retrospectively evaluated the utility of our MJBT. Between January 2016 and December 2019, we picked out 358 patients (78.2% male, mean age 69.6 years) with 370 consecutive coronary bifurcation lesions who underwent PCI. LM lesions and small SB (<1.5mm) cases were excluded. Among them, our MJBT was used in 130 lesions, while MV stenting was performed only with SB wiring or no protection in others. We searched temporary and permanent SB occlusion rates, SB entrap rates, POT demand, number of used balloons per lesion, procedure time and contrast volume. SB occlusion was defined as no blood flow or any TIMI flow grade decrease in SB after MV stenting. PCI and clinical data were followed during hospitalisation. Results: All PCI procedures were complete. Almost all lesions were treated with IVUS or OCT/OFDI. The majority of the patients had stable angina (73.8% in MJBT group, 58.8% in non-JBT group) and LAD-Dx lesions (78.4%, 78.1%). Stent diameter (2.9±0.4 mm in MJBT group and 3.0±0.4 mm in non-JBT group, p=0.62) and length (24.8±8.1 mm and 25.1±7.3 mm, p=0.74) were similar. SB balloon diameter and length in MJBT group were 1.8±0.3 mm and 12.1±2.4 mm. After MV stenting, no jailed SB balloon was entrapped. Temporary SB occlusion occurred in 40 (10.8%) of 370 bifurcation lesions. Temporary SB occlusion rate in MJBT group (4 of 130, 3.1%) was significantly lower than in non-JBT group (36 of 240, 15.0%, p=0.001). Permanent SB occlusion occurred in 2 (1.5%) in MJBT group and 16 (6.7%) in non-JBT group (p=0.03). MJBT group needed more balloons per lesion than non-JBT group (2.3±0.7, 1.9±0.9, p<0.001), but there were no significant differences in POT demand (39.2% vs 40.4%, p=0.86), SB post-dilatation rate (20.0% vs 20.0%, p=1.0), proximal ISA (26.2% vs 20.9%, p=0.43), procedure time (100.4±38.0 minutes vs 103.4±50.4 minutes, p=0.56) and contrast volume (224.3±78.0 ml vs 218.2±87.5 ml, p=0.51).

Conclusions: Our MJBT technique is a safe and easy procedure required little effort and time to prevent SB occlusion after MV stenting. It is notable that our method doesn't raise proximal ISA rate, POT demand and procedural time. It is especially useful for PCI for bifurcation lesions predicted as having a high risk of SB occlusion.

NSTEMI - Tools, devices and techniques, Stents and scaffolds - Tools, devices and techniques

Early evaluation of a novel robotic-assisted coronary angioplasty platform in unselected series of real-world patients

LORGAT Faizel [1]

(1) Christiaan Barnard Memorial Hospital, Cape Town, South Africa

Aims: Conventional PCI is associated with significant physical demands on the operator and has well documented occupational hazards. Robotically assisted angioplasty has the potential to reduce operator fatigue, orthopaedic issues and radiation exposure. We set out to use a novel robotic angioplasty platform in a real-world setting. The intention was to complete as much as technically possible with Robotic assistance. Crossover to manual was not automatically considered as failure.

Methods and results: Robotically assisted angioplasty was performed on the first six patients presenting with conventional indications for angioplasty after installation of the Robocath R1 device. The R1 is CE marked. The system consists of a remote interventional cockpit and a bedside unit which allows manipulation and delivery of conventional everyday guidewires and rapid exchange balloons and stents. The current platform is not yet capable of manipulating the guide catheter. The Right Femoral approach was employed in 4 cases and the Right Distal Radial approach in 2 cases. A representative spectrum of disease was encountered including in-stent restenosis, small vessel disease, calcified lesions, main stem stenosis and LAD-Diagonal bifurcation disease in a patient with borderline cardiogenic shock and renal failure requiring dialysis. The guidewires were rapidly and successfully deployed robotically in all six patients. This included robotic guidewire deployment into both LAD and Diagonal in a bifurcation stenosis. In one patient a stenosis in an AV Circumflex branch of the left coronary artery could not be crossed either robotically or manually. A total of 9 drug-eluting stents were successfully deployed. Success was defined as less than 10% residual stenosis. Elective post dilation was robotically performed in 7 stents and manually in 2 cases. During two stent deployments and post dilations, manual crossover was required due to technical issues with the robotic mechanism. In the case of the LAD Diagonal bifurcation lesion, a kissing balloon inflation was manually performed since the R1 can only manipulate one balloon at any one time. No adverse events were encountered either intra procedurally, in-hospital or 30 days post procedure. All patients were otherwise treated as per ESC guidelines.

Conclusions: This early and currently largest experience in the world with the new Robocath R1 confirms the feasibility, safety, and effectiveness of the system in a real-world situation. Operator fatigue and radiation exposure was significantly reduced. Some limitations of the current platform were defined. This will undoubtedly produce refinements in the technology. A formal study has already received ethical approval and will commence shortly to formally document radiation exposure, procedure time, efficacy, and outcomes.

Stable CAD - Tools, devices and techniques, Left main and multivessel disease - Tools, devices and techniques

Successful PCI impact on systemic blood circulation improvement

JARUSEVICIUS Gediminas [1,2], ZIUBRYTE Greta [1], JARUSEVICIUS Gediminas [1,2], GRUZIENE Aldona [3], KERZIENE Sigita [4]

(1) Hospital of Lithuanian University of Health Sciences Kaunas Clinics, Kaunas, Lithuania; (2) Institute of Cardiology, Lithuanian University of Health Sciences, Kaunas, Lithuania; (3) Institute of Physiology and Pharmacology, Lithuanian University of Health Sciences, Kaunas, Lithuania; (4) Department of Physics, Mathematics and Biophysics, Lithuanian University of Health Sciences, Kaunas, Lithuania

Aims: The primary aim of this study was to verify the impact of successful PCI on improvement of systemic blood circulation evaluated by arterial blood pressure waveform change, which has been accepted as more important parameter than numeric blood pressure value change. The secondary aim was to assess the blood pressure waveform utilisation for procedural success evaluation.

Methods and results: Seventy-five patients who have undergone percutaneous coronary intervention between 9th March 2019 and 30th May 2019 have been prospectively included into this single centre study. According to ordinary practice invasive arterial blood pressure were continuously monitored during PCI procedure. Arterial blood pressure waveform along with ECG were recorded and printed twice: at the beginning and at the end of the procedure. Arterial blood pressure waveform was analysed by software package ImageJ 1.52a. Statistical analysis was performed by software package SPSS 20.0. The chosen level of significance was $p<0.001$. In total, 150 arterial blood pressure waveforms were analysed. It was found 6.6%, $p<0.001$ increase of mean arterial blood pressure, 6.0%, $p<0.001$ reduction of heart rate and 18 (SD±10) milliseconds (3.9%), $p<0.001$ prolongation of R-R interval after successful PCI. All these together lead to 14.4%, $p<0.001$ increase of pulse wave area and 2.9%, $p<0.001$ increase of angle which mean total cardiac load reduction.

Conclusions: Angiographically and clinically successful PCI in addition to increased pulse wave area, pulse angle and minute heart volume, results in heart rate and total cardiac load reduction improving heart overall function. An arterial blood pressure waveform record, in addition to periprocedural monitoring, might be easy-to-use method for evaluation of procedure success and prediction of short- and long-term outcomes after PCI.

Left main and multivessel disease - Tools, devices and techniques

Three-year follow-up of PCI in patients with true left main bifurcation lesions

MAXIMKIN Daniil [(1)], MAXIMKIN Daniil [(1)], SHUGUSHEV Zaurbek [(1)], CHEPURNOY Aleksandr [(1)], MAMBETOV Aslan [(1)], FAIBUSHEVICH Aleksandr [(1)], SAFONOVA Olga [(1)]

(1) Peoples' Friendship University of Russia, Moscow, Russian Federation

Aims: To evaluate the long-term results of the use of drug-eluting balloon catheters in patients with left main (LM) bifurcation stenosis.

Methods and results: This analysis involved 142 patients with true bifurcations of the left main. Randomisation in 2 main groups: Group I (n=52) included patients, who received kissing-dilatation with traditional NC balloon catheters and Group II (n=52), who had a kissing-dilatation of the main bifurcation artery with a traditional NC balloon catheters, and a side branch - with drug-eluting balloon catheters. Retrospectively, the third (III) control group (n=38) was formed, where the two-stent technique was employed. All patients from the main groups had previously performed "provisional T" stenting and final "kissing balloon" dilation techniques. Coronary angiography and OCT were performed to evaluate the results of all patients. Inclusion criteria: true LM bifurcation stenoses according to QCA and OCT; SYNTAX score <32. Primary endpoints: incidence of MACE - death, MI, re-interventions. Secondary endpoints: the incidence of restenosis and late stent thrombosis. Results: the long-term results after 48 months was observed in 46 patients from Group I and 48 patients from Group II. The total incidence of MACE was 17.3 vs 6.25% in groups I and II respectively ($p<0.05$). When comparing the results in group II and III, the frequency of MACE was 6.25 vs 13.2%, respectively ($p<0.05$). Restenosis of the side branch of more than 50% according to QCA was detected in 8 patients (17.3%) from Group I and in 2 patients (4.2%) from Group II ($p<0.05$). In patients from group I, the average MLA in the side branch after 48 months compared with data after PCI was 5.58±1.34 and 4.12±1.21 mm^2, respectively ($p<0.05$), in the main branch - 6.34±1.56 and 5.88±1.14 mm^2, respectively ($p>0.05$). In patients from Group II, the average MLA were, respectively, 5.38±1.24 and 5.12±1.44 mm^2 in the side branch ($p>0.05$) and 6.68±1.75 and 6.36±1.22 mm^2 in the main branch ($p>0.05$). When comparing the data of MLA in the side branch in groups I and II, there was a significant difference (4.12±1.21 vs 5.12±1.44 mm^2; $p<0.05$). There were no cases of late thrombosis of the stents.

Conclusions: The use of drug-eluting balloon catheters for the "provisional T" stenting in patients with true LM bifurcation stenosis, is associated with significantly lower frequency of MACE and side branch restenosis, according to OCT data, compared with patients who used traditional NC balloon catheters for the "kissing- dilatation" and two-stent technique strategy.

Stents and scaffolds - Tools, devices and techniques

Incidence, predictors, and clinical outcome of stent thrombosis in patients undergoing PCI with bioresorbable polymer coated Ultimaster sirolimus-eluting stent: insights from the all-comer e-ULTIMASTER registry

AMINIAN Adel [(1)]

(1) C.H.U. Charleroi, Charleroi, Belgium

Aims: The technological advance of drug-eluting stents (DES) and improvement of percutaneous coronary intervention (PCI) strategies has reduced the incidence of stent thrombosis. However, the occurrence of stent thrombosis could still lead to outcomes such as myocardial infarction (MI) and cardiac death. The aim of this study was to investigate the incidence, predictors and clinical outcome of stent thrombosis up to 1 year in patients undergoing PCI with bioresorbable polymer-coated sirolimus-eluting stents.

Methods and results: The present study was a substudy of the e-Ultimaster registry (NCT 02188355), which is a large multicentre, international registry (4 continents, 50 countries) with uniform use of bioresorbable polymer Ultimaster sirolimus-eluting stent in unselected patients, representing daily clinical practice. A total of 36,916 patients were enrolled and 34,538 patients reached one-year follow-up or died and were included in this analysis. All endpoint-related serious adverse events were adjudicated by an independent clinical events committee. Out of 34,538 patients, 136 patients had definite stent thrombosis (0,4%) to 1 year. Among 213 cases of definite/probable stent thrombosis, 154 cases (72.3%) occurred within 1 month after index procedures (early stent thrombosis) with 44 acute stent thrombosis (20.6%) and 110 subacute stent thrombosis (51.6%). Of note, amongst patients with definite/probable stent thrombosis, 53% of patients experienced MI, and 42% of patients died. At 3-months follow-up, less patients with stent thrombosis were on DAPT, compared to those without stent thrombosis (80.4% vs 94.3%, $p<0.001$), but had higher bleeding rate (3.3% vs 1.3%; $p=0.02$). Logistic regression models with stepwise selection revealed that strongest predictive factors of early ST were a history of MI and treatment of STEMI, followed by male gender, bifurcation lesions, higher number of lesions treated and stents implanted, older age and higher BMI. PCI via radial access and treatment of lesions in the right coronary artery were identified as protective factors of early ST. Predictors of late ST (> 1 month) were a history of MI, treatment of STEMI, smoking, left main, chronic total occlusions, graft treated and higher number of lesions treated.

Conclusions: After implantation of bioresorbable polymer sirolimus-eluting stent in unselected population, the occurrence of stent thrombosis was infrequent (<1%) but was frequently associated with hard adverse events such as MI and cardiac death. In addition to the comorbidities and previous cardiac history, treatment of complex coronary lesions and STEMI remained to be independent predictors for definite or probable stent thrombosis. The protective role of radial access has to be interpreted by caution as its use might be linked to procedure complexity.

Stents and scaffolds - Tools, devices and techniques

The one-year clinical outcomes in 3,115 octogenarians undergoing PCI with bioresorbable polymer-coated Ultimaster sirolimus-eluting stent

ROGUIN Ariel [1]

(1) Hillel Yaffe Medical Center, Hadera, Israel

Aims: Coronary heart disease (CHD) is the leading cause of death of elderly men and women worldwide. The aging society will lead to increasing numbers of elderly patients with CHD undergoing percutaneous coronary intervention (PCI). The aim of this study was to investigate characteristics and clinical outcomes in octogenarians undergoing PCI in the contemporary drug-eluting stent era.

Methods and results: The e-Ultimaster (NCT 02188355) registry is a prospective, single-arm, multicentre, international registry which enrolled 36,916 patients (4 continents, 50 countries, 348 sites) with uniform use of bioresorbable polymer-coated Ultimaster sirolimus-eluting stent. A total of 34,538 (93.6%) patients reached one-year follow-up and were included in this study. Patients were divided into two groups according to their age; ≥80 years old (older group) and <80 years old (younger group). The primary endpoint of this study was target lesion failure (TLF) defined as a composite of cardiac death, target vessel-related myocardial infarction (MI), and clinically driven target lesion revascularisation (CD-TLR) at 1 year. All endpoint-related serious adverse events were adjudicated by an independent clinical events committee. Out of 34,538 patients, 3,115 patients (9.0%) were classified as the older group, 2971 (95.3%) were octogenarians and 143 (4.6%) were nonagenarians, and 1 (0.03%) was a centenarian. The mean age±standard deviation (SD) of the older group and the younger group was 83.4±3.0 years and 62.4±9.9 years, respectively. Patients in the older group were more frequently female (39.9% vs 22.4%, p<0.001), more often took oral anticoagulant medication (14.4% vs 5.7%; p<0.001) and presented more often with silent ischaemia but less frequently with acute coronary syndrome (ACS) than the younger group (silent ischaemia: 10.5% vs 9.3%, p=0.03; ACS: 53.1% vs 55.2%, p=0.03). The older group had more comorbidities (hypertension, renal impairment, previous PCI, and CABG, more complex lesions (multivessel disease, left main, small vessel and graft disease, bifurcation lesion, and moderate-severe calcification lesion), and shorter DAPT when compared to those of the younger group (all p<0.05). At 3-months, 92% of older and 90% of younger patients (p=0.024) were angina free, while this rate was 91% and 90% (p=ns), respectively. Up to one year, TLF was observed in 5.5% and 2.9% in the older and younger groups, respectively (p<0.001). After propensity matching of the two groups, one-year TLF rate was still significantly higher in older group compared to the younger group (5.4% vs 3.7%, p<0.001), which was mainly driven by higher incidence of cardiac death (2.9% vs 1.6%, p<0.001), and target-vessel MI (1.6% vs 1.0%, p<0.001). There was no difference in CD-TLR (1.9% vs 1.9%, p=0.74) as well as definite/probable stent thrombosis (0.86% vs 0.66%, p=0.19). Incidence of bleeding complications was significantly higher in elderly patients (4.4 vs 2.4%; p<0.001).

Conclusions: In this worldwide registry, the elderly population undergoing PCI was more frequently female and less frequently presented with ACS than the younger population. The elderly patients showed higher risks of cardiac death and target-vessel MI compared to younger patients. Bleeding complications were more frequent in elderly despite shorter duration of DAPT, while the incidence of CD-TLR and definite/probable stent thrombosis remained low even in the elderly population treated with a bioresorbable polymer-coated Ultimaster stent.

Stable CAD - Invasive imaging and functional assessment

Borderline coronary lesion assessment with quantitative flow ratio and its relation to iFR

KLECZYNSKI Pawel [1], KLECZYNSKI Pawel [1], DZIEWIERZ Artur [1], RZESZUTKO Lukasz [1], DUDEK Dariusz [1], LEGUTKO Jacek [1]

(1) Uniwersytet Jagielloński Collegium Medicum, Kraków, Poland

Aims: Quantitative flow ratio (QFR) is a recently developed image-based index for assessment of fractional flow reserve (FFR) for borderline coronary lesions. Instantaneous wave-free ratio (iFR) is an alternative measure that does not require the administration of adenosine to achieve hyperaemia. We sought to investigate a correlation between QFR and iFR in regard to reference method, FFR.

Methods and results: QFR was derived from a modelled hyperaemic flow velocity derived from angiography without adenosine-induced hyperaemia. The iFR is calculated by measuring the resting pressure gradient across a coronary lesion during the portion of diastole when microvascular resistance is low and stable. Values of QFR, iFR and FFR from 110 vessels in 44 patients with intermediate coronary lesions with mean percent diameter stenosis of 44.6±12.0% were compared. Mean FFR was 0.81±0.09 and 46 (41.8%) had FFR ≤0.80. Mean QFR was 0.81±0.1 and 44 (40%) had QFR≤0.80. Mean iFR value was 0.9±0.07 and 38 (34.5%) had iFR ≤0.89. An excellent agreement between QFR and iFR measurements was confirmed with mean difference of 0.09 (95% CI: -0.027 to 0.207). Also, we found a strong correlation between QFR and iFR r=0.8. The overall diagnostic accuracy (AUC in ROC analysis) of QFR in detecting iFR ≤0.89 was 0.91 (95% CI: 0.85-0.96; p<0.001). The optimal cutoff value of iFR was 0.91 with sensitivity, specificity, and accuracy of 83.3%, 77.3%, and 80.9% respectively. A 100% sensitivity was observed for cutoff value of 0.84 and a 100% specificity for cutoff value of 0.96.

Conclusions: QFR had good correlation with iFR and strong diagnostic performance in the evaluation of borderline coronary stenosis.

Stents and scaffolds - Invasive imaging and functional assessment

Evaluation of thromboresistance of everolimus-eluting fluoropolymer stents vs competitive DES using an ex vivo swine shunt model and a novel flow loop model under single antiplatelet therapy (SAPT)

JINNOUCHI Hiroyuki [(1)], JINNOUCHI Hiroyuki [(1)], KOLODGIE Frank [(1)], CHENG Qi [(1)], JANIFER Christine [(1)], SATO Yu [(1)], SAKAMOTO Atsushi [(1)], CORNELISSEN Anne [(1)], PERKINS Laura [(2)], VIRMANI Renu [(1)], FINN Aloke [(1)]

(1) Cvpath Institute Inc, MD, USA; (2) Abbott Vascular Inc, CA, USA

Aims: Recent clinical studies showed feasibility of 1-month dual antiplatelet therapy (DAPT) for patients receiving XIENCE everolimus-eluting stents. Our previous preclinical studies (i.e., ex-vivo porcine arteriovenous shunt (AV) studies under low dose heparin treatment) support the feasibility of such an approach. The aim of the current study was to evaluate platelet aggregation under SAPT in XIENCE and other drug-eluting stent (DES)s in real-time using an *in vitro* flow loop system circulating human platelets from healthy volunteers and ex-vivo porcine arteriovenous shunt model.

Methods and results: Using SAPT (i.e. aspirin), the thrombogenicity of XIENCE relative to other DESs (Synergy, and Onyx) was assessed acutely using a porcine AV shunt model. The stents were bisected, and each half was dual immunostained using antibodies against platelets (CD61/CD42b) and inflammatory markers (i.e. neutrophils (PM1) and monocytes (CD14)) and evaluated by confocal microscopy. Using human platelet after SAPT (i.e. aspirin only), the thrombogenicity of XIENCE relative to standard DESs (Synergy and Onyx) was assessed acutely using a flow loop model. Confocal microscopy imaged labelled platelets for 60 minutes from two areas for each stent. Three experiments were conducted (total number of analysed areas = 6 for each group). Results: In the shunt model, XIENCE showed significantly less platelet accumulation as compared to other DESs (percent of strut area): XIENCE, 10.0±6.0 vs Synergy, 18.3±7.4 vs Onyx, 31.2±19.7, $p<0.01$). In addition, inflammatory cell adherence was the least in XIENCE relative to other DESs for both neutrophils (XIENCE, 150±40 vs Synergy, 417±199 vs Onyx, 1262±901 positive cells/mm^2, $p<0.01$) and monocytes (XIENCE, 117±62 vs Synergy, 324±150 vs Onyx, 1044±715 positive cells / mm^2, $p<0.01$). In flow loop model, XIENCE showed significantly less percent coverage by platelets as compared to Synergy and Onyx over time (XIENCE vs Synergy; $p=0.027$, XIENCE vs Onyx; $p=0.021$; Synergy vs Onyx, $p=0.868$).

Conclusions: These results support clinical data showing the low rate of stent thrombosis for XIENCE versus competitor DES and suggest the feasibility of short-term DAPT for fluoropolymer coated stents.

Stable CAD - Tools, devices and techniques

Which scoring device brings out a real scoring effect? Comparison of scoring effects among three different devices in phantom vessels

KINOSHITA Yoshihisa [(1)], KINOSHITA Yoshihisa [(1)], SUZUKI Takahiko [(1)], ADACHI Yuuya [(1)]

(1) Toyohashi Heart Center, Aichi, Japan

Aims: Although several scoring devices are available in the real clinical field, device selection depends on the opinion of each physician regardless of lesion morphology in most cases because difference of characteristics of each scoring device is ambiguous. The aim of this study is to clarify the difference of scoring effect among 3 different scoring devices.

Methods and results: (Methods) We prepared 3 different scoring devices (WolverineTM Cutting BalloonTM (CB), ScoreFlexTM NC (SF), NSE AlphaTM (NSE), n=5, respectively. Balloon diameter is 3 mm.) and 2 different hardness silicon tube (Inner diameter is 3 mm in both types. Thickness is 9 mm in hard tube and 6 mm in soft tube). We dilated each device in each silicon tube with nominal pressure (NP) and high pressure (20 atm, HP) and took a picture using by micro CT. Then, we measured penetration depth of all scoring elements into the silicon tube wall and calculate percentage of penetration depth using the following formula; penetration depth/original scoring element height*100. Finally, we compared the percentage of penetration depth of each device. Statistical analysis was performed using by Kruskal-Wallis test. (Results) In a soft tube, CB showed significantly larger values than both SF and NSE at both pressure (50.6% vs 25.1% and 16.8% at NP and 86.1% vs 33.5% and 29.1% at HP, $p<0.01$ respectively). In the hard tube, CB showed similar results with that in the soft tube (62.6% vs 33.5% and 17.0% at NP and 93.3% vs 45.1% and 36.4% at HP, $p<0.01$ respectively). Then, SF showed significantly larger values than NSE only at NP in both tube (25.1% vs 16.8% in soft tube and 33.5% vs 17.0% in hard tube, $p<0.01$, respectively).

Conclusions: CB showed a certain scoring effect in any situation in comparison with SF or NSE. On the other hand, NSE showed the weakest scoring effect at NP in our experiment.

CTO - Tools, devices and techniques

Survival of patients with CTO of the right coronary artery

JAFFE Ronen [1], JAFFE Ronen [1], SLIMAN Hussein [1], FLUGELMAN Moshe [1], LAVI Idit [1], ZAFRIR Barak [1], SHIRAN Avinoam [1], EITAN Amnon [1]

(1) Carmel Medical Center, Haifa, Israel

Aims: The prognostic impact of revascularising chronic coronary total occlusion (CTO) is unknown. We studied the association between CTO revascularisation and survival in patients with uniform coronary anatomy consisting of isolated CTO of the right coronary artery (RCA).

Methods and results: A registry of 16,832 coronary angiograms was analysed. We identified 278 patients (1.7%) with isolated CTO of the RCA who did not have lesions within the left coronary artery for which revascularisation was indicated. Survival of 52 patients (19%) who underwent successful percutaneous coronary intervention was compared to those who did not receive revascularisation. Revascularised patients were younger (60.2 vs 66.3 years, p=0.001), had higher creatinine clearance (106 vs 83 ml/min, p<0.0001) and fewer co-morbidities than those who did not receive revascularisation. Lack of CTO revascularisation was a univariable predictor of mortality (HR=2.65, 95% CI: 1.06-6.4) over 4.3±2.5 years of follow-up. On multivariable analysis, the only predictors of mortality were increased age (HR 1.04, 95% CI: 1.01-1.07), reduced creatinine clearance (HR 1.02, 95% CI: 1.01-1.03) and ejection fraction below 55% (HR 2.24, 95% CI: 1.22-4.11).

Conclusions: Among patients with isolated RCA CTO who underwent extended follow-up, revascularisation was not an independent predictor of increased survival.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

One-year clinical outcomes of ultrathin biodegradable polymer coated sirolimus-eluting stents for multivessel treatment

AJMERA Prakash [1], AJMERA Prakash [1], POTHINENI Ramesh [2], CHAWLA Kamal Kumar [1], MANTRAVADI Sai Sudhakar [3], JARIWALA Pankaj Vinod [4], VIJAN Vinod [5], VIJAN Vikrant [5], POTDAR Anil [6], INAMDAR Manohar K [7], PATHAK Abhijit [8]

(1) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (2) Dr. Ramesh Cardiac and Multispeciality Hospital, Vijayawada, India; (3) Gleneagles Global Hospitals, Telangana, India; (4) Yashoda Hospitals - Somajiguda, Telangana, India; (5) Vijan Cardiac & Critical Care Centre, Maharashtra, India; (6) Parisoha Foundation Pvt. Ltd, Mumbai, India; (7) Ashwini Hospital, Maharashtra, India; (8) Swasthya Hospital And Medical Research Center, Maharashtra, India

Aims: Technical advancements in percutaneous coronary intervention (PCI) has led to increased use of it in high risk patient population like multivessel disease (MVD). Thus, the aim of this analysis was to present the safety and clinical performance of ultrathin-strut (60 µm) biodegradable polymer-coated Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) sirolimus-eluting stents (SES) in patients with MVD at one-year follow-up.

Methods and results: Two real-world, multicentre, all-comer registries conducted between May 2016 and March 2018, comprising 2472 patients, were retrospectively analysed for patients who underwent multivessel treatment. Both the registries included patients who underwent PCI with only Supraflex Cruz SES in India. Patients with either stable or unstable angina, or silent ischaemia and at least two lesions located in two or more major epicardial vessels were included. The primary endpoint was target lesion failure, a composite of cardiac death, target vessel related myocardial infarction and target lesion revascularisation at one year. Stent thrombosis was considered as safety endpoint, defined as per the Academic Research Consortium. A total of 406 patients with multivessel treatment were included. The mean age of the population was 58.01±10.30 years and 288 (70.9 %) were male. Of the total population, 193 (47.5 %) were hypertensive, 155 (38.2 %) were diabetic and 129 (31.8 %) had hyperlipidaemia. A total of 94 (23.2 %) patients had STEMI and 68 (16.7 %) had NSTEMI. Of the 824 lesions, 326 (39.6 %) were in left anterior descending artery, 265 (32.2 %) were in right coronary artery, 229 (27.8 %) were in left circumflex and 4 (0.5 %) in left main artery. Of the total lesions, 627 (76.1 %) were type B2/C lesions and 71 (8.6 %) were total occlusions. A total of 855 stents were deployed in 406 patients (824 lesions). Stents deployed per patients was 2.11±0.46. The mean stent length and diameter were 25.94±9.20 mm and 2.84±0.30 mm, respectively. At one year, details of 391 (96.3 %) patients were available and 15 (3.7 %) were lost to follow-up. Target lesion failure at one year occurred in 25 (6.4 %) patients, which consisted of 3 (0.8 %) cardiac deaths, 9 (2.3 %) target-vessel myocardial infarction and 13 (3.3 %) target lesion revascularisation. There were 3 (0.8 %) incidences of stent thrombosis; 2 (0.5 %) definite and 1 (0.3 %) probable stent thrombosis.

Conclusions: In patients with multivessel disease, Supraflex Cruz SES was safe and possesses higher clinical safety at one-year follow-up.

Stents and scaffolds - Tools, devices and techniques

Clinical practice and outcomes in patients on oral anticoagulants undergoing PCI with new-generation DES – Data from a large worldwide registry

SMITS Pieter [1]

(1) Maasstad Hospital, Rotterdam, the Netherlands

Aims: Patients on oral anticoagulants undergoing PCI are at high bleeding risk when treated with dual antiplatelet therapy to reduce the ischaemic risk. Careful assessment of these risks is necessary in patients with an indication for oral anticoagulants (OAC). We aimed to determine the clinical practice and outcomes of PCI with a new-generation DES and concurrent DAPT in patients treated with OAC.

Methods and results: e-Ultimaster is a prospective, worldwide, multicentre registry that enrolled patients with coronary artery disease requiring PCI, treated with a thin strut sirolimus-eluting stent (Ultimaster) with abluminal biodegradable polymer coating, between 2014 and 2018. Out of the 36,916 patients enrolled, a total of 34,538 patients (93.6%) completed 1-year follow-up or died. The primary endpoint of target lesion failure (TLF) at 1-year follow-up was defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularisation (TLR). An independent Clinical Event Committee reviewed and adjudicated all endpoint-related adverse events. A total of 1312 patients (3.8%) were treated with OAC at baseline and at 3-months follow-up after index PCI. A total of 52.1% (n=684) of OAC patients were on triple therapy (OAC + DAPT) both at baseline and at 3 months, while 47.9% (n=628) were on OAC + single antiplatelet therapy at 3-month follow-up. In the latter group 24% of the patients were not treated with DAPT and 76% stopped DAPT within 3 months post-PCI. Compared to patients on-DAPT at 3 months, patients off DAPT at 3 months were older (70.0 vs 72.5 years, p<0.001; 18.6 vs 25.0% octogenarians; p=0.005) and had a lower prevalence of hypertension (73.9 vs 68.1%). Renal impairment (14.9 vs 18.1%; p=0.12), history of MI (26.9 vs 27.0; p=0.95) and history of PCI (31.1 vs 33.3%; p=0.48) were not different. Clinical presentation and lesion complexity was largely similar in the 2 groups. In patients on versus off-DAPT at 3 months no differences were observed in mortality (0.7% vs 0.3% at 3-months; p=0.45 and 4.4% vs 3.7% at 1-year; p=0.58), target vessel MI (0.6% vs 1.3% at 3-months; p=0.25 and 1.0% vs 1.9% at 1-year; p=0.25) and target lesion revascularisation (0.6% vs 0.5% at 3-months; p=0.99 and 1.3% vs 1.4% at 1-year; p=0.99). At 1-year follow-up there were 5 definite/probable ST (0.8%) in the group of patients off-DAPT at 3 months as compared to 2 ST (0.3%) in patients on-DAPT at 3 months (p=0.27). Out of 5 ST in patients off-DAPT at 3 months, 3 ST occurred before 3-month follow-up while the patients were on DAPT at that moment. In patients off-DAPT at 3 months, bleeding rates were higher (3.4% vs 6.1% at 3 months; p=0.03 and 4.7% vs 8.1% at 1-year; p=0.01).

Conclusions: In this large worldwide registry on the Ultimaster stent, no outcome differences in ischaemic events were observed in PCI patients treated with triple therapy for 3 months or dual therapy treated PCI patients within 3 months, suggesting that these high-bleeding risk patients can be safely treated with short triple therapy or dual therapy with Ultimaster stents. Randomised data is needed to support this registry sub-analysis.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Use and safety of pressure wire studies during coronary angiography in New Zealand – A three-year national analysis – ANZACS QI-39

CICOVIC Sergej [1], WANG Tom [1], KERR Andrew [2], CHAN Daniel [1], SOMARATNE Jithendra [1], DIMALAPANG Eliazar [1], KASARGOD Chethan [1], DEVLIN Gerard [3]

(1) Auckland Hospital, Auckland, New Zealand; (2) Middlemore Hospital, Auckland, New Zealand; (3) Gisborne Hospital, Gisborne, New Zealand

Aims: To compare baseline characteristics (Age, gender, ethnicity, previous CABG) in a cohort of patients who undergo a pressure wire study (PWS) during a coronary angiogram. We aim to describe the characteristics of patients with haemodynamically significant and insignificant lesions (FFR < 0.8) and the treatment disposition of these patients. Also we describe in-hospital outcomes of patients in whom a coronary pressure wire study was performed.

Methods and results: This analyis used the "All New Zealand Acute Coronary Syndrome Quality Improvement" program (ANZACS-QI) web-based system, which in summary creates a clinical registry of all patients with acute coronary syndrome (ACS) with a data dictionary for all variable definitions. This data set includes all patients who underwent coronary angiography in New Zealand public hospitals since inception in 2010. In this analysis the study cohort included all patients enrolled in the ANZACS-QI registry between the dates 01/09/14 – 01/09/17. During the analysis period 46281 procedures were done. 28258 were dignostic coronary angiograms (DCA) and 18025 underwent PCI. In total 1901 patients had 2201 pressure wire studies performed. 1224 patients in the DCA group and 677 patients in the PCI group. PWS was done in 4.6% of all patients presenting to the catheterisation lab over this period. Interestingly PWS were more commonly done in patients who had DCA alone than those that went forward for PCI (5.1% vs 4.5% respectively). Patients that had a PWS were more commonly men (71%) of European descendent (76%). As would be expected, PWS were more likely to be positive in patients with traditional risk factors (hypertension, dyslipidaemia, diabetes and be current or be ex-smokers) than those without. The most common indication for a pressure wire study was a suspected acute coronary syndrome (excluding STEMI) and the second was chronic coronary artery disease. 5% of procedures with a suspected ACS had a PWS. 35% of these went forward to have a PCI. 7.2% of procedures with chronic coronary artery disease had a PWS with 24% going forward to have PCI. The most common coronary territory where PWS was performed was the left anterior decending (43%), with the right coronary artery (27%) and Circumflex artery (25%) having similiar frequnecy. Patients with a negative PWS (FFR > 0.8) proceeded to have PCI 9% of the time. Patients with a positive PWS (FFR < 0.8), proceeded to PCI 60% of the time and 40% had either OMT or CABG. We considered PWS results to be borderline positive if the FFR was 0.75-0.79 and borderline negative if the FFR 0.8-0.85. 429 FFR results were borderline positive, of which 34% did not go forward to have PCI. 572 FFR results were borderline negative and 16% of these went forward to have PCI. In total there were 499 deaths (1.2%). There were 117 cases of stroke (0.3%) and 221 post-procedural myocardial infarctions (0.5%). There was no statistically significant increase in complications with the use of PWS in either DCA or PCI groups when compared to not using PWS.

Conclusions: This is the largest real-world analysis of PWS use to date. It shows which patients and which coronary territories are likely to have a PWS, and and factors which are associated with a haemodynamically significant FFR results. It also allows us to see outcomes of patients in relation to their FFR results and specifically those with borderline results. It shows that PWS are safe and have no increased in hospital MACE when compared to those without PWS.

NSTEMI - Invasive imaging and functional assessment

Efficacy of quantitative flow ratio for diagnosing and predicting clinical outcomes in populations with angina and AMI

LEE Kwanyong [1], LEE Kwanyong [1], HWANG Byung-Hee [2], CHANG Kiyuk [2]

(1) The Catholic University of Korea Incheon St. Mary's Hospital, Incheon, Republic of Korea; (2) The Catholic University of Korea, Seoul St Mary's Hospital, Seoul, Republic of Korea

Aims: The quantitative flow ratio (QFR) is a novel angiography-based method for noninvasive functional assessment of intermediate coronary lesions. This study evaluated the diagnostic performance of the QFR against the fractional flow reserve (FFR) and their predictive abilities for clinical outcomes in a real-world all-comer population.

Methods and results: We assessed QFR for 1,077 vessels in 915 patients. The primary technical endpoint was the diagnostic performance of the QFR against the FFR. The primary clinical endpoint was target vessel failure (TVF) between two groups distributed by a QFR cut-off value of 0.8 during a median follow-up of 2.29 (1.15, 3.36) years. The diagnostic accuracy, sensitivity, specificity, positive predictive value, and negative predictive value of the QFR for identifying an FFR≤0.8 were 0.96, 0.94, 0.96, 0.94 and 0.96, respectively. The diagnostic accuracies of the QFR were comparable among stable angina (SA), unstable angina (UA) and AMI groups (0.96, 0.97 and 0.92, respectively). In addition, the accuracy of the QFR in vessels with a borderline FFR (≥0.75, ≤0.85) was 0.92, which is sufficiently high to predict physiologically significant lesions. The QFR>0.8 group showed a significantly lower incidence of TVF than the QFR≤0.8 group among the total population (3.4% vs 8.3%, p<0.001) and the deferred population (3.5% vs 8.1%, p=0.027).

Conclusions: Our study found that the noninvasive QFR method showed a similar high diagnostic accuracy and predictive ability for clinical outcomes compared to the FFR in real-world patients, including those with not only SA but also UA and AMI.

Stents and scaffolds - Tools, devices and techniques

Evaluation of clinical outcomes after ultrathin strut (60 µm) biodegradable polymer coated sirolimus-eluting stent implantation in patients with ACS

POTHINENI Ramesh [1], POTHINENI Ramesh [1], VIJAN Vikrant [2], POTDAR Anil [3], INAMDAR Manohar [4], PATHAK Abhijit [5], MANTRAVADI Sai Sudhakar [6], AJMERA Prakash [7], CHAWLA Kamal Kumar [7], JARIWALA Pankaj Vinod [8], VIJAN Vinod [2]

(1) Dr. Ramesh Cardiac and Multispeciality Hospital, Andhra Pradesh, India; (2) Vijan Cardiac & Critical Care, Maharashtra, India; (3) Parisoha Foundation Pvt. Ltd., Maharashtra, India; (4) Ashwini Hospital, Maharashtra, India; (5) Swasthya Hospital And Medical Research Center, Maharashtra, India; (6) Gleneagles Global Hospitals Group, Telangana, India; (7) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (8) Yashoda Hospitals - Somajiguda, Telangana, India

Aims: Drug-eluting stents (DES) have shown promising clinical results in the treatment of acute coronary syndrome (ACS) patients. However, studies with previous generation DES reported higher rates of stent thrombosis when used in patients with ACS. Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) is the latest-generation sirolimus-eluting stent (SES) with ultrathin struts (60µm) and biodegradable polymer. The present analysis was undertaken to evaluate the clinical outcomes at 12 months after Supraflex Cruz implantation in ACS patients.

Methods and results: We retrospectively identified and analysed 1,824 patients with ACS, from two prior multicentre real-world registries (n=2,472), who underwent PCI between May-2016 and March-2018 with only Supraflex Cruz SES. ACS was defined according to 2011 NSTEMI guidelines of the European Society of Cardiology and diagnosed according to clinical symptoms, electrocardiographic changes compatible with acute myocardial ischaemia, and elevation of cardiac biomarkers. The incidence of target lesion failure (TLF), a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularisation (TLR), was considered as primary outcome at 12-month follow-up. Stent thrombosis, defined as per Academic Research Consortium, was considered as a safety endpoint. The mean age of included patients was 56.0±10.8 years, among them 1329 (72.9%) were male. Out of 1,824 patients, 583 (32.0%), 842 (46.2%) and 555 (30.4%) patients presented with history of diabetes, hypertension and hypercholesterolaemia, respectively. 796 (43.6%), 689 (37.8%), 339 (18.6%) patients presented with unstable angina, ST-elevation myocardial infarction, and non-ST-elevation myocardial infarction, respectively. A total of 2,395 Supraflex Cruz stents were implanted to treat 2,128 lesions, of which 345 (16.2%) lesions were totally occluded and majority of lesions were characterised as type C (62.8%). The number of stents deployed per patient was 1.31±0.52 and per lesion was 1.13±0.34 with mean stent length and diameter of 25.3±9.0 and 2.87±0.3, respectively. A total of 96.1% of patients completed 12-month follow-up. The primary composite endpoint, TLF was observed in 92 (5.3%) patients, comprising of 15 (0.9%) cardiac death; 43 (2.5%) TV-MI; and 34 (1.9%) TLR at 12-month. Overall stent thrombosis was observed in 11 (0.6%) patients at 12-month follow-up.

Conclusions: From this analysis it is concluded that the treatment of ACS patients with Supraflex Cruz was associated with higher clinical safety and low rates of TLF at 12-month follow-up.

Stents and scaffolds - Tools, devices and techniques

Evaluation of ultrathin strut biodegradable polymer coated sirolimus-eluting stent in patients with small coronary arteries

POTHINENI Ramesh [1], POTHINENI Ramesh [1], VIJAN Vikrant [2], POTDAR Anil [3], INAMDAR Manohar [4], PATHAK Abhijit [5], MANTRAVADI Sai Sudhakar [6], AJMERA Prakash [7], CHAWLA Kamal Kumar [7], JARIWALA Pankaj Vinod [8], VIJAN Vinod [2]

(1) Dr. Ramesh Cardiac and Multispeciality Hospital, Andhra Pradesh, India; (2) Vijan Cardiac & Critical Care, Maharashtra, India; (3) Parisoha Foundation Pvt. Ltd., Maharashtra, India; (4) Ashwini Hospital, Maharashtra, India; (5) Swasthya Hospital And Medical Research Center, Maharashtra, India; (6) Gleneagles Global Hospitals, Telangana, India; (7) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (8) Yashoda Hospitals - Somajiguda, Telangana, India

Aims: Percutaneous coronary intervention in patients with small vessel disease is challenging due to higher rates of adverse cardiac events. The objective of this analysis was to evaluate clinical outcomes of the ultrathin (60 µm) strut biodegradable polymer-coated Supraflex Cruz sirolimus-eluting stent (SES) (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) in patients with small coronary arteries (≤2.5 mm).

Methods and results: We retrospectively identified and analysed 726 patients from two prior registries (n=2472), who had undergone percutaneous coronary intervention with only ≥1 Supraflex Cruz SES (≤2.5 mm) between May 2016 and March 2018. The primary endpoint was target lesion failure considered as a composite of cardiac death, target vessel myocardial infarction and target lesion revascularisation 12 months after the index procedure. An additional safety endpoint was stent thrombosis, defined as per Academic Research Consortium. In total, 807 Supraflex Cruz SES (1.1±0.3 stent/patient) were implanted to treat 771 lesions (1.1±0.4 stent/lesion) in 726 patients. The study population mean age was 57.6±10.0 years. Males, hypertensives, and diabetics contributed 491 (67.6%), 340 (46.8%), and 291 (40.1%) patients, respectively. Of the 726 patients, 318 (43.8%), 133 (18.3%), 175 (24.1%), and 100 (13.8%) patients presented with unstable angina, stable angina, ST-elevation myocardial infarction, and non- ST-elevation myocardial infarction, respectively. The primary endpoint of target lesion failure was observed in 43 (6.1%) patients, comprised of 5 (0.7%) cardiac death, 20 (2.9%) target vessel myocardial infarction and 18 (2.6%) target lesion revascularisation. Stent thrombosis was observed in 9 (1.3%) patients.

Conclusions: This retrospective analysis demonstrated that use of ultrathin strut biodegradable polymer-coated Supraflex Cruz SES provides favourable clinical outcomes in real-world patients who had received Supraflex Cruz SES (≤2.5 mm) 12 months after the index procedure.

Stents and scaffolds - Tools, devices and techniques

Clinical outcomes of biodegradable polymer-coated ultrathin strut sirolimus-eluting stents in a "real-world" patient population: two-year results from the T-flex registry

POTHINENI Ramesh [1], POTHINENI Ramesh [1], VIJAN Vikrant [2], POTDAR Anil [3], INAMDAR Manohar [4], PATHAK Abhijit [5], MANTRAVADI Sai Sudhakar [6], AJMERA Prakash [7]

(1) Dr. Ramesh Cardiac and Multispeciality Hospital, Andhra Pradesh, India; (2) Vijan Cardiac & Critical Care, Maharashtra, India; (3) Parisoha Foundation Pvt. Ltd., Maharashtra, India; (4) Ashwini Hospital, Maharashtra, India; (5) Swasthya Hospital And Medical Research Center, Maharashtra, India; (6) Gleneagles Global Hospitals, Telangana, India; (7) Malla Reddy Narayana Multispeciality Hospital, Telangana, India

Aims: New-generation drug-eluting stents (DES) have yielded improved clinical outcomes as compared to earlier-generation DES. These benefits may be partially attributable to ultrathin stent struts. The T-Flex registry aimed to assess clinical outcomes of the biodegradable polymer-coated ultrathin strut (60 µm) Tetriflex sirolimus-eluting stent (SES) (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) in a real-world population after 2-years.

Methods and results: This was an observational, multicentre, single-arm, investigator-initiated and retrospectively designed registry. During the study duration from May 2016 to January 2017, all consecutive patients from the study centres who were treated with Tetriflex SES, regardless of lesion complexity, comorbidities and acute presentation were analysed. The primary endpoint was incidence of target lesion failure defined as a composite of cardiac death, myocardial infarction, and target lesion revascularisation by percutaneous or surgical methods at 12 months. Follow-up was also scheduled at 2 years. Stent thrombosis was considered as a safety endpoint defined as per the Academic Research Consortium. A total of 1,203 patients with a mean age of 56.6±10.7 years were included in the registry. During the study duration, 1624 Tetriflex SES (1.35±0.53 stent/patient) were implanted to treat 1,430 coronary lesions (1.13±0.36 stent/lesion) in 1,203 patients. The study population had a male predominance (884 males, 73.5%), and comprised of 516 (42.9%) hypertensives, 402 (33.4%) hypercholesteraemics, 387 (32.2%) diabetics, and 236 (19.6%) smokers. Clinical presentation was unstable angina, stable angina, ST-elevation myocardial infarction, and non-ST-elevation myocardial infarction in 432 (35.9%), 312 (25.9%), 291 (24.2%) and 168 (14.0%) patients, respectively. Of the lesions treated, 1,194 (83.49%) were B2/C lesions and 214 (15%) were total occlusions. At the 2-year follow-up, target lesion failure was observed in 65 (5.9%) patients, comprising 9 (0.8%) cardiac death, 39 (3.5%) myocardial infarction, and 32 (2.9%) target lesion revascularisation. Stent thrombosis was observed in 10 (1.0%) cases during the follow-up period. Of these, 3 (0.3%), 4 (0.4%), and 3 (0.3%) cases were classified as definite, probable, and possible stent thrombosis, respectively.

Conclusions: The T-Flex registry demonstrated low rates of target lesion failure and stent thrombosis with Tetriflex SES at 2-year follow-up. These results suggest favourable outcomes with Tetriflex SES in "real-world" coronary artery disease patients at long-term follow-up.

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Posters

Stable CAD - Invasive imaging and functional assessment

Very long-term clinical outcomes of deferral lesions in haemodialysis patients

FUJIMOTO Masanobu [(1)], TAKASHIMA Hiroaki [(1)], WASEDA Katsuhisa [(1)], ANDO Hirohiko [(1)], NAKANO Yusuke [(1)], SAKURAI Shinichiro [(1)], SUZUKI Akihiro [(1)], OHASHI Hirofumi [(1)], AMANO Tetsuya [(1)]

(1) Aichi Medical University Hospital, Aichi, Japan

Aims: Haemodialysis is associated with an increasing risk of cardiovascular disease. Although deferral of a functionally non-significant lesion on the basis of fractional flow reserve (FFR) measurement showed favourable clinical outcomes, it was little known whether this would be the same in haemodialysis patients.

Methods and results: A total 285 patients with 402 deferral lesions were confirmed to participate in this study. Study endpoints consisted of major adverse cardiovascular events (MACE: any death, myocardial infarction, target vessel revascularisation) up to 5 years. In all patients, male gender was 76% and age was 68.8±9.1-years-old. Of 285 patients, 38 patients received haemodialysis treatment. Of 402 lesions, FFR less than or equal 0.80 was observed in 92 lesions and average FFR value was 0.86±0.07. Clinical follow-up was median 73 months. Any death, MI, TVR, MACE were observed in 32 patients (11.2%), 9 patients (3.16%), 47 patients (16.5%), 89 patients (31.2%), respectively. Univariate and multivariate regression analysis after adjusting for confounding factors showed that haemodialysis treatment (hazard ratio 2.97, 95% confidence interval 1.39 to 5.19, $p<0.01$) was only proved to be an independent predictor of MACE.

Conclusions: Haemodialysis patients are still at higher risk of MACE and need to pay attention to the management in their deferral lesions based on FFR.

Stable CAD - Diabetes

The impact of smoking history on clinical outcomes after PCI

ZIBAEENEZHAD Javd [1], SAYADI Mehrab [1], MOHAMMAD Seyyed Saeed [1], KHORSHIDI Soorena [1], HADIYAN Ehsan [1], BAHRAMALI Ehsan [2], RAZEGHIAN-JAHROMI Iman [1]

(1) Shiraz University of Medical Sciences, SHIRAZ, Islamic Republic of Iran; (2) Fasa University of Medical Sciences, Fasa, Islamic Republic of Iran

Aims: The impact of smoking on clinical outcomes after PCI is still a matter of great importance. In the present study, the association of history of smoking (hSmoking) with such outcomes were assessed.

Methods and results: From 2003 to 2019, 1,799 participants with stable coronary artery disease which performed PCI were considered. Occurrence of major adverse cardiac events (MACE) including revascularisation (PCI or CABG), myocardial infarction (MI), and coronary death were categorised into three time intervals including short-term (up to 24 hours), midterm (24 hours to 6 months), and long-term (more than 6 months) after index PCI. hSmoking was confirmed in 847 subjects with dominance of males. Patients with hSmoking were younger at the time of index PCI than non-hSmoking peers. The mean follow-up time was 66.5±10.66 months. There was no events in the short-term. Occurrence of MACE were significantly higher in hSmoking than non-hSmoking group especially in long-term interval. Male and female participants were not different in terms of MACE occurrence. However, female ones with hSmoking were more prone to MACE occurrence than male counterparts. Although number of patients with history of diabetes (hDM) and/or history of hypertension (hHTN) and/or history of hyperlipidaemia (hHLP) were lower in hSmoking than non-hSmoking group, but those with hSmoking experienced MACE significantly more than non-hSmoking. Moreover, concurrent existence of hSmoking with hDM, but not hHTN or hHLP, significantly increase MACE incidence. Type of MACE was not different in hSmoking compared to non-hSmoking group.

Conclusions: Unlike the smoker's paradox, we concluded that hSmoking is associated with MACE after PCI, of course in our population. Female gender and hDM facilitated the occurrence of MACE.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Safety of pressure-wire based revascularisation in diabetic patients

TRAVIESO GONZALEZ Alejandro [(1)], TRAVIESO-GONZALEZ Alejandro [(1)], CASTRO MEJIA Alex Fernando [(1)], MEJÍA RENTERÍA Hernán [(1)], PEREZ-VIZCAYNO María José [(1)], JIMENEZ QUEVEDO Pilar [(1)], NOMBELA FRANCO Luis [(1)], FERNÁNDEZ ORTIZ Antonio [(1)], ESCANED Javier [(1)], GONZALO Nieves [(1)]

(1) Hospital Clínico San Carlos, Madrid, Spain

Aims: The coronary pressure wire is a useful tool to guide revascularisation in ambiguous stenosis. However, its safety in some high-risk groups is not well established. The objective of this study is to assess the safety of deferring revascularisation in diabetic patients according to pressure guidewire evaluation.

Methods and results: In this single-centre retrospective study, we analysed a total of 444 consecutively patients (593 vessels) with intermediate stenoses, in which it was decided to defer revascularisation based on the results of FFR or iFR during the period from January 2012 to December 2016. 164 patients were diabetic (36.9%), and the mean follow-up was 43 months. The primary endpoint was defined as the combination of all-cause death, myocardial infarction (MI) and target vessel revascularisation (TVR). A comparison of outcomes between FFR and iFR-deferred patients was also performed. At 4 years of follow-up, 14 (8.5%) diabetic patients had the primary endpoint, in contrast with 18 (6.4%) of non-diabetics (Adjusted HR 0.99; 95% CI: 0.46 - 2.14; p=0.983). Diabetic patients had higher incidence of MI compared to non-diabetic patients (6.7% vs 3.2%; Adjusted HR 3.06; 95% CI: 1.09 – 8.62; p=0.034). However, they had similar rates of TVR (4.7% in diabetics, 4.2% in non-diabetics; Adjusted HR 1.13; 95% CI: 0.47 – 2.70; p=0.787) and target vessel myocardial infarction (0.9% vs 1.1%; Adjusted HR 0.9; 95% CI: 0.15 – 5.45; p=0.906). There were no differences regarding the incidence of MACE when iFR or FFR were used, either in diabetic patients (10.1% with FFR, 2.9% with iFR; p=0.232) and non-diabetics (6.4% with FFR, 6.6% with iFR; p=0.804). Nevertheless, in the per-vessel analysis, diabetic patients showed a remarkable higher incidence of TVR when deferred by FFR (6.4% with FFR, 0% with iFR; p=0.065), a difference that was not seen in non-diabetic vessels (5.1% with FFR, 2.0% with iFR; p=0.244).

Conclusions: Deferring treatment of coronary stenosis according to the results of pressure wire evaluation in diabetic patients is safe in terms of the incidence of TVR and target vessel myocardial infarction. The use of iFR compared with FFR in diabetics is associated with a trend towards less risk of TVR at follow-up.

Other Coronary interventions - Other

Acute recoil and late recoil after Orsiro coronary DES implantation

OHTA Yusuke [(1)], SATO Takao [(1)], OHTA Yusuke [(1)], TAYA Yuji [(1)], AIZAWA Yoshifusa [(1)]

(1) Tachikawa general hospital, Nagaoka, Japan

Aims: Acute stent recoil has been often observed following stent delivery balloon deflation in coronary arteries and the recoil rate varies by stent design. Several reports have described that acute recoil is also seen after percutaneous coronary intervention (PCI) with drug-eluting stent. Sirolimus-eluting Orsiro stent is an ultrathin stent, but its properties may easily lead to acute recoil and late after stent implantation. This study investigated the acute recoil and late recoil after Orsiro stent implantation based on intravascular ultrasound (IVUS).

Methods and results: We enrolled 32 patients (40 stents). Acute recoil: acute absolute recoil by quantitative coronary angiography was defined as the difference between the mean diameter of the last inflated balloon (X) and the mean lumen diameter of Orsiro immediately after balloon deflation (Y). Acute percent (%) recoil was defined as (X-Y)×100/ X. IVUS was performed within the culprit lesion. Plaque eccentricity (PE), %plaque, and calcification grade were assessed using IVUS. In addition, calcification grade was scored from 0 to 4 based on quadrants. Based on the median acute recoil value, the stents were divided into two groups: low (LAR, n=19) and high acute %recoil (HAR, n=21). Late recoil (1-year): A total of 1,920 paired cross-sectional areas (CSAs) were analysed on IVUS. Late absolute stent recoil was defined as stent area at post-procedure (X)-stent area at follow-up (Y). Late %recoil was defined as (X - Y)×100/ X. In each CSA, plaque morphology was classified as calcification with less than 2 quadrants (CLT2), calcification with more than 2 quadrants (CMT2), and fibrous and fibrofatty plaque. Results: Acute recoil: The acute %recoil was 5.8±4.3%. PE, %plaque, and stent/artery ratio were significantly higher in the HAR group than in the LAR group. In addition, significant differences in acute %recoil were not observed with respect to the types of stent diameter. In multivariate logistic regression analysis, mean PE>1.45 and mean %plaque volume>75% in the culprit lesions were significant positive predictors for the occurrence of acute %recoil (odds ratio (OR), 19.1; 95% confidence interval (CI),1.4-81.4, p=0.02; and OR, 5.6; 95% CI: 1.1-51.0, p=0.048, respectively). Late recoil: The late %recoil was 1.5±12.3%. CLT2 resulted in significantly greater late %recoil. In CMT2, the late %recoil was small.

Conclusions: Acute recoil of Orsiro stent might be influenced by an eccentric plaque with a large volume. Late recoil easily occurs in plaque with mild-moderate calcification.

Other Coronary interventions - Other

Coronary artery fistulas: a single-centre case series

TORRES Sofia [(1)], TORRES Sofia [(1)], VASCONCELOS Mariana [(1)], RESENDE Carlos [(1)], DIOGO Pedro [(1)], CRUZ M. Cristina [(1)], MOREIRA Jorge [(1)], PINHO Paulo [(1)], SILVA J. Carlos [(1)], MACIEL M. Júlia [(1)]

(1) Centro Hospitalar Universitário de São João, Porto, Portugal

Aims: The aim of this study was to describe the angiographic, clinical and therapeutic data of coronary artery fistulas detected over the last 12 years in a single tertiary care centre catheterisation laboratory.

Methods and results: Results: We identified 50 patients who were diagnosed with one or more coronary artery fistulas, with ages between 5 and 85 years (mean 59 years). 62% (n=31) were males. The great majority of patients had a single fistula (n=34, 68%), 11 patients had two fistulas (22%), 1 patient had 3 fistulas (2%) and 4 patients had multiple fistulas (8%). Coronary artery fistulas arose more frequently from the left anterior descending artery (n=27), followed by the right coronary (n=18), left circumflex (n=15), left main (n=5) and intermediate artery (n=2). The most frequent drainage site was the pulmonary artery (n=38). The majority of the coronary artery fistulas were incidentally found (n=32; 64%) and thought to have no significance for the patients' clinical status. As for the rest of the patients, coronary artery fistulas were diagnosed during evaluation of: a heart murmur (n=7); exertional chest pain with no associated significant atherosclerotic coronary artery disease (n=7); exertional dyspnoea (n=2); positive exercise stress test (n=1); NSTEMI and cardiac arrest (n=1). Regarding treatment, watchful waiting was the main approach (n= 40; 80%). 3 patients had their fistulas closed during surgery for another heart condition (CABG/aortic valve replacement). In 1 patient, heart surgery was specifically conducted for fistula closure. 6 patients (12%) underwent fistula transcatheter closure.

Conclusions: Coronary artery fistulas are rare coronary anomalies and the majority has no clinical relevance, so watchful waiting is the commonest approach. When they are haemodynamically significant or symptoms/complications arise, surgical or transcatheter closure should be considered.

CTO - Invasive imaging and functional assessment

Clinical outcomes of guidewire-induced vessel injury in retrograde vs antegrade approach for percutaneous intervention of coronary CTOs: insights from IVUS

SABBAH Mahmoud [1,2], SABBAH Mahmoud [1,2], KADOTA Kazushige [2], TADA Takeshi [2], KUBO Shunsuke [2], HABARA Seiji [2], TANAKA Hiroyuki [2], FUKU Yasushi [2], GOTO Tsuyoshi [2]

(1) Suez Canal University, Al Ismailia, Egypt; (2) Kurashiki Central Hospital, Okayama, Japan

Aims: Clinical and angiographic relevance of various guidewire (GW) induced vessel injuries following the successful crossing of a chronic total occlusion (CTO) segment in both the antegrade and retrograde approaches has not been sufficiently studied. We compared the in-hospital, and the long-term clinical and angiographic outcomes of the various IVUS detected GW induced coronary vessel injuries, following the successful crossing of the CTO segment between antegrade and retrograde approaches.

Methods and results: All IVUS images of 173 CTO lesions (157 patients) successfully revascularised between August 2011 and November 2012 in a high volume CTO centre were retrospectively analysed. IVUS detected GW induced coronary vessel injuries were compared between antegrade (113 lesions in 102 patients) (Ante. group) and retrograde (60 lesions in 55 patients) (Retro. group) approach, as were the in-hospital and the long-term clinical and angiographic outcomes. Although 1 in 4 lesions in the Retro group had prior unsuccessful attempts, thrombolysis in Myocardial Infarction flow grade 3 was obtained in all patients. CTO length (30±12.5 mm vs 18±7.5 mm, $p<0.001$), and total stent length (54±21 mm vs 42±19mm, $p=0.001$), were much longer in the Retro group. IVUS showed that, in the Retro group, the GW was more often tracks subintimal (55% vs 16%, $p<0.001$), induce dissections (70% vs 35%, $p<0.001$), and coronary haematoma (28% vs 5.3%, $p<0.001$), while final subintimal stenting was similar in both groups ($p=0.47$). Patients in the Retro group were likely to have increased risk of periprocedural myocardial infarction ($p=0.07$), angiographically visible dissections ($p<0.001$), slow flow ($p=0.02$), and perforations ($p=0.02$). There was no significant difference between the 2 groups regarding binary restenosis or target lesion revascularisation ($p=0.37$, and $p=0.64$, respectively). Five patients in the Retro group (9.4%) versus one patient in the Ante group (1%) died at one year ($p=0.02$), mostly due to non-cardiac death.

Conclusions: Intravascular ultrasound effectively differentiates between various GW induced vessel injuries and depicts subintimal GW tracking.GW crossing through the retrograde approach is associated with IVUS and angiographic coronary vessel injuries, which increased periprocedural complications. However, the long term clinical and angiographic outcomes were comparable between antegrade and retrograde approaches.

Euro20A-POS662
Posters

STEMI - Tools, devices and techniques, Other Coronary interventions - Other

In-hospital outcome of STEMI patients with chronic kidney disease

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Presence of any forms of renal insufficiency in ST-elevation myocardial infarction (STEMI) patients is associated with higher cardiovascular mortality and morbidity. The aim of this study was to assess in hospital outcome of STEMI patients with chronic kidney disease (CKD).

Methods and results: This prospective observational, single-centre study was conducted in our hospital from November 2014 to October 2019. The patients were categorised into two groups: CKD and non-CKD. CKD was defined as GFR of < 60 mL/min/1.73 m^2 as determined by Cockcroft-Gault formula. Patient's demographics, extent of coronary artery disease, procedural data, short (in-hospital) term outcomes were critically assessed. Results: A total number of 6,292 STEMI patients were included in the analysis. Out of these, 46.1% patients had CKD and 53.9% had no CKD. Patients with CKD were older than non-CKD group (mean age 60.78±10.96 years vs 50.35±9.9 years; p=0.0001). The STEMI CKD cohort was predominantly female (66.2% vs 42.9%; p=0.0001). They had higher cardiovascular risk factors namely diabetes mellitus (DM) (44.3%) and hypertension (HTN) (54.8%) in contrast to those without CKD. There were notably higher percentage of CKD patients presented with Killip class 3 and 4 (30.6% vs 15.7%; p=0.0001) and cardiogenic shock (16% vs 7.6%; p=0.000). In the CKD group 20% patients received thrombolytic therapy, 12.1% primary percutaneous coronary intervention, 8% pharmaco-therapy, 14.1% PCI only, 45.8% patients received medical management and in the non-CKD group (19.2%, 18.9%, 9.9%, 17.6%, 34.4% respectively). Multivessel disease was higher in the CKD group (50.2% vs 44.4%; p<0.05). In terms of outcomes, patients with CKD were more likely to develop in-hospital death (7.9% vs 3.2%; p=0.0001).

Conclusions: Patients with CKD were older, predominantly female, and had higher cardiovascular risk factors namely DM and HTN, higher rates of multivessel disease, higher rates of complications and mortality.

Other Coronary interventions - Other

Risk factors, management and in-hospital outcome of patients with STEMI in tertiary care hospital

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: ST-segment elevation myocardial infarction (STEMI) is a major cause of morbidity and mortality worldwide. The mortality in STEMI patients is influenced by advanced age, Killip class, time delay to treatment, presence of emergency medical system (EMS)-based STEMI networks, treatment strategy, history of MI, diabetes mellitus, renal failure, number of diseased coronary arteries, and left ventricular ejection fraction (LVEF). The purpose of this study was to assess demographic, clinical, procedural characteristics and in hospital outcome of patients with STEMI.

Methods and results: All STEMI patients admitted to our hospital from January 2015 to December 2019 were included in this prospective observational study. They were studied for risk factors, clinical characteristics, angiographic profile, procedural characteristics and in-hospital outcome. Results: A total 6,292 patients with STEMI were included in this study. Mean age of the patients was 55.16±11.63 years. Out of them 86.2% patients were male and 13.8% were female. Dyslipidaemia (75.6%) was the most common risk factor followed by smoking (55.7%), hypertension (51.4%), DM (42.2%), obesity (38.7%) and family history of ischaemic heart disease (28.4%). Chronic kidney disease was present in 36.3% patients. Most patients had mild left ventricular dysfunction (46.5%) and mean left ventricular ejection fraction was 44.09±6.7%. Coronary angiography was done in 54.4% cases; single-vessel disease was in 53% cases, double-vessel disease was in 28.8% cases and triple-vessel disease in 17.5% cases. Left anterior descending artery was the most common infarct related artery followed by right coronary artery. Thrombolytic therapy was given in 19.6% patients, 15.8% patients underwent primary percutaneous coronary intervention (PCI), 9% patients pharmaco-invasive therapy, 15.9% patients only PCI and 39.7% patients received medical management. Acute left ventricular failure developed in 22.6% patients, cardiogenic shock in 11.5% patients and arrhythmia in 16.3% patients. In-hospital mortality was 5.4%.

Conclusions: STEMI commonly affects individuals at a young age. Dyslipidaemia was the most common risk factor. Most patients received medical management and the mortality rate is very low.

Euro20A-POS664
Posters

STEMI - Tools, devices and techniques

Primary PCI in tertiary care hospital: five-year single-centre registry

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Worldwide primary percutaneous coronary intervention (PPCI) is the preferred reperfusion therapy in patients presenting with ST-segment elevation myocardial infarction (STEMI). The aim of the study was to describe five years' experience of PPCI in tertiary care hospital.

Methods and results: All consecutive STEMI patients who underwent PPCI from January 2015 to December 2019 in our hospital were included in this study. They were studied for risk factors, clinical characteristics, angiographic profile, procedural characteristics, and in-hospital outcome. Results: a total of 1,018 patients who underwent PPCI were studied. Out of these, 87.8% patients were male and 12.2% were female. Mean age of the patients was 54.24±11.57 years. Dyslipidaemia (83.9%) was the most common risk factor followed by hypertension (57.4%), smoking (55.5%), DM (49.2%), obesity (42%) and family history of ischaemic heart disease (33.2%). Chronic kidney disease was present in 36.3% patients. Most patients had mild left ventricular dysfunction (58.5%) and mean left ventricular ejection fraction was 45.35±6.4%. Mean symptom to balloon time was 390.76±264.13 minutes and door to balloon time 72.91±27.06 minutes. Left anterior descending artery (50.7%) was the most common infarct related artery followed by right coronary artery (41.1%). Multivessel disease was present in 40.7% patients. Thrombus aspiration was done in 84.3% cases. Drug-eluting stent was used in 91.5% cases. No-flow was developed in 3.4% patients. Post-TIMI III flow was achieved in 94.5 % cases. In-hospital mortality was 4%. Mean follow-up period was 24.65±16.02 months. Long-term mortality was 6.6%.

Conclusions: Primary PCI should be the preferred reperfusion therapy in our hospital as short-term and long-term results are excellent.

Euro20A-POS665
Posters

STEMI - Tools, devices and techniques, Other Coronary interventions - Other

In-hospital outcome of chronic kidney disease patients undergoing primary PCI

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Renal function of the patients undergoing PPCI remains unknown. Chronic kidney disease (CKD) is a powerful predictor of adverse events among STEMI patients. Contrast exposure during PPCI may aggravate renal function and complicated clinical outcome. The purpose of this study was to evaluate in-hospital outcome of CKD patients undergoing PPCI.

Methods and results: This prospective observational study enrolled 1,018 patients undergoing PPCI in our hospital from January 2015 to December 2019. The patients were categorised into two groups; CKD and non-CKD. CKD is defined as GFR of < 60 mL/min/1.73 m^2 as determined by Cockcroft-Gault formula. Patient's demographics, extent of coronary artery disease, short (in-hospital) and long-term outcomes were critically assessed. Results: A total number of 1,018 STEMI patients undergoing PPCI were included in the analysis. Out of these, 36.3% patients had CKD and 63.7% had no CKD. Patients with CKD were older than non-CKD group (Mean age 58.96±11.59 years vs 51.54±10.68 years; p=0.001). PPCI CKD cohort was predominantly female (47.6% vs 34.8%; p=0.006). They had higher cardiovascular risk factors namely hypertension (HTN) (63.2%) in contrast to those without CKD. There were notably higher percentage of CKD patients presented with Killip class 3 and 4 (17.0% vs 8.6%; p=0.0001) and cardiogenic shock (17.8% vs 10.8%; p=0.002). Triple-vessel disease was higher in CKD group (16.2% vs 13.3%). In terms of outcomes, patients with CKD were more likely to develop in-hospital death (7.6% vs 2.0%; p=0.0001). Mean follow-up period was 24.65±16.02 months. Long-term mortality was 10.6% in PPCI-CKD group and 4.3% in PPCI-non CKD group.

Conclusions: Patients with CKD were older with female predominance, had higher cardiovascular risk factors namely HTN, higher rates of triple-vessel disease, higher rates of complications and mortality.

STEMI - Tools, devices and techniques, Other Coronary interventions - Other

Pharmaco-invasive therapy in tertiary care hospital five-year single-centre registry

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Shortening the time to reperfusion of the infarct artery by prompt initiation of pharmacological reperfusion followed by early percutaneous coronary intervention (PCI) to consolidate the initial reperfusion process and prevent reocclusion of the infarct artery may be the optimal reperfusion strategy for patients with ST segment Elevation Myocardial Infarction (STEMI) when primary PCI is not feasible as it is in many developing countries. The purpose of the study was to describe five years' experience of pharmaco-invasive therapy (PIT) in tertiary care hospital.

Methods and results: All consecutive STEMI patients who underwent PIT from November 2014 to October 2019 in our hospital were included in this study. They were studied for risk factors, clinical characteristics, angiographic profile, procedural characteristics, and in-hospital outcome. Results: A total of 6,292 patients with STEMI were admitted during this period. Of these, 566 patients underwent PIT and included in this study. Mean age of the patients was 53.43±10.69 years. Out of these, 91% patients were male and 9% were female. Dyslipidaemia (77.4%) was the most common risk factor followed by smoking (58.8%), hypertension (50.7%), DM (42.4%), obesity (39.2%) and family history of ischaemic heart disease (32.7%). Most patients had mild left ventricular dysfunction (49.3%) and mean left ventricular ejection fraction was 44.33±7.04%. Drug-eluting stent was used in 99.6% cases. Post-TIMI III flow was achieved in 99.1 % cases. Cardiogenic shock developed in 2.5% cases; acute left ventricular failure in 2.35 cases and arrhythmia in 1.7% vases. In-hospital mortality was 1.2%. Mean follow-up period was 27.24±16.27 months. Long term mortality was 4%.

Conclusions: Pharmaco-invasive therapy has the potential to combine the best aspects of both pharmacological and interventional induced and sustained reperfusion with excellent short- and long-term outcomes.

Euro20A-POS667
Posters

STEMI - Tools, devices and techniques

Gender-based comparison on risk factors, clinical presentation and in-hospital outcome in patients with STEMI

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Gender differences exist in many aspects of ST-segment elevation myocardial infarction (STEMI), including age, risk factors clinical presentation, delay in diagnosis, angiographic profile and treatment. The aim of this study was to compare age, risk factors, angiographic profile and treatment between men and women.

Methods and results: A total of 6,292 patients with STEMI were admitted to our hospital from November 2014 to October 2019. Of these, 86.2% (5,423) patients were male and 13.8% (869) patients were female. Female patients were older than their male counterpart (mean age 57.68± 12.26 years vs 54.76±11.47 years; p=0.002). Women had a higher proportion of cardiac risk factors such as diabetes mellitus (49.5% vs 41%; p<0.0001), hypertension (61.8% vs 49.8%; p<0.0001) and obesity (42% vs 38.2%; p=0.004) as compared with men. Chronic kidney disease was more prevalent in females (66.2% vs 42.9%; p<0.0001). Acute left ventricular failure (23.1% vs 19.7%; p=0.02) and cardiogenic shock (12.9% vs 8.2%; p<0.0001) at presentation were more prevalent in females than males. Mean LVEF was 44.07±6.7 in men and 44.28±6.9 in women (p > 0.05). Men underwent coronary angiography (CAG) more often than women (p=0.0001). Vessel involvement in CAG was almost similar. Pharmaco-invasive therapy was done more often in men than women (OR 1.43; 95% CI: 1.02 to 1.99; p=0.0001). Women underwent medical management more often than men (OR 0.72; 95% CI: 0.59 to 0.88; p=0.0001) as their presentation was delayed. In-hospital mortality (9.8% vs 4.7%) was higher in women than men (p<0.0001).

Conclusions: Women were older than men, had more risk factors (hypertensive, diabetic, obese), and complications during presentation, received less aggressive therapy and had higher mortality rates than men.

Euro20A-POS668
Posters

CTO - Tools, devices and techniques

CTO PCI procedural aspects and in-hospital outcome

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) is a rapidly evolving area of interventional cardiology. The data regarding procedural technique and in-hospital clinical outcomes of CTO-PCI is currently not available in Bangladesh. This study was conducted to observe procedural aspects and in hospital outcome in patients undergoing CTO-PCI.

Methods and results: This was a retrospective observational study done in the department of cardiology in a specialised cardiac hospital in Bangladesh over a period of 6 months. A total of 92 patients having symptoms with at least one CTO lesion on coronary angiography (CAG) were enrolled. Procedural technique and in hospital outcome were observed. The success rate of CTO-PCI was 93%. The target CTO vessel were LAD (54.3%), followed by RCA (39.1%) & LCX (6.5%). In all 92 cases, ante grade wire escalation technique was adopted with rotablation was done in 6 cases, LM PCI in 18 cases and bifurcation PCI in 21 cases. Total duration of procedure was 48.09±2.48 mins and the amount of contrast used was 128.80± 52.745 ml. Wire crossing time was 30.99±12.15 mins and in most cases, the wire crossing the lesion was pilot-50 (69.6%) and followed by conquest pro (14.1%). In respect of procedural and in hospital outcome, the complications were slow flow (7.6%), cardiogenic shock (1.1%), stroke (1.1%), bleeding (2.2%), haematoma (4.3%) and death (1.1%).

Conclusions: This study demonstrated that CTO-PCIs had a higher success rate in our centre, consistent with other centres worldwide. Different procedural aspects of CTO PCIs were observed. Procedural and in-hospital outcome were favourable necessitating further large scale and long-term study.

Other Coronary interventions - Other

Prediction of contrast-induced nephropathy by Mehran risk score in patients undergoing routine percutaneous coronary angioplasty

MALIK Fazila [1]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Radiologic procedures utilising intravascular iodinated contrast media injections resulted in an increasing incidence of procedure-related contrast-induced nephropathy (CIN). The Mehran Risk Score (MRS) has been demonstrated to be clinically useful for prediction of CIN after elective PCI. The aim of this study was to assess the incidence and predictors of CIN in patients undergoing routine coronary angioplasty and also to assess the applicability of the Mehran Risk Score in the prediction of CIN in the Bangladeshi population.

Methods and results: This cross-sectional analytic study was carried out in our hospital from June 2018 to November 2019. This study assigned 101 consecutive patients who underwent routine PCI and was categorised to 4 groups according to MRS (low, medium, high, and very high risk). CIN was defined as an increase in serum creatinine concentration of 0.5 mg/dl or 25% above baseline within 48 hours after contrast administration. The effectiveness of the Mehran score was analysed using a receiver operating characteristic (ROC) curve and logistic regression model. Results: Among the study population, 11 patients developed CIN (Incidence 10.7%). Among the CIN patients, 81.82% patients underwent multivessel PCI & 18.18 % patients underwent single vessel PCI. Mean age of the patients with CIN was 59.8±11.32 and without CIN was 54.45±10.66. LVEF, eGFR, Contrast volume, fluoroscopy time & Mehran risk score were statistically significant predictors for developing CIN. None of the patients in the low risk group developed CIN. The risk of developing CIN in other groups was as follows: 26.7% in the medium risk group; 62.5% in the high risk group and 100% in the very high risk group. Logistic regression analysis showed that MRS was a highly significant for predicting CIN (P value <0.001). ROC curve for Mehran risk score was applied to study population and area under curve (AUC) was 0.96 with the cut off value for MRS 9 having sensitivity and specificity 72.7% and 93% respectively for development of CIN.

Conclusions: The Mehran risk score is an excellent tool for prediction of CIN in routine PCI patients not only in western populations but also in Bangladeshi population. All patients should be categorised based on the Mehran risk score and measures should be taken to prevent CIN.

Stable CAD - Invasive imaging and functional assessment

Impact of the difference of Y-connector valve status on the measurement of intracoronary pressure: insights from a bench test

WARISAWA Takayuki [1,2], WARISAWA Takayuki [1,2], NOUR Daniel [2,3], HOWARD James [2], DOI Shunichi [4], COOK Christopher [2], SELIGMAN Henry [2], KASAHARA Mizuho [1], MATSUDA Hisao [1], MIZUNO Koichi [1], AKASHI Yoshihiro [4]

(1) St. Marianna University School of Medicine Yokohama City Seibu Hospital, Kanagawa, Japan; (2) Imperial College London, London, United Kingdom; (3) James Cook University, Brisbane Campus, QLD, Australia; (4) St. Marianna University School of Medicine, Kanagawa, Japan

Aims: Although several technical cautionary issues have been acknowledged to measure accurate intracoronary physiology, the impact of the difference of Y-connector valve status has not been fully clarified. The aim of this study was to investigate the impact of the rotary valve Y-connector on the measurement of intracoronary pressure index.

Methods and results: Tested Y-connectors included OKAY II (Goodman Co., Ltd, Nagoya, Japan), Meg OKAY (Goodman), and COPILOT (Abbott Vascular, Santa Clara, CA, USA), all of which have both cock type and rotary valves. The delta Pd/Pa following opening or closing the rotary valve of Y-connector was assessed in the silicon-made coronary artery model which was circulated by the dedicated mechanical pump to achieve measurement of intra-vessel pressure. A pressure wire sensor was kept placed at the proximal point of the vessel through the measurement, in which diastolic pressure (Pd) should remain equal to aortic pressure (Pa) theoretically. First, equalisation was performed at closed-valve status and delta Pd/Pa was measured following opening the valve. Second, equalisation was performed at opened-valve status and delta Pd/Pa was measured following closing the valve. The measurements were performed 6 times in both sequences for respective 3 Y-connectors. The mean delta Pd/Pa values following changing valve status were 0.030±0.010 in OKAY II ($p=0.0023$), 0.036±0.015 in Meg OKAY ($p=0.0023$), and 0.00±0.00 in COPILOT, respectively. There was statistically significant difference between the Y-connectors ($p<0.001$). More importantly, in the OKAY II and Meg OKAY, mean delta Pd/Pa values were greater than the clinically applied drift value (>0.02).

Conclusions: The impact of the rotary valve status of Y-connector could not be ignored in order to achieve accurate intracoronary pressure measurement. Consideration on the different structures of Y-connector valve is also important.

Stents and scaffolds - Tools, devices and techniques

Long-term results of PCI in cardiac allograft vasculopathy in a tertiary hospital

LEÓN ALIZ Ebrey [1,2], LEÓN-ALIZ Ebrey [1,2], VILCHES SORIA Silvia [2], OTEO DOMINGUEZ Juan Francisco [2], GARCÍA TOUCHARD Arturo [2], FERNÁNDEZ DÍAZ José Antonio [2], GOICOLEA RIOGÓMEZ Francisco Javier [2]

(1) Hospital San Francisco de Asís, Madrid, Spain; (2) Hospital Puerta de Hierro-Majadahonda, Majadahonda, Spain

Aims: Cardiac allograft vasculopathy (CAV) affects 50% of cardiac transplants in long-term follow-up. Percutaneous coronary intervention (PCI) is a treatment option, but few studies show greater benefit and most of them show higher restenosis rates and target lesion revascularisation (TLR). The aim of this study is to review our experience using stents in percutaneous coronary interventions in cardiac allograft vasculopathy.

Methods and results: We studied retrospectively 38 patients with CAV treated with PCI from 2000 to 2017. Surveillance angiography was performed in 85% of stents. Stent restenosis (SR), stent thrombosis (ST), target lesion revascularisation (TLR) and patient survival are reported. Results: One-hundred and two stents were placed in 96 lesions: 16 bare-metal stent (BMS), 34 first-generation drug-eluting stent (FDES), 52 second and third generation drug-eluting stent (SDES). Primary success was obtained in 99% of lesions. 6% of stents were placed in left main coronary artery, 43% in left anterior descending coronary artery, 28% in circumflex coronary artery, and 23% in right coronary artery. Pre-PCI stenosis was 75.5±13.2%, average stent length 20.2±7 mm and average stent diameter 2.8±0.5 mm. Mean time from transplantation to PCI was 11.5±5 years. Mean clinical follow-up was 5.3± 4.4 years. Mean angiographic follow-up was 40±47 months. A total of 27 (31%) stents presented events during follow-up: 27 SR, no ST. 7 occurred in BMS, 9 in FDES, 11 in SDES (p=0.4). There were no differences in rates of SR between BMS and DES (44% vs 39%, p=0.24). We performed 15 (17.2%) TLR. Post-PCI survival was 72.7% at 5 and 50.3% at 10 years, and freedom from lesion SR and/or ST at 1 (96%), 5 (57%) and 10 (47%) years.

Conclusions: In cardiac transplant recipients, PCI with stent can be performed with high rates of primary success. Our series show a low rate of SR at 1-year-follow-up, similar to coronary disease in non-transplant patients. However, after a very long-term follow-up, the rate of SR is still high.

STEMI - Invasive imaging and functional assessment, Stable CAD - CT / MRI imaging

The impact of the eccentricity of the plaque on the max-lipid core burden index at the 4 mm segment value: near-infrared spectroscopy-IVUS study

OHTA Yusuke [1], SATO Takao [1], OHTA Yusuke [1], TAYA Yuji [1], AIZAWA Yoshifusa [1]

(1) Tachikawa general hospital, Nagaoka, Japan

Aims: Near-infrared spectroscopy (NIRS)-IVUS enables precise detection of lipid core burden. The max-lipid core burden index at the 4 mm segment, max-LCBI(4), of >400 is related to long-term outcomes of cardiovascular events. Max-LCBI(4) of >500 has been also reported to be associated with perioperative myocardial infarction. Though NIRS-IVUS can express lipid as max-LCBI using digitisation, it is difficult to quantify lipid volume. So, the aim of the present study is to investigate the impact of the eccentricity of the plaque on max-LCBI(4) value and PCI outcomes.

Methods and results: Seventy consecutive patients were enrolled, undergoing percutaneous coronary intervention (PCI) for acute coronary syndrome (ACS, N=30) and stable angina pectoris (SAP, N=40). Max-LCBI(4) and Max-LCBI(10) were evaluated in the culprit plaques. Plaque volume, vessel, and lumen area were measured on greyscale IVUS. In the present study, plaque eccentricity index (PEI) was also measured as following; PEI = (lumen diameter [LD] + the maximum thickness of plaque [Pmax] - minimum thickness of plaque [Pmin]) / (LD - Pmax + Pmin). First, patients were divided into 2 groups based on clinical presentation (ACS [N=30]) and SAP [N=40]). Furthermore, each group was divided into 2 groups based on the median value of PEI (the eccentric plaque group [EPG] and the concentric plaque group [CPG]). In the present study, as PCI outcomes, peak CPK value and final TIMI frame count in each group were measured. Result: In the ACS group, the mean age was 68±4 years old. Max-LCBI(4) and max-LCBI(10) were 601±148 and 487±156, respectively. Dividing the ACS group into EPG and CPG, there were no significant differences in baseline characteristics like age, gender, and LDL level. In addition, significant differences in plaque volume and lumen area were also not observed. Though there was a significant difference in max-LCBI(4) between the EPG and the CPG (522±148 and 687±125, p=0.03), a significant difference in max-LCBI(10) between the EPG and the CPG (490±139 and 517±119, p=0.18) was not shown. Furthermore, there were no significant differences in peak CPK value and TIMI frame count between the EPG and the CPG. In the SAP group, the mean age was 72±6 years old. Max-LCBI(4) and max-LCBI(10) were 210±82 and 116±58, respectively. As with the ACS group, the SAP group was divided into EPG and CPG. There were no significant differences in baseline characteristics like age, gender, LDL level and parameters of greyscale IVUS. Unlike the ACS group, max-LCBI(4) and max-LCBI(10) in the EPG of the SAP group were comparable to those in the CPG. There was no significant difference in PCI outcomes.

Conclusions: The eccentricity of the plaque in ACS with vulnerable plaque but not SAP might influence Max-LCBI(4). In eccentric plaque, plaque vulnerability might be underestimated compared to concentric plaque. In these cases, more longitudinal evaluations such as max-LCBI(10) might be also needed to evaluate the vulnerability of plaque.

Stable CAD - Invasive imaging and functional assessment

Lipid core burden index is associated with microcirculatory dysfunction even in stable angina pectoris: insights from intracoronary electrocardiography

OHTA Yusuke [(1)], SATO Takao [(1)], OHTA Yusuke [(1)], YUJI Taya [(1)], AIZAWA Yoshifusa [(1)]

(1) Tachikawa general hospital, Nagaoka, Japan

Aims: Near-infrared spectroscopy (NIRS)-IVUS enables precise detection of lipid core burden. Distal embolisation is one of mechanisms of microcirculatory dysfunction (MD) caused by percutaneous coronary intervention (PCI). The max-lipid core burden index at the 4 mm segment, max-LCBI(4), of >500 was related to perioperative myocardial infarction even in stable angina pectoris. Intracoronary electrocardiography (ECG) can detect slight ischaemia during PCI, maybe indicating distal embolisation. Thus, this study aimed to investigate whether plaques with low max-LCBI(4) influence MD, using intracoronary ECG.

Methods and results: Fifty consecutive patients who underwent PCI for stable angina pectoris due to stenosis of the proximal segment of the left anterior descending artery were enrolled. NIRS-IVUS was performed in all the patients before predilatation to evaluate for the culprit lesion. Total LCBI and max-LCBI(4) within the culprit lesion were measured. On greyscale IVUS, vessel area, lumen area, plaque volume, and percent (%) plaque volume were measured. Intracoronary ECG was performed at stent implantation to measure the time from the initiation of ST-segment elevation from the isoelectric baseline to the return of ST-segment to the isoelectric baseline after the deflation of the stent balloon, which was defined as the severity of the MD. The patients were divided into 2 groups according to median max-LCBI(4) (high- [n=25] and low- LCBI groups [n=25]). Results: The mean age was 72±6 years. Of the patients, 80% were male. The mean overall max-LCBI(4) was 140±100. Max-LCBI(4) was significantly higher in the high-LCBI(4) group than in the low-LCBI(4) group. No significant differences in age, body mass index, American College of Cardiology and American Heart Association classification and low-density lipoprotein level were found between the groups, as well as in the greyscale IVUS parameters such as %plaque volume. The mean time from the initiation of the ST-segment elevation from the isoelectric baseline to the return of ST-segment to the isoelectric baseline was significantly longer in the high-LCBI group than in the low-LCBI group (33 vs 12 sec, p=0.01) despite no change in the ST-segment on 12-lead ECG. The ST-segment elevation occurred only during stent balloon inflation and returned to the isoelectric baseline immediately after stent balloon deflation at a max-LCBI(4) of 0. The no-reflow and slow flow phenomena were not observed.

Conclusions: Even low max-LCBI(4) on NIRS-IVUS was associated with MD during PCI in patients with stable angina pectoris.

Other Coronary interventions - Calcified lesions

One-year outcomes of patients treated with intravascular lithotripsy in a real-world setting

WONG Bernard [1], WONG Bernard [1], EL-JACK Seif [1], NEWCOMBE Ruth [1], GLENIE Timothy [1], ARMSTRONG Guy [1], KHAN Ali [1]

(1) North Shore Hospital, Auckland, New Zealand

Aims: Intravascular lithotripsy (IVL) has been shown to be an effective calcium modification tool in preparing calcified coronary lesions prior to stent placement. Although short-term safety outcomes have been positive, longer term outcomes are yet to be determined. We share the one-year outcomes of patients treated with IVL during their PCI.

Methods and results: All patients treated with IVL between October 2018 and January 2019 during their PCI at our centre were included. Adverse outcomes at one year include cardiovascular mortality, recurrent myocardial infarction (MI) and unplanned revascularisation. During the study period, 26 patients were treated with IVL during their PCI at our centre. The mean age was 72±8 years and 69% were men. Indications for PCI were: ACS in 14 patients (54%), stable angina in 11 patients (42%), and PCI before transcatheter aortic valve implantation in 1 patient (4%). None of the patients had procedural complications or in-hospital adverse outcomes. At one year, three patients had recurrent non-STE elevation MI (2 early in-stent restenosis including a stent fracture in the right coronary artery, and 1 non-target vessel infarct). All three of these patients underwent further PCI successfully with drug-eluting stents. One patient with concurrent atrial fibrillation died from an intracranial haemorrhage whilst on triple antithrombotic therapy at 2 weeks. Two patients had died from unrelated causes.

Conclusions: Intravascular lithotripsy is a novel innovation in modifying coronary calcification to optimise stent placement that has been shown to be user-friendly with good short-term safety results. To our knowledge, this is the first one-year outcome data for a series of patients treated with IVL. Further research on the long-term outcomes of IVL is needed to guide clinicians to achieve successful results in PCI of calcified coronary lesions.

Left main and multivessel disease - Tools, devices and techniques, Other Coronary interventions - Other

Direct visualisations and 3D reconstructions of a post-TAVR PCI procedure performed in a human heart

ZHINGRE SANCHEZ Jorge [(1)], VALENZUELA Thomas [(1)], IAIZZO Paul [(1)]

(1) University of Minnesota, MN, USA

Aims: TAVR is an established procedure for treating severe aortic stenosis (AS) in patients considered at high risk of mortality during conventional surgical AVR. Despite the rapid implementation of TAVR procedures and mounting clinical evidence of its efficacies and safeties, questions remain regarding post-TAVR PCI. This study describes the use of Visible Heart® methodologies to highlight the procedural steps for deploying a stent in the left main (LM) of a perfusion-fixed human heart with a pre-implanted EvolutTM R device.

Methods and results: Direct endoscopic visualisations, fluoroscopy, and OCT were simultaneously used for the entire PCI procedure. Specifically, the endoscopic footage highlights the: 1) assessment of the aortic root sinus and pre-implanted EvolutTM R; 2) manoeuvrability of the guidewires, catheters, and balloons; 3) accessing the left coronary artery (LCA) ostium; and 4) deployment of the stent in the LM. In addition to these novel procedural visualisations, post-PCI imaging and analyses were performed using: 1) OCT; 2) micro-CT, 3) computational reconstruction and modelling, and 4) 3D printing. These video recordings illustrate that this TAVR frame and commissure posts partially obstruct the coronary ostia. Additionally, the difficulties in manipulating the catheters and guidewires past the frame and through the LM were directly visualised from a superior aortic view. The OCT and fluoroscopy revealed mild coronary artery disease (CAD) and presence of calcified vasculature. The minimal calcific depositions on the native leaflets and LM of this donor human heart correlated well as an AS and post-TAVR PCI model. The post-PCI imaging and reconstruction were acquired using micro-CT, detailing the nitinol TAVR frame and LM stent struts. Subsequently, both the implanted valve and stent were modeled and 3D printed from these high resolution micro-CT images. The resulting computational models and 3D prints of the aortic root, TAVR, and stent, detail post-implantation deformation of the valve frame and expanded stent struts. The combined endoscopic footage and 3D reconstructions highlight the complicated LM anatomy and tissue-device interactions that made this post-TAVR PCI procedure challenging.

Conclusions: Post-TAVR PCI is a topic of great discussion and interest due to the increased difficulties and ambiguities for executing these procedures. The use of these unique Visible Heart® multimodal imaging and post-implant analyses can provide interventional cardiologists with educational footage on how conventional clinical imaging translates to true tissue-device interactions and/or how to perform post-TAVR PCI procedures for treatment. Evident by the rising device development of next generation TAVR devices to facilitate PCI, these study methodologies can also be beneficial to medical device designers, since they provide critical insights into the prosthesis interactions within real human heart anatomies. This complete case procedure, accompanied with endoscopic videos, computational models, 3D prints, serves as a precursor to future TAVR evaluations (stenting, angioplasty, valve-in-valve (ViV), etc.) to better understand existing and imminent challenges that will need to be addressed in the post-TAVR PCI and valve procedure field.

Stable CAD - Adjunctive pharmacotherapy, Stents and scaffolds - Tools, devices and techniques

Clinical outcomes after DAPT cessation at one month among troponin negative patients undergoing PCI: a subanalysis of the ReCre8 trial

STELLA Pieter [(1)], VAN HEMERT Nicole [(1)], VOSKUIL Michiel [(1)], STEIN Mèra [(2)], FRAMBACH Peter [(3)], LEENDERS Geert [(1)], RITTERSMA Saskia [(1)], KRAAIJEVELD Adriaan [(1)], TANDJUNG Kenneth [(1)], AGOSTONI Pierfrancesco [(4)], STELLA Pieter [(1)]

(1) UMC, Utrecht, the Netherlands; (2) Zuyderland Medisch Centrum, Heerlen, the Netherlands; (3) National Institute of Cardiac Surgery and Interventional Cardiology, Luxembourg, Luxembourg; (4) Ziekenhuis Netwerk Antwerpen, Antwerp, Belgium

Aims: Current guidelines recommend six months of DAPT for patients undergoing elective PCI. This can be shortened or prolonged depending on individual patient characteristics. This subanalysis of the ReCre8 trial (NCT02328898) assessed the performance of a permanent polymer and polymer-free drug-eluting stent in troponin negative patients after DAPT cessation at one month.

Methods and results: In the ReCre8 trial, patients undergoing PCI were stratified for troponin and diabetic status and randomised to receive a permanent polymer or a polymer-free DES. Troponin negative patients were treated with one month of DAPT after which they continued with aspirin monotherapy. Endpoints included target-lesion failure, a composite of all net adverse clinical events and individual components of the endpoints and were assessed after DAPT cessation. A total of 1,491 patients were randomised of which 892 (59.8%) patients were troponin negative. Target-lesion failure between one and twelve months follow-up occurred in 4.1% in the permanent polymer stent group vs 4.7% in the polymer-free group (p=0.65). Stent thrombosis (definite or probable) occurred in 4 patients (0.9%) in the permanent polymer stent group and in 2 patients (0.4%) in the polymer-free group (p=0.40). There were no differences observed between stents for the separate endpoint components.

Conclusions: Based on the results of this subanalysis, a short period of DAPT of only one month in troponin negative patients seems safe with a low rate of stent thrombosis in both study arms.

Stable CAD - Adjunctive pharmacotherapy, Other Coronary interventions - Other

Patients with high bleeding risk undergoing PCI with DES implantation treated with short DAPT: a ReCre8 subanalysis

STELLA Pieter [(1)], VAN HEMERT Nicole [(1)], TANDJUNG Kenneth [(1)], VOSKUIL Michiel [(1)], STEIN Mèra [(2)], FRAMBACH Peter [(3)], LEENDERS Geert [(1)], RITTERSMA Saskia [(1)], KRAAIJEVELD Adriaan [(1)], AGOSTONI Pierfrancesco [(4)], STELLA Pieter [(1)]

(1) UMC Utrecht, Utrecht, the Netherlands; (2) Zuyderland Medisch Centrum, Heerlen, the Netherlands; (3) National Institute of Cardiac Surgery and Interventional Cardiology, Luxembourg, Luxembourg; (4) Ziekenhuis Netwerk Antwerpen, Antwerp, Belgium

Aims: The management of patients with high bleeding risk undergoing PCI has been under debate. Using data from the ReCre8 trial (NCT02328898), we aimed to examine the safety of aspirin monotherapy in high bleeding risk patients. We assessed target-lesion failure and bleeding events at twelve months in troponin negative patients with and without high bleeding risk using a division based on the new definition by the Academic Research Consortium for High Bleeding Risk.

Methods and results: In the ReCre8 trial, patients requiring PCI were stratified for troponin status and the presence or absence of diabetes after which they were randomised to implantation of a permanent polymer zotarolimus-eluting stent or a polymer-free amphilimus-eluting stent. Troponin negative patients were treated with one month of dual antiplatelet therapy, after which they continued with aspirin monotherapy. After one year, target-lesion failure, a composite of all net adverse clinical events and individual ischaemic and bleeding endpoints were assessed. A total of 892 troponin negative patients were enrolled and randomised of which 193 (21.6%) were identified as high bleeding risk. As compared to patients without high bleeding risk, patients with high bleeding risk more frequently presented with unstable angina, multivessel disease and a history of myocardial infarction and CABG. Procedural characteristics were similar between groups. At twelve months, target-lesion failure was comparable between groups with 8.3% in patients with high bleeding risk and 6.4% in patients without high bleeding risk (p=0.37). Patients with high bleeding risk had a higher risk of all net adverse clinical events with 20.7% vs 11.2% (p<0.001). Clinically relevant bleeding (Bleeding Academic Research Consortium bleeding type 2 to 5) was higher among high bleeding risk patients (4.7% vs 1.6%; p=0.010). During aspirin monotherapy this difference decreased: clinically relevant bleeding occurred in 2.1% of patients with high bleeding risk and in 0.7% of patients without high bleeding risk (p=0.089), suggesting aspirin monotherapy is relatively safe in high bleeding risk patients. In this troponin negative population treated with one month of DAPT, major bleeding (Bleeding Academic Research Consortium bleeding type 3 to 5) did not differ between groups (p=0.19).

Conclusions: This subanalysis shows that troponin-negative patients with high bleeding risk based on the new definition by the Academic Research Consortium have an increased incidence of clinically relevant bleeding events during DAPT. This difference disappears after cessation of DAPT and continuation of aspirin monotherapy.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

One-year clinical outcomes of polymer-free amphilimus-eluting stent implantation in patients with diabetes mellitus: the ReCre8 diabetes substudy

STELLA Pieter [1], VAN HEMERT Nicole [1], ROZEMEIJER Rik [1], VOSKUIL Michiel [1], STEIN Mèra [2], FRAMBACH Peter [3], RITTERSMA Saskia [1], KRAAIJEVELD Adriaan [1], TANDJUNG Kenneth [1], AGOSTONI Pierfrancesco [4], STELLA Pieter [1]

(1) UMC Utrecht, Utrecht, the Netherlands; (2) Zuyderland Medisch Centrum, Heerlen, the Netherlands; (3) National Institute of Cardiac Surgery and Interventional Cardiology, Luxembourg, Luxembourg; (4) Ziekenhuis Netwerk Antwerpen, Antwerp, Belgium

Aims: As the incidence of diabetes grows, the number of PCI patients with diabetes increases. However, the improvement of outcomes with new-generation DES as seen in the general population is not found in the diabetic population. Debate remains whether diabetics require a specific DES-design. The polymer-free amphilimus-eluting stent represents a novel elution-technology with potential enhanced clinical performance in diabetics. This sub-analysis of the ReCre8 trial assesses one-year post-discharge target-lesion failure of a permanent polymer and a polymer-free stent in a diabetic subgroup.

Methods and results: In this multicentre trial (NCT02328898), all-comer patients were randomised to either a permanent polymer zotarolimus-eluting stent or a polymer-free amphilimus-eluting stent after stratification for troponin status and diabetes mellitus. Endpoints were target-lesion failure, a composite of all net adverse clinical events and the separate events composing the combined endpoints. In total, 1,491 patients were randomised of which 304 (20.4%) patients were diabetics. Target-lesion failure was numerically higher in diabetics as compared to non-diabetics (5.6% vs 3.5%; p=0.084) and in insulin-dependent diabetics as compared to non-insulin-dependent diabetics (8.4% vs 4.3%; p=0.14). Among the diabetic population, target-lesion failure occurred in 11 (7.2%) patients with a permanent polymer stent versus 6 (4.0%) patients with a polymer-free stent at twelve months follow-up (p=0.21). A statistically significantly higher rate of all net adverse clinical events was present in patients treated with a permanent polymer stent: 15.7% vs 8.0% (p=0.035). Stent thrombosis was low in both study arms with 0 cases in the permanent polymer group and 1 case (0.7%) in the polymer-free group (p=0.32). Among insulin-treated diabetic patients, a higher risk of target-lesion failure was present in the patients treated with the permanent polymer stent as compared to the polymer-free stent (14.9% vs 2.1%; p=0.022). Similar results were seen for all net adverse clinical events (29.8% vs 8.3%; p=0.009). No cases of stent thrombosis occurred among the insulin-treated diabetes patients.

Conclusions: Based on the results of this subanalysis of the ReCre8 trial, diabetic patients could potentially benefit from this polymer-free stent implantation. The subgroup of insulin-treated diabetes patients exhibits the greatest advantage in the outcomes of this subanalysis. Future randomised controlled trials should evaluate a potential benefit of a polymer-free amphilimus-eluting stent in this specific patient population.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Impact of lesion complexity and stent characteristics on one-year clinical outcomes: a subanalysis of the ReCre8 trial

STELLA Pieter [1], VAN HEMERT Nicole [1], ROZEMEIJER Rik [1], VOSKUIL Michiel [1], STEIN Mèra [2], FRAMBACH Peter [3], RITTERSMA Saskia [1], KRAAIJEVELD Adriaan [1], TANDJUNG Kenneth [1], AGOSTONI Pierfrancesco [4], STELLA Pieter [1]

(1) UMC Utrecht, Utrecht, the Netherlands; (2) Zuyderland Medisch Centrum, Heerlen, the Netherlands; (3) National Institute of Cardiac Surgery and Interventional Cardiology, Luxembourg, Luxembourg; (4) Ziekenhuis Netwerk Antwerpen, Antwerp, Belgium

Aims: Patients undergoing coronary stenting with a complex lesion anatomy may experience different risks and benefits compared to non-complex anatomy. This sub-analysis of the ReCre8 trial (NCT02328898) assessed the impact of lesion complexity on post-discharge clinical outcomes at twelve months as well as the difference between the permanent polymer zotarolimus-eluting stent and the polymer-free amphilimus-eluting stent in a population with complex lesion anatomy.

Methods and results: Patients requiring PCI were stratified for troponin status and diabetes mellitus after which they were randomised to receive a permanent polymer zotarolimus-eluting stent or a polymer-free amphilimus-eluting stent. Patients with troponin positive disease were treated with twelve months of DAPT, troponin negative patients received one month of DAPT. During index procedure, lesion complexity was defined as non-complex (A/B1) or complex (B2/C) according to the American College of Cardiology/American Heart Association criteria. The primary endpoint was target-lesion failure at twelve months. Secondary endpoints were a composite of all net adverse clinical events and individual events that compose the combined endpoints. Kaplan-Meier time-to-event estimates for the endpoints were compared between groups using log-rank test. In total, 1491 patients were randomised and treated of whom 883 (59.2%) patients underwent complex PCI. Complex patients more frequently presented with ACS, multivessel disease and a history of myocardial infarction and CABG. Target-lesion failure was reached in 46 (5.2%) patients undergoing complex PCI and 12 (2.0%) non-complex patients (p=0.001). A higher rate of all net adverse clinical events was seen in complex patients (9.9% vs 6.6%; p=0.023). Target-lesion revascularisation more frequently occurred in patients undergoing complex PCI with 3.4% as compared to 1.0% in patients with non-complex PCI (p=0.003). Among patients undergoing complex PCI, no differences were observed between the two study stents with comparable rates of all evaluated endpoints. After adjustment for differences in baseline covariates, lesion complexity was an independent predictor of twelve months target-lesion failure (adjusted hazard ratio 3.2; 95% confidence interval 1.8 to 5.6; p<0.001) and all net adverse clinical events (adjusted hazard ratio 1.5; 95% confidence interval 1.1 to 2.1; p=0.023).

Conclusions: Complex PCI was associated with an increased risk of target-lesion failure, composite of all net adverse clinical events and revascularisation after twelve months. The two study stents show similar results in a complex population.

Stable CAD - Vascular access and bleeding

Transradial vs transfemoral coronary angiography and PCI in patients with previous CABG surgery: impact of access strategy on short-term safety and long-term efficacy outcomes

DEN DEKKER Wijnand [(1)], DEN DEKKER Wijnand [(1)], GROENLAND Frederik [(1)], WILSCHUT Jeroen [(1)], VAN DEN OORD Stijn [(1)], KARDYS Isabella [(1)], DILETTI Roberto [(1)], DE JAEGERE Peter [(1)], ZIJLSTRA Felix [(1)], DAEMEN Joost [(1)], VAN MIEGHEM Nicolas [(1)]

(1) Erasmus MC, Rotterdam, the Netherlands

Aims: Little data is available on access strategy for coronary angiography (CA) and percutaneous coronary intervention (PCI) in patients with prior coronary artery bypass graft surgery (CABG). The aim of the study was to investigate the effect of transradial access (TRA) and transfemoral access (TFA) on short-term major vascular complications (MVC) and long-term major adverse cardiovascular events (MACE).

Methods and results: This was a single-centre, retrospective cohort study. From July 2010 to December 2017, 1106 consecutive patients with prior CABG underwent CA or PCI. The primary safety endpoint was MVC at 30 days, a composite of major bleeding (BARC type 3 or 5), retroperitoneal haematoma, dissection, pseudoaneurysm and arteriovenous fistula. The primary efficacy endpoint was MACE at 1460 days, a composite of all-cause mortality, myocardial infarction, stroke and urgent target vessel revascularisation (UTVR). Kaplan-Meier curves and logistic regression were used for statistical analysis. Propensity score adjustment was performed where appropriate. A total of 1084 patients met our inclusion criteria, 469 patients in the TRA and 615 patients in the TFA group. There was an increase in TRA from 9% in 2010 to 65.4% in 2017 ($p<0.01$ for trend). Percentage of PCI and success rates for PCI were comparable for both TRA and TFA groups (66.3% vs 63.7%, $p=0.38$ and 96.2% vs 94.1%, $p=0.20$ respectively). Procedure time was comparable for both groups, but contrast use was significantly lower in de TRA group (125 [100-180] vs 150 [100-210], $p<0.01$). At thirty days, the cumulative incidence of MVC was lower in the TRA group (0.7% vs 3.0%, $p<0.01$) and this remained significant after propensity score adjustment (OR 0.25; 95% CI: 0.07-0.88; $p<0.03$). At 1460 days, the cumulative incidence of MACE was 31% for the TRA group and 34% for the TFA group respectively. Kaplan-Meier curves for TRA group and TFA group showed no difference for the primary efficacy endpoint ($p=0.93$).

Conclusions: In this retrospective study, we showed that TRA for CA and PCI in patients with prior CABG was associated with significantly less short-term major vascular complications and contrast use, but no difference in long-term MACE, compared to TFA.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

A single-centre experience of paclitaxel DEB only interventional strategy in de novo ostial lesions of large coronary vessels

PALANIAPPAN Ganapathi [(1)], PALANIAPPAN Ganapathi [(1)], M. SUNDRAN Rhuban [(1)], YEE SIN Tey [(1)], ASHARI Afif [(1)], KOLANTHAI VELU Jayakhanthan [(1)], ROSLAN Aslannif [(1)], THUM Chan Ho [(1)], SUNDARAJOO Mugilan [(1)], AHMAD Nor Faiqah [(1)], ARIFF NURUDDIN Amin [(1)]

(1) National Heart Institute, Federal Territory of Kuala Lumpur, Malaysia

Aims: To assess potential, safety, and efficacy of DEB-only interventional strategy in *de novo* ostial lesions of large coronary vessels according to recommendations by German Consensus Group.

Methods and results: This was a single-centre retrospective study on all patients that underwent angioplasty to *de novo* ostial lesions of large coronary artery with DEB between 2016 and 2018. Patients' baseline characteristics, angiographic data, post-procedural outcome, and intermediate-term follow-up were analysed. Endpoints analysed were all-cause mortality, and the occurrence of MACE during the intermediate-term follow-up. MACE was defined as a composite of cardiac mortality, myocardial infarction (MI), clinically driven target lesion revascularisation (TLR), and stroke. Data were collected using a case report form and data entry by the assistance of CRC. A total of 107 patients were studied, in which 107 *de novo* ostial lesions were treated with DEB. The mean age was 59±9.6-years-old, and there were 95 males (89%). The majority of the cases, 84 patients (78.5%) were elective cases, 15 patients (14%) had either NSTEMI/ unstable angina and 8 patients (7.5%) had STEMI. Most of the patients had multiple risk factors; with a majority of them, 81 patients (76%) with hypertension, followed by 59 patients (55%) with diabetes mellitus, 49 patients (46%) with hyperlipidaemia, and 47 patients (44%) had a history of smoking. A total of 50 patients (47%) had single-vessel disease, 40 patients (37%) had 2-vessel disease, and the remaining 17 patients (16%) had 3-vessel disease. The ostial LCX lesion was the most common target vessel with total of 48 patients (45%), followed by 29 patients (27%) with ostial LAD lesions, 26 patients (24%) with ostial RCA lesions, 1 patients (1%) with ostial LMS lesions, and another 3 patients (3%) with ostial SVG lesions. The mean vessel diameter was 2.7±0.5 mm with a mean lesion length of 24±18 mm. Percentage of stenosis pre-PCI was 88±11%, residual stenosis post predilation was 23±13%, and the final percentage of stenosis post-DEB was 14±18%. Predilations were mainly using compliant balloon in 65.4% of patients, scoring balloon in 20.6% and the remaining 14% patients, with non-compliant balloon. The mean predilation pressure was 12±4.1 atm. The mean DEB diameter and length were 2.6±0.5 mm and 22±8 mm. Mean DEB inflation pressure and duration were 8±2 atm and 57±19 seconds. 5 patients (4.7%) had dissections post DEB, and none was flow limiting. Thus, there were zero bailouts with stents. 3 patients (2.8%) had in-hospital mortality. 103 patients were discharged with DAPT, and only 1 patient being discharged with a single antiplatelet. The mean follow-up duration was 15±8 months, with a median of 13 months. 6 patients lost to follow-up. None of these patients had clinical TLR. 4 patients (2.8%) had MACE; with 2 of them had a myocardial infarction and 1 patient had cardiac death. All-cause mortality was 2 patients, with 1 patient had non-cardiac related death.

Conclusions: Our single-centre experience demonstrates for the first time that a DCB only strategy to *de novo* ostial lesions of large coronary vessel is safe and effective with low MACE rate at intermediate-term follow-up. Larger sample size studies are needed to evaluate fully the potential benefit. Most of the results of the recent DEB studies were promising, however, lacking in sample size and randomised control trial. Nevertheless, until further data available, DEB should be considered in patients with contraindications to DES, or prolong DAPT.

Other Coronary interventions - Calcified lesions

Acute and midterm results after rotational atherectomy with DEB comparing to rotational atherectomy with DES

IWASAKI Yoshihiro [(1)], IWASAKI Yoshihiro [(1)], NAKAMURA Shigeru [(1)], KOBAYASHI Tomoko [(1)], FUNATSU Atsushi [(1)], YOSHIDA Ritsu [(1)], KOIKE Jyunpei [(1)], NISHIURA Takashi [(1)]

(1) Kyoto Katsura Hospital, Kyoto, Japan

Aims: Percutaneous coronary intervention (PCI) by rotational atherectomy (Rota) in severe calcified lesion followed by drug eluting stents (DES) is effective. Recently drug-coated balloons (DCB) for small vessel showed favourable results. However, results of Rota and DCB in non-small calcified lesions are unclear.

Methods and results: Between January 2016 and August 2018, 472 calcified lesions were treated with Rota. We excluded reference vessels diameter less than 2.5 mm by QCA.104 lesions of Rota+DES group and 80 lesions Rota+DCB group were extracted. Clinical and procedural data of those case were retrospectively analysed. The primary endpoint was MACE at 1 year that were defined as cardiac death, non-cardiac death, target vessel related myocardial infarction or target lesion revascularisation (TLR). Clinical follow-up was performed 92% in Rota+DES and 98% in Rota+DCB. MACE at 1 year of Rota+DES and Rota+DCB were 8% vs11%, p=0.30) in terms of cardiac death (0% vs 0%), non-cardiac death (4% vs 3%, p=0.36), target vessel related myocardial infarction (0% vs 0%) and TLR (4% vs 8%, p=0.30).

Conclusions: After Rota+DCB, clinical outcomes at 1-year were comparable to Rota+DES in non-small calcified lesions. Rota+DCB treatment can be seen as a new strategy.

Stents and scaffolds - Tools, devices and techniques

Medium-term clinical results of Synergy stent compared with XIENCE stent based on culprit lesion

HIGASHI Kensaku [(1)], HIGASHI Kensaku [(1)]

(1) Kagoshima Medical Center, Kagoishima, Japan

Aims: The Synergy stent (S-EES) is a new-generation stent delivering abluminal-coated everolimus from a bioabsorbable polymer; but the clinical results of S-EES compared with XIENCE stent (X-EES) have not been reported. The aim of this study is to investigate the clinical results of S-EES relative to X-EES.

Methods and results: Percutaneous coronary interventions were performed in 1,845 lesions in our hospital from July 2015 to December 2018. 1,587 lesion which were received S-EES (n=721) and X-EES (n=866), were subject to this study. The primary endpoint was in-stent restenosis (ISR) at follow-up angiography or coronary CT. The secondary endpoint was target lesion failure (TLR). In-stent restenosis rate of S-EES was significantly increased than that of X-EES (10.4% vs 3.8%; $\chi 2$=18.859: p<0.001). Using the Kaplan-Meier method, the ISR rate of S-EES was significantly increased compared with that of X-EES (Logrank; $\chi 2$=15.566: p<0.001). When lesions were stratified into three groups based on the culprit lesion, ISR rate of S-EES was same that of X-EES in RCA lesion (8.4% vs 6.0%; $\chi 2$=0.806: p=0.427). TLF rate of S-EES was significantly increased when compared with that of X-EES (15.2% vs 7.2%; $\chi 2$=15.889: p<0.001). Using the Kaplan-Meier method, the TLF rate of S-EES was significantly increased compared with that of X-EES (Logrank; $\chi 2$=12.862: p<0.001). But in RCA lesion, TLF rate of S-EES was not increased than that of X-EES (12.2% vs 8.9%; $\chi 2$=0.922: p=0.354). Cox proportional hazard analysis revealed that S-EES was a significant risk factor associated with ISR and TLF (ISR: Hazard ratio=2.635; 1.598-4.346: p<0.001, TLF; Hazard ratio=2.004; 1.371-3.046: p<0.001).

Conclusions: ISR and TLF rates of S-EES are significantly increased compared with those for X-EES in medium-term clinical results in LCA lesions, not in RCA lesions.

Stable CAD - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

PCI in patients with ostium coronary artery lesions: three-year follow-up

MAXIMKIN Daniil [1], MAXIMKIN Daniil [1], SHUGUSHEV Zaurbek [1], CHEPURNOY Aleksandr [1], FAIBUSHEVICH Aleksandr [1], BARANOVICH Vladislav [1], MAMBETOV Aslan [1], VERETNIK Galina [1]

(1) Peoples' Friendship University of Russia, Moscow, Russian Federation

Aims: To increase the effectiveness of percutaneous coronary interventions (PCI) in patients with ostium coronary artery lesions.

Methods and results: 170 patients were included in the study. Inclusion criteria: ostium atherosclerotic lesions of left arterial descending (LAD) or left circumflex (LCx) > 70% according to angiography and intravascular ultrasound (IVUS); myocardial ischaemia according stress test and FFR measurement. All patients were randomised into 2 groups. In group I (n=85), according to IVUS, atherosclerotic plaque spread from the ostium of LAD and/or LCx to the left main coronary artery (LMCA), and in group II (n=85), the plaque did not spread into the LMCA. In Group I, all patients were initially treated with "Provisional T" stenting of the LMCA, and in Group II, precision stenting of the ostium LAD or LCx. Long-term results were evaluated at 24 and 48 months. Primary endpoints: frequency of MACE (death, MI, revascularisations). Secondary endpoints: frequency of restenosis according to angiography and IVUS. Results: during hospitalisation, complications were not associated with PCI, survival was 100% in all groups. The conversion to complete bifurcation stenting occurred in 5 patients from Group I and conversion to provisional stenting in 3 patients from Group II. The long-term results after 24 months were observed in 70 patients from Group I and 72 patients, from Group II. Nonfatal myocardial infarction (MI) was observed in 2 (2.7%) of patients from group II and not in Group I. The incidence of haemodynamic significant stent restenosis and was observed in 4 patients (5.7%) in Group I, and in 7 patients (9.8%) in Group II ($p<0.05$). The target lesion revascularisation (TLR) was performed in 4 patients (5.7%) in Group I, and in 9 patients (12.5%) in Group II ($p<0.05$). The total frequency of MACE in groups I and II was 4(5.7%) and 9(12.5%), respectively ($p<0.05$). The survival was 100% in both groups. The long-term results after 48 months were observed in 58 patients from Group I and 54 patients, from Group II. All types of death were registered in 1 patient from Group I and 2 patients from Group II. Nonfatal myocardial infarction (MI) was observed in 1 patient (1.7%) and 2 patients from Group II (3.7%) ($p>0.05$). The incidence of haemodynamic significant stent restenosis was observed in 3 patients (5.7%) in Group I, and in 5 patients (9.3%) in Group II ($p<0.05$). The target lesion revascularisation (TLR) was performed in 4 patient (6.9%) in Group I, and in 7 patient (13%) in Group II ($p<0.05$). The total frequency of MACE in groups I and II was 5(8.6%) and 10(18.5%), respectively ($p<0.05$). Freedom from cardiac events (Kaplan-Meier analysis) was a significant difference (92.5 in Group I and 84.5 in Group II ($p<0.05$).

Conclusions: IVUS analysis of ostium stenosis of coronary arteries can help in choosing the optimal stenting technique, as well as reliably improving long-term PCI results. Patients after precision stenting of the ostium have worse long-term results, compared with patients after provisional T-stenting.

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Stable CAD - Invasive imaging and functional assessment, Left main and multivessel disease - Invasive imaging and functional assessment

The role of OCT and FFR measurement to improve the efficiency of PCI in patients with left main bifurcation lesions

MAXIMKIN Daniil [1], MAXIMKIN Daniil [1], SHUGUSHEV Zaurbek [1], CHEPURNOY Aleksandr [1], FAIBUSHEVICH Aleksandr [1], MAMBETOV Aslan [1]

(1) Peoples' Friendship University of Russia, Moscow, Russian Federation

Aims: To evaluate the role of intravascular imaging methods (OCT, FFR), in determining the haemodynamic significance of stenosis of the left main coronary artery (LMCA) bifurcation and their prognostic significance.

Methods and results: 177 patients were selected for this study. Inclusion criteria: true bifurcation stenosis of the LMCA according to quantitative coronary angiography (QCA) and OCT; FFR (LCx or LAD) <0,8, minimal lumen area (MLA) LM <6 mm^2; total risk according SYNTAX score I <32. After coronary angiography, all patients underwent OCT in LM and measurement of the FFR in LAD and LCx, in order to determine the haemodynamic significance of the lesion. The study included 98 patients, who have haemodynamic significant lesion was confirmed by both methods (OCT and FFR), and there was a complete coincidence. Initially, all patients performed "provisional T" stenting of the LMCA (1-stent strategy). After the procedure, FFR was measured in the side branch bifurcation (LCx or LAD). Drug-eluting stents were implanted in all patients. At the end of the stenting procedure, all patients underwent OCT for evaluating the optimal stent implantation. Control group, primary endpoints: frequency of MACE (death, myocardial infarction, repeated revascularisations). Secondary endpoints: frequency of restenosis according to Q&A and OCT. The follow-up were 48 months. Results: for the 197 patients who were initially selected for the study, the data on the haemodynamic significance lesions of LM coincided in 118 patients, who reached the main cohort of patients. A comparative analysis of the OCT and FFR in 79 patients revealed a mismatch of data. At the same time, FFR was positive in 67 (84.8%) patients, negative in 12 (15.2%). On the contrary, according to OCT, haemodynamically significant stenosis occurred in 12 (15.2%) patients, and in 67 (84.8%), was insignificant ($\chi 2=39.68$ $p<0.05$). Further, the patients were divided into 2 groups. Group I (n=80) included patients with FFR SB >0.8, and Group II (n=38), FFR SB<0.8. Patients in group 2 were implanted with a second stent (reverse-crush and reverse-culotte techniques). The long-term results were monitored in all patients. Freedom from cardiac events (Kaplan-Meier analysis) were not significant different in both group (100 and 97.4%; $p>0.05$). The frequency of haemodynamically significant restenosis and target lesion revascularisation (TLR) according to OCT and FFR was observed in 5 patient (6.25%) in group I and in 4 patients (10.5%) in group II ($p>0.05$).

Conclusions: The FFR measurement of patients with true LMCA bifurcation stenosis before the stenting procedure allows the clinician to correctly determine the strategy of stenting, comparing the OCT. FFR measurement not only before stenting procedure, but also after, provides similar long-term outcomes for the primary endpoint, regardless of the stenting strategy.

Stents and scaffolds - Tools, devices and techniques

Clinical outcomes after treatment of bare metal and drug-eluting in-stent restenosis with a thin strut bioresorbable polymer coated sirolimus-eluting stent

SAKHOV Orazbek [(1)], SAKHOV Orazbek on behalf of eUltimaster investigators [(1)]

(1) City Cardiological Center, Almaty, KAZAKHSTAN

Aims: The risk for in-stent restenosis (ISR) and associated clinical events is lower after DES (DES-ISR) compared to BMS (BMS-ISR), but the number of patients presenting with ISR is not declining due to the expansion of the indications for PCI and improved prognosis of CAD. Data about the efficacy of treatment with a DES for the treatment of BMS-ISR compared to DES-ISR is limited.

Methods and results: Patients with at least one BMS-ISR (n=545) and at least one DES-ISR (n=1,278) requiring PCI were selected from the global e-Ultimaster registry. Patients with both a BMS-ISR and a DES-ISR were excluded. All patients reached 1-year follow-up or died during follow-up. Lesions requiring treatment were implanted with the thin strut Ultimaster stent with sirolimus, as antiproliferative agent eluted from an abluminally applied bioresorbable polymer coating. The primary endpoint was target lesion failure (TLF) at 1 year defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). All primary endpoint related serious adverse events were adjudicated by an independent clinical events committee. The mean age for the BMS-ISR versus the DES-ISR group was similar (65.6±10.8 vs 65.3±10.8 years, p=0.62) as well as the percentage of male (80.9% vs 78.6%, p=0.28). The prevalence of diabetics was lower in the BMS-ISR group (31.4% vs 42.3%, p<0.001). The presence of other cardiovascular risk factors such as smoking, hypertension and hypercholesterolaemia was similar between the two groups (p>0.05). More patients in the BMS-ISR group had a previous MI (60.2% vs 52.6%, p=0.005). Less patients in the BMS-ISR group presented with ACS as indication for the PCI (43.1% vs 51.6%, p<0.001). The prevalence of multivessel disease was similar in both groups (46.2% vs 49.3%, p=0.24). The total number of lesions identified per patient in the BMS-ISR arm was 1.9±1.1 vs 2.1±1.2 (p=0.003) in the DES-ISR group. There were more bifurcations (14.7% vs 9.7%) and more long lesions with a length ≥ 25 mm (53.9% vs 46.8%) in the BMS-ISR arm (all p<0.01), but more small vessels ≤ 2.75 mm (39.5% vs 46.6%) and grafts (1.8% vs 3.8%) in the DES-ISR arm (all p<0.05). At 1-year, there were no differences in the TLF rate (4.8% vs 5.0%) or its individual components: cardiac death (1.3% vs 1.3%), TV-MI (1.3% vs 1.2%) and TLR (2.8% vs 3.4%); all p>0.05. A definite/probable stent thrombosis was reported for 1.1% vs 0.8% (p=0.58) of the patients in BMS-ISR and DES-ISR, respectively.

Conclusions: Treatment with a contemporary DES of in-stent restenosis within a bare metal or a drug-eluting stent resulted in low clinical event rates irrespective of the origin of the in-stent restenosis.

STEMI - Tools, devices and techniques

Trends in the use of IABP and mortality in patients with STEMI complicated by cardiogenic shock

UMPORNWIROJKIT Warawut [(1)], TUNGSUBUTRA Wiwun [(1)], UMPORNWIROJKIT Warawut [(1)]

(1) Siriraj Hospital, Bangkok, THAILAND

Aims: To assess the implications of IABP-SHOCK II in patients with ST-segment elevation myocardial infarction (STEMI) complicated by cardiogenic shock in clinical practice in a large tertiary referral centre in Thailand.

Methods and results: This retrospective, single-centre study analysed patients with STEMI complicated by cardiogenic shock who presented to a large tertiary care centre in Thailand during June 2008 to May 2016. Patients with mechanical complications were excluded. Comparison between 2 cohorts of patients, the early cohort (patients treated from 2008-2012) and late cohort (patients treated from 2013-2016), was performed. Data were collected to determine clinical characteristics, management, use of IABP, complications and 30-day mortality. Results: In 852 patients with STEMI, 183 patients were complicated by cardiogenic shock and included in the analysis. 118 patients had IABP implanted, 67.7% in the early cohort and 60.7% in the late cohort (p=0.327). The majority of patients received the IABP after percutaneous coronary intervention (67.2% early cohort vs 60.8% late cohort p=0.473). Left-ventricular assist device and extracorporeal membrane oxygenation were rarely used. Non-CABG TIMI major bleeding and minor bleeding were high (10.5% early cohort vs 10.3% late cohort p=0.965) and (11.6% early cohort vs 14.1% late cohort p=0.636), respectively. Blood transfusion was given for non-CABG bleeding in a very high proportion of patients (31.4% early cohort vs 33.3% late cohort p=0.791). Clinical evidence of sepsis was common (29.6% early cohort vs 40.5% late cohort p=0.124). There were no significant differences in 30-day mortality in the early cohort and late cohort, 33.7% vs 33.3%, (difference 0.3, 95% CI: -15.5-13.9, p=0.962), respectively. There was no significant improvement in the 30-day mortality rate, p=0.674 for trend.

Conclusions: There has been no significant reduction in the use of IABP in STEMI patients with cardiogenic shock. Complications including sepsis, TIMI major bleeding and 30-day mortality remain high without a significant improvement on survival over a 9 year period. Managing these critically ill patients, even with advanced therapies in a large tertiary care centre in Thailand, remains a challenging responsibility.

NSTEMI - Vascular access and bleeding, Stents and scaffolds - Tools, devices and techniques

Treatment and outcome of upper extremity dysfunction after transradial PCI

CHEUNG Elena [1,4], CHEUNG Elena [1,4], ZWAAN Eva [1,4], KOFFLARD Marcel [2], SCHREUDERS Ton [3], COERT Henk [4], ALINGS Marco [1,4], IJSSELMUIDEN Alexander [1], HOLTZER Carlo [2]

(1) Amphia molengracht, Breda, the Netherlands; (2) Albert Schweitzer Ziekenhuis, Dordrecht, the Netherlands; (3) Erasmus MC, Rotterdam, the Netherlands; (4) UMC Utrecht, Utrecht, the Netherlands

Aims: The aim of this study was to offer insight into the different complications, management, treatment, and outcome of upper extremity dysfunction (UED) following transradial percutaneous coronary interventions (TR-PCI).

Methods and results: Retrospective analysis of patients included in the ARCUS trial (a multicentre cohort study providing insight in the occurrence of UED after TR-PCI) who were referred to a hand centre following TR-PCI. Referral was indicated when patients had new-onset or exacerbation of symptoms in the upper extremity. The primary study endpoint was defined as the percentage of patients with persisting UED. In the ARCUS trial 440 patients underwent TR-PCI of whom 109 (25%) fulfilled pre-specified criteria for referral to a hand centre with hand specialists. Female gender, higher Body Mass Index (BMI), pre-existent osteoarthritis and sensibility disorders were significantly more present in the referral group. Most frequent referral indication was pain in the intervention upper extremity (UE) at six months of follow-up. Despite criteria for referral, 66 patients choose to refrain from referral, and only 43 patients (39%) elected to undergo additional assessment (by a plastic surgeon, hand therapist, neurologist and/or general practitioner). Carpal tunnel syndrome was most frequently diagnosed (41.9%) followed by symptomatic osteoarthritis (35%). Of the referred patients, 28 patients (65%) required further medical treatment. The most frequent treatment applied was immobilization therapy. Seventeen patients (61% of 28) had persisting symptoms despite treatment.

Conclusions: Twenty-five percent of the patients following a TR-PCI met the referral criteria to a hand centre. Only 39% of these patients elected to undergo targeted medical treatment. Despite this treatment, symptoms of UED persisted in 61% of patients. Improving awareness among cardiologists in recognizing symptoms in the upper extremity and in motivating patients to seek medical help sooner, will most likely benefit treatment results. Therefore, awareness among cardiologists and subsequent development of guidelines on diagnosis and treatment are needed to minimise persisting UED following TR-PCI.

CTO - Tools, devices and techniques

No-reflow complicating CTO coronary revascularisation

DALL'ARA Gianni [1], TESTA Luca [2], TUMSCITZ Carlo [3], MATTESINI Alessio [4], GASPARINI Gabriele Luigi [5], GROTTI Simone [1], BOLLATI Mario [2], TARANTINO Fabio [1], DI MARIO Carlo [4], OREGLIA Jacopo Andrea [6]

(1) Morgagni-Pierantoni Hospital, Forlì, Italy; (2) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy; (3) Ospedale Cona Ferrara, Province of Ferrara, Italy; (4) Careggi University Hospital, Metropolitan City of Florence, Italy; (5) Humanitas Research Hospital, Metropolitan City of Milan, Italy; (6) Niguarda Hospital, Milan, Italy

Aims: To assess the incidence of no-reflow in patients undergoing chronic total occlusion (CTO) percutaneous coronary interventions (PCI), analyse possible causes, differential diagnosis, and identify useful management approaches.

Methods and results: In this multicentre observational study, all CTO PCI procedures performed between January 2018 and April 2019 were reviewed to collect no-reflow complications, defined as thrombolysis in myocardial infarction (TIMI) flow ≤1 in a patent epicardial artery. Patients clinical, anatomical, and procedural characteristics were analysed. Out of 461 PCIs, 2 were complicated by no-reflow (0.43%). In one case PCI was performed on a long segment of the right coronary artery, after use of a dissection/re-entry technique by knuckle wiring. In the second patient, no-reflow developed after proximal left anterior descending artery stenting, with a short subintimal tracking. Intravascular ultrasound was used to exclude complications in the epicardial vessel in both cases. Distal embolisation seems the most plausible cause, and intracoronary adenosine effectively improved flow. Both patients had a type 4a myocardial infarction, asymptomatic in the first case, in the second associated with chest pain, ECG changes and new regional wall motion abnormality at echocardiography.

Conclusions: No-reflow in CTO recanalisation is rare but associated with a high risk of periprocedural myocardial infarction, with incomplete protection from ischaemia offered by the pre-existing collateral network.

Stents and scaffolds - Adjunctive pharmacotherapy, Left main and multivessel disease - Adjunctive pharmacotherapy

The clinical impacts of new potent antiplatelet agents according to the target vessel in patients with AMI

KIM Byong-Kyu [1], KIM Byong-Kyu [1], BAE Kwi-hyun [2], CHOI Kang-un [1], BAE Jun-ho [1], NAH Deuk-young [1]

(1) Dongguk University Gyeongju Hospital, Gyeongsangbuk-do, Republic of Korea; (2) Daegu Fatima Hospital, Daegu, Republic of Korea

Aims: Current guidelines recommend new potent antiplatelet agents in patients with acute myocardial infarction (AMI). However, it is uncertain which antiplatelet agents are beneficial for improving clinical outcomes in AMI patients with left main coronary artery (LMCA) as a target vessel. The aim of this study was to investigate optimal antiplatelet therapy according to the target vessel in patients with AMI.

Methods and results: A total 11,731 patients who underwent percutaneous coronary intervention (PCI) after AMI were analysed from the Korean Acute Myocardial Infarction Registry (KAMIR) – National Institute of Health (NIH) database. One-year major adverse cardiac and cerebrovascular events (MACCE) were defined as a composition of all-cause death, non-fatal MI, repeat revascularisations including repeated percutaneous coronary intervention and coronary bypass grafting, cerebrovascular accident and rehospitalisations. A total 1,607 (13.7%) patients who had changed their antiplatelet agents during admission were excluded from the analysis. Clopidogrel was prescribed in 7,524 (64.1%) patients. Potent antiplatelet agents such as prasugrel and ticagrelor were prescribed in 2,600 (22.2%) patients. During one-year follow-up, compared with clopidogrel, potent antiplatelet agents significantly reduced MACCE (6.9% versus 12.1%, log-rank $p<0.001$) in AMI patients who underwent PCI. These results were mainly derived by the patients with left anterior descending artery, left circumflex artery and right coronary artery as target vessels. Potent antiplatelet agent users showed significantly reduced MACCE (6.6% versus 11.5%, log-rank $p<0.001$; 6.5% versus 9.4%, log-rank $p=0.045$; 4.9% versus 10.0%, log-rank<0.001, respectively). However, in patients with LMCA as a target vessel, potent antiplatelet agents not only did not reduce MACCE, but also slightly increased MACCE, although this was not statistically significant (33.3% versus 32.0%, log-rank $p=0.850$).

Conclusions: In the new potent antiplatelet agent era, the target vessel should be considered when selecting antiplatelet agents in patients with acute myocardial infarction.

Stents and scaffolds - Adjunctive pharmacotherapy, Other Coronary interventions - Other

Academic research consortium, high bleeding risk definition could predict long-term outcomes after PCI with rotational atherectomy

ENDO Nana [1], ENDO Nana [1], TANAKA Kazuki [1], INAGAKI Yusuke [1], EBIHARA Suguru [1], OTSUKI Hisao [1], NAKAO Masashi [1], YAMAGUCHI Junichi [1], HAGIWARA Nobuhisa [1]

(1) Tokyo Women's Medical University, Tokyo, Japan

Aims: Recently, the Academic Research Consortium (ARC) High Bleeding Risk (HBR) definition has been proposed to estimate bleeding events after percutaneous coronary interventions (PCI) and subsequent clinical outcomes. However, there has been little evidence on the efficacy of ARC-HBR definition in patients undergoing PCI with rotational atherectomy (RA), a possible HBR subset.

Methods and results: Consecutive 336 patients who underwent PCI with RA between 2004 and 2014 were enrolled. Patients were divided into HBR and non-HBR group according to ARC-HBR definition. The incidences of bleeding events defined as TIMI major plus minor and all-cause death were examined. The median follow-up was 1,383 days. As a whole study population, atrial fibrillation (AF) was documented in 17.9% and haemodialysis was undergoing in 42.3%. HBR group (251 patients; 74.7%) showed higher prevalence of AF (21.2 vs 8.2%, p=0.004), chronic kidney disease (69.6 vs 11.8%, p<0.001) and lower left ventricular ejection fraction (45.8±11.3 vs 50.9±10.9%: p<0.001), higher C-reactive protein level (1.30±0.17 vs 0.52±0.16 mg/dL: p=0.002), and higher brain natriuretic peptide level (756.1±79.2 vs 145.3±32.3: p<0.001) in comparison with non-HBR group. During the observation period, the bleeding events occurred in 40 patients (11.9%) and all-cause death was observed in 110 patients (32.9%). Kaplan-Meier analysis showed that the incidence of bleeding events and all-cause death were significantly higher in the HBR group (at 3-year: 14.4% vs 6.9%, log-rank test: p=0.027 and 28.3% vs 8.3%, log-rank test: p<0.001, respectively).

Conclusions: The ARC-HBR definition could predict clinical outcomes in patients undergoing PCI with RA and might be useful for decision making of antithrombotic treatment strategy in contemporary practice.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Clinical performance of ultrathin strut biodegradable polymer-coated sirolimus-eluting stents in young patients with coronary artery disease: results of twelve-month outcomes

AJMERA Prakash [(1)], AJMERA Prakash [(1)], POTHINENI Ramesh [(2)], CHAWLA Kamal Kumar [(1)], MANTRAVADI Sai Sudhakar [(3)], JARIWALA Pankaj Vinod [(4)], VIJAN Vinod [(5)], VIJAN Vikrant [(5)], POTDAR Anil [(6)], INAMDAR Manohar K [(7)], PATHAK Abhijit [(8)]

(1) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (2) Dr. Ramesh Cardiac and Multispeciality Hospital, Vijaywada, India; (3) Gleneagles Global Hospitals, Telangana, India; (4) Yashoda Hospitals - Somajiguda, Telangana, India; (5) Vijan Cardiac & Critical Care, Maharashtra, India; (6) Parisoha Foundation Pvt. Ltd., Mumbai, India; (7) Ashwini Hospital, Akluj, India; (8) Swasthya Hospital and Medical Research Center, Ahmednagar, India

Aims: Prevalence of coronary artery disease in young patients has been associated with conventional risk factors along with lifestyle factors. The current sedentary lifestyle, with stress and unhealthy eating habits have been major determinants of atherosclerotic coronary lesions. Therefore, we aimed to evaluate the clinical outcomes at twelve months after implantation of ultrathin (60 µm) strut biodegradable polymer-coated Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) sirolimus-eluting stent (SES) in real-world patients of young age with coronary atherosclerotic lesions.

Methods and results: We retrospectively identified data from two real-world, all-comers, multicentre registries (2,472 patients). From total 2,472 patients included in two Supraflex Cruz registries, we retrospectively extracted and analysed 464 young patients (≤45 years), who underwent percutaneous coronary intervention with only Supraflex Cruz SES between May 2016 and March 2018 for treatment of coronary artery disease. The primary endpoint was target lesion failure at 12 months after index procedure, which was agglomeration of cardiac death, target vessel myocardial infarction and target lesion revascularisation. Stent thrombosis, defined as per Academic Research Consortium, was considered as a safety endpoint. The average age of the patients was 40.28±4.5 years. The analysed population had a male predominance (366 patients: 78.9%). Diabetes, hypertension and hypercholesterolaemia was present in 132 (28.4%), 153 (33.0%), and 129 (27.8%) patients, respectively. The patients with acute coronary syndrome accounted to be 72.6% (unstable angina: 25.6%; ST-elevation myocardial infarction: 31.9%; non-ST-elevation myocardial infarction: 15.1%). A total 578 stents were implanted to treat 525 lesions. The left anterior descending artery was the most targeted vessel (55.6%). There was predominance of single vessel disease (258 patients; 55.6%), followed by double vessel disease (171 patients; 36.9%) and least was the occurrence of triple vessel disease (35 patients; 7.5%). Type A, B1, B2 and C lesions accounted for 55 (10.5%), 61 (11.6%), 76 (14.5%), 333 (63.4%) lesions, respectively. 101 (19.2%) lesions were totally occluded. Mean stent length and diameter were 25.39±8.97 and 2.95±0.34 mm, respectively. The 12 months clinical follow-up data was obtained for 456 (98.3%) patients. The incidences of target lesion failure at 12 months occurred in 20 (4.4%) patients. This included 2 (0.4%) cardiac deaths, 10 (2.2%) target vessel myocardial infarctions and 8 (1.8%) target lesion revascularisations. There were only 2 incidences of stent thrombosis at 12-month follow-up.

Conclusions: From the light of these results, it can be concluded that the Supraflex Cruz SES is safe to be used in a real-world young patient population (≤45 years), accounting for the occurrence of low rates of clinical events at 12-month follow-up after the index procedure.

Other Coronary interventions - Other

Late stage improvement of left ventricular obstruction after percutaneous transluminal septal myocardial ablation in medically refractory patients with hypertrophic obstructive cardiomyopathy

HIRUMA Takashi [(1)], TAKAMISAWA Itaru [(1)], HIGUCHI Ryosuke [(1)], SAJI Mike [(1)], NANASATO Mamoru [(1)], IGUCHI Nobuo [(1)], TAKAYAMA Morimasa [(1)]

(1) Sakakibara Heart Institute, Tokyo, Japan

Aims: Percutaneous transluminal septal myocardial ablation (PTSMA) has been reported with reduction of left ventricular pressure gradient (LVPG) immediately after alcohol ablation for the appropriate site of septal myocardium and followed by further reduction at one-year time due to fibrotic contraction. However, detailed serial evaluation of LVPG was scarcely undertaken in late stage. The aim of this study is to assess late stage reduction of LVPG and clinical effectiveness after PTSMA.

Methods and results: Out of 392 patients underwent PTSMA from December 2007 to December 2019 in our institution a total of 160 consecutive patients followed exceeding 5 years were evaluated. These patients consisted of 57 males and 103 females with an age of 63.2±15.1 years and their clinical data were retrospectively analysed. The sites of LV obstruction were outflow alone (OT: n=101), middle ventricular (MV: n=36) and OT+MV (n=23). Average clinical follow-up period was 6.7±3.0 years after PTSMA. We injected 2.7±1.3 ml amount of ethanol into 1.7±0.8 septal branches. Peak creatine kinase was 1341±1461 IU/l. The incidence of complete atrioventricular block in 18 patients resulted in permanent pacemaker implantation in 6 patients (3.8%). Echo evaluated LVPG at rest decreased from 105±48 mmHg before PTSMA to 54±44 mmHg immediately (5.1±3.0 days after), then 46±43 mmHg at 1 year, 33±31 mmHg at 3 years, and 23±24 mmHg at 5 years after PTSMA. Interventricular septal thickness decreased from 16.8±3.5 mm to 15.0±3.1 mm at 1 year, 14.1±2.7 mm at 3 years, then 13.7±2.8 mm at 5 years ($p<0.001$), similarly LV posterior wall thickness decreased from 12.1±2.3 mm to 11.5±1.8 mm at 1 year, 11.1±1.6 mm at 3 years, then 10.9±1.7 mm at 5 years ($p<0.01$). The proportion of New York Heart Association functional class I increased from 1.3 % before PTSMA to 70.6 % at 1 year, 72.8 % at 3 years and 65.5 % at 5 years. The in-hospital mortality rate was 1.3% at PTSMA, and overall survival rate was 93.1 % at 5 years. In the multivariate analysis, age (hazard ratio 1.08, confidence interval 1.01-1.16, $p=0.026$) was the only independent predictor of overall mortality.

Conclusions: The effectiveness of PTSMA appeared to show immediate reduction of PG with loss of contraction at the extruding myocardium and the further gradual reduction of PG due to subsequent contraction of necrotic site. Furthermore, regression of the non-septal area of LV with prior secondary hypertrophy is strongly derived.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Vascular complications of the distal transradial approach in patients with AMI who underwent primary PCI

MATSUBARA Yuki [1], YAMADA Takeshi [1], MATSUBARA Yuki [1], MIZUGUCHI Yukio [1], TANIGUCHI Norimasa [1], NAKAJIMA Shunsuke [1], HATA Tetsuya [1], TAKAHASHI Akihiko [1]

(1) Sakurakai Takahashi Hospital, Kobe, Japan

Aims: The distal transradial approach (dTRA) for coronary catheterisation is a newly introduced alternative to the conventional transradial approach. This study investigated the incidence of vascular complication of the dTRA in patients with acute myocardial infarction (AMI) who underwent primary percutaneous coronary intervention (PCI).

Methods and results: Consecutive 131 patients with AMI who underwent primary PCI between April 2018 and October 2019 were investigated. The dTRA was used as the primary approach whenever feasible in this study period. The bleeding complication after dTRA and the patency of the radial artery were investigated. The patency of the radial artery was examined using Doppler ultrasound during the follow-up period. Among the 131 AMI patients, 116 patients (88.5%) underwent successful primary PCI using the dTRA. The patients included 83 men (71.6%), and the mean age was 70.4±12.9 years. A 5 or 6 Fr sheath (conventional or slender) was used in the primary procedure. The average time to achieving haemostasis was 5.0±4.1 hours; TIMI minor bleeding was observed in 2 patients (1.5%) and there were no TIMI major bleeding. Colour Doppler sonography of the radial artery was performed in 90 patients with the mean follow-up period of 229±183 days, and radial artery occlusions were not observed in this series.

Conclusions: The application of dTRA is considered to have low incidences of bleeding complications and radial artery occlusions in patients with AMI.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Performance of an ultrathin strut biodegradable polymer-coated sirolimus-eluting stent in females with coronary artery disease: results of twelve-month follow-up

AJMERA Prakash [(1)], AJMERA Prakash [(1)], POTHINENI Ramesh [(2)], CHAWLA Kamal Kumar [(1)], MANTRAVADI Sai Sudhakar [(3)], JARIWALA Pankaj Vinod [(4)], VIJAN Vinod [(5)], VIJAN Vikrant [(5)], POTDAR Anil [(6)], INAMDAR Manohar K [(7)], PATHAK Abhijit [(8)]

(1) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (2) Dr. Ramesh Cardiac and Multispeciality Hospital, Vijaywada, India; (3) Gleneagles Global Hospitals, Telangana, India; (4) Yashoda Hospitals - Somajiguda, Telangana, India; (5) Vijan Cardiac & Critical Care, Maharashtra, India; (6) Parisoha Foundation Pvt. Ltd., Mumbai, India; (7) Ashwini Hospital, Akluj, India; (8) Swasthya Hospital and Medical Research Center, Ahmednagar, India

Aims: Though there is male predominance in patients undergoing percutaneous coronary intervention, there has been persistent gender disparities in clinical outcomes weighing more towards the female. Thus, this analysis sought to assess the clinical performance of ultrathin strut (60 µm) biodegradable polymer-coated Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) sirolimus-eluting stent in real-world females with coronary atherosclerotic lesions.

Methods and results: We retrospectively identified data from two real-world, all-comers, multicentre registries (2472 patients). From total 2,472 patients included in two Supraflex Cruz registries, we retrospectively extracted and analysed 678 female patients, who underwent PCI with only Supraflex Cruz SES between May, 2016 and March, 2018 for treatment of coronary artery disease. The primary endpoint was target lesion failure, which was an agglomeration of cardiac death, target vessel myocardial infarction and target lesion revascularisation at 12 months follow-up. Stent thrombosis, defined as per Academic Research Consortium, was considered as a safety endpoint. The average age of the patients was 57.7±10.6 years. Mean systolic and diastolic blood pressure were 126.2±16.0 and 80.8±8.8 mmHg, respectively. Of all, 277 (40.9%) patients were diabetic, 362 (53.4%) patients were hypertensive, 229 (33.8%) patients had hypercholesterolaemia and 86 (12.7%) patients were smokers. The patients with acute coronary syndrome accounted to be 72.9% (unstable angina: 34.5%; ST-elevation myocardial infarction: 26.5%; non-ST-elevation myocardial infarction: 11.9%). In 678 patients, total 891 stents were implanted to treat 802 lesions. Therefore, number of stents per patient was 1.31±0.53. The predominantly diseased artery was the left anterior descending artery (391 patients; 48.8%) followed by right coronary artery (266 patients; 33.2%). Type A, B1, B2 and C lesions accounted for 87 (10.8%), 106 (13.2%), 128 (16.0%), and 481 (60.0%) lesions, respectively. Mean stent length and diameter were 25.1±8.9 mm and 2.83±0.3 mm, respectively. The 12 months clinical follow-up data were obtained for 655 (96.6%) patients. Rate of target lesion failure was 4.9% (39 patients), which included 5 (0.8%) cardiac deaths, 15 (2.3%) target vessel myocardial infarctions and 12 (1.8%) target lesion revascularisations at 12 months follow-up. There were only 4 cases of stent thrombosis up to 12 months after index procedure.

Conclusions: The results of this analysis reflects the fact that the Supraflex Cruz SES is safe to be used in real-world females, with low clinical event rates at 12 months follow-up after implantation. However, results of future studies with a larger number of patients and longer follow-up would further support these results.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Twelve-month clinical outcomes after implantation of a long ultrathin strut biodegradable polymer-coated sirolimus-eluting stents in atherosclerotic coronary lesions

AJMERA Prakash [(1)], AJMERA Prakash [(1)], POTHINENI Ramesh [(2)], CHAWLA Kamal Kumar [(1)], MANTRAVADI Sai Sudhakar [(3)], JARIWALA Pankaj Vinod [(4)], VIJAN Vinod [(5)], VIJAN Vikrant [(5)], POTDAR Anil [(6)], INAMDAR Manohar K [(7)], PATHAK Abhijit [(8)]

(1) Malla Reddy Narayana Multispeciality Hospital, Telangana, India; (2) Dr. Ramesh Cardiac and Multispeciality Hospital, Andhra Pradesh, India; (3) Gleneagles Global Hospitals, Telangana, India; (4) Yashoda Hospitals - Somajiguda, Telangana, India; (5) Vijan Cardiac & Critical Care, Maharashtra, India; (6) Parisoha Foundation Pvt. Ltd., Mumbai, India; (7) Ashwini Hospital, Akluj, India; (8) Swasthya Hospital and Medical Research Center, Ahmednagar, India

Aims: The treatment of long lesions with percutaneous coronary intervention has been crucial; as long lesions have been allied with lower procedural success rates and higher incidences of adverse events. Due to such concerns, it has become important to optimise the treatment of long lesions for better quality of life for these patients. Thus, this analysis aimed to evaluate clinical outcomes at 12 months after implantation of the long Supraflex Cruz (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) sirolimus-eluting stent in real-world patients with long coronary artery lesions.

Methods and results: We extracted and analysed data of 1,241 patients who underwent Supraflex Cruz implantation for treatment of long (≥28 mm) atherosclerotic coronary lesions, from the two all-comers multicentre registries (2,472 patients) in which real-world patients underwent PCI between May, 2016 and March, 2018 with only Supraflex Cruz, a latest-generation SES with ultrathin strut (60 µm) comprising of biodegradable polymer coating. In this analysis, the primary endpoint was target lesion failure, a composite of cardiac death, target vessel myocardial infarction and target lesion revascularisation at 12 months follow-up. Stent thrombosis was considered as a safety endpoint defined as per the Academic Research Consortium. Mean age of the patients was 56.0±10.8 years and 74.9% were male. As it is known that long lesions are self-indicators of complex and high risk patients; such that the proportion of acute coronary syndrome patients was 79.9% (unstable angina: 39.6%; ST-elevation myocardial infarction: 26.9%; non-ST-elevation myocardial infarction: 13.4%), hypertensive patients was 46.6%, diabetics was 33.6% and hypercholesteraemic patients accounted for 31.9%. About 19% patients were smokers and 16% patients had a family history of CAD. In 1,241 patients, a total 1,441 stents were implanted to treat 1,360 lesions. Left anterior descending artery was the most targeted lesion (50.3%), followed by right coronary artery (34.6%), left circumflex artery (15.1%) and saphenous vein graft (0.1%). All were type C lesions and of all, 243 (17.9%) lesions were totally occluded. Average stent length and diameter was 33.9±5.8 mm and 2.9±0.3 mm, respectively. The range of stents that were used was 28, 32, 26, 40, 44, 48 mm of length. Of these, 447 (31.0%), 435 (30.2%), 244 (16.9%), 147 (10.2%), 95 (6.6%), 73 (5.1%). The 12 months clinical follow-up data were obtained for 1185 (95.5%) of patients. Target lesion failure rate was 6.6%, which included 11 (0.9%) cardiac deaths, 36 (3.0%) target vessel myocardial infarctions and 31 (2.6%) target lesion revascularisations at 12 months follow-up. There were 10 cases of stent thrombosis at 12 months follow-up.

Conclusions: The results of this analysis provide support for the use of long (≥28 mm) Supraflex Cruz SES for treating long coronary atherosclerotic lesions, as there were low rates of clinical events at 12 months after implantation in real-world patients.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Mid- and long-term follow-up of ACS caused by spontaneous coronary dissection

FERNANDEZ GONZALEZ Luis [1], FERNANDEZ GONZALEZ Luis [1], GARCIA SAN ROMAN Koldobika [1], ASTORGA BURGO Juan Carlos [1], ACIN LABARTA Aida [1], ARRIOLA MEABE Josune [1], LARREA EGURBIDE Jose Felix [1], DIAZ CALVO Jorge [1], LARRAZABAL LOPEZ Jagoba [1], HORRILLO ALONSO Nagore [1], BLANCO MATA Roberto [1]

(1) Cruces, Barakaldo, Spain

Aims: Nowadays, spontaneous coronary dissection (SCAD) is considered as a cause of acute coronary syndrome with a predisposition to the female gender, occurring at an early age and commonly without typical cardiovascular risk factors. Sometimes it is associated with pregnancy and puerperium. The pathophysiology consists in the development of a false lumen that could compromise distal flow by compression of the true lumen of the coronary artery. The development of highly sensitive biomarkers and early angiography its diagnostic has increased exponentially.

Methods and results: This was a retrospective single-centric registry of all spontaneous coronary dissection confirmed cases either by angiography or by intracoronary imaging since the beginning of 2011 until February of 2019 with a minimum of 6 months of follow-up. Clinical and imaging characteristics, treatment modalities, in hospital outcomes and mid- and long-term follow-up were evaluated. Thirty-two patients with SCAD were identified of whom 28 (87,5%) were female. Mean age was 52 years. There was a low proportion of cardiovascular risk factors such as hypertension (16,7%), diabetes (8%), hypercholesterolaemia (15%) or active smoking status (25%) without sex differences. 4 patients had thyroid disfunction and 2 of them associated puerperium status. Presentation was ST-elevation myocardial infarction (STEMI) in 40%, non-STEMI 46,7%, unstable angina in 19,2% and 3,3% cardiac arrest. Coronary angiography was performed in all patients during the first 24-48 hours depending on the type of presentation. Intracoronary imaging was only performed in 30% of cases. Initial conservative management was carried out in 57%, simple angioplasty in 30% and coronary stenting in 13% of all patients. In all patients, a routine coronary angiography was undergone in the following 5-7 days to the index procedure in the case of stable patients or urgently in the case of clinical instability. Progression of coronary dissection was observed in 5 patients (2 with initial conservative management, 1 with simple angioplasty and 2 with previous coronary stenting). Coronary re-occlusion was observed in 3 cases, 2 of these were solved with simple angioplasty, the other one was treated medically. Clinical follow-up was carried out in all patients, in most of them an imaging technique such as computer tomography was performed showing, in the majority of patients, total extinction of the coronary dissection. SCAD recurred in 2 patients with no other major cardiac adverse events.

Conclusions: SCAD is an uncommon cause of acute coronary syndrome affecting a young predominantly female population with low cardiovascular previous risks. Although in-hospital mortality is low, percutaneous coronary intervention is associated with high rates of complications. Initial management may be conservative, except in cases with compromised coronary flow in which simple angioplasty should be performed. Close follow-up is needed due to the risk of recurrence.

STEMI - Adjunctive pharmacotherapy, Stable CAD - Adjunctive pharmacotherapy

Double or triple antithrombotic therapy for PCI patients with atrial fibrillation: a meta-analysis of randomised clinical trials

ANDO' Giuseppe [(1)], SAPORITO Francesco [(1)], SCALISE Renato [(1)], MANCUSO Filippo [(1)], LATERRA Giulia [(1)], MAZZONE Paolo [(1)], NAPPI Pierluigi [(1)], SALITO Armando [(1)], ANDO' Giuseppe [(1)]

(1) University of Messina, Messina, Italy

Aims: Optimal antithrombotic therapy in patients with atrial fibrillation (AF) undergoing PCI is not established. Double or triple antithrombotic therapy (DAT/TAT) including or excluding aspirin in association with oral anticoagulant and P2Y12 inhibitor are currently two available options and we sought to evaluate efficacy and safety outcomes for DAT vs TAT.

Methods and results: We searched PubMed, EMBASE and Cochrane databases for non-vitamin K oral anticoagulants (NOAC)-based randomised controlled trials comparing DAT vs TAT from inception to September 30, 2019. Four randomised studies, with a total of 10,938 patients have been included (PIONEER AF-PCI, RE-DUAL PCI, AUGUSTUS and ENTRUST-AF PCI). A pre-specified statistical analysis plan was written, and the review protocol was registered at PROSPERO. Median age of included patients was 70 years and roughly half presented with ACS. Follow-up ranged from 6 to 14 months in the included trials. Bleeding events occurred more frequently than ischaemic events. DAT as compared to TAT was associated to an increased risk of stent thrombosis (RR 1.54, 95% CI: 1.10-2.14; p=0.03), myocardial infarction (RR 1.23, 95% CI: 1.04-1.46; p=0.03) and cardiovascular mortality (RR 1.09, 95% CI: 1.01-1.19; p=0.04). ISTH major or clinically relevant non-major bleeding was reduced with DAT as compared to TAT (RR 0.59, 95% CI: 0.62-0.93; p=0.03). A consistent effect was observed in all safety endpoints. Intracranial haemorrhage was numerically reduced by DAT. No difference for all-cause death was observed. NOAC-based TAT appeared to provide the best compromise between efficacy and safety, whereas NOAC-based DAT demonstrated the highest prevention of bleeding at the cost of a slightly lower ischaemic protection. The main limitation of this study consists in that it represents a meta-analysis from study-level aggregated data. Individual patient-level analysis would allow exploring the impact of treatment on specific subgroups.

Conclusions: Antithrombotic treatment in patients with AF undergoing PCI represents a trade-off between ischaemia and bleeding. DAT, as compared to TAT, is associated to an excess of stent thrombosis and myocardial infarction, but a reduced risk of major bleeding. A careful patient selection based on baseline ischaemic and bleeding risk may optimise the net clinical balance in this population.

STEMI - CT / MRI imaging, Stents and scaffolds - Invasive imaging and functional assessment

Correlation between optimal coronary functional assessment results and cardiac magnetic resonance in patients after primary PCI

POPADIC Viseslav [1], POPADIC Viseslav [1], ZDRAVKOVIC Marija [1], HINIC Sasa [1]

(1) KBC Bežanijska kosa, Belgrade, Serbia

Aims: This study aims to properly evaluate if the optimal epicardial blood flow restoration measured by FFR/iFR is in correlation with proper myocardial blood flow restoration evaluated by cardiac magnetic resonance in terms of microvascular obstruction. This study will answer if previously derived optimal post-PCI FFR in acute coronary syndrome is applicable to patients after STEMI and whether it is enough to perform an optimal pPCI or further evaluation by cardiac magnetic resonance is important in patients after STEMI in terms of further prognosis.

Methods and results: The patients with diagnosed STEMI in a 6-hour time frame, with a single-vessel disease on angiography, haemodynamically stable, without severe comorbidities, were evaluated by FFR/iFR, post-pPCI with TIMI 3 flow. All patients had optimal results, FFR values of above 0.91, and performed iFR with results above 0.89 are referred to cardiac magnetic resonance on 5-7 days after STEMI to evaluate the existence and expansion of microvascular obstruction. These patients were then divided into two groups, one with and one without signs of microvascular obstruction on cardiac magnetic resonance. The cutoff FFR value of optimal FFR in acute coronary syndrome was derived from several studies showing that the FFR value of 0.91 after PCI has similar outcomes in terms of MACE as treating patients with a stable form of coronary artery disease. The cardiac magnetic resonance is performed 5-7 days after pPCI and 6 months after. The patients are also followed up in terms of major adverse cardiovascular events (MACE) one year after pPCI, according to the existence of microvascular obstruction on cardiac magnetic resonance despite optimal FFR results after pPCI. By previous iFR results, the correlation with FFR values is about to be interpreted. Also, an expert echocardiographic study with strain rate will be done in these patients in index hospitalisation in both groups and afterward, after 6 months, to evaluate possible differences between the two groups.

Conclusions: Certain post-PCI FFR values could be an important aspect of treating patients with acute coronary syndromes, but it is still unknown whether these values are applicable to patients with STEMI. Additional evaluation with cardiac magnetic resonance in patients with STEMI could demonstrate which patients are at a greater risk of future major cardiovascular events.

Stable CAD - Invasive imaging and functional assessment

Relationship of signal attenuation and cholesterol crystals as detected by OCT to no-reflow phenomenon in PCI

NISHIDE Seiji [(1)], SUZUKI Nobuaki [(1)], KIMURA Takahiro [(1)], AOYAGI Takashi [(1)], KANAMORI Kenta [(1)], SHIRATORI Yoshitaka [(1)], HAYAMI Noriyuki [(1)], KOZUMA Ken [(2)]

(1) Division of Cardiology, Teikyo University Mizonokuchi Hospital, Kawasaki, Japan; (2) Teikyo University, Tokyo, Japan

Aims: The no-reflow phenomenon (NR) is associated with worse long-term outcomes after percutaneous coronary intervention (PCI). Attenuated plaque observed in intravascular ultrasound images is known to be a risk of NR, whereas the predictor in optical coherence tomography images has yet to be established. The aim of this study was to assess the plaque characteristics which are associated with the incidence of NR by using frequency-domain optical coherence tomography (FD-OCT).

Methods and results: We enrolled 101 lesions (25 % for acute coronary syndrome; 14% for in-stent restenosis) for which FD-OCT-guided PCI was performed. When the lesion is severely obstructed, balloon dilatation of 2.0 or 2.25-mm diameter was performed in advance. Preprocedural FD-OCT image was analysed qualitatively as following; degrees of attenuated plaque and sheet calcification were assessed at frame with minimal lumen area, and thrombus, micro-vessel, plaque disruption, cholesterol crystal and calcified nodule were assessed at whole culprit plaque. NR was defined as the deterioration of TIMI flow without mechanical obstruction on the angiogram during PCI procedure. NR was observed in 5 (5%) lesions. Incidence of thrombus, plaque disruption, cholesterol crystals, micro-vessel, calcified nodule, sheet calcification and attenuated plaque was 19%, 11%, 36%, 27%, 13%, 19% and 79%, respectively. Entire circumferential attenuated plaque was observed in 23%. In comparison with non-NR group, NR group showed greater incidence of cholesterol crystals (80% vs 33%, p=0.053) and entire circumferential attenuated plaque (100% vs 19%, p<0.001). In the other characteristics, no significant difference was observed between the two groups. The coexistence of the entire circumferential attenuated plaque and cholesterol crystals was more frequently observed in the NR group (80% vs 10%, p=0.001), and considered as a good predictor of NR (sensitivity: 80%, specificity: 90%, positive predictive value: 29%, negative predictive value: 99%).

Conclusions: Entire circumferential attenuated plaque with cholesterol crystals is a risk of NR in FD-OCT-guided PCI. Further randomised trials are necessary in the future to test if these findings can be applicable for considering the indications for distal protection devices.

NSTEMI - Adjunctive pharmacotherapy

Very short DAPT after percutaneous coronary revascularisation and new DES: a meta-analysis of five randomised trials

VERDOIA Monica [1,2], VERDOIA Monica [1,2], GIOSCIA Rocco [2], KEDHI Elvin [3], SURYAPRANATA Harry [4], DE LUCA Giuseppe [2]

(1) Nuovo Ospedale degli Infermi, Province of Biella, Italy; (2) Azienda Ospedaliero Universitaria Maggiore della Carità di Novara, Province of Novara, Italy; (3) Isala ziekenhuis, Zwolle, the Netherlands; (4) Radboudumc, Nijmegen, the Netherlands

Aims: Very early discontinuation of dual antiplatelet therapy (DAPT), reaching extremely reduced 1-3 months duration, has been recently cleared in percutaneous coronary interventions performed with modern DES. However, the huge number of proposed strategies and pharmacological combinations, still prevent the generalisation and large scale application of recent findings. The aim of the present meta-analysis was to evaluate the prognostic impact of different regimens of very short DAPT as compared to a standard 12 months treatment in patients undergoing PCI with new DES.

Methods and results: Literature and main scientific session abstracts were searched for randomised clinical trials (RCT). The primary efficacy endpoint was mortality, primary safety endpoint was the occurrence of major bleedings. A pre-specified analysis was conducted according to the antiplatelet agent selected at long-term. We included 5 RCTs, with a total of 30,621 patients; among them 49.97% were randomised to a very short (1-3 months) DAPT, followed by ASA monotherapy in one trial and P2Y12 alone in 4 studies. A shorter DAPT duration significantly reduced the rate of major bleeding events (2%, vs 3.1%, OR [95% CI]= 0.62 [0.46, 0.84], p=0.002; phet=0.02), although it did not significantly impact on overall mortality (1.3% vs 2%, OR [95% CI]=0.97[0.73,1.29], p=0.84; phet=0.18). The reduction in bleeding events was even more significant in trials randomizing event-free patients at the time of DAPT discontinuation. Similar occurrence in myocardial infarction and stent thrombosis was observed between shorter vs standard 12-moth DAPT.

Conclusions: Based on the current meta-analysis, the discontinuation of DAPT after a very short (1-3 months) period is associated with a significant reduction in major bleeding as compared to the standard 12 months therapy, with no increase in major ischaemic events and comparable survival.

Stable CAD - Vascular access and bleeding

Mechanical compression protocol for femoral access haemostasis after coronary angiography. The secret: do not transfix the artery!

OLIVEIRA Dinaldo [1,2,3], OLIVEIRA Dinaldo [1,2,3], OLIVEIRA Carolina [1,2], MENDES Edvaldo [2], GADELHA Isabel [2], MIRANDA Vitor [2], SOUSA FILHO Jose [3]

(1) Federal University of Pernambuco, State of Pernambuco, Brazil; (2) Hapvida Hospital Ilha do Leite, State of Pernambuco, Brazil; (3) University of Pernambuco, State of Pernambuco, Brazil

Aims: The objectives of this study were to describe vascular complications at femoral access site after coronary angiography using a mechanical compression protocol with a metal compressor.

Methods and results: This was a real-world registry (from January 2017 to August 2019) that enrolled 1,000 patients (age = 56±10 years) with stable CAD and clinical indication of coronary angiography. These patients did not undergo surgical or percutaneous revascularisation previously. Clinical, social and economic data were collected by questionnaire applications. All patients had their femoral arteries cannulated at the first attempt (not transfixed), and not guided by either ultrasound or fluoroscopy. After completion of the procedure a 6 Fr introducer was removed, and a 3 cm square sterile gauze pad was placed on puncture site, then this gauze was pressed by the acrylic disk (part of the mechanical compressor) against the skin, so that it depressed the skin by 1 centimetre. Compression was maintained for 20 minutes, followed by a compressive bandage that was maintained for 24 hours. For 4 hours all patients were resting without walking. Patients returned at 7 and 30 days for re-evaluation. A descriptive statistical analysis was performed. There were more men, 656 (65.6%) than women, 344 (34.4%). The prevalence of married individuals was 730 (73%), family income <3 minimum wages 750 (75%), and elementary education, 560 (56%). Personal history: hypertension 800 (80%), diabetes mellitus 370 (37%), dyslipidaemia 210 (21%), smoking 160 (16%), stroke 140 (14%). Family history: hypertension 750 (75%), diabetes mellitus 530 (53%), myocardial infarction 270 (27%), stroke 150 (15%), dyslipidaemia 70 (7%) and chronic kidney disease 40 (4%). At 30-day follow-up the rates of vascular complications were: haematomas> 5 cm = 0.9% (9 cases), haematomas <5 cm or bruises = 1.8% (18 cases) and 1 vascular surgery = 0.1% (1 case). There were no deaths, myocardial infarctions, strokes, or urgent coronary artery bypass graft surgeries related to the procedures.

Conclusions: Vascular complications were low. The non-transfixing puncture technique associated with the use of a mechanical compressor may represent a cheap, safe, and efficient haemostasis strategy, especially in developing countries. Haemostasis without compromising limb perfusion is possible with this compressor technique, and further refinement of the puncture technique is critical to the results and should be sought.

Stable CAD - Tools, devices and techniques

Focal vs diffuse patterns of coronary artery disease as a predictor of the placebo controlled efficacy of PCI: the iFR-pullback stratified analysis of ORBITA

RAJKUMAR Christopher A [1,2], RAJKUMAR Christopher A [1,2], SHUN-SHIN Matthew J [1,2], AMARIN Laura [1], SELIGMAN Henry [1,2], AHMAD Yousif [1,2], WARISAWA Takayuki [1], COOK Christopher [1,2], RUPARELIA Neil [2], FRANCIS Darrel [1,2], AL-LAMEE Rasha [1,2]

(1) Imperial College London, London, United Kingdom; (2) Hammersmith Hospital, London, United Kingdom

Aims: Instantaneous wave-free ratio pullback (iFR-pullback) assessments are capable of characterising coronary artery disease (CAD) with a focal or diffuse pattern, however, the clinical importance of this distinction is unclear. We used data from the ORBITA trial to test if the pre-randomisation pattern of CAD predicts the placebo-controlled efficacy of PCI within the ORBITA trial.

Methods and results: In ORBITA, 200 patients with stable angina were randomised to PCI or placebo and remained blinded to treatment allocation until follow-up at 6 weeks. Of these, 164 patients underwent iFR pullback assessment prior to randomisation. Six cardiologists independently graded the pullback trace as a focal or diffuse pattern of pressure loss, blinded to the allocation arm and coronary angiogram. Regression modelling was used to test if the disease pattern predicted the placebo-controlled impact of PCI on stress echocardiography ischaemia and symptomatic endpoints. In the 164 patients with iFR pullback 83 were classified as focal and 81 as diffuse. Focal stenoses were significantly more ischaemic than diffuse lesions (focal mean FFR and iFR 0.60±0.15 and 0.65±0.24 respectively, diffuse mean FFR and iFR 0.78±0.10 and 0.88±0.08 respectively, p<0.0001). Across the cohort, PCI was more likely to reduce stress echo ischaemia in comparison with a placebo procedure (OR 3.44, 95% CI: 1.83 to 6.47, p<0.0001). When stratified by physiological pattern of disease, PCI for focal stenoses offered a significantly greater reduction in stress echo ischaemia than PCI for diffuse disease (Pinteraction=0.0265). In this cohort, the estimated effect of PCI on between-arm pre-Randomisation-adjusted total exercise time was 9.32 seconds (95% CI: -17.1 to 35.7s; p=0.487). When stratified for pattern of CAD, there was no detectable association for a focal pattern versus diffuse pattern of pressure loss (Pinteraction=0.705). While in this cohort, PCI improved Seattle Angina Questionnaire (SAQ) angina frequency score more than placebo (OR, 1.88; 95% CI: 1.05-3.37; p=0.034;), there was no detectable evidence of interaction between improvement in SAQ angina frequency score following PCI and the pattern of CAD (Pinteraction=0.392). Finally, PCI was more likely to result in freedom from angina than placebo (OR, 2.90; 95% CI: 1.42–5.92; p=0.0035). However, there was no detectable evidence of interaction between the pattern of disease and the effect of PCI on the likelihood of achieving freedom from angina (Pinteraction=0.995).

Conclusions: Within this sub-study of the ORBITA trial, focal stenoses were associated with significantly more ischaemia than diffuse lesions, and concordantly, there was significantly greater regression of ischaemia following PCI of focal stenoses when compared to PCI of diffusely diseased vessels. However, for symptomatic endpoints, there was no detectable difference between placebo-controlled PCI of focal stenoses or diffusely diseased vessels.

Stents and scaffolds - Tools, devices and techniques, Other Coronary interventions - Other

Application of 2018 ESC/EACTS guideline-endorsed high ischaemic risk features in patients treated with DES: insights from a large-scale Asian population

WANG Haoyu [1], WANG Haoyu [1], GAO Runlin [1], YANG Yuejin [1], WANG shuze [3], XU Bo [2], DOU Kefei [1]

(1) Department of Cardiology, Coronary Heart Disease Center, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; (2) Department of Cardiac Catheterization Laboratories, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; (3) University of Michigan, MI, USA

Aims: Recently, the 2018 ESC/EACTS guidelines on myocardial revascularisation have been proposed to standardise the definition of high ischaemic events risk (HIR) features. However, the prevalence and the expected ischaemic event rate of HIR patients defined by ESC/EACTS-endorsed criteria are currently unknown in real-world percutaneous coronary intervention practice. We sought to investigate the impact of HIR features on clinical outcomes after drug-eluting stents implantation and whether this effect is influenced by high bleeding risk (HBR).

Methods and results: Between January 2013 and December 2013, a total of 10,167 consecutive patients undergoing PCI were prospectively enrolled in Fuwai PCI Registry. The primary ischaemic endpoint was target lesion failure (TLF) (comprising cardiac death, target vessel myocardial infarction, and target lesion revascularisation] and the primary bleeding endpoint was clinically relevant bleeding defined as Bleeding Academic Research Consortium (BARC) type 2, 3, or 5 bleeding. Guideline-endorsed HIR features were in the present study and definitions were as follows: diffuse (defined as lesion length ≥20 mm) multivessel disease in patients with diabetes, CKD (defined as estimated glomerular filtration rate <60 ml/min/1.73 m^2), ≥3 stents implanted, ≥3 lesions treated, bifurcation with 2 stents implanted, total stent length >60 mm, and treatment of CTO, and history of ST-elevation myocardial infarction. HBR was defined based on the highest quartile of PARIS bleeding score (≥6 or <6). Median follow-up was 29 months. 5149 patients had at least 1 HIR feature (50.6%), who experienced significantly increased risks of TLF (adjusted hazard ratio [HR]: 1.59, 95% confidence interval [CI]: 1.32-1.93; p<0.001), compared to those with non-HIR features. In contrast, the risk of clinically relevant bleeding was statistically similar between the 2 groups (HRadjust: 0.85 [0.66-1.09]; p=0.200). By including ESC/EACTS-endorsed HIR criteria as a continuous variable within the same multivariable models, the risk of adverse ischaemic events tended to be greater as the number of high-risk procedural characteristics increased (per number of high-risk features increase: for TLF, HRadjust: 1.15, 95% CI: 1.07-1.23; Ptrend<0.001; for MACE, HRadjust: 1.33, 95% CI: 1.22-1.46; Ptrend<0.001). There was no statistical interaction between HBR and HIR features in regard to TLF (adjusted Pinteraction=0.855) and clinically relevant bleeding (adjusted Pinteraction=0.269), suggesting a consistent effect within ESC/EACTS-endorsed HIR features. Results were consistent when categorizing patients into HBR according to PARIS bleeding risk score ≥8 points.

Conclusions: ESC/EACTS-endorsed HIR criteria were associated with a substantial risk of ischaemic events, with no increase in clinically relevant bleeding in routine clinical practice; and these associations did not seem to be modified by HBR status.

Stents and scaffolds - Adjunctive pharmacotherapy

Benefit of longer than one-year DAPT on cardiovascular events in patients who are at high-risk for bleeding or ischaemic events after PCI

WANG Haoyu [1], WANG Haoyu [1], XU Bo [2], GAO Runlin [1], YANG Yuejin [1], DOU Kefei [1]

(1) Department of Cardiology, Coronary Heart Disease Center, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China; (2) Department of Cardiac Catheterization Laboratories, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

Aims: Dual-antiplatelet therapy (DAPT) exceeding 1 year may increase bleeding risk despite reducing the risk of ischaemic events. The benefits and harms of prolonging DAPT with aspirin and clopidogrel beyond 1 year after percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation for patients with high-risk for bleeding or an ischaemic event remains unknown.

Methods and results: Between January 2013 and December 2013, all consecutive patients undergoing PCI were prospectively included in the Fuwai PCI Registry. We evaluated 7,521 patients who were at high risk for ischaemic or haemorrhagic complications and were event free (no death, myocardial infarction [MI], stroke, stent thrombosis [ST], any revascularisation, or major bleeding) at 1 year after the index procedure. Subjects were divided into 2 groups: DAPT>1-year group (n=5,252) and DAPT≤1-year group (n=2,269). Patients at high-risk for ischaemic or bleeding events were defined as having at least one additional clinical feature and one angiographic feature according to TWILIGHT trial criteria. The clinical criteria for high risk were an age of at least 65 years, female sex, troponin-positive acute coronary syndrome, established vascular disease, diabetes mellitus that was being treated with medication, and chronic kidney disease. Angiographic criteria included multivessel coronary artery disease, a total stent length of more than 30 mm, a thrombotic target lesion, a bifurcation lesion treated with two stents, an obstructive left main or proximal left anterior descending lesion, and a calcified target lesion treated with atherectomy. The primary outcome was major adverse cardiac and cerebrovascular events [MACCE] (a composite of all-cause death, MI, or stroke). During a median follow-up of 30 months after the index procedure, DAPT>1-year with aspirin and clopidogrel was associated with a reduction in risk for MACCE compared with DAPT≤1-year (1.5% vs 3.8%; adjusted hazard ratio [HR]: 0.36; 95% confidence interval [CI]: 0.27-0.50; p<0.001) in multivariable Cox regression model. This difference was largely driven by a lower risk of all-cause mortality. In contrast, the risk of Bleeding Academic Research Consortium (BARC) type 2, 3 or 5 bleeding was statistically similar between the 2 groups (1.0% vs 1.1%; adjusted HR: 0.81; 95% CI: 0.50-1.30; p=0.373). After propensity score matching, incidence of MACCE was still lower in the DAPT>1-year group than the DAPT≤1-year group (1.6% versus 4.5%; hazard ratio, 0.34; 95% confidence interval, 0.22-0.52; p<0.001) and the rates of BARC type 2, 3 or 5 bleeding was not different between the 2 groups (1.1% versus 0.9%; adjusted hazard ratio, 1.12; 95% confidence interval, 0.57-2.18; p=0.744). In subgroup analysis, the treatment effect of prolonged DAPT was consistent across subgroups regardless of acute coronary, syndrome, DAPT score, or, type of used drug-eluting stent.

Conclusions: DAPT continuation with aspirin and clopidogrel beyond 1-year after DES implantation resulted in a significantly lower rate of MACCE, with no higher risk of clinically relevant bleeding in patients who were at high-risk for ischaemic or bleeding events. Our results suggest that prolonged DAPT may improve clinical outcomes after PCI for high-risk patients if they were free of ischaemic or bleeding events at 1 year.

Other Coronary interventions - Other

Outcome in elderly patients with myocardial infarction undergoing PCI using radial vs femoral access

KANIC Vojko [1], KANIC Vojko [1], KOMPARA Gregor [1], NAJI FRANJO Husam [1]

(1) University Medical Center Maribor, Maribor, Slovenia

Aims: Radial access (RA) has been increasingly used in interventional cardiology and has become the dominant access site for percutaneous coronary intervention (PCI). Data on the relationship between (RA) and outcome in patients with myocardial infarction (MI) undergoing PCI in the elderly are scarce and inconclusive. The aim of our study was to assess whether RA *per se* is associated with 30-day mortality in patients older than 80 years of age with MI undergoing PCI in our centre.

Methods and results: We retrospectively studied 639 consecutive patients older than 80 years of age with MI who underwent PCI between January 2011 and December 2017. RA was used in 232 (36.3%) patients. The 30-day mortality in the RA and femoral access (FA) groups was observed. Data were analysed using descriptive statistics. RA patients had a significantly lower 30-day unadjusted mortality [29 (12.5%) patients died in the RA group compared to 103 (25.3%) patients in the FA group; $p<0.0001$]. After adjusting for confounders, the difference was no longer significant (adjusted OR: 0.77; 95% CI: 0.45 to 1.32). Cardiogenic shock, out of hospital cardiac arrest, hypertension, ST-elevation MI, TIMI flow 0/1 after PCI, and bleeding predicted 30-day mortality. However, age and RA were not found to predict 30-day mortality.

Conclusions: RA provides a better 30-day outcome in patients older than 80 years of age with MI (ST-elevation MI and non-ST-elevation MI) undergoing PCI. RA was not independently associated with mortality. This result suggests that the better outcome with RA in our centre is at least partially influenced by confounding factors, most probably bleeding and haemodynamic impairment, However, in daily practice, RA should be preferred whenever possible. From a clinical point of view, it is irrelevant whether RA is associated with a better outcome *per se* or if the better outcome is linked to fewer bleeding events and lower rates of other complications due to RA. This is particularly true for patients with a higher bleeding risk (older patients, women, underweight patients, and patients with renal dysfunction).

Left main and multivessel disease - Tools, devices and techniques, Other Coronary interventions - Other

Prognostic impact of 2018 ESC/EACTS guideline-endorsed high ischaemic risk features on clinical outcomes in patients treated with drug-eluting stents

WANG Haoyu [1], WANG Haoyu [1], DOU Kefei [1], XU Bo [3], GAO Runlin [1], YANG Yuejin [1], WANG Shuze [2]

(1) Department of Cardiology, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; (2) University of Michigan, MI, USA; (3) Department of Cardiac Catheterization Laboratories, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

Aims: Recently, the 2018 ESC/EACTS guidelines on myocardial revascularisation have been proposed to standardise the definition of high ischaemic events risk (HIR) features. However, the prevalence and the expected ischaemic event rate of HIR patients defined by ESC/EACTS-endorsed criteria are currently unknown in the real-world percutaneous coronary intervention practice. We sought to investigate the impact of HIR features on clinical outcomes after drug-eluting stents implantation and whether this effect is influenced by high bleeding risk (HBR).

Methods and results: Between January 2013 and December 2013, a total of 10,167 consecutive patients undergoing PCI were prospectively enrolled in Fuwai PCI Registry. The primary ischaemic endpoint was target lesion failure (TLF) (comprising cardiac death, target vessel myocardial infarction, and target lesion revascularisation] and the primary bleeding endpoint was clinically relevant bleeding defined as Bleeding Academic Research Consortium (BARC) type 2, 3, or 5 bleeding. Guideline-endorsed HIR features were in the present study and definitions were as follows: diffuse (defined as lesion length ≥20 mm) multivessel disease in patients with diabetes, CKD (defined as estimated glomerular filtration rate <60 ml/min/1.73 m^2), ≥3 stents implanted, ≥3 lesions treated, bifurcation with 2 stents implanted, total stent length >60 mm, and treatment of CTO, and history of ST-elevation myocardial infarction. HBR was defined based on the highest quartile of PARIS bleeding score (≥6 or <6). Median follow-up was 29 months. 5149 patients had at least 1 HIR feature (50.6%), who experienced significantly increased risks of TLF (adjusted hazard ratio [HR]: 1.59, 95% confidence interval [CI]: 1.32-1.93; p<0.001), compared to those with non-HIR features. In contrast, the risk of clinically relevant bleeding was statistically similar between the 2 groups (HRadjust: 0.85 [0.66-1.09]; p=0.200). By including ESC/EACTS-endorsed HIR criteria as a continuous variable within the same multivariable models, the risk of adverse ischaemic events tended to be greater as the number of high-risk procedural characteristics increased (per number of high-risk features increase: for TLF, HRadjust: 1.15, 95% CI: 1.07-1.23; P trend<0.001; for MACE, HRadjust: 1.33, 95% CI: 1.22-1.46; P trend<0.001). There was no statistical interaction between HBR and HIR features in regard to TLF (adjusted Pinteraction=0.855) and clinically relevant bleeding (adjusted Pinteraction=0.269), suggesting a consistent effect within ESC/EACTS-endorsed HIR features. Results were consistent when categorizing patients into HBR according to PARIS bleeding risk score ≥8 points.

Conclusions: ESC/EACTS-endorsed HIR criteria were associated with a substantial risk of ischaemic events, with no increase in clinically relevant bleeding in routine clinical practice; and theses associations did not seem to be modified by HBR status.

Other Coronary interventions - Other

PCI complexity and risk of adverse events in relation to high bleeding risk among patients receiving drug-eluting stents

WANG Haoyu [1], WANG Haoyu [1], DOU Kefei [1], XU Bo [2], GAO Runlin [1], YANG Yuejin [1]

(1) Department of Cardiology, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; (2) Department of Cardiac Catheterization Laboratories, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China

Aims: The relation between complex percutaneous coronary intervention (PCI), high bleeding risk (HBR), and adverse events after coronary artery implantation of drug-eluting stents has been incompletely characterised. This study sought to investigate the ischaemic and bleeding events after complex PCI including a stratification according to HBR estimated by PARIS bleeding risk score.

Methods and results: Between January 2013 and December 2013, 10,167 consecutive patients undergoing PCI were prospectively enrolled in Fuwai PCI Registry. Complex PCI was defined when having at least one of the following characteristics: 3 vessels treated, ≥3 stents implanted, ≥3 lesions treated, bifurcation with 2 stents implanted, total stent length >60 mm, treatment of chronic total occlusion, unprotected left main PCI, in-stent restenosis target lesion, and severely calcified lesion requiring a rotablator system. The primary ischaemic endpoint was major adverse cardiovascular events (MACE) [composite of cardiac death, myocardial infarction, and definite/probable stent thrombosis], and primary bleeding endpoint was Bleeding Academic Research Consortium (BARC) type 2, 3, or 5 bleeding. The median duration of follow-up was 29 months. In adjusted Cox regression analysis, patients having complex PCI procedures experienced higher risks of MACE (hazard ratio [HR]: 1.63, 95% confidence interval [CI]: 1.38-1.92; p<0.001), compared with non-complex PCI. In contrast, the risk of clinically relevant bleeding was statistically similar between the 2 groups (HR: 0.86 [0.66-1.11]; p=0.238). There was no statistical interaction between HBR (PARIS bleeding score ≥8 or <8) and complex PCI in regard to MACE (adjusted Pinteraction=0.388) and clinically relevant bleeding (adjusted Pinteraction=0.279).

Conclusions: Patients who had undergone complex PCI resulted in substantially more ischaemic events, without an increase in clinically relevant bleeding risk; and these associations did not seem to be modified by HBR status. More intensified antiplatelet therapy may be beneficial for patients with complex percutaneous coronary revascularisation procedures.

STEMI - Invasive imaging and functional assessment

Efficacy of OCT-guided scoring balloon angiography for spontaneous coronary artery dissection

WATANABE Shingo [1], WATANABE Shingo [1], USUI Michio [1], KUJIRAOKA Hirofumi [1]

(1) Tokyo Yamate Medical Center, Tokyo, Japan

Aims: Spontaneous coronary artery dissection (SCAD) is an uncommon but important cause of acute coronary syndrome. The optimal treatment of ACS due to SCAD remains undetermined. It is considered that SCAD is a relatively common disease among young women, and stentless PCI is desirable considering the possibility of future pregnancies.

Methods and results: We report on 4 cases of SCAD successfully treated with scoring balloon angiography under optical coherence tomography (OCT) without stent implantation. The average age of the 4 cases was 30.5 years. All patients visited our hospital with chest pain and underwent CAG with STEMI. In three cases, CAG showed severe stenosis in the mid-LAD. In one case, CAG showed occlusion in the mid-diagonal branch. We performed OCT to distinguish between plaque rupture and SCAD as a cause of acute myocardial infarction. OCT showed an entry intimal tear proximal to the dissection site in all cases. In all cases, we performed POBA with scoring balloon to fenestrate the false lumen distal of the dissection site to allow communication and back-bleed of intramural haematoma into the true lumen. Following the POBA, there was normalisation of flow to TIMI-3 to the distal artery.

Conclusions: OCT was able to readily visualise the double-lumen morphology characteristic of this entity and to identify the entry tear, the circumferential and longitudinal extent of the disease. OCT-guided scoring balloon angiography is reasonable option for spontaneous coronary artery dissection.

Stable CAD - Invasive imaging and functional assessment

The relationship between the severity of physiological stenosis and long-term clinical outcome in patients who underwent PCI for intermediate coronary lesions

NAGASAKA Takashi [(1)], NAGASAKA Takashi [(1)], AIHARA Kazufumi [(1)], ISHIBASHI Yohei [(1)], TAKAMA Noriaki [(1)], MASAHIKO Kurabayashi [(1)]

(1) Gunma University Hospital, Gunma, Japan

Aims: Our aim in this study is to investigate the long-term clinical outcome of patients who underwent PCI after FFR and assessed the differences depending on the severity of FFR.

Methods and results: Between May 2016 and December 2018, a total of 148 intermediate coronary lesions evaluated by FFR and treated with PCI were enrolled. Lesions were divided into two groups.There was no significant difference in age, gender, ejection fraction (EF), the rate of hypertension, the rate of dyslipidaemia, the rate of smoking and medication at baseline between the two groups. According to angiographic findings, the severe group had significantly lower mean FFR values (severe group; 0.61±0.09 vs mild group; 0.76±0.02, $p<0.01$) and longer lesions (severe group; 28.5±10.1 mm vs mild group; 32.9±12.9 mm, $p=0.029$). No significant difference was shown with respect to cardiac death, MI and TLR. Whereas, the severe group was significantly associated with slow flow during PCI procedure (severe group; 18.2±9.6% vs mild group; 10.7±7.1%, $p=0.039$).

Conclusions: This study showed clinical outcomes in patients who underwent PCI for intermediate coronary lesions were excellent regardless of physiological stenosis severity based on FFR. However, it was revealed that physiological severity of coronary stenosis is correlated with higher risks of slow flow during PCI procedures.

Euro2OA-POS732
Posters

Stents and scaffolds - Tools, devices and techniques

Two-year clinical outcomes of Japanese patients after Ultimaster stent implantation in real-world practice: a substudy of the e-ULTIMASTER registry

KURAMITSU Shoichi [(1)], KURAMITSU Shoichi [(1)]

(1) Kokura Memorial Hospital, Kitakyushu, Japan

Aims: The ULTIMASTER stent is a newer generation sirolimus-eluting stent with a bioresorbable polymer (BP-SES). Recent randomised controlled trials showed the long-term safety and efficacy of BP-SES, whereas there is little data regarding clinical outcomes of BP-SES in real-world practice. We sought to assess two-year clinical outcomes of Japanese patients after BP-SES implantation in the e-ULTIMASTER registry.

Methods and results: The e-ULTIMASTER registry is a large, prospective, single-arm, multicentre registry that is designed to further validate the safety and efficacy of the BP-SES in unselected patients enrolled worldwide. Of 34,538 patients currently enrolled in this registry, 910 Japanese patients were included. The primary endpoint was the cumulative 2-year incidence of target vessel failure (TLF), defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CDTLR). The current study population included predominantly patients with stable coronary artery disease (78.8%). However, the great majority of patients had high-risk features such as advanced age (69.6±9.9 years), diabetes mellitus (43.9%), renal failure (22.2%), and prior percutaneous coronary intervention (41.9%), bifurcation lesion (23.4%), chronic total occlusion (7.0%), and left main coronary artery lesion (7.8%). At 2-year, TLF rate was 9.8%, with cardiac death of 2.1%, TV-MI of 1.3% and CDTLR of 7.6%. Definite or probable stent thrombosis was very low (0.48%).

Conclusions: Despite high-risk patient and lesion characteristics, BP-SES yielded favourable 2-year clinical outcomes of Japanese patients, highlighting the safety and efficacy of BP-SES in real-world practice.

Stable CAD - Tools, devices and techniques

Reducer, the new kid on the block for refractory angina therapy: a single-centre experience

BRÍZIDO Catarina [1], BRÍZIDO Catarina [1], MADEIRA Sérgio [1], GONÇALVES Mariana [1], BRITO João [1], OLIVEIRA FÉLIX Afonso [1], RAPOSO Luís [1], MESQUITA GABRIEL Henrique [1], GONÇALVES Pedro [1], CAMPANTE TELES Rui [1], ALMEIDA Manuel [1]

(1) Santa Cruz Hospital, Carnaxide, Portugal

Aims: The coronary sinus Reducer emerged as a complementary therapy in patients with severe angina symptoms refractory to optimal medical therapy and not amenable to revascularisation. The aim of this study was to assess the safety and efficacy of the Reducer in a real-world cohort of patients presenting with refractory angina.

Methods and results: Thirteen patients with refractory angina, objective evidence of myocardial ischaemia attributable to the left coronary artery and deemed unsuitable for revascularisation were treated with the Reducer at a single centre between April 2018 and June 2019. Safety endpoints were procedural success and complications. Efficacy endpoints, assessed at 6-month follow-up, were reduction in Canadian Cardiovascular Society angina (CCS) class, improvement in quality of life assessed by the Seattle Angina Questionnaire (SAQ) and reduction in pharmacological antianginal therapy. Ten patients (77%) had end-stage coronary artery disease without revascularisation targets (previous CABG±PCI in 8 and previous PCI in 2) and 3 patients had microvascular disease without epicardial stenosis. Procedural success was achieved in all patients, with no device related complications. There was one cardiac tamponade, promptly treated with pericardiocentesis. Regarding the efficacy endpoint, 10 patients (77%) had a reduction of at least one CCS class, 7 patients (54%) at least two classes, and 4 patients (31%) became asymptomatic, with a significant CCS class reduction from 3 (IQR 2-3) to 1 (IQR 0-2) (p=0.004) at 6-month follow-up. Concerning SAQ, there was a significant improvement in ability to perform physical activities (p=0.04), angina frequency (p=0.003), satisfaction with current angina treatment (p=0.004) and enjoyment of life (p=002). Seven patients (54%) had at least 1 antianginal drug reduction. There was no significant change in symptom status between 6 months and 1 year for those patients who completed 1-year follow-up.

Conclusions: In this real-world, single-centre experience, implantation of the Reducer was safe and associated with improvement of angina and quality of life in patients with refractory angina unsuitable for revascularisation.

Other Coronary interventions - Other

The transradial and transfemoral approach in patients with prior CABG and treated with PCI

JANUSZEK Rafal [1], JANUSZEK Rafal [1], SIUDAK Zbigniew [2], MALINOWSKI Krzysztof [5], WANHA Wojciech [3], WOJAKOWSKI Wojciech [3], GASIOR Mariusz [4], STANISLAW Bartus [5], DUDEK Dariusz [5]

(1) SP ZOZ Szpital Uniwersytecki w Krakowie, Kraków, Poland; (2) Jan Kochanowski University of Kielce, Kielce, Poland; (3) Medical University of Silesia, Katowice, Poland; (4) Silesian Center for Heart Diseases, Zabrze, Poland; (5) Collegium Medicum Uniwersytet Jagielloński, Kraków, Poland

Aims: The relationship between periprocedural complications and the type of vascular access in patients with prior history of coronary artery bypass grafting (CABG) and treated with percutaneous coronary interventions (PCIs) is less investigated than in the overall group of patients treated with PCI. Therefore, the aim of the current study was to assess the relation between type of vascular access and selected periprocedural complications in a group of patients with prior history of CABG and treated with PCIs.

Methods and results: Based on a nationwide registry (ORPKI), the authors analysed 536,826 patients treated with PCI between 2014 and 2018. The authors extracted 32,225 cases with prior history of CABG. Patients with femoral and radial access as well as right and left radial access were then compared. This comparison was proceeded by propensity score matching (PSM). After PSM, multifactorial analysis revealed that patients treated with PCI from femoral access were significantly more often related to periprocedural deaths (odds ratio [OR]: 1.79; 95% confidence interval [CI]: 1.1-3.0, p=0.02) and cardiac arrests (OR: 1.98; 95% CI: 1.38-2.87, p<0.001). Following adjustments for Killip class grade and the occurrence of cardiac arrests before PCI, the significance remained for procedural related cardiac arrests (OR: 1.59; 95% CI: 1.09-2.35, p=0.01). However, comparison of right and left radial access showed no significant differences between procedure-related complications.

Conclusions: The femoral compared to radial access is related to a higher rate of periprocedural cardiac arrests in patients with a prior history of CABG treated with PCI.

Other Coronary interventions - Calcified lesions

The transradial and transfemoral approach in patients treated with PCI and rotational atherectomy

JANUSZEK Rafal [1], JANUSZEK Rafal [1], SIUDAK Zbigniew [2], MALINOWSKI Krzysztof [3], JĘDRYCHOWSKA Magdalena [1], STASZCZAK Bartłomiej [3], PAWLIK Artur [1], BARTUŚ Stanisław [3], DUDEK Dariusz [3]

(1) University hospital, Kraków, Poland; (2) Jan Kochanowski University of Kielce, Kielce, Poland; (3) Collegium Medicum Uniwersytet Jagielloński, Kraków, Poland

Aims: The relationship between periprocedural complications and the type of vascular access in patients treated with percutaneous coronary interventions (PCIs) and rotablation is less investigated than in the overall group of patients treated with PCIs. Therefore, the aim of the current study was to assess the relation between the type of vascular access and selected periprocedural complications in the group of patients treated with PCI and rotablation.

Methods and results: Based on the nationwide registry (ORPKI) we analysed 536,826 patients treated with PCI between 2014 and 2018. We extracted 2,713 patients treated with PCI and rotational atherectomy, where 1,018 (37.5%) patients had femoral vascular access and 1,653 (60.9%) radial. Then we compared patients with femoral and radial approach. The comparison was proceeded by propensity score matching (PSM). After PSM, the multifactorial analysis revealed that patients treated with PCI from femoral access were significantly less often related to coronary artery perforation (odds ratio [OR]: 0.29; 95% confidence interval [CI]: 0.08-0.92, p=0.04). We did not confirm a significant relationship related to vascular access for periprocedural rate of deaths (p=0.99), cardiac arrests (p=0.41), puncture site bleeding (p=0.99), allergic reactions (p=0.32), myocardial infarctions (p=0.48), no-reflows (p=0.82) and the overall complications rate (p=0.31).

Conclusions: In the analysed group of patients, femoral access in comparison to the radial was related to lower rate of coronary artery perforations in patients treated with PCI and rotablation.

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Posters

Stents and scaffolds - Tools, devices and techniques, CTO - Tools, devices and techniques

Mesh-covered stent vs DES implantation in diseased SVG: comparative analysis of short-term complications

CAFRI Carlos [1,2], HARTSHTARK Stav [1,2], KEZERLE Louise [1,2], COHEN Avshalom [1,2], BARRETT Orit [1,2], CAFRI Carlos [1,2]

(1) Soroka Medical Center, Be'er Sheva, Israel; (2) Ben Gurion University of the Negev, Be'er Sheva, Israel

Aims: SVG PCI is considered a high-risk procedure, with substantial rates of atheromatous and thrombotic embolisation leading to coronary flow disturbances, Periprocedural MI and death. Since treatment possibilities have limited benefits once microvascular obstructions have occurred, the prevention of them remains of the utmost importance. A potential preventive strategy is the utilisation of mesh-covered stents, such as MGuardTM (InspireMD –Tel Aviv, Israel). In this study we sought to explore the angiographic and clinical short term complications when performing SVG PCI using MGuardTM versus DES

Methods and results: We reviewed data from 86 cases of SVG-PCI with implantation of MGuardTM, and 88 cases with implantation of DES over a 12-year period. The two groups were analysed and compared in terms of baseline characteristics, angiographic complications, and 30-day clinical complications. Results: We found no difference between groups regarding our primary endpoint, which was the composite of intraprocedural thrombotic events (No reflow /distal embolisation), Periprocedural MI and 30-day mortality (9.3% MGuardTM vs 8% DES, p=0.38). All individual rates of events were similar between groups as well. Independent predictors of the primary endpoint were also investigated, and found to be Total Stents Length (OR, 1.035; 95% CI: 1.001-1.071, p=0.047), and Stent Maximum Pressure (OR, 0.735; 95% CI: 0.566-0.955, p=0.021).

Conclusions: The mesh-covered stent (MGuardTM) failed to prove any favourable angiographic or clinical outcomes compared with DES, when are applied for the angioplasty treatment of diseased SVG.

Stable CAD - Invasive imaging and functional assessment, Other Coronary interventions - Other

Impact of clinical and haemodynamic factors on coronary flow reserve and invasive coronary flow capacity in non-obstructed coronary arteries: a patient level pooled analysis of the DEBATE and ILIAS studies

STEGEHUIS Valérie [1], STEGEHUIS Valérie [1], WIJNTJENS Gilbert [1], BAX Matthijs [2], CHAMULEAU Steven [1], VOSKUIL Michiel [3], KOCH Karel [1], DI MARIO Carlo [4], VRINTS Christiaan [5], HAUDE Michael [6], BOERSMA Eric [7], SERRUYS Patrick [8], PIEK Jan [1], VAN DE HOEF Tim [1]

(1) Amsterdam UMC - Locatie AMC, Amsterdam, the Netherlands; (2) Haga Hospital (Leyweg), The Hague, the Netherlands; (3) University Medical Center Utrecht, Utrecht, the Netherlands; (4) Careggi University Hospital, Metropolitan City of Florence, Italy; (5) University Hospital Antwerp, Antwerp, Belgium; (6) Städtische Kliniken Neuss - Lukaskrankenhaus - GmbH Notaufnahme, Neuss, Germany; (7) Erasmus Medical Center, Rotterdam, the Netherlands; (8) Imperial College London, London, United Kingdom

Aims: Coronary Flow Reserve (CFR) is a physiological index for the assessment of myocardial flow impairment due to focal or microcirculatory coronary artery disease (CAD). Coronary flow capacity (CFC) is another flow-based concept in diagnosing ischaemic heart disease, based on hyperaemic average peak velocity (hAPV) and CFR. We evaluated clinical and haemodynamic factors which potentially influence CFR and CFC in non-obstructed coronary arteries.

Methods and results: Intracoronary Doppler flow velocity measurements to obtain CFR and CFC were performed after inducing hyperaemia in 390 non-obstructed vessels of patients who were scheduled for elective percutaneous coronary intervention (PCI) of another vessel. Akaike's Information Criterion (AIC) revealed age, female gender, history of myocardial infarction, hypercholesterolaemia, diastolic blood pressure, oral nitrates and rate pressure product as independent predictors of CFR and CFC. After regression analysis, age and female gender were associated with lower CFR and age was associated with worse CFC in angiographically non-obstructed vessels.

Conclusions: Age and female gender are associated with lower CFR, and age with worse CFC in an angiographically non-obstructed coronary artery. CFC seems to be less sensitive to variations in clinical and haemodynamic parameters than CFR, and therefore is a promising tool in contemporary clinical decision making in the cardiac catheterisation laboratory.

Stents and scaffolds - Adjunctive pharmacotherapy

Early thrombogenicity of coronary stents: comparison of bioresorbable polymer sirolimus-eluting and bare metal stents in an aortic rat model

VERHAEGEN Carole [2], VERHAEGEN Carole [2], KAUTBALLY Shakeel [1,2], CASTANARES Diego [1], BRUSA Davide [2], AYDIN Selda [1], BOUZIN Caroline [2], OURY Cecile [3], BEAULOYE Christophe [1,2], HORMAN Sandrine [2], KEFER Joelle [1,2]

(1) Cliniques universitaires Saint-Luc UCLouvain, Woluwe-Saint-Lambert, Belgium; (2) Institut de Recherche Clinique et Expérimentale, Université de Louvain UCLouvain, Brussels, Belgium; (3) Chu De Liège, Liège, Belgium

Aims: Although 1-month dual antiplatelet therapy (DAPT) in patients treated with bare metal stents (BMS) is well established, the optimal duration of DAPT after implantation of drug-eluting stent (DES) is still under debate. The safety of a shortened DAPT is under investigation with a concern about the risk of stent thrombosis. Biological data on platelet activation and prothrombotic response *in vivo* after bioresorbable polymer sirolimus-eluting stent (BP-SES) implantation are scarce. The aim of our study was to compare the early thrombogenicity of BP-SES with BMS in an aortic rat model.

Methods and results: Thirty rats underwent stent implantation in the abdominal aorta: BMS (Pro-Kinetic Energy; N=15) and BP-SES (Ultimaster Tansei; N=15) were compared regarding their early thrombogenicity. Exposure of CD62P and binding of fibrinogen at the integrin receptor at platelet surface were not different between BMS and BP-SES over time. Thrombus coverage of the scaffold was similarly low in both groups at day 1 (0.55 vs 0.1%, p=0.84) and day 28 (0 vs 0.1%, p=0.44); thrombotic deposits disappeared totally at day 84. The endothelial strut coverage was similarly high at 1 month (90 vs 95%, p=0.64) and 3 months (87 vs 97%, p=0.99) after BMS and BP-SES, respectively. There was zero stent thrombosis observed at any time.

Conclusions: This study demonstrates the low early thrombogenicity of a BP-SES implanted in an aortic rat model, not different than a BMS. These data could be helpful to support the safety of a shortened DAPT duration at 1 month after a BP-SES implantation in the human coronary.

Stable CAD - Tools, devices and techniques, Bifurcation lesion - Tools, devices and techniques

Incorrect bifurcation procedures as a cause of complications such as stent thrombosis

BAGHDASARYAN David [(1)], BAGHDASARYAN David [(1)]

(1) Nork-Marash Medical Center, Yerevan, ARMENIA

Aims: A step-by-step detailed study of a bifurcation intervention which was done without using generally accepted methods, and which ultimately led to complications.

Methods and results: Stenting was performed on a 54 year old female patient. The bifurcation intervention was in the mid-part of the left anterior descending (LAD) artery from which the Diagonal 1 (D1) branch originated. Conventional methods for bifurcation interventions were not used during the stenting and an angiographically satisfactory result was obtained. After 5 days, the patient was admitted with a diagnosis of STEMI and LAD stent thrombosis was visualised. Angioplasty was performed on both vessels, with the extraction of thrombus of the LAD and followed by stenting the ostial segment of the D1.

Conclusions: Failure to use conventional bifurcation techniques can cause complications such as stent restenosis and stent thrombosis.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

A new risk score outperforms Liu, Chen and Maioli scores for prediction of contrast-induced nephropathy after coronary angioplasty

BRÁS Diogo [1], BRÁS Diogo [1], ROCHA Ana Rita [1], PAIS João [1], CARRINGTON Mafalda [1], PIÇARRA Bruno [1], NEVES David [1], FERNANDES Renato [1], AGUIAR Jose [1], PATRICIO Lino [1], ACS Portuguese National Registry on [2]

(1) Hospital do Espírito Santo de Évora, EPE, Evora, Portugal; (2) Sociedade Portuguesa De Cardiologia, Lisbon, Portugal

Aims: According to a systematic 2015 review (Samuel A Silver, British Med J), Liu, Chen and Maioli scores should be used to predict the risk of contrast-induced nephropathy, since these were the scores with better predictive capacity regardless of the amount of contrast administered. Whether these scores keep good predicting capacity in the Portuguese population remains to be demonstrated. The authors intend to validate 3 pre-existing risk scores of CIN after angioplasty (PCI) in the Portuguese population and compare them with a newly created score.

Methods and results: This retrospective study gathers data from a national multicentre registry. We have included ST-segment elevation myocardial infarction (STEMI) and non-STEMI patients that underwent PCI. Patients on dialysis were excluded. The variable CIN was defined as an increase of 25% or 0.5 mg/dL relative to baseline serum creatinine in the first 72 hours after contrast administration. The Liu, Chen and Maioli scores are defined as follows: Liu: age ≥75 years: 1 point (p); left ventricle ejection fraction (LVEF) <40%: 1 p; admission creatinine >1.5 mg/dL: 2 p. Chen: age ≥ 70 years: 4 p; past MI: 5 p; diabetes: 4 p; hypotension: 6 p; LVEF ≤45%; anemia: 3 p; eGFR <60 mL/min: 7 p; HDL <39 mg/dL: 3 p; urgent PCI: 3 p. Maioli: Age ≥73 years: 1 p; diabetes: 2 p; LVEF ≤45%: 2 p; eGFR ≤44 mL/min: 2 p; admission creatinine >1.5 mg/dL: 2 p; angiogram in the last 72 h: 3 p; preprocedural creatinine ≥ admission creatinine: 2 p. New-score: age ≥75 years: 2 p; female: 1 p; infarct-related artery – LAD: 1 p; multivessel disease: 1 p; diabetes: 1 p; chronic kidney disease: 2 p; Killip class >1: 3 p. We assessed the prediction quality of every score through ROC curve analysis and compared the results afterwards. We have also analysed the intrahospital complications and mortality. The sample is composed of 5,489 patients, with mean age is 64±13 years in which 78% are males. The mean Liu score was 0.5±0.8 p, Chen score 15.4±5.4 p, Maioli score 6.3±1.7 p and the New-score 2.3±1.9 p. Time from PCI to maximum creatinine was 0.8±9.6 days. Patients who suffered CIN had higher rate of complications and higher intrahospital death (0.8 vs 3.9%, p<0.001). The c-statistic for CIN prediction of the pre-existing scores performed poorly: Liu score 0.612 (0.599-0.625), Chen score 0.598 (0.584-0.611) and Maioli score 0.574 (0.561-0.587). The c-statistic from Chen and Liu scores did not differ between them (p=ns). Nonetheless it was significantly different between Chen and Maioli scores 0.023 (p=0.005, 0.006-0.04), as well as between Liu and Maioli scores 0.038 (p<0.001, 0.018-0.059). The New-score performed slightly better than existing scores: c-statistic 0.658 (0.639-0.677) and it differed significantly from the Liu score (difference between areas 0.04; p<0.001). Positive predicting value is 28% and negative predicting value is 88%.

Conclusions: We conclude that the 3 pre-existing scores suggested by the systematic review to predict CIN lack predictive capacity for individuals in the Portuguese population that suffered from acute coronary syndromes in this registry. One possible explanation relates to significant differences between baseline populations, as both Liu and Chen scores were tested in Asian populations and Maioli score was tested predominantly in elective setting. The New-score showed a slightly better predicting capacity than the other scores and could be a tool to guide future studies in our population with CIN.

STEMI - Invasive imaging and functional assessment, NSTEMI - Invasive imaging and functional assessment

Right ventricular function in anterior myocardial infarction

NOBILE Domenico [(1)], NOBILE Domenico [(1)], FATTOUCH Khalil [(1)]

(1) Villa Maria Eleonora Hospital Srl, Province of Palermo, Italy

Aims: The aim of this study was to assess right ventricular disfunction in anterior AMI comparing the traditional echocardiographic parameters with STE data; to determine the prognostic role of right ventricular disfunction in patients with anterior AMI.

Methods and results: The findings of this study are based on a prospective case-control study involving 44 patients with acute coronary syndrome (ACS) due to an isolate occlusion of left anterior descendant (LAD). Echocardiographic and STE parameters were measured within 72 hours of anterior IMA diagnosis (T0) and 3 months after the coronary revascularisation (T1). Haemodynamic and clinical stabilities and adverse events were verified after 6 months (T2). The data obtained were compared with a control group of 22 patients. RESULTS: echocardiographic indexes of cardiac function were assessed and there were no significant differences in right ventricular function indexes between patients with anterior AMI and control group patients at T0 (TAPSE 23±3 e 24±4; RVFAC% 42±9 e 43±8). Conversely, STE analysis assessed a significant reduction of the strain of the right ventricular free wall in patients with AMI diagnosis at T0 (−15.2± 4.6 e −22.5± 4.4 p-value= 0,001) with greater reduction in medial (−15.7±6.6 e −22.1±5.7) and apical (−11.6±5.4 e −21.5±5.2) segments. To verify the "ventricular interdependence" we compared the EF with the right ventricular strain and a strongly positive correlation was observed between the right ventricular strain and EF of the left ventricle (Pearson's coefficient R = 0.738; p<0.001). The 44 patients with anterior AMI were divided into 2 groups based on STE right ventricular disfunction (strain cut off =-19%) to assess the prognostic role of the right ventricular strain. They were assessed 6 months after the AMI (T2) and adverse events frequency was verified (chest pain, acute heart failure and re-hospitalisation). We found that 22% of patients with normal right ventricular strain results in adverse events, while the 56% of patients with reduced strain results in adverse events. The univariate analysis showed a statistically significant association between the presence of right ventricle involvement assessed by STE and the adverse events observed during follow-up (odds ratio, 15.8).

Conclusions: According to the results of our study, in spite of the apparent normality of the traditional right ventricular function parameters (FAC, TAPSe), in patients with anterior AMI, there is a subclinical dysfunction of the right ventricle that can be detected by using STE. Right ventricular dysfunction is likely to be secondary to left ventricular dysfunction, as a result of "ventricular interdependence." Right ventricular dysfunction correlates with a poorer prognosis. In patients with anterior AMI, right ventricular strain could be used to identify those with higher risk of mortality and re-hospitalisation, therefore the routinely use of STE should be encouraged.

CTO - Tools, devices and techniques

Multicentre experience of PCI for ostial left anterior descending artery CTO

KWON Osung [8], KWON Osung [8], YOON Yong-Hoon [1], LEE Pil Hyung [2], YOON Chang-Hwan [9], CHUN Kook-Jin [6], YOUNG JOON Hong [1], LEE Jang Hoon [4], TAEK KYU Park [3], LEE Jong-Young [7], LEE Seung-Whan [2]

(1) Chungnam National University Hospital, Daejeon, Republic of Korea; (2) Asan Medical Center, Seoul, Republic of Korea; (3) Samsung Medical Center, Seoul, Republic of Korea; (4) Kyungpook National University Hospital, Daegu, Republic of Korea; (5) Chonnam National University Hospital, Gwangju, Republic of Korea; (6) Pusan National University Yangsan Hospital, Gyeongsangnam-do, Republic of Korea; (7) Kangbuk Samsung Hospital, Seoul, Republic of Korea; (8) The Catholic University of Korea Eunpyeong St. Mary's Hospital, Seoul, Republic of Korea; (9) Seoul National University Bundang Hospital, Gyeonggi-do, Republic of Korea

Aims: Chronic total occlusion (CTO) lesions often involve the ostium of the left anterior descending artery (LAD), which poses technical challenges owing to specific characteristics, such as a higher prevalence of ambiguous stumps, large angle of attack from the guiding catheter, the presence of a large side branch, or coexistence of left main coronary artery (LMCA) disease. Thus, we evaluated the "real-word" practice of PCI for ostial LAD-CTO in terms of the techniques, complications, and outcomes based on a multicentre registry.

Methods and results: In total, 270 consecutive patients who underwent PCI for ostial LAD-CTO at 13 major cardiac centres in South Korea were included. Ostial LAD-CTO was defined as a LAD-CTO lesion the proximal cap of which was confined within 1 mm from the carina of the distal LMCA bifurcation. Ostial LAD-CTOs were frequently accompanied by stumpless lesion entry (43.4%), whereas significant bending within the occluded segment was less frequent (14.4%). The overall success rate was 85.9%, and the retrograde approach tended to contribute more frequently to technical success in patients with concomitant LMCA disease, stumpless CTO, interventional collaterals, and higher Japanese-CTO scores. Apparent dissection or haematoma requiring rescue or additional procedure at the LMCA or left circumflex artery occurred in 14 patients (5.2%), with a higher tendency in patients who had LMCA disease than in those without (12.1% vs 3.8%). Among patients who were successfully treated with an average number of 1.7 stents, target-vessel failure occurred in 30 patients (11.1%) during a median 3.3 years of follow-up.

Conclusions: PCI for ostial LAD-CTO showed a high success rate with an acceptable mid-term rate of target-vessel failure. However, clinically relevant dissection can occur around the LMCA with a non-negligible rate, indicating the need for operator awareness.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Characteristics and clinical outcomes of de-escalation from prasugrel to clopidogrel in patients with AMI: insight from the Japan AMI registry (JAMIR)

YASUDA Satoshi [1], HONDA Satoshi [1], NISHIHIRA Kensaku [1], TAKEGAMI Misa [1], KOJIMA Sunao [2], ASAUMI Yasuhide [1], TAKAHASHI Jun [3], KOSUGE Masami [4], TAKAYAMA Morimasa [5], SUMIYOSHI Tetsuya [5], OGAWA Hisao [1], KIMURA Kazuo [4]

(1) National Cerebral and Cardiovascular Center, Osaka, Japan; (2) Kawasaki Medical School Hospital, Okayama, Japan; (3) Tohoku University, Miyagi, Japan; (4) Yokohama City University Medical Center, Kanagawa, Japan; (5) Sakakibara Heart Institute, Tokyo, Japan

Aims: A potent P2Y12 inhibitor, prasugrel is increasingly used in patients with acute myocardial infarction (AMI). In clinical practice, de-escalation of P2Y12 inhibitor may occur because of specific clinical scenarios. However, little is known about characteristics and outcomes of patients who underwent de-escalation strategy in real-world clinical practice.

Methods and results: We studied 2,712 patients with AMI treated initially with prasugrel between December 2015 and May 2017 using the database of Japan Acute Myocardial Infarction Registry (JAMIR). Of these, 112 (4%) were discharge on clopidogrel (de-escalation group; switching 8±13 days after admission) and remaining 2,607 continued prasugrel at discharge (continued group). We compared in-hospital and post-discharge outcomes between the groups. De-escalation group had higher incidence of heart failure, history of cerebrovascular disease, and were more likely to receive mechanical circulatory support, urgent CABG and oral anticoagulation than continued group. Incidence of in-hospital major bleeding (BARC type 3 or 5 bleeding) was significantly higher in de-escalation group than in continued group (14.3% vs 2.3%, p<0.001), while in-hospital ischaemic events (composite of cardiovascular death, MI and stroke) was comparable between groups (3.6% vs 4.1%, p=0.78). During mean follow-up of 309±133 days after discharge, no significant differences were observed in ischaemic events (2.2% vs 2.8%, p=0.74) or major bleeding (1.1% vs 1.6%, p=0.72) between the de-escalation and continued groups.

Conclusions: Patients with de-escalation from prasugrel to clopidogrel before discharge had higher bleeding risk profile and more frequent in-hospital bleeding events than those continued prasugrel. However, there were no significant differences in ischaemic events or bleeding events after discharge between patients with and without de-escalation.

Stable CAD - Invasive imaging and functional assessment

In-procedure physiological assessment of intracoronary OCT-derived FFR for optimal revascularisation

TANIGAKI Toru [1], TANIGAKI Toru [1], OKUBO Munenori [1], KAWASE Yoshiaki [1], OMORI Hiroyuki [1], HIRATA Tetsuo [1], KIKUCHI Jun [1], SOBUE Yoshihiro [1], OTA Hideaki [1], KAMIYA Hiroki [1], MATSUO Hitoshi [1]

(1) Gifu Heart Center, Gifu, Japan

Aims: Optical coherence tomography-derived fractional flow reserve (OFR) is a novel modality for physiological lesion assessment based on intra-coronary imaging. The accuracy of in-procedure physiological assessment using OFR remains unclear. We sought to evaluate the value of OFR before, during and after coronary revascularisation for the agreement with wire-based fractional flow reserve (FFR) as a gold standard.

Methods and results: Patients with functionally significant coronary stenosis were enrolled and underwent optical coherence tomography (OCT)-guided coronary revascularisation. OCT-pullback and FFR measurement were performed before, during and after percutaneous coronary intervention (PCI). OFR values were measured by using the software of Pulse Medical Imaging Technology. OFR and FFR values during PCI mean the value measured just after balloon dilatation or stent implantation and before final optimisation. We analysed a total of 90 OCT-pullbacks data in 30 vessels from 30 patients and OFR was compared with wire-based FFR. Mean value of pre-PCI OFR (OFRpre), during-PCI OFR (OFRduring) and post-PCI (OFRpost) were 0.69±0.11, 0.82±0.09 and 0.89±0.07. Mean value of pre-PCI FFR (FFRpre), during-PCI FFR (FFRduring) and post-PCI FFR (FFRpost) were 0.69±0.09, 0.84±0.10 and 0.91±0.07. Mean differences between each OFR and FFR (OFRpre-FFRpre, OFRduring-FFRduring, and OFRpost-FFRpost) were -0.02±0.07, -0.03±0.06 and -0.03±0.04. Mean OFR analysis time were 80±31, 66±24 and 69±19 seconds for each OCT pullback before, during and after PCI.

Conclusions: OFR had good agreement with wire-based FFR measured before, during after coronary revascularisation. OFR might enable to assess the physiological severity of coronary stenoses and the optimality of revascularisation without in-procedure measurement of wire-based FFR.

Stents and scaffolds - Tools, devices and techniques

Comparison of baseline characteristics and one-year outcomes between Japanese and non-Japanese patients treated with Ultimaster stent: a substudy of the e-ULTIMASTER registry

KURAMITSU Shoichi [(1)], SHOICHI Kuramitsu [(1)]

(1) Kokura Memorial Hospital, Kitakyushu, Japan

Aims: Geographical and clinical practice variations remain influencing factors on clinical outcomes of patients undergoing percutaneous coronary intervention. We sought to assess the differences in baseline clinical characteristics between the Japan and non-Japan cohorts as well as 1-year clinical outcomes in the e-ULTIMASTER registry.

Methods and results: The e-ULTIMASTER registry is a large, prospective, single-arm, multicentre registry that is designed to further validate the safety and efficacy of the Ultimaster drug-eluting stent (DES) (Terumo, Japan) in unselected patients enrolled worldwide. Currently, 34,538 patients (Japan cohort, n=910; non-Japan cohort, n=33,628) enrolled in the e-ULTIMASTER registry have completed 1-year follow-up. The primary endpoint was the cumulative 1-year incidence of target lesion failure (TLF), defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CDTLR). Compared with the non-Japan group, the Japan group had high-risk features such as advanced age, diabetes mellitus, renal failure, and prior percutaneous coronary intervention (69.6±9.9 vs 64.2±11.2 years; 43.9% vs 27.7%; 22.2% vs 6.5%; 41.9% vs 25.4%; p<0.001, respectively). The Japan group included predominantly patients with stable coronary artery disease (78.8%), whereas 55.9% of the non-Japan group presented with acute coronary syndrome (p<0.001). The Japan group had considerably greater lesion complexity such as bifurcation lesion, chronic total occlusion, and left main coronary artery lesion (23.4% vs 11.9%; 7.0% vs 5.0%; 7.8% vs 3.1%, all p<0.01, respectively). Several differences in procedural characteristics between both groups were also observed, e.g. intravascular ultrasound was much more frequently used in the Japan group than the non-Japan group (81.8% vs 2.2%, p<0.001). At 1-year, TLF rate was significantly higher in the Japan group than the non-Japan group, mainly driven by a higher rate of CDTLR (6.4% vs 3.0%; 4.8% vs 1.5%, p<0.001, respectively), although the rates of cardiac death and TV-MI were comparable between both groups (1.5% vs 1.2%, p=0.41; 0.8% vs 0.9%, p=0.74, respectively). The incidence of definite / probable stent thrombosis was also not different (0.33% vs 0.62%, p=0.27). Propensity score matching was performed to adjust for the differences in baseline characteristics between two groups, creating 692 matched pairs. After matching, clinical outcomes including TLF, cardiac death, TV-MI, CDTLR and ST were comparable between both groups (all p>0.05).

Conclusions: Several significant differences in baseline clinical features between the Japan and non-Japan cohorts were observed in the e-ULTIMASTER registry, being associated with the differences in health-care policies and standard of PCI procedures among countries. Despite these differences, both Japan and non-Japan cohorts yielded favourable 1-year clinical outcomes.

Bifurcation lesion - Tools, devices and techniques

Contemporary implantation of two different types of drug-eluting bifurcation dedicated stents in complex bifurcation stenosis: first experience

FOULADVAND Farhat [(1)], FOULADVAND Farhat [(1)], ZHEZHOVSKI Sashko [(1)], DIMITROV Nikolay [(1)], MAKSUDOV Oktaj [(1)], PENCHEV Plamen [(1)]

(1) Heart and Brain Center of Excelence, Burgas, Bulgaria

Aims: Though provisional stenting is preferred strategy for bifurcation stenosis, it is not rare for a two-stent strategy to be needed. Dedicated stents to treat the main branch (MBS) and others that protect the side branch (SBS) can offer better behaviour for the bifurcation side. We decided to adopt both types of dedicated stents to go through bifurcations, first to implant the dedicated SBS and after to fix the main branch with a second dedicated MBS. By this technique we attempt to have less metal at the carina side but still have easy access to the side branch.

Methods and results: From January 2018 to August 2019 we treated 14 patients with coronary bifurcations. Mean age 65±12 years with 11 males. All lesions were Medina 1,1,1 and by initial decision the strategy was to use two stents. In 9 patients IVUS was used as adjunctive diagnostic method at least at the end of the procedure and in 5 patients catheter based FFR was used during and the end of the procedure. Once the SB stent was positioned a POT was performed. Then a second dedicated stent (MBS) was positioned in the main vessel. Procedure was completed by POT, kissing balloon, and final POT. The procedure was mandatorily ended either by IVUS study or FFR measurement. One- and six-month clinical follow-up was planned as also was angiographic control at one year. Mean procedure time was 129,8±19,9 min and the mean X-ray time was 28.8±7.0 min. The mean amount of contrast medium was 104.9±22.6 ml. Mean number of coronary wires was 2.4±0.6; mean number of all type balloons was 5.7±1.2. Procedure success was achieved in all patients and device success was also 100 percent. We were able to position all SBS stents at first attempt. Repositioning of the wire from SB toward the MB didn't present any difficulties. All second dedicated MBS stents predilatation passed and were implanted with success. Final MB FFR was >0.94 and the SB FFR was >0.92. In the final IVUS assessment the probe easily passed in both MB and SB and the carina was well opened; also, both stents were well apposed to the vessel wall. All patients at first-month follow-up were free of symptoms. Up to the present time, 4 patients were studied at one-year follow-up and the angiographic results demonstrate lack of restenosis of both BM and SB for all 4.

Conclusions: Both of the dedicated stents used in our work demonstrate easy placement, particularly when all the steps of the bifurcation treatment procedure are respected. The combination of a dedicated side branch stent, especially if it is drug-eluting, and afterwards placing a dedicated MB stent, has the rationale of reducing the amount of metal at the carina site and to permit SB access during the procedure. This combination according to our experience is absolutely feasible without increasing the procedural risk of complication or increasing other procedural variables such as time or contrast medium.

STEMI - Tools, devices and techniques

Trends in AMI in young patients and the benefit of timely revascularisation: a single-centre study from India

SHARMA raghav [(1)], SHARMA Raghav [(1)], NARSIMHAN arvind yuvaraj [(1)], KUMAR N PRATHAP [(1)]

(1) Civil Hospital Ambala Cantt, Haryana, India

Aims: India is currently in the fourth stage of epidemiological transition where cardiovascular disease is the leading cause of mortality and morbidity. Myocardial infarction (MI) in the "young" is a significant problem. This study is planned to look at the profile and benefits of timely intervention in young patients presenting with ST elevated myocardial infarction STEMI.

Methods and results: Data of all patients admitted in the department of cardiology from December 2017 to September 2019 were evaluated. A total of 549 patient were admitted with ST-segment elevation acute myocardial infarction (STEMI) and taken for primary PCI with a door-to-needle time of less than 60 mins. All patients with non-ST elevated myocardial infarction (NSTEMI), unstable angina and post-thrombolysis were excluded from the study. Out of 549 STEMI patients, total of 91 patients had an age of less than 45 years and EKG documented STEMI. Subgroup analysis showed a mean age of 36.26 years with maximum age of 45 and minimum age of 21 years. Out of 91 patients, 84 were male and 7 were females. Risk factor were smoking (64.83%), systemic hypertension (38.46%), family history (1.09%), substance abuse (1.09%), stressful life (35.16%) and diabetes mellitus (15.3%). The most common symptom and presentation was chest pain and anterior wall myocardial infarction (46%) and inferior wall myocardial infarction (44%). All patients with obstructive CAD had single vessel disease (64.83%), double vessel disease (15.38%0, triple vessel disease (19.78%) and no left main involvement. 15.38% patient had SCAD. Left anterior descending (LAD) was commonest culprit artery (54.94%) followed by right coronary artery (25.27%). Successful primary PCI was performed in all patient with door to needle time less than 60 mins. There was no procedural complication, in hospital mortality or MACE in any of patient at 30 days of procedure.

Conclusions: Acute myocardial infarction in young adult occurred most commonly in males. Smoking was the most common risk factor. AWMI owing to LAD artery involvement was the most common presentation. Timely intervention plays a key role as it not only has shown favourable short term mortality benefit but also a long term morbidity and mortality benefit.

Stable CAD - Tools, devices and techniques, Other Coronary interventions - Calcified lesions

Comparison of intracoronary lithoplasty and rotablation for the treatment of severely calcified vessels: ROTA.shock trial

BLACHUTZIK Florian [(1)], BLACHUTZIK Florian [(1)], SCHLATTNER Sophia [(1)], HEYER Jannis [(1)], DOERR Oliver [(1)], BOEDER Niklas [(1)], WEISSNER Melissa [(1)], DAHMER Marko [(1)], BAYER Matthias [(1)], HAMM Christian [(1)], NEF Holger [(1)]

(1) Universitätsklinikum Gießen, Giessen, Germany

Aims: Intracoronary lithoplasty has been recently introduced in clinical practice and provides the unique possibility to fracture coronary calcifications also in deeper vessel layers. The aim of this ongoing study is to randomly compare the effects of rotablation and coronary lithoplasty on severely calcified coronary lesions using optical coherence tomography (OCT).

Methods and results: Coronary lithoplasty and rotablation were randomly performed in 5 patients with severe lesion calcification. Optical coherence tomography was performed pre-procedural as well as at the very end of the procedure to compare lumen/stent areas, plaque mass, and vessel wall configuration. Patient clinical data and procedural characteristics were collected additionally. The mean patient age was 79±8 years. All patients were symptomatic with stable angina. Target vessel was the left anterior descending (LAD) in 3 and the right coronary artery (RCA) in 2 patients. Minimal lumen area pre-procedural was 1.78±0.59 mm^2, mean lumen area pre-procedural was 4.97±1.88 mm^2. Mean plaque volume before interventional treatment was 19.53±8.44 mm^3 with an average angle of 149±63°. Mean and minimum stent area were larger after lithoplasty as compared to rotablation (11.43±2.73 mm^2 vs 8.51±2.07 mm^2 and 7.50±2.42 mm^2 vs 5.41±2.25 mm^2). Fractures of the calcified plaque reaching into the vessel media could be observed in all cases of lithoplasty, but in no case where rotablation was performed (2/2 vs 0/3). Mean lumen gain was larger after lithoplasty as after rotablation (6.93±3.49 mm^2 vs 4.02±4.18 mm^2). No differences regarding stent symmetry (eccentricity index after rotablation 0.65±0.18 vs lithoplasty 0.63±0.15) or strut malapposition (mean malapposition area 0.65±0.43 mm^2 vs 0.69±0.55 mm^2) could be observed when comparing rotablation and lithoplasty. There were no periprocedural adverse events.

Conclusions: Coronary lithoplasty is a promising treatment option for severely calcified coronary lesions and seems to be associated with a larger mean and minimum stent area as compared to rotablation. This might be caused by the induction of fractures of the calcified plaque in deeper vessel layers.

Stable CAD - Invasive imaging and functional assessment

Comparison of angiography-guided and stent-enhancement-guided PCI in routine clinical practice

BLACHUTZIK Florian [1], BLACHUTZIK Florian [1], SCHLATTNER Sophia [1], HEYER Jannis [1], WEISSNER Melissa [1], BOEDER Niklas [1], DÖRR Oliver [1], BAYER Matthias [1], DAHMER Marko [1], HAMM Christian [1], NEF Holger [1]

(1) Universitätsklinikum Gießen, Giessen, Germany

Aims: The aim of this ongoing study is to randomly compare angiography-guided and stent-enhancement-guided PCI using optical coherence tomography (OCT).

Methods and results: Angiography-guided and stent-enhancement-guided PCI were randomly performed in 8 patients with clinically relevant coronary stenoses and indication for interventional treatment. Optical coherence tomography (OCT) was performed at the end of the procedure to compare stent areas, overlap length, and vessel wall configuration. Patient clinical data and procedural characteristics were collected additionally. The mean patient age was 64±12 years. All patients were symptomatic with stable angina. Angiography-guided PCI was performed in 3, stent-enhancement-guided PCI was performed in 5 patients. Mean amount of contrast media, radiation dose, and procedure time did not differ between angiography- and stent-enhancement-guided PCI (198±95 ml vs 198±53 ml, p=0.98; 4771±977cGy*cm^2 vs 4200±896cGy*cm^2, p=0.43; 61±11 min vs 65±15 min, p=0.75). There were no significant differences regarding mean stent diameter and stent area as determined by OCT (angio: 2.17±0.52 mm vs stent-enhancement: 2.29±0.51 mm, p=0.76; angio: 6.23±1.36 mm^2 vs stent-enhancement: 6.3±2.68 mm^2, p=0.97). In 3 of 5 cases with stent-enhancement-guided PCI, additional post-dilatation was performed due to stent-underexpansion visualised by stent-enhancement technique. Sequential stent implantation was performed in 4 out of the 8 patients (2 angio-guided, 2 stent-enhancement-guided). OCT revealed a stent gap in both cases with angio-guidance, in both cases with stent enhancement performed, there was a short stent overlap as intended. There were no periprocedural adverse events.

Conclusions: The implementation of stent-enhancement-techniques in routine clinical practice may provide the opportunity to easily improve the procedural outcome of PCI and seems not to be associated with a higher contrast load, radiation dose or a longer procedure time as compared to classical angiographic PCI.

Stable CAD - Vascular access and bleeding, Other Coronary interventions - Other

Interim analysis of procedural and one-month follow-up of patients participating in a multicentre prospective prevalence study to hand dysfunction after distal radial artery access for coronary angiography or angioplasty

FORD Tom [1,8], FORD Tom [1,8], HARB Stefan [2], HASSAN Ahmed [3], IONESCU Eugenio [6], KOLIASTASIS Leonidas [4], ZAPPI Dimitri [5], NAVARRO Andres [7], RANKIN Stephen [8], KIEMENEIJ Ferdinand [9]

(1) Gosford Hospital, NSW, Australia; (2) LKH Graz, Graz, Austria; (3) Hospital St Jansdal, Harderwijk, the Netherlands; (4) Athens Naval and Veterans Hospital, Athens, Greece; (5) Hospital Dona Helena, Joinville, Brazil; (6) Clinica Cardiovascular del Caribe Carrera, Cordoba, Colombia; (7) ICBA Instituto Cardiovascular, Buenos Aires, Argentina; (8) ICAMS University of Glasgow Cardiovascular Research Centre, Glasgow, United Kingdom; (9) Tergooi - Blaricum, Blaricum, the Netherlands

Aims: To study the short- and long term effect of distal transradial artery access (dTRA) for coronary angiography (CAG) or intervention (PCI) on hand function. This is an interim analysis of the one-month follow-up of 129 out of 163 included patients.

Methods and results: Study design: This is a prospective non-randomised multicentre (n=7) prevalence study on hand dysfunction after dTRA for CAG and/or PCI. Hand function tests (Levine Katz [LK] and DASH questionnaires, pinch grip test and sensibility test with Semmes Weinstein filaments [SW]) are performed at baseline and at 1, 6 and 12 months. Secondary endpoints include procedural success rate, bleeding and haematoma, proximal and distal radial artery occlusion and many more. Study population: A total of 349 patients undergoing dTRA in experienced centres will be analysed. In order to compensate for loss of follow-up (FU) a total of 400 patients will be enrolled. Procedural results: From 7/8/2018 to 20/12/2019, 163 patients who underwent dTRA for CAG or PCI, were included. Of these, 112 were male (69%). Mean age was 63.8±13.3 years (range 42-90). Puncture success was achieved in 100% of patients. dTRA failed for other reasons in 6 patients (3.6%) of which 3 were due to severe proximal radial artery spasm. One patient (0.6%) developed an uneventful hand haematoma which required re-application of the haemostasis bandage. No access site bleeding other than prolonged oozing in 12 patients (7.3%) occurred, requiring repositioning of the haemostasis bandage. A 1-month follow-up (1mFU) was completed in 129 patients. Bleeding occurred in 5 patients (3.9%) (BARC 1, n=3; BARC 3, n=2, both not access related). Distal RAO was found in 1 patient (0.8%). Forearm RAO was not encountered. No individual significant decrease in reported disability, muscular strength and sensibility in the punctured hand was reported. No significant differences were found in DASH scores at baseline (10.75) and at 1-mo FU (11.5), in LK scores (1.32 and 1.30 respectively), in pinch grip tests (left hand 10.8 and 11.3 kg; right hand 11.4 and 11.9 kg respectively) and in SW test scores of the average filament weight (filament 1=0.07 gr; 2=0.4 gr, 3=2 gr, 4=4 gr, 5=300 gr) of 6 dorsal hand dermatomes (left hand 1.34 and 1.28; right hand 1.22 and 1.25 respectively).

Conclusions: This interim analysis shows that dTRA for CAG and/or PCI has a high success rate and is not associated with hand dysfunction and serious sequelae at one-month follow-up. The study will be completed to full enrolment and to one-year follow-up.

2020 PCR e-Course Coronary interventions

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Posters

CTO - Tools, devices and techniques

Mortality analysis in a series of 456 patients treated by coronary intervention of a CTO

SUBINAS Asier [1], SUBINAS Asier [1], RUMOROSO José Ramón [1], SADABA Mario [1], ROMERO Alaitz [1], CACICEDO Ángela [1], ORIA Garazi [1], ZUGAZABEITIA Germán [1], QUINTANA Olga [1], URKULLU Alazne [1], SALCEDO Alberto [1]

(1) Hospital Galdakao-Usansolo, Bilbao, Spain

Aims: There is little information on the causes of mortality in the series of patients undergoing an attempt of percutaneous coronary intervention on a chronic total occlusion. In fact, mortality outcomes substantially differ between clinical studies. Our study evaluates the outcome results of a single-centre CTO series on the long-term period, specifically focused on mortality analysis.

Methods and results: All patients undergoing an attempt of percutaneous coronary intervention on a CTO in our institution between 2002-2019 were prospectively included in registry. Clinical, angiographic and procedural data were collected. Through an exhaustive follow-up of all patients in the series, an analysis of mortality and its causes was performed. In the same way, a comparison was made between the successful revascularised group (n=367) and the failure group (n=89) in revascularisation. Kaplan–Meier survival curves were plotted, and the log-rank test was used for comparison between groups. The data were analysed using the statistical package SAS. A total of 466 CTOs (456 patients) were included. In 367 (80%) the procedure was successful. Median age was 63.2 years. Basal and angiographic features in both groups were similar. The follow-up rate was 99,8% and in-hospital mortality was 0.43%. After a median follow-up of 6.2 years (IQR 2.7-9.6) 99 deaths were registered from which 17,9% (67 cases) corresponded to the successful group and 35,5% (32 cases) to the failed group (p<0,01). Major adverse cardiac events and cardiac mortality in successful vs failed groups were 17,4% (64 cases) vs 34.1% (30 cases) (p<0,01) and 6,2% (23 cases) vs 20,5% (18 cases) (p<0,01) respectively. Kaplan-Meier curves at five years showed a higher cardiac death survival in the successful group (log rank= 0,005). Independent predictors of cardiac mortality were chronic renal failure (HR 5,01; 95% CI: 2,11-11,89; p<0,01), coronary three vessel disease (HR 3,63; 95% CI: 1,02-12,93; p<0,01) and procedural failure (HR 2,98; 95% CI: 1,23-7,22; p<0,01). Among the causes of non-cardiac mortality (58 cases), neoplasms were the most frequent cause (21 cases) followed by infectious or septic processes (12 cases). Among the neoplasms, those of digestive origin were the most frequent (8 cases) followed by those of pulmonary origin (5 cases).

Conclusions: We observed a significant reduction in the rate of cardiac mortality and total mortality in the group of patients successfully revascularised from a coronary total chronic occlusion. Furthermore, major adverse cardiac events were also significantly lower in the successful group. Among the causes of non-cardiac mortality, neoplasms were the most frequent cause.

Stents and scaffolds - Tools, devices and techniques

Clinical performance of a new ultrathin sirolimus stent in a real-world scenario (analysis from 790 consecutive patients)

FALCÃO Felipe [(1)], FALCÃO Felipe [(1)], CANTARELLI Fabiano [(1)], CANTARELLI Rodrigo [(1)], MOTA Flávio [(1)], NAVARRO Manuela [(1)], MOTA Henrique [(1)], SANTOS Martinelly [(1)], SANSÔNIO André [(1)], CAVALCANTI Daniel [(1)], OLIVEIRA Flávio [(1)]

(1) Hospital Dom Helder Câmara, State of Pernambuco, Brazil

Aims: The goal of this study was to evaluate the safety and performance of the Inspiron® coronary stent (Scitech Medical™, Goiás, Brazil). The Inspiron® sirolimus-eluting stent uses an ultrathin L-605 cobalt-chromium alloy with a 75µm strut thickness platform coated with an abluminal biodegradable polymer. The polymer is eliminated from the body through the tricarboxylic acid cycle in 6-9 months, releasing 80% of the drug within 30 days after its deployment.

Methods and results: This was a prospective, non-randomised, single-centre registry. To represent clinical practice, all patients and lesion were included in this registry. Clinical follow-ups were performed at six and twelve months. The endpoints were the occurrence of all-cause death, definite stent thrombosis, and new revascularisation. Were included 790 patients and 1067 lesions. The mean age was 60.42±14.94 years, 57% were male, and 74.7% presented with acute coronary syndrome. Diabetes mellitus was presented in 90.8% of patients, previous myocardial infarction, and previous coronary angioplasty in 17.9% and 11.3%, respectively. TIMI flow pre-procedural ≤ 2 was observed in 51.8% of patients. Direct stenting was possible in 33.9% of the lesions and the number of stents used per lesion was 1.29±0,57. The total stent length per lesion was 29.4±16.1. Angiographic success was achieved in 99.1%. The incidence of all-cause death was 11.5% (6.2% in-hospital and 5.3% in the follow-up) and definitive stent thrombosis was 0.2%. New revascularisation was performed in only 5.8% (restenosis: 2.2%; progression of disease in another lesion: 3.6%). Based on the multivariate regression analysis, only chronic renal failure was an independent predictor of adverse events (OR: 3.3; 95% CI:1.22-8.92).

Conclusions: The results of this registry demonstrate the safety and excellent performance of the Inspiron® stent in daily clinical practice with a low rate of adverse cardiac events.

NSTEMI - Tools, devices and techniques

Evaluation of the relationship of copeptin levels with clinical and angiographic scoring systems in unstable angina patients

DEVECI Onur Sinan [(1)], DEVECI Onur Sinan [(1)], OZMEN Caglar [(1)], KARAASLAN Muhammed Bugra [(1)], DENIZ Ali [(1)], KANADASI Mehmet [(1)], USAL Ayhan [(1)]

(1) Cukurova University Faculty of Medicine, Department of Cardiology, Adana, Turkey, Adana, Turkey

Aims: To identify the serum copeptin levels in patients diagnosed with UA and evaluate the relationship of these levels with the clinical and angiographic severity of patients.

Methods and results: Out of the 335 patients that were included at first; after exclusion, 200 patients who were diagnosed with UA and underwent coronary angiography (CAG) have been included in this study. Each patient underwent a clinical evaluation which included 12-lead ECG, echocardiographic evaluation and standard laboratory tests (blood count, sodium, potassium, creatinine, glomerular filtration rate, HbA1c, high sensitive Troponin-c level (hscTn), creatinine kinase myocardial bound (CK-MB) and copeptin levels) and GRACE 1.0 risk score calculation at the time of admission. hscTn and CK-MB levels have been re-evaluated at the 6th hour. SYNTAX score was calculated after CAG. Patients were divided into two groups according to their coronary angiography results and they have been categorised as patients with non-critical or normal coronary angiography (Group-1, n: 105) and patients with critical CAD (Group-2, n: 95). The rate of cases with a GRACE score higher than 140 in group-2 were significantly higher than Group 1 ($p<0.001$). The SYNTAX score and copeptin levels were significantly higher in the Group 2 than the Group 1 ($p<0.001$ for both data). When the correlation between serum copeptin levels and CAD severity was examined, a high level of positive correlation has been found between copeptin levels and SYNTAX scoring (Rho: 0.944 with Spearman correlation analysis and p value <0.001). When the serum copeptin level was determined as the threshold at 18 pmol/l as a predictor of high SYNTAX score, the diagnostic sensitivity has been found to be 98.9%, the specificity has been found to be 100%, the positive predictive value has been found to be 100%, the negative predictive value has been found to be 99.1%, and the area under the curve (AUC) has been found to be 1.0.

Conclusions: In conclusion, our study revealed that the intention of identifying high-risk patients among UA cases using both conventional scoring systems and the serum copeptin level could have beneficial effects to detect the right group of patients for an early invasive strategy.

Stents and scaffolds - Tools, devices and techniques

The impact of insulin treatment in a patient with diabetes mellitus on clinical outcome in the e-ULTIMASTER registry

INIGUEZ-ROMO Andres [(1)], INIGUEZ-ROMO Andres [(1)]

(1) Álvaro Cunqueiro Hospital, Vigo, Spain

Aims: Diabetes mellitus (DM) is common in patients with an indication for a coronary revascularisation and associated with a more complex coronary disease pattern and higher event rates. The aim of this study is to evaluate the impact of insulin treatment on the 1-year clinical event rates.

Methods and results: From the e-Ultimaster registry that enrolled 36,916 patients globally, a pre-specified subgroup analysis in patients with DM who completed the 1-year follow-up, was accomplished. Patients with DM were classified in insulin treated DM (ITDM) and non-insulin treated DM (NITDM). All received a thin strut cobalt chromium sirolimus-eluting Ultimaster stent with a bioresorbable polymer coating applied only on the abluminal side. The primary endpoint was target lesion failure (TLF) at 1-year defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent clinical events committee adjudicated all endpoint-related serious adverse events. To adjust for differences in baseline patient and lesion characteristics, a weighted propensity score analysis was performed. The ITDM group and the NITDM group included 2036 and 7667 patients, respectively. Mean age in ITDM vs NITDM was 64.8±10.8 vs 65.7±10.5 years (p<0.001), male gender was 67.9% vs 74.7% (p<0.001) and the indication for PCI was ACS in 48.9% vs 51.0 (p=0.09). A previous PCI was reported more frequently in ITDM group (34.4% and 30.4%; p=0.001). The number of treated lesions was slightly higher in the ITDM group (1.42±0.7 vs 1.40±0.7, p=0.03) and presence of multivessel disease was similar (52.2% vs 52.3%, p=0.91). Lesions in the ITDM group were more complex (type C lesions: 34.4 vs 29.4%; p<0.001) and radial access was used less in ITDM (69.2% vs 80.7%; p<0.001). The number of Ultimaster stents implanted per patient was 1.5±0.8 in both arms (p=0.67). The implanted total stent length was 33.5±22.1 mm and 31.5±21.7 mm (p=0.34). DAPT at 3 months was similar between the groups, while more patients in the ITDM group were still on DAPT at 1-year. Angina status at 1-year was similar between the 2 groups: no angina in 88.9% vs 89.7% (p=0.32) of patients. After propensity adjustment, the baseline patient and lesion characteristics of the 2 groups were well balanced. At 1-year, the propensity adjusted TLF rate was 5.5% vs 4.1% (p=0.008) for the ITDM and the NITDM group. Death was reported for 4.0% vs 3.0% (p=0.03) of the patients. The incidence of cardiac death was 2.8% vs 2.0% (p=0.04). An TV-MI occurred in 1.4% vs 1.0% (p=0.12). The CD-TLR rate was 2.6% vs 1.9% (p=0.03). A definite/probable stent thrombosis was reported for 1.0% vs 0.7% (p=0.15) of the patients.

Conclusions: Patients with diabetes mellitus on insulin treatment have a higher incidence of clinical events than patients with diabetes not treated with insulin. Requirement for insulin treatment represents a higher risks subset.

Stents and scaffolds - Invasive imaging and functional assessment

Impact of polymer differences on arterial healing one year after bioabsorbable-polymer and biodegradable-polymer DES implantation: high-resolution coronary angioscopy observations

NOJIMA Yuhei [(1)], ADACHI Hidenori [(1)], IHARA Madoka [(1)], KURIMOTO Tetsuya [(1)], OKAYAMA Keita [(2)], SAKATA Yasushi [(2)], NANTO Shinsuke [(1)]

(1) Nishinomiya Municipal Central Hospital, Nishinomiya, Japan; (2) Osaka University Graduate School of Medicine, Suita, Japan

Aims: A large meta-analysis comparing bioabsorbable-polymer drug-eluting stents (BA-DES) with biodegradable-polymer drug-eluting stents (BD-DES) demonstrated no significant superiority in clinical results, suggesting similar safety and efficacy. Currently, the advantages of BA-DES daily use versus BD-DES remain unknown. The aim of the present study was to assess the degree of arterial healing after BA-DES and BD-DES implantation using a high-resolution coronary angioscopy (CAS).

Methods and results: A total of 132 DES (61: BA-DES and 71: BD-DES) were prospectively observed on CAS 12±1 months after coronary intervention. Grade of neointimal coverage (NIC) over the stent was also assessed into 4 grades from 0 (no coverage) to 3 (complete coverage). Grade of yellow-coloured plaque (YCP) was also classified into 4 grades from 0 (white) to 3 (intensive yellow). High-grade YCP was defined as maximum grade ≥2. Moreover, the prevalence of high-grade YCP and the incidence of stent thrombosis were investigated. The dominant NIC grade revealed much higher in BA-DES than in BD-DES ($p<0.0001$). Also, BA-DES showed less NIC heterogeneity grades than BD-DES ($p=0.006$). The prevalence of high-grade YCP was less BA-DES than BD-DES (21% versus 41%, $p=0.024$). However, the incidence of thrombus demonstrated no significant difference ($p=0.27$). Multivariate analysis indicated that hypercholesterolaemia [odds ratio (OR), 3.17; 95% confidence interval (CI): 1.19-8.46, $p=0.021$], past history of myocardial infarction [OR, 4.33; 95% CI: 1.33-14.1, $p=0.015$], and the usage of BP-DES [OR, 0.37; 95% CI: 0.16-0.83, $p=0.018$] were independent predictors the prevalence of high-grade YCP.

Conclusions: Comparison with BD-DES, BA-DES revealed a higher dominant grade associated with less heterogeneity NIC and less prevalence of the high-grade YCP. BA is more suitable than BD in terms of optimal arterial healing after DES implantation.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Clinical outcomes after radial vs femoral access in female patients enrolled in the e-ULTIMASTER registry

MALIK Fazila [(1)], MALIK Fazila [(1)]

(1) National Heart Foundation Hospital & Research Institute, Dhaka, Bangladesh

Aims: Radial access (RA) is the preferred method for patients undergoing a PCI and is associated with a reduced bleeding and cardiac event rate. Despite the higher expected bleeding risk, female patients might be less likely to receive RA because of the smaller arterial diameter. However latest development of more optimised devices allows even patients with smaller radial arteries to be treated by radial access. The aim of this study is to compare frequency, clinical presentation and 1-year outcomes of female patients treated with RA versus femoral access (FA).

Methods and results: Female patients (n=8,101) from the e-Ultimaster registry enrolled from across the world were analysed according to the access site: RA (n=6,603, 81.5%) and a FA (n=1,498, 18.5%). All patients were treated with the Ultimaster stent. The primary endpoint was target lesion failure (TLF) at 1 year defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularisation (CD-TLR). An independent clinical events committee adjudicated all endpoint-related serious adverse events. Patients with RA were older (68.0±10.7 vs 67.3±11.2 years, p=0.03), but with lower prevalence of diabetes (29.7% vs 39.7%; p<0.001), renal impairment (7.0% vs 12.2%; p<0.001) and haemodialysis (0.5% vs 3.9%;p<0.001). A medical history of MI (16.9% vs 21.6%, p<0.0001). PCIs (21.0% vs 26.1%, p<0.001) and CABGs (3.0% vs 9.5%, p<0.0001) was also less common in the RA group. In the RA group, there were less type C (22.5% vs 31.7%, p<0.0001), ostial (6.0% vs 7.7%, p<0.01) and severely/moderately calcified lesions (18.6% vs 20.8%, p=0.03). Multivessel treatment (13.5% vs 22.7%, p<0.001) and the number of lesions treated per patient (1.4±0.7 vs 1.5±0.8; p<0.001) were performed less often in the RA group. The patients in RA group presented more frequently with ACS (56.7% vs 49.3%, p<0.001) and in particular with non-ST elevated MI (25.9% vs 19.0; p<0.001). At discharge, an access site vascular complication occurred less often in the RA group (1.5% vs 4.7%, p<0.001) with less prolonged bleedings (>30 min) at the puncture site (0.03% vs 0.2%, p=0.02). At 1-year 64% of patients in RA and 71% of patients in FA group were still on DAPT (p<0.001) and 89% of patients in both groups were free from angina. The TLF and TVF rates at 1-year were 2.8% vs 3.8% (p=0.05) and 3.1% vs 4.3% (p=0.03) for the RA and the FA group, respectively. There was no difference in incidence of any death (2.0% vs 2.6%; p=0.16); cardiac death (1.1% vs 1.7%; p=0.09) overall MI (1.0% vs 1.1%; p=0.68), TV-MI rate (0.8% vs 1.0%; p=0.43), TLR (1.4% vs 1.9%; p=0.10) or definite and probable stent thrombosis (0.4% vs 0.7%; p=0.11) in RA and FA groups respectively. After propensity score matching to adjust for baseline and procedural characteristics, the difference in access site vascular bleedings (1.4% vs 4.8%, p<0.001) and prolonged bleedings at the puncture site (0.03% vs 0.2%, p=0.04) in favour of the RA group remained. There were no statistically significant differences in TLF or its components at 1 year.

Conclusions: Radial access was used in most of the female patients who underwent PCI. Patients selected for radial access had less severe CAD, but more frequently acute coronary syndrome. Vascular access site complications and prolonged bleedings occurred less often with radial access.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Utility of coronary perfusion balloons for patients with ACS

SUZUKI Hitomi [1], HARADA Ken [1], MATSUNAGA Shun [1], HIGO Sayaka [1], TESHIMA Yuto [1], HARADA Kazuhiro [1], NAGAO Tomoyuki [1], SHINODA Norihiro [1], MARUI Nobuyuki [1], AMANO Tetsuya [3], MATSUBARA Tatsuaki [4], MUROHARA Toyoaki [2]

(1) Chūbu Rōsai Hospital, Aichi, Japan; (2) Nagoya University Hospital, Aichi, Japan; (3) Aichi Medical University, Aichi, Japan; (4) Aichi Gakuin University, School of Dentistry Hospital, Aichi, Japan

Aims: We evaluated the efficacy of using perfusion balloons with a longer inflation time for treating ACS patients.

Methods and results: We retrospectively examined the efficacy of using perfusion balloons in patients with ACS. From January 2016 to July 2018, 124 patients with ACS underwent PCI. Among them, 36 patients were treated using perfusion balloons; 30 had STEMI and 6 non-STEMI. The average onset-to-balloon time was 314±82 min. The reasons for using perfusion balloon were as follows: a large amount of thrombus formation (n=19), young patients for whom stenting was not recommended (n=10), risk for slow flow phenomenon due to large amounts of plaque (n=6), and one patient could not take antiplatelet agents. The appropriate balloon size was decided using intravascular ultrasound, and we used balloons that were the same or slightly smaller than the lesion vessel diameter. A distal protection device was used to treat one patient. If adequate vessel dilatation and good coronary blood flow were achieved, stents were not implanted. After one year, 35 patients underwent follow-up coronary angiography. Clinical characteristics are as follows: The mean age was 62±13 years and 34 patients (92 %) were male. Their average body mass index was 26±4.2 kg/m^2, and 23 patients (64 %) were current smokers. Their LDL cholesterol and haemoglobin A1c levels were 130±41 mg/dL and 6.6±1.6 %, respectively. The culprit vessel was the right coronary artery (RCA) in 18 cases, the left anterior descending (LAD) in 13 cases and the left circumflex (LCX) in 5 cases. We performed thrombus aspiration therapy in 26 patients (70 %) before dilatation using a perfusion balloon. Balloon sizes were 2.5 mm (n=2), 3.0 mm (n=22), 3.5 mm (n=7) and 4.0 mm (n=5), with an average of 3.2±0.4 mm. The average inflation pressure was 8.3±3.1 atm and the average inflation time was 256±146 s, which depended upon the patients' symptoms or electrocardiogram change. Coronary blood flows following PCI were as follows: TIMI flow grade 3 in 31 cases, TIMI grade 2 in 5 cases and TIMI grade 1 in 1 case. Of six patients who demonstrated the slow flow phenomenon, five required IABP support. Three patients developed the slow flow phenomenon after stent implantation and the other three patients were treated without stenting. Furthermore, 9 patients did not require stent placement at the primary PCI. Among them, 6 patients did not have target lesion restenosis at 1-year follow-up on coronary angiography. However, 2 patients underwent stent placement because residual thrombus was noted following IABP removal. In another case, RCA (#3) lesion was dilated by a 3.0 mm perfusion balloon; however, three months later the patient developed ACS and it was discovered that the same coronary segment was occluded. CABG surgery was performed because this patient had another CTO of LAD. Compared with stent-implanted patients, six patients who were treated without stenting used the same size balloon (3.3±0.5 mm vs 3.2±0.3 mm). However, they had higher inflation pressures (9.8±3.0 atm vs 7.7±2.5 atm) and longer inflation times (325±198 s vs 230±117 s) than those of stent-implanted patients. Three of the stent-implanted patients developed in-stent restenosis at 1-year follow-up and underwent DEB therapy.

Conclusions: We conclude that long inflation using perfusion balloons may be a valuable option for treating patients with ACS, especially in those for whom stent implantation is not recommended.

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Posters

NSTEMI - Tools, devices and techniques, Stable CAD - Tools, devices and techniques

Balloon-assisted tracking: a practical solution to avoid radial access failure due to difficult anatomical challenges

FELEKOS Ioannis [1], FELEKOS Ioannis [1], PAVLIDIS Antonios [2,3], HUSSAIN Rafaqat [1]

(1) Liverpool Heart and Chest Hospital, Liverpool, United Kingdom; (2) St Thomas' Hospital, London, United Kingdom; (3) Queen Elizabeth Hospital, London, United Kingdom

Aims: The balloon assisted tracking (BAT) technique is utilised to overcome various anatomical difficulties during radial procedures when standard measures fail. The aim of this study was to evaluate the efficacy and safety of the BAT technique in overcoming anatomical difficulties during radial coronary procedures.

Methods and results: We retrospectively reviewed 1,100 consecutive patients undergoing coronary procedures from the transradial approach (TRA) between May 2015 and May 2017. Anatomic variations and equipment used were recorded from procedure logs. Overall, 30 patients (2.7%) required the use of BAT. Mean age was 66.7 years, with a range from 48 to 90 years (53.3% female). Out of these 30 cases, 86.7% of the patients underwent percutaneous coronary intervention (PCI) while the remaining patients underwent coronary angiography alone. Acute coronary syndrome cases represented 63.3% of the cases whilst the remaining patients were elective procedures. Anatomical difficulties included severe, non-resolving radial spasm (66.6%), catheter induced radial or brachial perforation (16.6%), small calibre and/or diseased radial artery (10.0%), severe radial, branchial and/or subclavian tortuosity (3.0%) and radial loops (3.0%). Anatomical difficulties were overcome in all cases (100%). Coronary procedures were successfully completed in all 30 cases without the need for alternative arterial access. Mean added procedural time was 131 secs. There were no procedure-related complications.

Conclusions: Balloon assisted tracking is a highly successful and safe technique for overcoming fast the various anatomical complexities, which minimises the need for alternative arterial access. It can be applied both in elective and acute coronary interventions.

Other Coronary interventions - Other

Cardiovascular interventions live – education or show? Evaluation of professionals: perceptions of the LIVE study

NUNEZ GIL IVAN J [(1)], NUÑEZ GIL Ivan [(1)], ARANAZ Jesus [(2)], BAS Marian [(1)], FELTES Gisela [(1)], MACAYA Carlos [(1)], FERNANDEZ ORTIZ Antonio [(1)]

(1) Hospital Clínic San Carlos, Madrid, Spain; (2) Hospital Ramón y Cajal, Madrid, Spain

Aims: In recent years, we have witnessed an increase in the number of medical interventions performed live, generally, in the context of medical courses. Our goal is to know the opinion of the professionals involved regarding the safety and teaching value of this type of interventions.

Methods and results: We conducted a brief voluntary survey in electronic format, focusing mainly on the field of cardiovascular disease. It was simultaneously submitted to 360 professionals. We obtained 99 validated answers in one month (September-October 2019). 82.8% of the participants were male, mostly consultants (83.8%; residents / fellows 16.2%). Regarding the age profile, 26.3% of participants were between 25-35 years, 46.5% between 36-45 years and 27.3% were> 45 years. The participants were predominantly interventional cardiologists (60.6%), while 5.1% were electrophysiologists and 2% cardiac surgeons, from various countries in Europe, America and Asia. The average score recorded in respect to the educational value of live procedures performed in courses was 4.02±0.90 (1 = none, to 5 = essential). In relation to safety, the average score was 3.55±1.03 (1 = very insecure; 5 = as safe as a normal procedure).

Conclusions: In general, professionals consider courses with live procedures of great educational value and acceptably safe for the sick, but with a margin for improvement. In addition, the surveyed professionals were in agreement with the conception of these type of courses for medical training, but showed less acceptance of its use for the general population, suggesting other types of educational/promotional approaches.

Stable CAD - Vascular access and bleeding, Other Coronary interventions - Other

Angiographic features of distal radial artery

HYODO Yusuke [(1)], HYODO Yusuke [(1)]

(1) Kimitsu Chuo Hospital, Chiba, Japan

Aims: Distal radial artery (dRA) access for coronary catheterisation has been reported to be safe and useful. There aren't any data on angiographic features of dRA. The aim of this study was to clarify the angiographic features of dRA.

Methods and results: From August 2018 to November 2019, 173 patients underwent coronary angiography or angioplasty via dRA. In these patients, 126 patients could have had their angiographic data of dRA and conventional access point of the radial artery (cRA) evaluated. We divided these patients into 3 groups according to the feature of superficial palmar branch of radial artery (SPB). (Major group: The diameter of SPB is the same as the diameter of dRA or larger. Minor group: The diameter of SPB is smaller than the diameter of dRA. Absent group: SPB is absent.) We evaluated the incidence of each group, and compared the diameter ratio of dRA to cRA between 3 groups. The number of patients was 11 in the major group, 90 in the minor group and 25 in the absent group respectively. The mean diameter ratio of dRA to cRA of major group was significantly lower than the other groups. (0.82 vs 0.94 vs 0.93 $p<0.01$).

Conclusions: Angiography showed several types of SPB. The type of SPB may affect the diameter ratio of dRA to cRA.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Radial artery occlusion and compression time: is shorter better?

AHMAD Bassam [(1)], DE LABRIOLLE Axel [(1)], MOLINA Javier [(1)], DELORME Laurent [(1)], PETRONI Thibaut [(1)], ANDRE Romain [(1)], ANDRIOAIA Calin [(1)]

(1) Clinique du Pont de Chaume, Montauban, France

Aims: To compare the incidence of post-PTCA radial artery occlusion (RAO) and the safety of a new haemostatic bracelet with two different compression durations for the radial artery.

Methods and results: 231 consecutive post-PTCA patients were randomised 1:1 over 1 hour or 4-hour compression durations with a PreludeSync bracelet (Merit). RAO was defined as the absence of a Doppler flow signal performed 24 hours after the procedure. Statistical significance was defined as $p<0.05$. Results: All patients had a 6 Fr radial sheath inserted. No significant difference was observed between the compression duration of one hour (n=116) and 4 hours (n=115) in terms of demographic characteristics with the exception of sex (83/33 vs 96/19, p 0.03). There was no significant difference in the incidence of RAO between the groups at 24 h (3.4% vs 2.6%, p=0.71) and at 1 week (1.7% vs 2.6%, p=0.64). The bleeding rate was significantly higher in the "1h compression" group than in the "4h compression" group, (40.5% vs 20%, $p<0.001$).

Conclusions: The 1-hour and 4-hour compression durations do not show any significant differences between the groups with regard to the short-term incidence of RAO. The high bleeding rate in both the 1h group, and as well as the 4h group argues for offering compression time greater than 4 hours. Further work is needed to determine the optimal compression time for PreludeSync (Merit) bracelet.

Stable CAD - Vascular access and bleeding

One hour vs two hours haemostatic time for coronary angiography in the distal radial artery approach

SOICHIRO Washimi [(1)], MIZUGUCHI Yukio [(1)], YUKI Matshubara [(1)], YAMADA Takeshi [(1)], TANIGUCHI Norimasa [(1)], NKAJIMA Shunsuke [(1)], HATA Tetsuya [(1)], TAKAHASHI Akihiko [(1)]

(1) Sakurakai Takahashi Hospital, Kobe, Japan

Aims: The distal transradial approach (dTRA) is a newly developed technique results in fewer complications at the puncture site and greater comfort for patients compared with the conventional transradial approach. However, there is a paucity of data with the haemostatic method after sheath removal. The present study aimed to compare the rate of bleeding complications and patients' comfort between 1 and 2 hours haemostatic time after sheath removal in patients undergoing diagnostic coronary angiography (CAG) by dTRA.

Methods and results: Between March 2018 and November 2019, 315 patients who underwent CAG using a 4 Fr sheath system by single operator in our hospital were enrolled in the study. After procedure, continuous compression was performed using STEPTY™, a compression tape with a 6-mm-thick pad at the central portion, and the patient's arm was wrapped in an elastic bandage for 1 hour (1-hour group, n=83), or 2 hours (2-hours group, n=232) after CAG. We evaluated the bleeding complication and patients' compliant related to the puncture site, under these set time of compression in both groups. According to bleeding complication which had a need for re-compression, none of patient were observed in both groups. According to subcutaneous haemorrhage, 2 (2.4%) in the 1-hour group and 12 (5.2%) in the 2-hours group were observed (p=0.295). However, no major bleeding, clinically overt blood loss with decrease in haemoglobin >3 g/dl, occurred in both groups. According to the patients' pain compliant, 1 (1.2%) in the 1-hour group and 11 (4.7%) in the 2-hour group were observed (p=0.149). According to the numbness in the fingers during haemostasis, 3 (3.6%) in the 1-hour group and 26 (11.2%) in the 2-hours group were observed (p=0.040).

Conclusions: In the haemostasis of dTRA, 1 hour compression time was better than 2 hours compression time for diagnostic CAG using 4 Fr sheath system because of the higher comfort along with equivalent rates of bleeding complications as was demonstrated in this study

Stable CAD - Vascular access and bleeding

Distal radial artery approach to prevent radial artery occlusion

RIVERA Agustin [1], EID-LIDT Guering [1], RIVERA Agustin [1], JIMENEZ Joaquin [1], ESTRADA Kathia [1], GASPAR Jorge [1]

(1) Instituto Nacional de Cardiología Ignacio Chávez, CDMX, Mexico

Aims: The main complication of transradial intervention is radial artery occlusion (RAO). This is relevant because it limits the radial approach for future interventions and disables this conduit for coronary bypass grafts and arteriovenous fistula. Observational studies suggest that distal radial access could reduce RAO incidence. The primary endpoint of our study was to compare the efficacy of the distal and proximal transradial approaches in terms of RAO incidence. The safety endpoint was the incidence of complications between these two methods.

Methods and results: From May to December 2019, 205 consecutive patients at a single university centre (National Institute of Cardiology Ignacio Chavez) who underwent cardiac catheterisation and were suitable for both radial accesses, were randomised by 1:1 fashion to either distal radial artery approach (DR) (n=100) or proximal (conventional) radial artery approach (PR) (n=105). In both cases, a 20-gauge catheter needle with the through-and-through technique were used. Hydrophilic introducer sheaths were utilised in every case. The arterial access was obtained by interventional cardiology fellows with experience in proximal radial approach. Haemostasis was achieved with a pneumatic compression device (TR band, Terumo®; Japan) with patent haemostasis technique. The RAO was evaluated 24 hours after the procedure by ultrasound examination and was defined as the absence of both colour pattern and pulsed wave registry. There were no differences between baseline characteristics in both groups. The median transradial access time was 2.77 minutes (IQR 1.42 – 4.45 minutes) for DR and 1.32 (IQR 1.05 – 2.30 minutes) for PR ($p<0.01$). The primary endpoint was reached in 2.0% (n=2) and in 10.5% (n=11) in DR and PR groups respectively (p=0.013). The safety endpoint was reached in 10% (n=10) in the DR group and 9.5% (n=10) in the PR group (p=0.90), all of them were EASY < 1 haematoma.

Conclusions: The use of the distal radial artery approach significantly reduced the incidence of RAO at 24 hours confirmed by ultrasound with no differences in safety endpoints compared to proximal (conventional) approach but with longer time to access.

Other Coronary interventions - Other

Experience with Excimer laser in complex PCI in real practice

JURADO Alfonso [1], JURADO Alfonso [1], MARTÍN Lorena [1], RODRÍGUEZ Laura [1], GONZÁLVEZ Ariana [1], HERNÁNDEZ Harol [1], JIMÉNEZ-VALERO Santiago [1], GALEOTE Guillermo [1], MORENO Raúl [1], GONZÁLEZ Rosa [2], LÓPEZ SENDÓN José Luis [1]

(1) University Hospital La Paz, Madrid, Spain; (2) Infanta Cristina Hospital nursery, Parla, Spain

Aims: One of the devices we have available for complex percutaneous coronary intervention (PCI) is the coronary excimer laser (ELCA) which, by means of the emission of pulsed light waves, performs photoablation of atheromic plaque. This technology still has a low utilisation rate in our environment. We aim to present the experience with this technology at a high-volume centre for complex PCIs.

Methods and results: This was a retrospective observational analysis of patients who underwent PCI with ELCA. The baseline characteristics of the patients, the characteristics of the procedures and the presentation of adverse events at one year of follow-up were evaluated. Thirty-six patients were analysed (69.4±9.4 years; 88.9% male). 34.3% were diabetic. The average LVEF of 56.7±9%. Clinical presentation was stable coronary artery disease in 55.5% and NSTE-ACS in 44.4%. The treated vessel was the left main in 8.3%, left anterior descending in 30.5%, left circumflex in 16.6% and right coronary artery in 44.4% of cases. The procedure with ELCA was done on a scheduled basis in 86.1% and *ad hoc* in 13.9%, with radial/ulnar access in 41.7% and femoral in 58.3%. The indication for ELCA was severe calcification: 27.7%, uncrossable lesions: 13.8%, undilatable lesions: 2.7%, in-stent restenosis: 11.1% and a combination of the above in 41.6%. In 2 of the procedures, rotational atherectomy was associated. A 0.9 mm catheter was used in 84.4% and a 1.4 mm catheter in 15.6%. The average frequency used was 69.1±15 Hz (although 80 Hz was the most common). The average energy applied was 71±12 J/mm^2 (although the most used was 80 J/mm^2) and the average number of pulses of 5037±3301. The laser catheter was able to cross the lesion without predilating in 81.6% of the cases. After the laser application, the lesion was post-dilated in 85% of the cases, achieving an adequate expansion of the balloon in 85.3%. Angiographic success was 98.4%. There were only three complications of the procedure, 2 minor vascular ones due to femoral access and a coronary perforation solved with prolonged inflation and implantation of a DES. At one year of follow-up, there was no cardiac death, infarction related to the procedure or stent thrombosis. Two patients presented a need for revascularisation of the treated lesion.

Conclusions: ELCA therapy is used in complex lesions, almost a third of them with severe calcification. In 41.6% of cases, several of the classic indications of ELCA coexist. After the use of ELCA, a procedure success rate of 98.4% is achieved with also good results after one year of follow-up.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Can on admission serum cortisol level be a predicator of coronary artery lesion complexity in patients diagnosed with ACS?

BRAUKYLIENE Rima [(1)], ALDUJELI Ali [(1)], KRIVICKAS Zilvinas [(1)], BRAUKYLIENE RIMA [(1)], SUKYS Marius [(1)], JURENAS Martynas [(1)], UNIKAS Ramunas [(1)], GUSTIENE Olivija [(1)], BAKSYTE Giedre [(1)], ZALIADUONYTE Diana [(1)]

(1) Lithuanian University of Health Sciences, Kaunas, Lithuania

Aims: Numerous laboratory tests have been proposed to predict the complexity of coronary artery lesions in myocardial infarction. Serum cortisol is one such laboratory marker and SYNTAX I is one of the most proven grading scores used to evaluate the complexity of coronary artery disease (CAD). No data are currently available on the impact of serum cortisol levels on SYNTAX score. The aim of this study was to discover the interdependence between plasma cortisol levels and SYNTAX I score in patient diagnosed with ACS.

Methods and results: This prospective study included 94 patients diagnosed with ACS and underwent primary percutaneous intervention (PPCI) between May 2018 and November 2018. The plasma cortisol level was measured on admission in all selected patients. Study endpoints were defined as major adverse cardiac events (MACE) and all-cause mortality at in-hospital, and 24-month follow-up. The mean age of the patients was 63.9±11,6 years and 65% were males. There was a positive correlation between cortisol level and SYNTAX I score (Spearman test r = 0.202; $p<0.05$). Plasma cortisol level tended to be higher in STEMI vs NSTEMI (Mean value 803.42 nmol/l±354 vs 566.95 nmol/l±279); a significant difference was found using Mann-Whitney U test ($p=0.007$). A total of 10 deaths (7.9% of the total population) were registered during follow-up. Our results revealed that short-term and long-term mortality was associated with plasma cortisol level (Mann-Whitney U test $p=0.039$).

Conclusions: Our study reveals a significant interdependence between plasma cortisol level and SYNTAX I score.

Stents and scaffolds - Tools, devices and techniques

Very long-term results of 4Ps BRS implant in a real-world setting: the REABSORBS registry (REgistro ABSORB Sanremo)

LEONCINI Massimo [1], LEONCINI Massimo [1], RAPETTO Claudio [1], SCARDALA Raffaele [1]

(1) SSD Cardiologia Interventistica - Sanremo Hospital, Sanremo, Italy

Aims: Evaluating very long-term outcomes of Patient Selection-Predilation-Proper Sizing-Postdilation (4Ps) technique-implanted everolimus-eluted BRS Absorb in a real-world setting.

Methods and results: This registry included all consecutive patients (pt) treated with BRS in our cath lab between December 2012 and March 2017. Registered endpoints are: cardiac death (CD), target vessel myocardial infarction (TV-MI), scaffold thrombosis (ScT), target vessel revascularisation (TVR), target vessel failure (TVF), ischaemia-driven target lesion revascularisation (ID-TLR), angiographic success (AS) defined as: successful BRS deployment, residual stenosis (RS) < 30%, final TIMI 3 flow. 220 pt (58.6±9.5 years; male 85.5%; diabetics 15.9%) were enrolled, 253 PCI were performed (90.5% radial) on 321 lesions and 376 BRS were implanted. 166 PCI (65.6%) were performed in STEMI, NSTEMI or UA. Stenoses were mainly on LAD (168, 52.3%); 210 lesions (65.4%) were Ellis type B2-C; in particular 100 (31.2%) were soft plaques with thrombus and only 16 (5.0%) stenoses were calcific but none were severe. 187 pt (85%) were on DAPT with new P2Y12 inhibitors. Preprocedural QCA showed an 83.7±15.2% diameter and 21.6±11.3 mm length stenosis and a 2.89±0.41 mm reference vessel diameter. Predilation with non-compliant balloon (NCB) at 19.6±3.8 atm was performed in 366 cases (97.3%) with balloon-artery ratio 1:1 in 282 (77%). After careful sizing BRS was released at 12.9±2.7 atm; BRS length per vessel was 32.7±18 mm; marker-to-marker BRS overlap was present in 84 PCI (22.3%), a DES-BRS overlap in 47 (18.7%). 17 PCI (6.7%) were IVUS or OCT-guided. Post-dilation with NCB at 21.8±4.2 atm was performed in 376 cases (100%), NCB was 0.5 mm oversized in 156 (41.5%). At QCA no RS was >30%; there were 3 final TIMI flow < 3 (all in STEMI pts) and 1 BRS implant failure, leading to a 98.9% AS. At a median follow-up (FU) of 1520 days (interquartile range 1295-1887) in the overall cohort we had 3 CD (1.4%, 2 for heart failure, 1 sudden death at 32 month), 7 TV-MI (3.2%), 21 TVF (9.5%), 17 TVR (7.7%), 11 ID-TLR (5.0%), 10 restenosis (4.5%), 2 very late definite ScT (0.9%) causing NSTEMI, 1 very late possible ScT (0.5%) referred to the sudden death episode. One ScT of a 2.5x28 mm BRS occurred at 20 months FU (reference vessel diameter RVD 2.4 mm, final minimum lumen diameter, MLD 2.1 mm), the other ScT of a 2.5x23 mm BRS occurred at 15 months FU (RVD 2.3 mm, final MLD 2.2 mm); DAPT was interrupted respectively at 4 months and 1 week before events.

Conclusions: In our experience, with the limitations of a single-centre registry, Absorb 4Ps implants in a population with complex but non-calcified lesions, and with a large presence of soft plaque, seems to have a good AS and a low rate of events at a median FU of 51 months. Extra caution should be taken when dealing with 2.5 mm diameter BRS implanted in small vessels.

CTO - Invasive imaging and functional assessment

Recovery of absolute coronary blood flow and microvascular resistance after CTO percutaneous intervention

KEULARDS danielle [1], KEULARDS Danielle [1], KARAMASIS Grigoris [3], ALSANJARI Osama [3], DEMANDT Jesse [1], VAN 'T VEER Marcel [1], ZELIS Jo [1], DELLO Simon [1], EL FARISSI Mohamed [2], KONSTANTINOU Klio [3], TEEUWEN Koen [1]

(1) Catharina Ziekenhuis Eindhoven, Eindhoven, the Netherlands; (2) Basildon University Hospital, Basildon, United Kingdom; (3) Essex Cardiothoracic Centre, Basildon, United Kingdom

Aims: This study aimed to investigate longitudinal physiological changes in the recanalised coronary CTO vessel and its dependent myocardium after successful percutaneous coronary intervention (PCI).

Methods and results: In this pilot study, 25 patients, scheduled for elective CTO PCI with viable myocardium and angiographically visible collaterals were included. Absolute coronary blood flow and absolute microvascular resistance were measured invasively using continuous thermodilution. Measurements were performed immediately after successful CTO PCI and at short-term follow-up. In a subgroup of patients, physiological measurements were performed at the predominant donor vessel before CTO PCI, immediately afterwards and at follow-up. Results: Absolute coronary blood flow in the recanalised CTO artery increased from 148±53 ml/min immediately after PCI to 221±77 ml/min at follow-up ($p<0.001$). In agreement, absolute resistance in the myocardial territory perfused by the CTO artery, decreased from 545±255 WU immediately after the procedure to 387±128 WU at follow-up ($p=0.014$). There were no significant changes in the absolute coronary blood flow and resistance in the predominant donor between baseline and follow-up. Positive remodelling of the distal CTO vessel with an increase in lumen diameter was observed.

Conclusions: After successful CTO PCI, blood flow in the recanalised artery and microvascular function of the dependent myocardium are not immediately normal but recover over time.

Other Coronary interventions - Other

The prevalence of risk factors and pattern of obstructive coronary artery disease in young Indian females (below 45 years of age) undergoing PCI: a multicentre experience

JARIWALA Pankaj [(1)], JARIWALA Pankaj [(1)], PATIL Rahul [(1)], CHAWLA Kamaldeep [(1)]

(1) Yashoda Hospitals - Somajiguda, Telangana, India

Aims: Cardiovascular diseases (CVD) have become the most imperative causes of mortality and morbidity in developing countries like India. Moreover, the presence of obstructive CAD in young women is usually neglected, due to the notion that women are at very low risk of developing CAD at a young age. In a retrospective analysis, we aimed to study the prevalence of risk factors and patterns of obstructive coronary artery disease in Indian females less than 45 years of age among those who underwent percutaneous coronary intervention (PCI).

Methods and results: This was a retrospective, observational, multicentre study of young Indian females (< 45 yrs) who underwent PCI as per guidelines at three high volume centres in India. The study evaluated the prevalence of risk factors, clinical and angiographic pattern of obstructive CAD in young Indian women. Of 3,656 patients, young females constituted 3.1% of PCIs of those who presented with obstructive coronary artery disease. Hypertension and diabetes were the most common risk factors in 43.4% of these young females. The acute coronary syndrome was the most common clinical presentation. ST-segment elevation myocardial infarction (STEMI) was seen in 51.3% of cases. Single vessel disease was common with left anterior descending artery involvement as the most common angiographic feature either as a single or double vessel disease.

Conclusions: Coronary artery disease is not uncommon in young Indian females. Preventive measures should be taken and regular screening should be made for obstructive CAD, particularly in those with symptoms and risk factors.

Stable CAD - Invasive imaging and functional assessment

Saline-induced hyperaemia to assess FFR

IZAGA-TORRALBA Elena [1], GUTIERREZ Alejandro [1], IZAGA-TORRALBA Elena [1], RIVERO Fernando [2], GOMEZ-LARA Josep [3], ALFONSO Fernando [2]

(1) Hospital Universitario Puerta del Mar, Cádiz, Spain; (2) Hospital de La Princesa, Madrid, Spain; (3) Bellvitge University Hospital, L'Hospitalet de Llobregat, Spain

Aims: A new method based on the principle of thermodilution has been validated to quantify volumetric coronary absolute flow. This technique requires an intracoronary infusion of saline at room temperature through a dedicated catheter which induces steady-state maximal hyperaemia at a flow rate ≥15 mL/min. Our aim was to compare FFR using intracoronary saline infusion (FFRsaline) to conventional FFR with adenosine (FFRadenosine).

Methods and results: In 118 patients with suspected coronary disease in three centres, FFRsaline and FFRadenosine were measured. Intracoronary infusion of saline was set at a mean flow rate of 18.9±1 (18-20 ml/min) and endo-venous infusion of adenosine was set at a mean rate of 165 (150-180 mcg/kg/min). The mean value of FFRsaline was 0.89±0.07 and FFRadenosine was 0.90±0.05. The mean difference between both methods was 0.03±0.03 that can be attributed to the microcatheter effect on the coronary flow. The mean differences were significant lower in the left anterior descending (LAD) (p=0.02) and showed a non-significant tendency to be lower in vessels with a normal FFR (>0.8) (p=0.055). The ROC curves for FFRsaline showed an excellent AUC. Using a FFRadenosine ≤0.80, the AUC was 0.9 (95% CI: 0.76 – 1) and using a FFRadenosine ≤0.75 was 0.98 (95% CI: 0.98 – 1). FFRsaline and FFRadenosine showed a good correlation (r=0.73). Considering a cutoff value of 0.8, both methods were concordant in 110/118 cases (93%) and when using a cutoff value of 0.75 the concordant was even higher 116/118 cases (98%). When FFRsaline was negative (FFR>0.8) all but two cases were also negative according to FFRadenosine and when using a cutoff value of 0.75 all the cases (100%) with negative FFRsaline had also a negative FFRadenosine.

Conclusions: Despite the effect of microcatheter on coronary flow, FFRsaline showed a good concordance with FFRadenosine. FFRsaline could be a useful alternative to defer coronary lesions.

Stents and scaffolds - Adjunctive pharmacotherapy

The possible role of colchicine in preventing contrast-induced acute kidney injury in patients undergoing elective PCI

OKTAY Veysel [(1)], JAFAROV Urfan [(1)], CIRALI Ilknur Calpar [(1)], SARILAR Mert [(1)], MIRZAYEV Khayel [(1)], JAFAROV Urfan [(1)], ABACI Okay [(1)]

(1) İstanbul Üniversitesi - Cerrahpaşa Kardiyoloji Enstitüsü, Istanbul, Turkey

Aims: Contrast-induced acute kidney injury (CI-AKI) is a serious complication of percutaneous coronary interventions (PCI) and is associated with increased morbidity and mortality. The aim of this study was to investigate the preventive role of colchicine on CI-AKI in patients undergoing elective PCI considering to its anti-inflammatory and renoprotective effects.

Methods and results: This study was designed as a single-centre, randomised and open-label study including 280 patients undergoing elective PCI with an estimated glomerular filtration rate (eGFR) of > 45 mL/min/1.73 m^2. 140 patients were randomised to the colchicine treatment group (mean age, 60+9 years), whereas 140 patients were randomised to the control group (mean age, 61+7 years). CI-AKI was defined as either a 50% relative increase in serum creatinine levels from the baseline or a 0.3 mg/dL increase in the absolute value that measured 48 hours after PCI. Colchicine treatment was started 24 hours before the PCI and continued 48 hours after PCI. Logistic regression analysis was performed to identify the independent predictors of CI-AKI. CI-AKI was occurred in 6 of the 140 patients (4%) in the colchicine group and in 13 of the 140 patients (9%) in the control group (odds ratio OR, 0.42; 95 confidence interval CI, 0.20 to 0.82; p=0.02). In patients under colchicine treatment, the rate of eGFR reduction after PCI was significantly lower than in that in those not under colchicine treatment (69+13 vs 66+15, p=0.227; 72+11 vs 63+13 p<0.001). In logistic regression analysis, age (OR=1.3, 95% CI: 1.1-1.6, p=0.005), diabetes mellitus (OR=2.24 95% CI: 1.17-3.31, p<0.001) and colchicine treatment (OR=0.84 95% CI: 0.72-0.98, p=0.020) were independent predictors of CI-AKI.

Conclusions: Prophylactic oral administration of colchicine may protect against CI-AKI in patients undergoing elective PCI with mildly or moderately decreased eGFR values.

Stable CAD - Vascular access and bleeding

Comparison of transradial vs transfemoral diagnostic coronary angiography in terms of oxidative stress: which one is more physiological?

OKTAY Veysel [1], KESKIN Bengisu [1], SERIN Ebru [1], OKSEN Dogac [1], OZKAN Alev Arat [1]

(1) Istanbul Üniversitesi - Cerrahpaşa Kardiyoloji Enstitüsü, Istanbul, Turkey

Aims: Oxidative stress during diagnostic procedures is an important factor for the development of many complications. In this study, we aimed to compare the oxidative response in patients undergoing diagnostic transradial or transfemoral coronary angiography.

Methods and results: In this prospective, single-centre study we randomised 60 patients with stable angina pectoris undergoing diagnostic heart catheterisation to either transradial (n=30) or transfemoral (n=30) approach. The levels of plasma total oxidative status (TOS) were measured just before and after the procedure. The clinical and laboratory findings were compatible between the two groups. In patients undergoing transradial coronary angiography, the percentage of patients with normal coronary arteries was significantly higher than the patients undergoing transfemoral coronary angiography (66% vs 25% p=0.006). Although the levels of plasma TOS after coronary angiography were increased in both groups, this was more pronounced in transfemoral group as compared with the transradial group (20+18; 34+21 vs 18+10; 23+11 p<0.001).

Conclusions: In this study, we showed that the oxidative stress response associated with diagnostic heart catheterisation is more evident in patients undergoing transfemoral coronary angiography.

Other Coronary interventions - Other

Comparison of traditional vs artificial intelligence-based coronary artery disease risk prediction scores in young patients with ACS

VOHRA Shweta [1], VOHRA Shweta [1], SETHI Rishi [1], RAO J Shiv Kumar [2], S Ramakrishnan [AIIMS Hospital], KAR Sujoy [2], GUPTA Prashant [Microsoft India Development Centre], SHARMA Prachi [1], PRADHAN Akshyaya [1], VISHWAKARMA Pravesh [1], BHANDARI Monika [1], NARAIN Varun Shankar [1], CHANDRA Sharad [1], DWIVEDI Sudhanshu [1], CHAUDHARY Gaurav [1], SHARMA Akhil [1]

(1) King George's Medical University, Uttar Pradesh, India; (2) Apollo Hospitals, Hyderabad, India

Aims: To compare artificial intelligence (AI) based novel risk score with traditional risk scores in young (less than 40 years age) patients presenting with acute coronary syndrome and to estimate the relative efficacy of different coronary artery disease (CAD) risk scores in young Indian patients.

Methods and results: 314 young patients (mean age 36.14 years) presenting with acute coronary syndrome (ACS) were enrolled. The three clinically most pertinent risk assessment models (Framingham Risk score [FRS], World Health Organisation risk prediction charts [WHO/ISH], and QRISK3 scores) and AI-based novel risk score (AICVD) were applied on day 1 of the presentation, and we attempted to see whether there was one risk score versus any of the other risk scores that could have predicted the event earlier if it had been applied before the occurrence of the acute coronary syndrome. WHO/ISH provided the lowest high-risk estimate with only 1 (0.9%) patient estimated to be having >20% 10-year risk. The FRS estimated high-risk (>20% 10-year risk) in 3 (1%) patient. The QRISK3 estimated high-risk (>10% 10-year risk) in 20 (6.5%) patients. In comparison, the AICVD risk prediction model stood tall above the others by identifying 73 (23.2%) patients as having a high-risk of CV events at 7 years ($p<0.001$).

Conclusions: This is perhaps the first study which has compared artificial intelligence based novel risk prediction models with the three most commonly applied models in young Indian patients. We found that a cohort of young Indian patients presenting with ACS, when studied retrospectively, were identified as "high-risk" more often by the AICVD risk prediction model than their traditional counterparts. The WHO/ISH risk prediction charts and FRS were the poorest predictors. Performance of QRISK3 score also remained less than satisfactory. These findings suggest that the AICVD risk prediction model is a promising tool to assess CV risk in the Indian population.

NSTEMI - Adjunctive pharmacotherapy

The effect of high-dose vs low-dose intensive statins in patients with non-ST segment elevation ACS: insight from a multicentre clinical cohort

CHEN Pengyuan [1], CHEN Pengyuan [1], LIU Yuanhui [2], FAN Hualin [3], ZENG Lihuan [3], HE Pengcheng [2]

(1) Guangdong General Hospital's Nanhai Hospital, Foshan, China; (2) Guangdong Cardiovascular Institute, Guangzhou, China; (3) South China University of Technology, Guangdong, China; (4) Southern Medical University, Guangdong, China

Aims: Intensive statin use remains a standard treatment in acute coronary syndrome (ACS) patients. However, the initial dose of statins has always been debated. The aim of current study is to determine the association between different dosages of in-hospital statin therapy and prognosis in patients receiving percutaneous coronary intervention (PCI).

Methods and results: Non–ST-segment elevation ACS patients were retrospectively enrolled from January 2010 to December 2014 from five centres in China. Patients who received atorvastatin or rosuvastatin during hospitalisation were included. All patients were categorised as high-dose (atorvastatin 40 mg or rosuvastatin 20 mg) or low-dose (atorvastatin 20 mg or rosuvastatin 10 mg) statin group. The in-hospital all-cause death was the primary outcome. The long-term all-cause death was recorded. Of 7,008 patients included, 5,248 received low-dose intensive statin therapy (mean age: 64.28±10.39; female: 25.2%); 1,760 high-dose intensive statin therapy (mean age: 63.68±10.59; female: 23.1%). there was no significant difference of in-hospital all-cause death between the two groups (adjusted OR, 1.27; p=0.665). the prognosis was similar between the two groups during long-term follow-up (30-day, adjusted HR, 1.28; p=0.571; 3-year, adjusted HR, 0.83; p=0.082). But there is a robust association between the high-dose statin and reduction of in-hospital dialysis (adjusted OR, 0.11; p=0.030). The primary analyses were confirmed by subgroup analyses.

Conclusions: For NSTE-ACS patients who received revascularisation, an in-hospital high-dose intensive statin regimen is not associated with lower risk of in-hospital and follow-up all-cause death. Considering a robust beneficial effect of high-dose intensive statin with in-hospital dialysis, an individualised high-dose intensive statin strategy should be the rational in a specific population.

NSTEMI - Invasive imaging and functional assessment, Stable CAD - Invasive imaging and functional assessment

Coronary plaque tissue characterisation in patients with premature coronary artery disease

XIE Jianchang [(1)], XIE Jianchang [(1)], HUANG Jinyu [(1)]

(1) Hangzhou First People's Hospital, Zhejiang, China

Aims: Premature coronary artery disease (CAD) studies rarely involves coronary plaque characterisation. We characterise coronary plaque tissue by radiofrequency intravascular ultrasound (IVUS) in patients with premature CAD.

Methods and results: From July 2015 to December 2017, 220 patients from the Department of Cardiology, Affiliated Hangzhou First People's Hospital, Zhejiang University School of Medicine with first occurrence of angina or myocardial infarction within 3 months were enrolled. Patients with premature CAD (n=47). The mean age was 53.53±7.24 vs 70.48±8.74 years.

Conclusions: Coronary plaque tissue was more fibrotic with less necrotic and calcified components in premature CAD than in later CAD, and the range and degree of atherosclerosis were significantly lower.

Stents and scaffolds - Tools, devices and techniques

One-year clinical results of real-life registry of Angiolite cobalt-chromium sirolimus-eluting stent (RANGO registry)

PEREZ DE PRADO Armando [(1)], PEREZ DE PRADO Armando [(1)]

(1) Hospital Universitario de León, León, Spain; (2) Vall d'Hebron University Hospital, Barcelona, Spain

Aims: After the positive pre-clinical, and initial angiographic and clinical results (FIH study, ANCHOR NCT02776267; RCT, Angiolite vs XIENCE NCT03049657) with Angiolite, a CoCr-SES, we decided to analyse the results in a non-selected, real-world population. The primary objective of this registry was ¬the occurrence of TLF as a composite of cardiac death, target vessel related MI or clinically-driven TLR at 6, 12 and 24 months. Secondary endpoints were the individual components of the primary objective, MACE (all-cause death, any MI or any revascularisation), and stent thrombosis.

Methods and results: We have conducted an observational, prospective, multicentric registry in patients with different clinical indications. All consecutive patients who underwent a PCI with the use of at least one Angiolite stent and who gave informed consent were included from 17 centres from July 2017 to June 2018. The exclusion criteria were absolute contraindication for DAPT, cardiogenic shock, high probability of missing follow-up visits, and refusal to participate in the study. We here report the 1-year clinical results of the Rango that finally included 654 patients. The population included a broad spectrum of patients, with a higher risk profile than the patients who received Angiolite stent in the RCT, being slightly but significantly older (mean age 66±12 vs 62±10, p=0.002), with a higher prevalence of previous MI (18.4% vs 7.3%), previous PCI / CABG (21.6% vs 10.9%), and multivessel disease (48.1% vs 22.7%); all p<0.05. Another relevant difference between the registry and the RCT population was the clinical indications: 23.1% of the registry patients have STEMI as the indication for the PCI as compared with only 10.9% of the Angiolite RCT patients (p=0.004). At 1 year, TLF occurred in 10 patients (1.53%): there were 2 cardiac deaths, 8 clinically driven TLRs (5 of them after target vessel related MI) and 7 target vessel-related MIs (2 of them died as a result). One-year MACE occurred in 32 patients (4.89%), with 7 total deaths, 14 MIs of any type and 22 new revascularisation procedures. Stent thrombosis was detected in 5 cases (0.61%): 2 acute, 1 subacute, and 1 probable late stent thrombosis.

Conclusions: The one-year results of this real-world registry demonstrated the high efficacy and safety profile of the CoCr-SES Angiolite, even in high risk populations.

Stable CAD - Tools, devices and techniques

Radial Cradle, a wearable arm support device for radial access procedures, helps reduce first operator radiation dose

KHIALANI Bharat [(1)], HOOLE Stephen [(1)], KHIALANI Bharat [(1)], KYRANIS Stephen [(1)], LAMBERT Ben [(1)]

(1) Royal Papworth Hospital NHS Foundation Trust, Cambridge, United Kingdom

Aims: Radial access procedures are associated with higher first operator radiation doses which can be deleterious e.g. cataracts. Right radial access in particular results in higher eye doses due to suboptimal positioning of personal protection equipment (PPE) when the arm is abducted on arm boards. This can be corrected by moving the arm medially. Radial Cradle™ passively supports the arm in a medial, ergonomic orientation enabling better PPE (table lead under-skirt deployment and lead Perspex screen more medial). We sought to confirm if this device would lower first operator radiation doses.

Methods and results: Fifty consecutive right radial access percutaneous coronary interventions - PCI (26 using Radial Cradle™ (RC) and 24 using arm board (AB)) had fluoroscopic and cine image guidance in standard views acquired at 15 frames per second in low dose mode using a Philips Azurion. PPE was positioned as per standard practice by the operator. Insta-dose badges provided by the same vendor were worn at the left collar of the first operator to provide first operator effective dose (uSv) per procedure. The normalised effective dose was calculated by dividing the effective dose by the dose area product (DAP - $Gy.cm^2$) delivered to the patient. Historic average first operator effective and normalised dose for the preceding month (45 cases) using arm boards were also compared to account for any Hawthorn effect – a change in radiation awareness behaviour and operator dose as result of being observed. Positioning the right arm medially using Radial Cradle™ significantly reduced first operator mean effective and normalised effective doses when compared with arm boards (RC: 5.6±12.5 vs AB: 23.6±34.8 uSv, p=0.004 and RC: 0.20±0.39 vs AB: 0.91±1.71 $uSv/Gy.cm^2$, p=0.007 respectively). This equated to an important 76.3% reduction in mean effective first operator dose and 78.3% reduction in mean normalised dose. The first operator Insta-dose recording was undetectable in 10/26 (38.5%) of PCI cases using Radial Cradle™. The table lead under-skirt PPE was deployed in 100% of Radial Cradle™ cases, but was obstructed by the use of the arm boards and remained undeployed in all arm board cases. The lead Perspex screen PPE was used in all cases. Historic mean effective and normalised effective doses using arm boards were higher than arm board doses observed in the trial (30.4 vs 23.6 uSv and 0.95 vs 0.91$uSv/Gy.cm^2$, respectively), confirming a modest dose lowering due to the Hawthorn effect.

Conclusions: Positioning the right arm medially using Radial Cradle™ for right radial access PCIs significantly reduces first operator dose, by enabling optimal PPE positioning. Procedural dose awareness using Insta-dose also modestly reduces first operator dose, compared to historic controls.

Left main and multivessel disease - Tools, devices and techniques

Left main PCI in a peripheral centre in India: a unique challenge

PARALE Gurunath [(1)], PARALE Gurunath [(1)]

(1) Ashwini Sahakari Rugnalaya, Maharashtra, India

Aims: Performance of PCI in a peripheral centre with infrastructural issues and socioeconomic issues pose a unique challenge. PCI of unprotected left main coronary artery in this situation is furthermore daunting. To study the feasibility, outcome and also to identify the predictors of MACCE after PCI of unprotected left coronary artery done in a peripheral centre and compare the results with the studies done in near ideal environment.

Methods and results: 83 consecutive patients from February 2008 till September 2019 who underwent PCI of left main coronary were included in this study. Data of all these patients with regard to clinical presentation, procedural details and follow-up was obtained. SYNTAX and EuroSCORE was calculated in all patients. Primary endpoint was MACCE (mortality, stroke, revascularisation). Mean age of the patients was 64.3 yrs, and a majority of the patients presented with ACS 54 (65%). A majority of the patients had multiple risk factors 58 (69.9%) and also renal failure 63 (75.63%). Mean SYNTAX score was 23.61 and mean EuroSCORE 36.04. A cumulative MACCE rate at the end of 5 yrs was 17/83 (20.5%). Mean event-free survival was 7.2 years. Except for the EuroSCORE, which predicted MACCE at 6 months, no other parameters including the SYNTAX score were predictive though lower SYNTAX scores had higher event free survival.

Conclusions: PCI of the left main coronary artery in challenging environment of a peripheral centre is feasible with comparable results and many times lifesaving.

Stable CAD - Invasive imaging and functional assessment

The influence of cardiac phase on the diagnostic performance of the resting full-cycle ratio as non-hyperaemic physiological assessment

OHASHI Hirofumi [(1)], TAKASHIMA Hiroaki [(1)], OHASHI Hirofumi [(1)], ANDO Hirohiko [(1)], NAKANO Yusuke [(1)], SAKURAI Shinichiro [(1)], SUZUKI Akihiro [(1)], FUJIMOTO Masanobu [(1)], AMANO Tetsuya [(1)]

(1) Aichi Medical University, Nagakute, Japan

Aims: Recently, non-hyperaemic physiologic indices have become widespread for evaluating physiological lesion assessment. The resting full-cycle ratio (RFR) is a unique non-hyperaemic indices which is calculated as the point of absolutely lowest distal pressure to aortic pressure during entire cardiac cycle. It is unclear whether RFR may detect functionally significant coronary stenosis that cannot be detected with other resting indices due to differences in the cardiac cycle. The aim of this study is to compare the diagnostic performance of RFR based on cardiac cycle.

Methods and results: This study was a prospectively enrolled observational study. A total of 156 consecutive patients with 220 intermediate lesions were enrolled in this study. The RFR was measured after adequately waiting for stable condition, while FFR was measured after intravenous administration of ATP (180 mcg/kg/min). Lesions with FFR ≤0.80 were considered functionally significant coronary artery stenosis. In all lesions, reference diameter, diameter stenosis, lesion length, RFR, and FFR were 3.0±0.7 mm, 45±13%, 13.0±8.8 mm, 0.90±0.09, and 0.82±0.10, respectively. Functional significance was observed in 88 lesions (40%) of all lesions. RFR systole was observed in 24 lesions (10.9%). Regarding to the coronary lesions, RFR systole was more frequent in non-LAD (LAD; 4.2%, left circumflex artery (LCX); 9.8%, and right coronary artery (RCA); 30.4%, respectively, $p<0.018$). RFR showed a significant correlation with FFR in both systole and diastole ($y = 1.063x + 0.096$, $R = 0.918$, $y = 0.626x + 0.391$, $R = 0.733$, $p<0.001$, respectively). The ROC curve analysis showed similar agreement in both systole and diastole (systole; optimal cut-off to detect ischaemia: 0.92, AUC: 0.881, 95% CI: 0.704-1.058, diastole; optimal cut-off to detect ischaemia: 0.89, AUC: 0.864, 95% CI: 0.814-0.914, respectively, $p<0.001$). RFR provided a good diagnostic accuracy in both systole and diastole (79.6% and 87.5%, respectively, $p=0.58$).

Conclusions: RFR showed higher diagnostic performance for physiological lesion assessment, and it did not differ between systole and diastole. RFR is an alternative non-hyperaemic indice to evaluate physiological lesion severity in daily practice.

Stable CAD - Vascular access and bleeding

Comparison of 4 Fr vs 5 Fr sheaths for diagnostic coronary angiography via the snuffbox approach

KIM Yongcheol [1,2], ROH Ji Woong [3], KIM Yongcheol [1,2], KIM Hee-Yeol [3], AHN Youngkeun [2], JEONG Myung Ho [2]

(1) Yongin Severance Hospital, Yongin, Republic of Korea; (2) Chonnam National University Hospital, Gwangju, Republic of Korea; (3) Bucheon St. Mary's Hospital, Bucheon, Republic of Korea

Aims: Although a shorter haemostasis duration would be expected when compared with the conventional radial approach as the diameter of the distal radial artery is smaller than that of the conventional radial artery, the optimal duration of haemostasis in diagnostic coronary angiography (CAG) via the distal radial approach, termed the snuffbox approach, has not been well investigated.

Methods and results: We retrospectively collected data from 171 patients (55 and 116 patients in the 4 Fr and 5 Fr sheath groups, respectively). The patients had suspected myocardial ischaemia and were undergoing diagnostic CAG via the snuffbox approach at a single centre between January 2019 and August 2019. The mean age of the study population was 67.6±11.0 years, and 69% were male. The left snuffbox approach was performed in 146 (85.4%) patients. The mean snuffbox puncture time, defined as the time interval between local anaesthesia and sheath cannulation, was 145.1±120.8 seconds. The haemostasis duration was significantly shorter in the 4 Fr sheath group than in the 5 Fr sheath group (70 [62-90] vs 120 [120-130] min; $p<0.001$). There were local haematomas, defined as ≤5 cm in diameter, at the puncture site in 8 patients (4.7%). Moreover, there were no conventional and distal radial artery occlusions after haemostasis in the study population during hospitalisation.

Conclusions: Successful haemostasis without the occlusion of both radial arteries was obtained within 2 hours for diagnostic CAG via the snuffbox approach using the 4 Fr or 5 Fr sheaths.

STEMI - Vascular access and bleeding

Feasibility of primary PCI via the snuffbox approach in patients with STEMI

KIM Yongcheol [1,4], KIM Yongcheol [1,4], LEE Jun-Won [2], LEE Sang Yeub [3], BAE Jang-Whan [3], LEE Sang Jun [2], JEONG Myung Ho [1], LEE Seung-Hwan [2], AHN Youngkeun [1]

(1) Chonnam National University Hospital, Gwangju, Republic of Korea; (2) Yonsei University Wonju Colleage of Medicine, Wonju, Republic of Korea; (3) Chungbuk National University Hospital, Cheongju, Republic of Korea; (4) Yongin Severance Hospital, Yongin, Republic of Korea

Aims: Recently, distal radial approach, called snuffbox approach, has gained the interest of interventional cardiologists, but there is a lack of data about the feasibility of snuffbox approach as an alternative route for primary percutaneous coronary intervention (PCI). Therefore, this study aimed to investigate the feasibility of the snuffbox approach in patients with ST-segment elevation myocardial infarction (STEMI).

Methods and results: A total of 138 patients presenting with STEMI in whom primary PCI via the snuffbox approach was attempted at 3 hospitals from October 2017 to September 2019 were analysed. The success rate of snuffbox puncture in the setting of STEMI was 92.8% (128/138). Successful primary PCI via the snuffbox approach was achieved in all 128 patients. The snuffbox puncture time (defined as the time interval from local anaesthesia induction to successful sheath cannulation) was 2.7±1.6 min, and snuffbox puncture was performed within 5 min in 95.3% of patients. Moreover, the proportion of the puncture time to the door-to-balloon time was 3.3%. The left snuffbox approach was selected in 103 (80.5%) patients, and primary PCI via the snuffbox approach was performed using a 6-Fr guiding catheter in 125 (97.7%) patients. There was no major bleeding; however, there were 4 (3.1%) cases of access-site complications, including 3 cases of local haematoma (≤ 5 cm diameter) and 1 case of local numbness, which improved 3 months later.

Conclusions: The snuffbox approach for primary PCI in the setting of STEMI was feasible in terms of the puncture success rate, puncture time, and procedure success rate on the basis of our experience. Moreover, this new approach showed a low occurrence rate of bleeding complications even in patients treated with potent antithrombotic medications. Further large randomised control trials are needed to confirm the feasibility and safety of the snuffbox approach for primary PCI.

STEMI - Invasive imaging and functional assessment, NSTEMI - Invasive imaging and functional assessment

Different microcirculation responses to ischaemic injury of culprit and non-culprit vessels in patients with ACS

HYEYEON Moon [(1)], YOON-SUNG Jo [(1)], HYEYEON Moon [(1)], KYUNGIL Park [(1)]

(1) Dong-a University Hospital, Busan, Republic of Korea

Aims: This study investigated whether microvascular dysfunction differed between culprit and non-culprit vessels in patients with acute coronary syndrome (ACS) who underwent percutaneous coronary intervention (PCI).

Methods and results: In 115 prospectively recruited patients, after successful PCI, culprit and non-culprit intracoronary haemodynamic measurements were performed and repeated at 6-month follow-up. 13N-ammonia positron emission tomography (PET) was performed at the 6-month follow-up visit to determine absolute myocardial blood flow (MBF). The resistance values of each vessel were calculated using the coronary pressure data and the MBF values obtained from 13N-ammonia PET data. In 334 vessel analyses of registered patients, the culprit vessel group showed a lower fractional flow reserve (FFR) and coronary flow reserve (CFR) than the non-culprit vessel group at baseline and 6-month follow-up, respectively. The value of index of microcirculatory resistance (IMR) was different between the two groups in the baseline but not 6-month follow-up. The microvascular resistance at rest and hyperaemic microvascular resistance were not different between the two groups, but resistance to stenosis was higher in the culprit vessel group, under both resting and hyperaemic status ($p=0.02$ and $p<0.01$, respectively). In the culprit vessel analysis, the FFR and IMR decreased whereas CFR increased ($P< 0.01$ for all) during the 6-month follow-up. However, there was no change in IMR, CFR and FFR from the baseline to the 6-month follow-up in the non-culprit vessel analysis.

Conclusions: There was a different microcirculation response to myocardial ischaemia between culprit and non-culprit vessels in patients with ACS.

Other Coronary interventions - Other

Retrospective single-centre experience in distal radial puncture: Queen Elizabeth II-Sabah Heart Centre

CHU Chong Mow [1], CHU Chong [1], TAN You Zhuan [2]

(1) Gleneagles Kota Kinabalu Hospital, Sabah, Malaysia; (2) Queen Elizabeth II Hospital, Sabah Heart Centre, Sabah, Malaysia

Aims: Distal radial artery access for coronary angiogram was introduced since 2017. It is known to have a good success rate and a low risk of complications. There are few advantages for this procedure compared to conventional radial puncture. This is a retrospective single centre study on the distal radial approach as a feasible vascular access option in day-to-day practice in a government hospital. To assess the success rate with the distal radial approach, complication rates and to review optimal tourniquet time to secure haemostasis.

Methods and results: A retrospective single-centre, single-operator, case series. A total of 35 patients had distal radial puncture performed. Patients were recruited if they had a good distal radial pulse, and been planned for an angiogram. Verbal consent and explanation by the operator was accomplished before the procedure. A good procedural success rate of 97% with a very low complication rate of 3% with median average compression time of 30-60 mins.

Conclusions: Distal radial puncture is an alternative vascular excess with good procedure success with minimal complication that is feasible in day-to-day practice in a busy government hospital.

NSTEMI - Vascular access and bleeding, Stable CAD - Vascular access and bleeding

Comparison of 30-day outcome of the radial vs femoral access in patients treated with PCI and scaffold implantation: results from the German Austrian ABSORB registry (GABI-R)

WEIN Bastian [1], WEIN Bastian [1], ZACZKIEWICZ Myron [1], GRAF Matthias [1], ZIMMERMANN Oliver [1], RIEMER Thomas [2], TORZEWSKI Jan [1], KASTNER Johannes [3], WÖHRLE Jochen [4], HAMM Christian [5]

(1) Klinikverbund Kempten-Oberallgäu gGmbH, Immenstadt, Germany; (2) IHF GmbH Institut für Herzinfarktforschung, Ludwigshafen, Germany; (3) University of Vienna, Vienna, Austria; (4) Department of Cardiology, Angiology, Pneumonology and Intensive Care, Medical Campus Bodensee, Friedrichshafen, Germany; (5) Kerckhoff-Klinik GmbH, Bad Nauheim, Germany

Aims: Radial (RA) instead of femoral access (FA) for coronary interventions has become a Class-IA guideline recommendation, but when the decision of the access site is to the discretion of the operator, differences in adverse event rates mitigate. We compared the RA and FA 30-day outcome in the all-comer patients recruited for the multicentre observational German Austrian ABSORB Registry (GABI-R) in regard to all-cause mortality, stroke, myocardial infarction (MI), and TIMI major bleedings (TMB).

Methods and results: All patients were treated with a bioresorbable vascular scaffold, access site was to the discretion of the operator. In total, 3137 patients were included by different 92 centres and received percutaneous coronary interventions (PCI) for acute MI in 51.5% and non-acute settings in 48.5%. RA was performed in 47.8% and had a higher median radiation exposure (3896 vs 3082 cGycm², p<0.001), but no difference in the amount of contrast used. There was no difference in regard to all-cause mortality (0.53% vs 0.49%, p=0.86), the combination of death, MI and stroke (1.87% vs 1.83%, p=0.94), but a trend towards more TMB (0.47% vs 1.04%, p=0.07) with FA. These outcomes were found in the subgroups of patients with ST-, non-ST-elevation-MI and non-acute PCI as well.

Conclusions: In this contemporary GABI-R cohort, in which access site was to the discretion of the operator, both access routes appear to be safe for the patient, but RA was associated with a higher radiation exposure. Patients like our cohort, with no difference in 30-day outcome between radial and femoral access and overall low adverse event rates, seem to be predestined to gather and maintain proficiency in both access routes, without putting them at risk.

Stable CAD - Vascular access and bleeding

Optimal haemostatic time for the distal radial artery approach: re-evaluation based on the results of current haemostatic protocols

MIZUGUCHI Yukio [(1)], MIZUGUCHI Yukio [(1)], ASAO Yuki [(1)], SUGISAKI Kahoruko [(1)], YAMADA Takeshi [(1)], TANIGUCHI Norimasa [(1)], SHUNSUKE Nakajima [(1)], TETSUYA Hata [(1)], TAKAHASHI Akihiko [(1)], NAKANO Hideya [(1)]

(1) Sakurakai Takahashi Hospital, Kobe, Japan

Aims: The distal radial artery approach (dTRA) is expected to reduce access site complications such as bleeding and vascular occlusion. We aimed to identify an optimal compression protocol by retrospectively evaluating the safety and efficacy of haemostatic protocols currently applied for dTRA at our institute.

Methods and results: For this study, 851 patients who underwent coronary angiography (CAG) or percutaneous coronary intervention (PCI) in our hospital were selected. Diagnostic CAG via the dTRA with a 4 Fr sheath system (CAG group) was used in 604 patients, while PCI via the dTRA using a 5 or 6 Fr sheath system including a Glidesheath slender was used in 247 patients (PCI group). After sheath insertion, low-molecular-weight heparin was administered at bolus doses of 3000 IU and 100 IU/kg in the CAG and PCI groups, respectively. Continuous compression using a compression tape with a 6-mm-thick pad at the central portion was applied on the patient's arm, wrapping it with an elastic bandage for 2 hours after CAG or 3 hours after PCI. The pain during compression was assessed using the visual analogue scale. We also evaluated radial artery occlusion using the pulse Doppler method a day after the procedure. One participant (0.2%) in the CAG group and 31 (12.6%) in the PCI group ($p<0.001$) showed bleeding complications that required recompression for bleeding after decompression. Subcutaneous haemorrhage after haemostasis was observed in 5 (0.8%) and 15 patients (6.1%) in the CAG and PCI groups, respectively ($p<0.001$). Furthermore, 22 patients (42%) with such bleeding complication had primary PCI for acute coronary syndrome. No major bleeding occurred in either group. Distal RAO detected by ultrasonography was observed in 1 patient (0.4%) in PCI group but not in the CAG group. Thirteen (2.2%) and 20 patients (8.1%) in the CAG and PCI groups, respectively, experienced significant pain.

Conclusions: The CAG group demonstrated a low incidence of bleeding without radial occlusion, indicating that compression time can be further shortened. The patients who received primary PCI showed a higher incidence of bleeding complications even after 3 hours of compression. Further classification of individual patients might be needed for a revised haemostatic protocol.

STEMI - Tools, devices and techniques, Other Coronary interventions - Other

Results of a telemedicine infarction care programme in a Brazilian low-income area from 2015 to 2018

PRUDENTE Mauricio Lopes [1], FRANÇA Victor [1], BARBOSA Flávio [1], FERNANDES Fernando [1], JUNIOR Alvaro [1], ARAÚJO Adriano [1], BORGES Pedro [1], AMARAL Leonardo [1], NERY Max [1], PRUDENTE Maurício [1], GARDENGHI Giulliano [1]

(1) Hospital Encore, State of Goiás, Brazil

Aims: In Brazil, AMI affects 300,000 people/year with a mortality rate of 30% – 80% of these in the first 24 hours. Telemedicine aims to optimise the steps from screening to treatment. Knowing the difficulty of contact between emergency units and tertiary services, the system seeks to link screening, medical assistance and transport, facilitating the transfer of patients to catheterisation laboratories. The main objective of this study was to check the interval from the first medical contact-to-the balloon (M2B) and the door-to-balloon interval (D2B), also evaluating the in-hospital mortality.

Methods and results: A cohort study of 110 subjects (age: 58±11 years old; 72.7% male) diagnosed with STEMI in one of five universal health system emergency care centres from a Brazilian midwestern city, between November 2015 and August 2018. The Latin® telemedicine system was used as a bridge between the first medical care and the notification to the referral centre for haemodynamics for AMI treatment in the area. After obtaining a 12-lead electrocardiogram, assessed at distance by a cardiologist, if the patient had less than 12 hours of symptoms and ICU beds were available, the patients were transferred to the referral centre. All evaluated patients underwent PCI, 96.3% radially accessed, with a D2B time of 54.3±37.7 minutes, with BMS implants in 90.6% of the cases and pharmacoinvasive therapy in 9.4%. Of the treated patients, 44.5% of the cases were due to lesions in the anterior descending coronary artery and 42.7% in the right coronary artery. The M2B interval was greater than 120 minutes in 80.2% of cases with a mean time of 183.9±87.2 minutes. Considering cardiorespiratory arrest events, 4.6% occurred prior to arrival at the hospital and 9.1% after admittance. After PCI, the length of hospital stay was of 6±4 days. The mortality rate was 8.3% (9 cases).

Conclusions: The D2B interval was adequate in the evaluated sample, with a mean time of 54.3±37.7 minutes, however the M2B interval was not ideal in most of these cases, reflecting the need for improvement in transfer times and reinforcing the need for thrombolysis at the emergency units. The mortality found in this research reflects an improvement in the care of patients originated from the public Brazilian health system.

Stable CAD - Vascular access and bleeding

Transradial vs transfemoral approach for coronary angiography in patients submitted to coronary bypass graft surgery

FARIA Daniel [(1)], FARIA Daniel [(1)], SANTOS Miguel [(1)], BAPTISTA Sérgio [(1)], FARTO E ABREU Pedro [(1)]

(1) Hospital Prof. Doutor Fernando Fonseca, Amadora, Portugal

Aims: Coronary angiography of native coronary arteries by the transradial approach results in reduced morbidity and mortality. However, in patients with coronary grafts, the efficacy and safety of the transradial approach is subject to debate. We aimed to find if the transradial approach is still a viable option in patients with coronary grafts by comparing total procedure time and patient radiation exposure with the transfemoral approach.

Methods and results: This was a prospective registry of consecutive patients with a history of previous coronary artery bypass graft (CABG) surgery who underwent diagnostic coronary angiography and/or percutaneous coronary intervention. We evaluated and compared procedure time (minutes) and patient radiation exposure (mGy/cm^2). There were 690 procedures in patients with a past history of CABG surgery, 90 via transradial and 600 via transfemoral approach. The mean age was 69.1±9.5 years (75.2% males). Patients were divided by the number of known grafts: single-draft (17.7%, n=122), double-graft (37.1%, n=256), triple-graft (38.8%, n=268) and four or more grafts (6.3%, n=44). Angiographic success was reached in 78.8% in the transradial group versus 100% in the transfemoral group (p<0.001). The main reason for angiographic failure (22.2%, n=20) was impossible graft ostium engagement (14.4%, n=13) followed by difficult guide-wire progression in the supra-aortic branches (11.1%, n=10). There were no significant differences between the two approaches regarding procedure time (57.8 + 36.6 minutes for transradial vs 52.8 + 36.4 minutes for transfemoral p=0.233) or patient radiation exposure (1138 mGy/cm^2 [IQR 629-1756] for transradial vs 1000 [IQR 622-1507] mGy/cm^2 for transfemoral, p=0.253) between the groups.

Conclusions: Our study suggests that the transradial angiography can be successfully performed in post-CABG patients without a significant increase in procedural time or radiation exposure. However, approximately one-fifth of patients with an initial transradial approach had to switch due to technical difficulties.

Other Coronary interventions - Other

Clinical frailty scale predicts future adverse cardiovascular events in patients with ST-segment elevation myocardial infarction

KUROBE Masanari [1], KUROBE Masanari [1], SATAKE Akinori [1], MAKINO Yuichiro [1], MIZUTANI Koji [1], MIZUTANI Yoshiaki [1], ICHIMIYA Hitoshi [1], UCHIDA Yasuhiro [1], WATANABE Junji [1], KANASHIRO Masaaki [1], ICHIMIYA Satoshi [1]

(1) Yokkaichi Municipal Hospital, Yokkaichi, Yokkaichi, Japan

Aims: The Clinical Frailty Scale (CFS) is a simple tool to assess patients' frailty and may help to predict adverse outcomes in elderly patients. However, the prognostic impact of CFS on clinical outcomes in patients with ST-Segment elevation myocardial infarction (STEMI) after successful percutaneous coronary intervention (PCI) has not been previously investigated.

Methods and results: We performed primary PCI in 197 consecutive patients with STEMI between January 2016 and June 2018. Evaluation of the patient's degree of frailty was based on bedside judgment and other clinical information. Patients were categorised into 2 groups based on the CFS stages: CFS 1-3 and CFS 4. Of these patients, CFS 4 was present in 42 (21.3%). During the follow-up, 38.1% in CFS 4 group and 7.7% in CFS 1-3 group experienced major adverse cardiovascular events (MACE) defined as death from any cause, non-fatal myocardial infarction and rehospitalisation for heart failure. On Kaplan-Meier analysis, the proportion of MACE-free survival was significantly lower in the CFS 4 group (log-rank $p<0.001$). After adjustment for confounding factors, the CFS (per 1 grade increase) remained an independent significant predictor of MACE on multivariable Cox proportional hazard analysis (hazard ratio 1.33 [95% confidence interval: 1.02 to 1.73, $p=0.033$]).

Conclusions: In addition to assessing the degree of frailty, the CFS was significantly associated with future adverse cardiovascular events in patients with STEMI. Therefore, evaluating the CFS grade might constitute an ultimate risk prediction concept in regard to cardiovascular patients with complex needs. Our study will help enable cardiovascular clinicians to notify the importance of risk assessment including frailty.

STEMI - CT / MRI imaging, Other Coronary interventions - Other

Impact of skeletal muscle mass on prognosis in patients with ACS

MIZUGUCHI Yukio [(1)], MIZUGUCHI Yukio [(1)], YAMADA Takeshi [(1)], TANIGUCHI Norimasa [(1)], HATA Tetsuya [(1)], NAKAJIMA Shunsuke [(1)], TAKAHASHI Akihiko [(1)]

(1) Sakurakai Takahashi Hospital, Kobe, Japan

Aims: Sarcopenia, which is defined as an age-related generalised loss of skeletal muscle mass and dysfunction, is known as a potential predictor of the prevalence and prognosis of atherosclerotic cardiovascular disease and chronic kidney disease. However, the clinical significance of skeletal muscle loss on the prognosis in patients with acute coronary syndrome (ACS) has not been fully clarified yet. This study aims to investigate the prognostic value of skeletal muscle mass for ACS patients.

Methods and results: We retrospectively evaluated 282 ACS patients who underwent primary percutaneous coronary intervention in our hospital between January 2008 and December 2014 and evaluated skeletal muscle mass by using the psoas muscle mass index (PMI) calculated from non-contrast CT. During the follow-up period (median: 5.9 years), all-cause mortality was 22.3% (63 patients) in this study population. The patients were divided into 2 groups according to the cut-off value of PMI for all-cause death. There were no significant differences in either the location of the culprit lesion and the number of stenosed vessels between the 2 groups. Five-year mortality was significantly higher in the low-PMI group than high-PMI group. Multivariate logistic regression analysis indicated that age and PMI were independent predictors of mortality in ACS patients.

Conclusions: ACS patients with sarcopenia were significantly worse prognosis than without sarcopenia.

CTO - CT / MRI imaging

Agreement in left ventricular function measured by echocardiography and cardiac magnetic resonance in patients with CTO

LI Jiahui [(1)], LI Jiahui [(1)], ZHANG Lijun [(1)], WANG Yueli [(1)], ZUO huijuan [(1)], YANG Xueyao [(1)], HAN ye [(1)], HUANG Rongchong [(2)], HE Yi [(1)], SONG Xiantao [(1)]

(1) Beijing Anzhen Hospital, Capital Medical University and Beijing Institute of Heart Lung and Blood Vessel Disease, Beijing, China; (2) Beijing Friendship Hospital, Capital Medical University, Beijing, China

Aims: To determine the agreement in left ventricular (LV) function, including end-systolic volume (LVESV), end-diastolic volume (LVEDV) and ejection fraction (LVEF), measured by two-dimensional transthoracic echocardiography (2DTTE) and cardiac magnetic resonance (CMR) in patients with CTO, and in patients with and without segmental wall motion abnormality (WMA).

Methods and results: Eighty-eight CTO patients were enrolled in this study. All patients underwent imaging by 2DTTE and CMR within one week. The correlation and agreement of LV function, including LVESV, LVEDV and LVEF, measured by 2DTTE and CMR were assessed using Pearson correlation and Cohen's kappa analysis. Bland-Altman analysis was used to evaluate the bias and limits of agreement (LOA) with CMR reference. 88 patients (mean age 57±10 years, 83% male) were included and most of them presented with unstable angina pectoris (77.3%). The correlation coefficients for LVEF, LVESV and LVEDV were 0.50, 0.81, and 0.64, respectively. LVESV and LVEDV were underestimated whereas EF was overestimated by 2DTTE. The agreement of LVEF ≥50% and <50% was less positive (k= 0.623). Compared with patients without echocardiographic segmental WMA, those with WMA had lower correlation coefficients for LVEF, LVESV and LVEDV (0.66 vs 0.84, 0.87 vs 0.96 and 0.85 vs 0.87, respectively) while greater bias in LVEF (4.8% vs -0.4%) and LVESV (-7.5 ml vs -4.6 ml).

Conclusions: In CTO patients, the discrepancy between 2DTTE and CMR in LV function evaluation cannot be neglected, especially in those with abnormal ventricular motion. In this condition, further CMR evaluation should be considered to help improve assessment before revascularisation and avoid the potential risk for misclassification.

CTO - CT / MRI imaging

CT angiography derived RECHARGE score predicts successful PCI in patients with CTO

LI Jiahui [1], LI Jiahui [1], WANG Rui [1], TESCHE Christian [3], SCHOEPF Joseph [2], PANNELL Jonathan [2], CHEN Yalei [1], LI Jianan [1], HE Yi [1], HUANG Rongchong [4], SONG Xiantao [1]

(1) Beijing Anzhen Hospital, Capital Medical University and Beijing Institute of Heart Lung and Blood Vessel Disease, Beijing, China; (2) Medical University of South Carolina, SC, USA; (3) Heart Center Munich-Bogenhausen, Munich, Germany; (4) Beijing Friendship, Capital Medical University, Beijing, China

Aims: To investigate the feasibility and accuracy of coronary CT angiography (cCTA) derived RECHARGE score (RECHARGEcCTA) to predict procedural success and 30-minutes wire crossing in percutaneous coronary intervention (PCI) for chronic total occlusion (CTO), catheter angiography (CA, RECHARGECA) as reference.

Methods and results: 124 consecutive patients (median age 54 years old, 79% male) with 131 CTO lesions who underwent cCTA prior to CA with CTO-PCI were retrospectively analysed. The RECHARGEcCTA scores were calculated and then compared with RECHARGECA and other CTA-based prediction scores, including J-CTOCT, CT-RECTOR and KCCT scores. All patients signed the informed content. The procedural success rate of the CTO-PCI procedures was 72%, and 61% of cases achieved with 30-minutes wire crossing. No significant difference was observed between RECHARGEcCTA score and RECHARGECA score for procedural success (median 2 vs median 2, p=0.084). However, the RECHARGEcCTA score was higher than that of the RECHARGECA score for 30-min wire crossing (median 2 vs median 1.5, p=0.001). The area under the curve (AUC) of the RECHARGEcCTA and RECHARGECA score for predicting procedural success showed no statistical significance (0.718 vs 0.757, p=0.655). The sensitivity, specificity, positive predictive value, negative predictive value of RECHARGEcCTA score of ≤ 2 for predictive procedural success was 78%, 60%, 43% and 87%, respectively. The RECHARGEcCTA score showed equally discriminative performance compared with other CTA-based prediction scores (AUC= 0.718 versus 0.665–0.717, all p>0.05).

Conclusions: The non-invasive cCTA-derived RECHARGE score performs better than invasive determination in the prediction of a 30-minute wire crossing of CTO-PCI.

STEMI - Adjunctive pharmacotherapy

Is ticagrelor superior to clopidogrel in the reduction of coronary no-reflow in acute STEMI?

SHAWKY ELSERAFY Ahmed [1], SHAWKY ELSERAFY Ahmed [1], ELETRIBY Shehab [1], ELEWA Mohammed [1]

(1) Ain Shams University Faculty of Medicine, Al Waili, Egypt

Aims: Primary PCI is the preferred reperfusion strategy for STEMI because it offers prompt and complete recanalisation of an occluded infarct-related artery. However, in spite of successfully restored TIMI grade 3 epicardial blood flow, myocardial reperfusion is not regained in some patients. This phenomenon is referred to as coronary no-reflow. Such patients with no-reflow have a higher incidence morbidities and death. Our objective was to compare the effect of 180 mg ticagrelor versus 600 mg clopidogrel loading doses, on the incidence of no-reflow in STEMI patients.

Methods and results: This study was carried out on 100 patients, presented with acute STEMI, in the period between November 2018 and February 2019 who underwent primary percutaneous coronary intervention (PCI). All patients were subjected to history, clinical examination, ECG recording before and after primary PCI, blood samples before primary PCI for (creatinine, CK total, CK-MB in addition to routine laboratory investigations), and echocardiography after primary PCI. Patients were divided into two groups; 50 patients received a 600 mg loading dose of clopidogrel and the other 50 received a 180 mg loading dose of ticagrelor prior to primary PCI. The primary endpoint was the occurrence of no-reflow defined as TIMI flow grades ≤2 and or MBG of 0 or 1. The secondary endpoint was the occurrence of major adverse cardiac events during hospital stay. The primary endpoint of no-reflow occurred in 17 (34%) patients in the clopidogrel group versus 12 (24%) patients in the ticagrelor group. This difference was not statistically significant (p-value 0.271). There was no significant statistical difference in the occurrence of major adverse cardiac events either.

Conclusions: The incidence of no-reflow does not seem to be affected by the type of P2Y12 inhibitor loading received in the setting of STEMI.

Stents and scaffolds - Invasive imaging and functional assessment

Improved clinical outcomes with intravascular ultrasound-guidance during PCI with a second-generation DES: a meta-analysis of randomised controlled trials

NABAIS Sérgio [1,2], NABAIS Sérgio [1,2], LIAO Chia-Te [2], ZHANG Zhenyu [2], PANNIYAMMAKAL Jeemon [2]

(1) Salisbury District Hospital, Salisbury, United Kingdom; (2) London School of Economics and Political Science, London, United Kingdom

Aims: To elucidate if intravascular ultrasound (IVUS) compared with angiography only for guidance during percutaneous coronary intervention (PCI) with second or later generation DES is associated with better clinical outcomes.

Methods and results: Design: Meta-analysis of randomised controlled trials (RCT) comparing IVUS-guided versus angiography-guided PCI with second or later generation DES. The primary endpoint evaluated was MACE, a combination of all-cause and cardiac mortality, myocardial infarction (MI), target lesion revascularisation (TLR), target vessel revascularisation (TVR), and stent thrombosis (ST). The pooled risk ratio (RR) and 95% CIs were calculated using a random-effects model. The trials were assessed for their risk of bias using version 2 of the Cochrane risk-of-bias tool. Data sources: Systematic search of MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials, plus manual search of the references of relevant literature. Eligibility criteria for selecting studies: RCTs comparing IVUS guidance vs angiography guidance for PCI using second or later generation DES and with clinical follow-up data at 12 months or later, were included in the meta-analysis. We excluded non-randomised studies and those using bare-metal stents or first-generation DES. Results: Four trials (RESET, IVUS-XPL, CTO-IVUS, ULTIMATE) comprising 3,793 patients (1,894 in the IVUS group and 1,899 in the angiography group) met the eligibility criteria. At one year, IVUS-guided PCI compared with angiography-guided PCI resulted in a significant reduction in MACE (3.0% vs 5.9%; RR 0.51, 95% CI: 0.38-0.70, p<0.001; no statistical heterogeneity between studies, I2=0%, p=0.85), TLR (1.9% vs 3.7%; RR 0.52, 95% CI: 0.34-0.79, p=0.003; I2=0%, p=0.92;), and TVR (2.3% vs 4.1%; RR 0.58, 95% CI: 0.37-0.91, p=0.019; I2=0%, p=0.84). Although numerically lower in the IVUS group, the differences in cardiac death (0.4% vs 0.9%; RR 0.49, 95% CI: 0.22-1.08, p=0.075; I2=0%, p=0.93), all-cause death (1.3% vs 1.8%; RR 0.68, 95% CI: 0.35-1.32, p=0.26; I2=0%, p=0.63), MI (0.4% vs 0.8%; RR 0.51, 95% CI: 0.22-1.18, p=0.12; I2=0%, p=0.8) or ST (0.2% vs 0.6%; RR 0.46, 95% CI: 0.14-1.47, p=0.19; I2=0%, p=0.55) did not reach the pre-specified level of statistical significance. The visual inspection of the funnel plots raised no suspicion of publication bias, and this was confirmed by the Harbord test (MACE, p=0.55; death, p=0.47; cardiac death, p=0.12; TLR, p=0.58; TVR=0.69; ST, p=0.70).

Conclusions: Compared with angiography guidance, IVUS guidance during contemporaneous PCI with second-generation DES resulted in a significantly lower risk of MACE, TVR and TLR. Guidelines on percutaneous revascularisation should support the routine use of IVUS-guidance for most current PCI procedures.

CTO - Invasive imaging and functional assessment

Clinical significance of post-stent intravascular ultrasound for CTO PCI with DES

OSUNG Kwon [1], KWON Osung [1], PIL HYUNG Lee [2], SEUNG-WHAN Lee [2], JONG-YOUNG Lee [3], DUK-WOO Park [2], SOO-JIN Kang [2], YOUNG-HAK Kim [2], CHEOL WHAN Lee [2], SEONG-WOOK Park [2], SEUNG-JUNG Park [2]

(1) The Catholic University of Korea, Eunpyeong St. Mary's Hospital, Seoul, Republic of Korea; (2) Asan Medical Center, Seoul, Republic of Korea; (3) Kangbuk Samsung Hospital, Seoul, Republic of Korea

Aims: Despite wide use of intravascular ultrasound (IVUS) for stent implantation, few studies have evaluated its use for chronic total occlusion (CTO) percutaneous coronary intervention (PCI). This study aimed (1) to evaluate clinical benefits of performing post-stent IVUS for preventing adverse clinical events (2) to identify IVUS parameters for predicting target-lesion revascularisation (TLR)/reocclusion and (3) to assess the cut-off values of IVUS parameters in CTO-PCI.

Methods and results: A total of 1,077 patients with 1,077 CTO lesions treated with drug-eluting stents (DES) were included. Clinical outcomes for a median of 6.3 years were compared between subjects with or without post-stent IVUS using the inverse probability weighting method. Of 1,077 patients, post-stent IVUS was performed in 838 (77.8%) while remaining 239 (22.1%) cases did not undergo post-stent IVUS. In the weighted population, the risk of TLR/reocclusion was significantly lower in subjects with post-stent IVUS (9.6% vs 18.9%, hazard ration [HR], 0.54; 95% confidence interval [CI], 0.34 to 0.86, p=0.01), compared to those without post-stent IVUS, which consequently led to a significantly lower rate of target-lesion failure (TLF) (a composite of cardiac death, target-vessel myocardial infarction, and TLR/reocclusion) (21.4% vs 32.6%, HR 0.66; 95% CI: 0.48 to 0.92, p=0.01). In multivariate Cox-regression analysis, the minimal stent area (MLA) measured by IVUS was only identified as the independent predictor of TLR/reocculsion (HR, 0.78; 95% CI: 0.64 to 0.95; p=0.01). For receiver-operating characteristic analysis, the best MSA cut-off value was 4.9 mm^2 for prediction of TLR/reocclusion with a sensitivity of 63.0% and a specificity of 58.3% (area under curve=0.632, p=0.001).

Conclusions: In CTO-PCI with DESs, post-stent IVUS evaluation was associated with a decreased risk of TLR/reocclusion, and consequently a lower incidence of TLF. The MSA may be the most important IVUS optimisation criteria for preventing TLR/reocclusion with the cut-off value of 4.9 mm^2 for CTO lesions.

Euro20A-POS844
Posters

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

The coronary guidewire trick for increasing transradial access success in little old ladies

SAMAJA Gustavo [1,2], SAMAJA Gustavo [1,2], TEJERINA Heber [1], LESCANO Yesica [1], ESCALANTE José [1]

(1) Policlínico Bancario, Buenos Aires, Argentina; (2) Hospital de Alta Complejidad "Pte. Juan Domingo Perón", Formosa Province, Argentina

Aims: Transradial access (TRA) success is higher than 95%. In some populations though it is lower: women, elderly and small patients. In little old ladies (LOL) TRA success is low. LOL have a high risk of bleeding and vascular complications (VC), making TRA a great tool. Our manoeuvre for increasing TRA success in LOL is the "The Coronary Guidewire Trick" (CGWT). Basically, we use a 0.014" wire for sheath insertion, instead of the short straight 0.021" wire commonly used. The advantages we've seen are less vascular trauma; better understanding about anatomy by looking at the wire route; position in the subclavian artery or aorta when inserting the sheath.

Methods and results: The CGWT: after puncturing radial artery, we advance a 0.014" coronary wire until the distal tip reaches the aorta or proximal subclavian artery; then we insert the radial sheath over the 0.014" wire; after inserting the sheath, we advance the 0.035" wire in parallel to the 0.014" wire; and with the distal tip of the 0.035" wire being positioned in the aorta, we remove the coronary wire and complete the procedure as usual. The population treated was 500 consecutive TRA PCI attempted in LOL, defined as women older than 80 years and smaller than 150 cm. Exclusions: absent radial pulse, abnormal Allen's test, Raynaud's disease, shock. We analysed demography; procedure; feasibility (procedure completed through TRA), PCI success (residual stenosis <20% and TIMI 3 without MACE); in-hospital MACE; VC (major: bleeding requiring prolonged hospitalisation, surgical intervention or blood transfusion; pseudoaneurysm; arteriovenous fistula; limb ischaemia and nerve damage and minor: haematoma, neuritis). Results: 500 of the 535 PCIs in LOL screened; mean age, 86 years (80-98) and mean height 142 cm (136-150); STEMI 32%, ACSNSTE 59%, stable 9%; single vessel PCI 92%; feasibility 97%; procedural success 94%; MACE 9%; major VC 0,2% and minor VC 5,5%.

Conclusions: In LOL, a population where we expect a technically challenging TRA and high access failure, our "Coronary Guidewire Trick" may be a tool for increasing the likelihood of success. Increasing TRA success in LOL could break the "Risk-Treatment Paradox" found in this population: despite being especially beneficial in LOL, TRA is less used in this group of patients when compared with the general population.

2020 PCR e-Course Coronary interventions

Euro20A-POS849
Posters

Stents and scaffolds - Invasive imaging and functional assessment

Strut coverage of the ultrathin Biomime stent: a single-centre experience from the MILES-UK registry

CHATTOPADHYAY Sudipta [1,3], CHATTOPADHYAY Sudipta [1,3], TAYLOR Gerard [1], CHOUDHURY Anirban [2], DESILVA Ramesh [1]

(1) Bedford Hospital South Wing, Bedford, United Kingdom; (2) Morriston Hospital, Swansea, United Kingdom; (3) Milton Keynes University Hospital, Milton Keynes, United Kingdom

Aims: Biomime is an ultrathin strut (65µm) biodegradable polymer coated sirolimus-eluting stent assessed in the MILES-UK registry, a post-maketing registry. We studied the strut coverage of this stent using optical coherence tomography (OCT).

Methods and results: MILES-UK Registry participants in our centre who underwent staged PCI were included in this study. At the staged second procedure, we undertook opportunistic OCT analysis of the Biomime stents implanted at the baseline visit. OCT was analysed using the Medis QIvus software with manual review of every frame recorded. All frames with luminal or strut artefacts adjudged severe enough to affect analysis, were excluded. Struts were identified as well-defined signal rich images with signal void beyond it. Inappropriately detected struts were removed and undetected ones added manually. Distances were measured from the stent detection point i.e. mid-point of the stent bloom to the luminal contour along the radial axis to the stent and lumen centre and also as the minimal distance between them. A strut was defined as "malapposed" if this distance was negative i.e. lumen contour was abluminal to the stent and >87 µm (strut thickness (65 µm) + polymer(2 µm) + axial resolution of the OCT (20 µm)). These struts were excluded from the coverage analysis. As the software automatically measured distances from the mid-point of the stent bloom, the half of the blooming thickness was not added for malapposition measurements. A strut was defined as "covered" if this distance was positive i.e. lumen contour was endoluminal to the stent and "uncovered" if it was negative; i.e., lumen contour was abluminal to the stent. As the significance of measured stent coverage by a thickness less than the axial resolution of OCT remains questionable, the data was reanalysed excluding the struts with coverage <20 µm. Twenty-eight of 111 (25.2%) patients (age 68.5±10.2 yrs, male 82%) recruited to the MILES-UK Registry at our centre underwent OCT 3 months (median 91 days, range 58-178 days) post-implant. 46 Biomime stents (1091 mm) were implanted. 7187 (83.4% of the acquired frames) were analysed. 5546 of 5671 (97.8%) frames with struts were analysable. 1069 mm (97.98% of the implanted length) of stent were as analysed. There were an average of 2256.71 struts/patient and 10.71±1.76 struts/frame/patient. 63165 struts were detected of which 1553(2.46%) were "malapposed". Of the rest, 59363 (96.35%) were "covered" and 2249 (3.65%) were "uncovered". The data was recalculated excluding 5101/63165 (8.07%) struts with <20 µm thickness of coverage from coverage analysis leaving 56511 struts. Of these, 54266 (96.03%) were "covered" and the rest uncovered. The mean thickness of tissue over the "covered" struts was 77.7±31.2 µm along the radial axis to the stent centre, 79.1±30.9 µm to the lumen centre and 76.5±30.4 µm as the shortest distance. On excluding struts with <20 µm thickness of coverage the measurements were 82.5±30.8 µm, 84.3±30.9 µm and 81.8±30.4 µm respectively. The mean area of tissue covering on the endoluminal surface of stent was 0.61±0.29 mm^2. The mean area of malapposition was 0.15±0.16 mm^2.

Conclusions: This is the largest study to assess stent coverage in an ultrathin stent. 96% of the apposed struts of the Biomime stent are covered at 3 months after implantation. This suggests that shortening dual antiplatelet therapy could be considered for this stent.

Bifurcation lesion - Tools, devices and techniques

The bifurcation angle is important in stenting the ostium of the left anterior descending artery using the Szabo technique

REDDY Muni Venkatesa [1]

(1) Jagjivan Ram Hospital, Maharashtra, India

Aims: Percutaneous coronary interventions of an ostial lesion are a challenging procedure even for an experienced interventional operator, especially if the bifurcation angle is less than 75 or if the lesion has a 0,0,1 Medina classification. Various techniques have been described to achieve a stable stent position in such lesions. The interventional strategy for an ostial left anterior descending artery (LAD) has to be decided upfront either to aim for a precise ostial stent position or to bring the stent back across the left circumflex ostium into the left main stem.

Methods and results: Radial approach, 6 Fr guidewire, Szabo technique of ostial stent placement. Precise ostial stenting is possible upfront in a wide bifurcation angle but plaque shift is common with the narrow angle and necessitates further treatment during the Szabo technique.

Conclusions: Szabo technique is safe for precise stent placement at the ostial LAD in wide angle bifurcation. It prevents the unwanted stent movement with a high success rate, requiring less contrast use and fluro time.

Stents and scaffolds - Tools, devices and techniques

Determining the effects of stent overexpansion on polymer integrity of third-generation DES using electron microscopy

TOUMA George [1],

(1) Hurstville Private Hospital, NSW, Australia

Aims: To develop a reproducible technique using electron microscopy that can assess polymer integrity of drug-eluting stents. To systematically overexpand drug-eluting stents and assess polymer disruption using electron microscopy.

Methods and results: Three brands of third generation drug-eluting stent types were chosen. XIENCE PRIME, Promus element and Resolute Integrity. They were inflated to nominal pressure as control. They were subsequently overexpanded using a standardised inflation protocol and assessed. All stents were assessed via electron microscopy for polymer damage and stent length. Proximal, middle and distal portions of each stent were assessed on the inner and outer diameter using a standardised protocol. Controlling inflation of the stents to a nominal pressure did not result in any polymer disruption. Increasing polymer damage was seen with progressive overexpansion and side branch inflation compared to control. Kissing balloon inflation was associated with less polymer damage than inflation through the side of the stent. Polymer lifting and fissure was clearly seen with this novel protocol.

Conclusions: Current reviews of stent overexpansion focus on diameter achieved and mechanical properties. Assessment of polymer degradation has not been a focus. We have developed a robust protocol for assessment of polymer damage during drug-eluting stent implantation. Polymer degradation is increased with over expansion across all platforms. Inflation through the side strut was associated with greater polymer degradation than kissing balloon inflation. This may impact drug-eluting stent performance. It is important to choose a stent with adequate expansion capabilities, preferably within manufacturer specifications. Future experiments will look at polymer disruption following bench deployment of bifurcation drug-eluting stents using the DK crush, culotte and TAP technique.

Other Coronary interventions - Other

A clinical prognostic score model of contrast-induced acute kidney injury in patients who underwent emergency PCI

YUAN Ying [1], YUAN Ying [1], QIU Hong [1], HU Xiaoying [1], ZHANG Jun [1], WU Yuan [1], QIAO Shubin [1], YANG Yuejin [1], GAO Runlin [1]

(1) Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

Aims: Previous risk score models of contrast-induced acute kidney injury (CI-AKI) were based mainly on elective percutaneous coronary intervention (PCI) cases, and the risk factor profile of CI-AKI in patients who underwent an emergency PCI procedure is still unclear. Our study aimed to develop a prognostic score model of CI-AKI and perform temporal validation in an emergency PCI population.

Methods and results: Consecutive patients who underwent emergency PCI at our hospital between 2013 and 2018 were enrolled and chronologically divided in a 2:1 manner into a development cohort and a validation cohort. CI-AKI was defined as an increase in serum creatinine (SCr) ≥0.5 mg/dL (44.2 μmol/L) above baseline within seven days after exposure to contrast medium. A total of 3,564 patients who underwent emergency PCI were eventually enrolled and divided into the development cohort (2,376 patients) and the validation cohort (1,188 patients). The incidence of CI-AKI in the development cohort was 6.61% (157/2376). The CI-AKI risk score model was constituted by 8 variables: female sex (1 point), history of transient ischaemic attack (TIA)/stroke (1 point), left ventricular ejection fraction (LVEF) classification (1 point per class), big endothelin-1 (ET-1) classification (1 point per class), estimated glomerular filtration rate (eGFR) classification (1 point per class), intra-aortic balloon pump (IABP) application (1 point), left anterior descending (LAD) stenting (1 point) and the administration of diuretics (2 points). Patients could be further categorised into three groups: low risk, moderate risk and high risk, corresponding to risk scores of 3-6, 7-10 and ≥11, respectively. The CI-AKI prognostic score model showed good performance in both the development cohort (calibration slope=0.954, c-statistic=0.837, 95% confidence interval [CI]: 0.806-0.869) and the validation cohort (calibration slope=0.914, c-statistic=0.787, 95% CI: 0.731-0.844).

Conclusions: Under a more appropriate CI-AKI definition, the CI-AKI prognostic score model is a simple and accurate tool that can be used for CI-AKI risk assessment and stratification in patients who undergo emergency PCI.

Left main and multivessel disease - Diabetes

Unprotected left main PCI in diabetic patients: a retrospective analysis of practice and clinical outcome

SCALONE Giancarla [1], SCALONE Giancarla [1], MARIANI Luca [1], DI VITO Luca [1], AIMI Alessandro [1], SILENZI Simona [1], GROSSI Pierfrancesco [1]

(1) Hospital C and G "Mazzoni", Province of Ascoli Piceno, Italy

Aims: Randomised trials have shown that percutaneous coronary intervention (PCI) might be an acceptable alternative in patients with left main disease (LMD) and coronary artery disease (CAD) of low or intermediate anatomical complexity. The optimal coronary revascularisation strategy in diabetic patients with complex multivessel disease remains controversial. We aim at assessing the feasibility and the efficacy of PCI of LMD in diabetic patients, in a group of patients treated in a high volume catheterisation centre without on-site cardiothoracic surgical support.

Methods and results: We retrospectively enrolled 145 patients undergoing PCI for unprotected LMD "*de novo*" lesions ≥50%. Patients were allocated in two groups: those with or without diabetes mellitus (DM). We evaluated the incidence of major adverse cardiovascular events (MACEs) defined as composite of cardiac death, non-fatal myocardial infarction and target vessel revascularisation. Mean age of study population was 73.7±10.6 years old, with 51 (35%) with DM. There were no clinical, angiographic and procedural differences between the two groups. At 12 months, there were no differences in MACEs between the two groups (p=0.57). In diabetic patients, median time of events was 4 months and clinical presentation of stable coronary artery disease was the only independent predictor of MACEs (OR -0.39, 95% CI: -0.72- -0.05, p=0.025).

Conclusions: PCI of LMD in diabetic patients seems an effective option. Clinical presentation is related to adverse events, that mostly happen within 6 months from PCI.

Other Coronary interventions - Calcified lesions

A real-world multicentre registry of coronary lithotripsy for the treatment of calcified lesions

CUBERO-GALLEGO Hector [1], CUBERO-GALLEGO Hector [1], MILLAN Raul [2], GOMEZ-LARA Josep [3], FUERTES-BARAHONA Monica [4], AMAT-SANTOS Ignacio [5], SALVATELLA Neus [2], TIZON-MARCOS Helena [2], GOMEZ-HOSPITAL Joan Antoni [3], MORIS Cesar [1], VAQUERIZO Beatriz [2]

(1) Hospital Universitario Central de Asturias, Oviedo, Spain; (2) Hospital del Mar, Barcelona, Spain; (3) Hospital Universitario de Bellvitge, L'Hospitalet de Llobregat, Spain; (4) Hospital Universitario Joan XXIII, Tarragona, Spain; (5) Hospital Clínico Universitario de Valladolid, Valladolid, Spain

Aims: Coronary lithotripsy is a balloon-based technique used to treat calcified lesions. Despite successful early results in select coronary lesions, there are little real-world data published about coronary lithotripsy. The main objectives of this study were to provide further insight about the safety and efficacy of coronary lithoplasty for the treatment of calcified coronary lesions and report short-term clinical outcomes from an unselected and high-risk population.

Methods and results: This was a prospective, multicentre registry, which included consecutively all cases with calcified coronary lesions that underwent coronary lithotripsy with the Coronary Rx Lithoplasty System (Shockwave Medical, Inc., Fremont, CA, USA) between August 2018 and August 2019. This study was conducted at 5 hospitals within a single country. A target lesion located in a small vessel (<2.5 mm) and the presence of severe dissection prior to coronary lithotripsy were the exclusion criteria of this registry. An independent central core lab completed QCA. This registry included 57 patients (66 lesions). A relatively elderly population (72.6±9.4 years) with high proportions of patients with diabetes (56%), chronic kidney disease (35%) and multivessel disease (84%). All lesions were classified as type B/C. The most frequently treated artery was the left anterior descending artery, including 45% of bifurcated lesions. Multivessel revascularisation was performed in 30% of patients. In more than half of the patients, vascular access was radial. More than 75% of lesions were pre-dilated. It is notable that the concomitant use of other plaque-modification devices before the coronary lithoplasty was found to be safe: rotational atherectomy was used in 5 lesions (7.6%) before the coronary lithotripsy and cutting/scoring balloons were used before the lithoplasty balloon in 16 lesions (24.2%). On average, coronary lithotripsy required the use of 1.17±0.41 balloons delivering 3 therapies (range, 2.5-4) with a mean of 60 pulses. Successful coronary lithotripsy was achieved in 98% of cases. QCA was adequately performed on 61 lesions before and after the procedure (5 cases did not show enough quality for the correct analysis). Mean reference vessel diameter was 2.8±0.5 mm and lesion length was 26±10.4 mm. In 13% of cases, lithoplasty balloon was broken during therapy. There were few procedural complications: 2 cases of significant dissections (none related to lithoplasty balloon rupture) were successfully treated with drug-eluting stent implantation. One patient experienced stent thrombosis 2 days after successfully undergoing target lesion revascularisation.

Conclusions: This is a real-world multicentre registry, which supports the feasibility, safety, and short-term efficacy of percutaneous coronary interventions for calcified lesions using coronary lithotripsy in an unselected and high-risk population with promising results. In addition, the present study is the first to demonstrate the safety of the concomitant use of other plaque-modification devices with the lithoplasty balloon.

Left main and multivessel disease - Tools, devices and techniques

Unprotected left main PCI in the elderly: a retrospective analysis of practice and clinical outcome

SCALONE Giancarla [1], SCALONE Giancarla [1], MARIANI Luca [1], AIMI Alessandro [1], DI VITO Luca [1], SILENZI Simona [1], GROSSI Pierfrancesco [1]

(1) Hospital C and G "Mazzoni", Province of Ascoli Piceno, Italy

Aims: Percutaneous coronary intervention (PCI) for unprotected left main disease (LMD) has improved over time. Randomised trials have shown that PCI might be an acceptable alternative in patients with LMD and coronary artery disease of low or intermediate anatomical complexity. Moreover, PCI could represent a reasonable option in elderly patients, not suitable for surgical revascularisation. We aim at assessing the feasibility and the efficacy of PCI of LMD in older population, in a group of patients treated in a high volume catheterisation centre without on-site cardiothoracic surgical support.

Methods and results: We retrospectively enrolled 145 patients undergoing PCI for unprotected LMD "*de novo*" lesions ≥50%. Patients were allocated in two groups: those with age < or ≥ of 75 years old. We evaluated the incidence of major adverse cardiovascular events (MACEs) defined as composite of cardiac death, non-fatal myocardial infarction and target vessel revascularisation. Mean age of study population was 73.7±10.6 years old, with 75 (51.7%) with age ≥ of 75. Younger patients had more frequently smoking habit and family history of coronary artery disease than the other group ($p<0.001$ and $p=0.039$, respectively). The older patients had more hypertension, renal failure, and higher value of EuroSCORE than younger population ($p=0.025$, $p=0.028$, and $p<0.001$, respectively). Three-vessel disease and calcified lesions were more frequent in the older group than in the other one ($p=0.029$ and $p<0.001$, respectively). At 12 months, there were no differences in MACE between the two groups ($p=0.333$). In the older population, median time of events was 5 months and clinical presentation of no-ST-elevation acute coronary syndrome was the only independent predictor of MACEs (OR 1.44, 95% CI: 10.983- 18.127, $p=0.04$). On the other hand, in the younger population, left ventricular ejection fraction (OR-0.020, 95% CI: -0.031--0.00; $p=0.002$) was the only predictor of MACE.

Conclusions: PCI of LMD in elderly patients seems an effective option. Clinical presentation is related to adverse events, that mostly happen within 6 months from PCI.

Other Coronary interventions - Calcified lesions

Midterm outcomes of stent-less coronary intervention using rotational atherectomy and DEB for de novo lesions under DES-unfavourable conditions

SHIRAISHI Jun [(1)], SHIRAISHI Jun [(1)], KATAOKA Eisuke [(1)], OZAWA Takaaki [(1)], ITO Daisuke [(1)], KOJIMA Akiteru [(1)], KIMURA Masayoshi [(1)], KISHITA Eigo [(1)], NAKAGAWA Yusuke [(1)], HYOGO Masayuki [(1)], SAWADA Takahisa [(1)]

(1) Japanese Red Cross Kyoto First Hospital, Kyoto, Japan

Aims: We investigated midterm angiographic and clinical outcomes in patients with *de novo* lesions undergoing rotational atherectomy followed by drug-coated balloon (DCB) dilation. Implantation of DES has been a mainstay of the interventional treatment of coronary artery disease; however, there still remain several DES-unsuitable clinical/lesion conditions. Nowadays stent-less PCI using DCB for *de novo* lesions has attracted more attention, and rotational atherectomy, which tends not to cause major dissection but to debulk intima, might be one of suitable pre-treatments before DCB.

Methods and results: Thirty consecutive patients (34 lesions) undergoing rotational atherectomy followed by DCB for *de novo* lesions were enrolled. Cases requiring bailout stenting and those with in-stent restenosis as culprit lesions were excluded. Clinical/lesion specific factors for performing the stent-less PCI included diffuse/severe calcification, ostial lesion, calcified nodule, inlet/outlet of aneurysm, severe thrombocytopenia, bleeding cancer, and/or sequelae of Kawasaki disease. The prevalence of diabetes mellitus and haemodialysis was 60.0% and 36.7%, respectively. Left anterior descending coronary artery was the most common target vessel (41.2%), and frequency of AHA/ACC type B2/C lesions was 97.1%. The final burr size used was 1.83±0.23 mm, and additional pre-balloon dilation was performed in 67.6% of the lesions. The mean DCB diameter was 2.71±0.47 mm, and inflation pressure was 9.0±2.2 atm. As an intravascular imaging guidance, optical frequency domain imaging (OFDI) was more frequent than IVUS. Angiographic success (defined as the <50% stenosis without flow delay on final CAG, as evaluated by visual estimation according to the AHA classification and the TIMI grade) was obtained in 94% of the lesions. No acute closure but 1 sustained no reflow occurred. In quantitative coronary angiography analysis, baseline reference diameter, lesion length, minimal lumen diameter, and acute gain were 2.83±0.89, 19.95±12.85, 0.74±0.48, and 1.20±0.63 mm, respectively. Repeat angiography (mean interval, 6.6 months after procedure) was performed for 19 lesions. Frequency of binary restenosis was 21.1%, and late lumen loss was 0.34±0.30 mm. One-year clinical outcomes included 5 deaths (2 sudden deaths, 1 cardiac death, 2 non-cardiac deaths), 2 strokes, and 2 target-lesion revascularisations. Neither definite myocardial infarction nor acute/subacute closure of target vessels was detected.

Conclusions: Midterm outcomes of stent-less PCI using rotational atherectomy and DCB under OFDI or IVUS guidance might be feasible among *de novo* lesions complicated with DES-unfavourable conditions.

STEMI - Adjunctive pharmacotherapy, NSTEMI - Adjunctive pharmacotherapy

Comparison of platelet inhibition in patients with ACS treated with morphine vs no morphine after a loading dose of swallowed vs chewed ticagrelor

ASHER Elad [1], ASHER Elad [1], MAZIN Israel [2], ABU-MUCH Arsalan [2], GUETTA Victor [2], SEGEV Amit [2], ELIAN Dan [2], BARBASH Israel [2], FEFER Paul Fefer [2], BEIGEL Roy [2], MATETZKY Shlomi [2]

(1) Shaare Zedek Medical Center, Jerusalem, Israel; (2) Sheba Medical Center, Ramat Gan, Israel

Aims: Dual antiplatelet therapy represents standard care for treating patients with acute coronary syndromes (ACS). Ticagrelor is a direct-acting P2Y12 inhibitor and, unlike clopidogrel and prasugrel, does not require metabolic activation. Morphine is also a commonly used medication in ACS to help relieve pain. Nevertheless, over the past few years there has been some concern raised about the drug-drug interactions with antiplatelet agents and delayed gastric absorption causing impaired platelet inhibition as well as an association with worsened clinical outcomes.

Methods and results: We prospectively compared platelet inhibition in response to a ticagrelor loading dose (180 mg) in 100 consecutive ACS patients (both ST-elevation [n=50] and non-ST-elevation [n=50] myocardial infarction [STEMI/NSTEMI]). Patients were either treated by morphine (M) (n=17) or not (NM) (n=83) by the discretion of the attending cardiologist on admission. A ticagrelor loading dose was either swallowed (n=50) or chewed (n=50) in order to overcome delayed gastric absorption. Platelet inhibition was determined in response to ADP by VerifyNow and expressed as PRU at baseline, 1 hour, and 4 hours after loading dose. There were no differences in baseline characteristics between patients in both groups. Platelet reactivity was higher at 1 hour in the M group vs NM groups regardless of whether ticagrelor was swallowed (233±25 vs 140±92, p<0.01) or chewed (156±112 vs 57±56, p<0.001). Nevertheless, at 4 hours platelet reactivity was higher in the M group if ticagrelor was swallowed (96±107 vs 47±58, p=0.03) but not if it was chewed (59±53 vs 37±33, p=0.06). Moreover, infarct size (as measured by lower left ventricular ejection fraction and higher peak troponin level) was larger among the M group (45%±11 vs 51%±11, p=0.02 and 41±29 mic/l vs 15±19 mic/l, p<0.001, respectively), as was the number of vessel disease by angiography (2.06 vs 1.57, p=0.02).

Conclusions: Our findings suggest that beyond drug-drug interaction and delayed gastric absorption of ticagrelor, which contributes to delayed response to P2Y12 antagonists in patients treated with morphine there is also association to platelet hypo-responsiveness that might be related to the extent of the myocardial infarction and thrombus burden in patients treated with morphine.

STEMI - Vascular access and bleeding, NSTEMI - Vascular access and bleeding

Dual hand circulation assessment prior to transradial procedures for PCI

CURTIS Elizabeth [(1)], CURTIS Elizabeth [(1)], FERNANDEZ Ritin [(1,2)], MORONEY Tracey [(1)], LEE Astin [(3)]

(1) University of Wollongong, NSW, Australia; (2) St George Hospital, NSW, Australia; (3) Wollongong Hospital, NSW, Australia

Aims: The objective of this scoping review was to map the literature in relation to assessment of dual hand circulation prior to and after coronary procedures.

Methods and results: A systematic scoping review was carried out for both published and unpublished studies including RCTs and observational studies following the Joanna Briggs methodology. Medline, Embase, CINAHL and the Cochrane Library were searched for publications between January 2000 and December 2020 that reported on hand circulation assessment prior to and after transradial coronary procedures. The search yielded 68 papers; 5 studies were included that met the criteria with a total of 11,348 participants. Various methods were used to evaluate the effectiveness of hand circulation assessment such as radial artery occlusion, transradial failure, diagnostic accuracy of testing and capillary lactate levels. Three studies, with a total of 9,732 participants, included patients with abnormal hand circulation results. Normal hand circulation results were recorded in just over 95% or participants. One study including 8,463 participants identified abnormal Allen's test to be a predictive factor in transradial failure. While another study involving 1,035 participants found higher incidence of radial artery occlusion in participants with normal hand circulation assessment results. The search identified an additional four studies carried out which document interventionalist practices with a total of 2,785 interventionalists. These studies recorded the use of hand circulation assessment pre procedurally, with 52% of interventionalists carrying out testing prior to transradial approach. Three of these studies evaluated the use of assessment for radial artery occlusion post procedure, two thirds (66%) of respondents identified that they carry out regular assessment for radial artery occlusion post procedure. The reverse Allen's test was most commonly used to assess palmar arch collaterals followed by the modified Barbeau test. In addition, a variety of non-invasive methods including digital pressures, plethysmography, pulse oximetry and duplex ultrasonography to supplement physical examination were used.

Conclusions: There is no consensus on whether assessing collateral circulation of the hand is beneficial in patients having transradial coronary procedures. Practices and the choice of test depends upon the preference of the interventionalist.

Euro20A-POS860
Posters

Stable CAD - Tools, devices and techniques

Radiation exposure and image quality using different angiographic protocols during PCI

RUBINACE Riccardo [1], RUBINACE Riccardo [1], FRANCESCHINI Matteo [2], RUFINI UgoO [1], CASTRIGNANO Marika [1], DE MARCO Nadia [1], VINCIGUERRA Fernando [1], FEDELE Silvio [1], FERRAIULO Giuseppe [1], SCIAHBASI Alessandro [1]

(1) Hospital Sandro Pertini, Metropolitan City of Rome, Italy; (2) Hospital Tor Vergata Roma, Metropolitan City of Rome, Italy

Aims: The use of ionised radiation in interventional cardiology procedures is associated with a possible increased risk of stochastic effects for patients and physicians. Modern radiologic systems are equipped with dedicated programs aimed to reduce this radiation exposure but sometimes this advantage is paid for in term of image quality. The purpose of this project was to compare different angiographic protocols for percutaneous coronary procedures in term of radiation exposure and image quality.

Methods and results: We recorded different cine-acquisitions using two different pre-set programs (CARDIAC and LOW DOSE) and two different details of acquisition (NORMAL vs LOW) during the same angiographic projection in the setting of percutaneous coronary interventions. An INNOVA IGS 520 (General Electrics) angiographic system was used for all the acquisitions. The radiation dose was evaluated using the Air Kerma (AK) and the Dose Area Product (DAP) achieved directly from the angiographic system. The operator radiation exposure was measured using an electronic dosimeter arranged in the middle front of the physician. The DAP, AK and the operator radiation dose were normalised for the frames' number of every single acquisition in order to avoid possible biases correlated with the length of the acquisition. The image quality was evaluated at the end of the study using a scale from 0 to 10 by two different operators unaware of the protocol utilised. All measures were obtained in 12 different procedures performed by the same operator. The use of LOW details of acquisition was associated with a significant reduction of the DAP (19±9 mGy/cm^2), AK (0.4±0.2 mGy) and operator exposure (0.04±0.03 µSv) compared to NORMAL details (DAP 37±16 mGy/cm^2, p<0.001, AK 0.7±0.3 mGy, p<0.001, operator dose 0.09±1.1 µSv p=0.01). Using the same details, there were no significant differences between the CARDIAC (DAP: 39±14 mGy/cm^2, AK: 0.7±0.3 mGy, operator 0.08±0.06 µSv for NORMAL details and DAP: 20±8 mGy/cm^2, AK: 0.4±0.2 mGy, operator 0.04±0.03 µSv for LOW details) and DOSE CONTROL (DAP: 35±18 mGy/cm^2 p=0.14, AK 0.7±0.3 mGy, p=0.19, operator 0.11±0.11 µSv for NORMAL details and DAP: 19±9 mGy/cm^2 p=0.54 e AK 0.3±0.2 mGy p=0.71, operator 0.04±0.03 µSv, p=0.93 for LOW details). The image quality using LOW details (7.35±1) was significantly worst compared to the NORMAL details (8.5±0.8, p=0.01) with an unacceptable image quality using the combination of DOSE CONTROL protocol and LOW details. On the other hand, the best setting in term of exposure and image quality was the CARDIAC protocol with LOW Details.

Conclusions: The use of LOW details of acquisitions was correlated with a significant reduction in term of radiation exposure compared to NORMAL details but it is also associated with a significant worsening in term of image quality. Combining different pre-set protocols and different details of acquisition it is possible to significantly reduce the patient and operator radiation exposure without compromising the image quality.

Other Coronary interventions - Other

Patients' assessment of a newly established heart lounge

MORTENSEN Karoline Schou [(1)], MORTENSEN Karoline [(1)], FAERCH Jane [(1)], LARSEN Kim Schulz [(2)], NOERGAARD Marianne Wetendorff [(1)]

(1) Rigshospitalet, opgang 2, Copenhagen Municipality, Denmark; (2) Medtronic, Copenhagen, Denmark

Aims: With a focus on continuous quality improvement, to examine cardiac patients' experiences of their stay in a heart lounge at a large university hospital and how these are related to what they have expected and their satisfaction with care, privacy and stay.

Methods and results: A prospective questionnaire survey was performed with patients undergoing an invasive procedure with same day discharge. All patients admitted to the Heart Lounge were eligible for inclusion. The survey covered stabile patients undergoing elective trans-radial or trans-femoral coronary angiography or percutaneous coronary interventions, pacemaker and ICD implantations and patients admitted for pacemaker generator replacements. All patients were provided with a questionnaire prior to discharge and were informed of voluntary participation and anonymity in the answers. Data collection period was November and December 2019. The patients were provided the opportunity to complete the questionnaire either by hand or via the internet on an IPAD with logins to a specified website. The specific questions included in the questionnaire were all statements related to the patients' stay in the heart lounge; e.g., waiting time, privacy, hospital catering service and information while in the lounge; e.g., "I experienced enough respect for my privacy when the staff was handing over personal information". Patient responses to each question were scored in a six-point Likert scale from strongly agree to strongly disagree. In addition, two open questions were asked: "What was your most positive experience with your stay in the heart lounge" and "What could have made your stay in the heart lounge even better". Finally, patients had to answer and score two questions:" How satisfied are you overall with the heart lounge" and "How likely are you to recommend staying in the heart lounge to others"? The patients ranked these answers on a scale from 0-10. Data from 82 patients, 23 (28%) female and 59 (72%) male, mean age 50±11 years were analysed. The results showed that patients were predominantly satisfied within all parameters; 82% agreement on satisfactory catering service, 89% agreed that their privacy was respected, 89% agreed that their expectations for the heart lounge were met, 95% agreed that a sufficient information was given and 98% agreed that the lounge was a comfortable place to wait for examination and treatment. The patient's descriptions of the most positive experiences can be condensed within the themes: Interaction with staff and experiences of room and interior design and with suggestions for improvement of catering service and lighting in the lounge. 81% of respondents would recommend the heart lounge to others.

Conclusions: A heart lounge is suitable for selected patients' stay before and after undergoing an invasive procedure with fulfilled expectations and great satisfaction from the patients. The results may be useful for other hospitals that desire to give patients a different experience by establishing a heart lounge with less hospitalisation.

Other Coronary interventions - Other

Prediction of live operator radiation exposure from a real-time patient dose tracking system

ISON Glenn [1,2], ISON Glenn [1,2], KRISHNAMOORTHY Roopa [1], KEEN Amber [1], PRASAN Ananth [1], ROY James [1]

(1) St George Hospital, NSW, Australia; (2) Hurstville Private Hospital, NSW, Australia

Aims: Increasing operator radiation dose due to rising procedure volume and complexity is an ongoing concern in invasive cardiology. Real-time wearable radiation monitors are not widely adopted as they are problematic due to high cost and inconsistent use. Current in-built dose tracking systems are patient centred and do not account for operator exposure. We attempted to calculate real-time operator dose levels for the eye, torso and lower legs using radiation monitors and correlated this to the live readouts of the colour coded patient skin dose tracking system (Canon MedicalTM).

Methods and results: Using a full torso phantom (RandoTM) and multiple portable radiation monitors (PolymasterTM), we measured the radiation scatter dose levels at the primary operator and assistant positions in the cathlab at, eye (155 cm), torso (100 cm) and lower leg (155 cm). Multiple angiographic views were studied. The measurements were done with the over and under table shielding in their usual procedural positions and the usual x ray dose settings selected. A coefficient between the dose levels displayed by the real time colour patient dose tracking system and the experiments measured dose at each operator position and height was calculated. Over 300 measured data sets where collected. The calculated coefficients for 1st operator using fluoroscopy were: in the AP position; eye 22.46, body 60.42, knee 0.6. For Rao 30 Cra 30 position, eye 25.66, body 99.98, knee 0.25. For Rao 30 Cau 30 position, eye 0.29, body 80.76, knee 0.69. For Lao 30 Cra 30 position, eye 16.92, body 120.91, knee 1.1. For Lao 30 Cau 30 position, eye 1.1, body 94.01, knee 1.6. The calculated coefficients for the 2nd operator using fluoroscopy were: In the AP position, eye 6.1, body 14.84, knee 20.34. For Rao 30 Cra 30 position; eye 8.78, body 18.28, knee 36.29. For Rao 30 Cau 30 position; eye 2.76, body 17.7, knee 31.85. For Lao 30, Cra 30 position; eye 5.51, body 38.11, knee 47.54. For Lao 30, Cau 30 position; eye 0.84, body 29.48, knee 23.45. The calculated coefficients for the 1st operator using angiography were: In the AP position; eye 13.1, body 26.81, knee 0.73. For Rao 30, Cra 30 position; eye 14.5, body 50.49, knee 0.03. For Rao 30, Cau 30 position; eye 0.21, body 53.36, knee 0.43.For Lao 30, Cra 30 position; eye 15.9, body 64.69, knee 0.61.For Lao 30, Cau 30 position; eye 12.58, body 64.02, knee 0.62. The calculated coefficients for the 2nd operator using angiography were: In the AP position; eye 4.27, body 8.37, knee 9.96. For Rao 30 Cra 30; eye 7.17, body 13.5, knee 20.41. For Rao 30 Cau 30; eye2.32, body 12.08, knee 22.93. For Lao 30 Cra 30; eye 2.65, body 19.9, knee 28.14. For Lao 30 Cau 30; eye 5.88, body 17.63, knee 8.74.

Conclusions: We have shown the potential for an easily applicable coefficient between the displayed patient dose tracking and operator radiation exposure. This allows for an accurate estimate of real time operator eye, torso and lower leg radiation dose. Adoption of this approach, we believe, would further encourage operators to adopt radiation protection strategies including alteration of angiographic views and dynamic shielding. All catheterisation labs with a built-in patient dose system should consider calculating a local coefficient to estimate local operator exposure. Additionally, patient dose tracking system vendors should incorporate a coefficient to their software and consider adding an operator avatar to the patient one on the real-time monitoring display.

STEMI - Tools, devices and techniques, NSTEMI - Tools, devices and techniques

Nursing management of patients requiring mechanical circulatory support devices

DEIBLE Regina [1], DEIBLE Regina [1]

(1) ABT, Santa Clara, CA, USA

Aims: Cardiogenic shock (CS) is a haemodynamically complex syndrome often associated with high mortality. Despite advances in reperfusion and MCS, management remains variable & outcomes poor. While the growing body of evidence begs for timely recognition of CS, haemodynamic monitoring, escalation to MCS, and centralised care; variations in CS management persist and may contribute to high mortality rates. Many have hypothesised that a need for a multidisciplinary "shock team" to provide timely diagnosis and utilize standardised protocols would equate to reduced practice variations and improved clinical outcomes.

Methods and results: We review published data, evidence-based data, cardiogenic shock (CS) working group progress and practice patterns demonstrating the impact of CS team approach to care. We highlight experience of "Shock Centres" with specific focus on the nursing management of patients requiring mechanical circulatory support devices. Addtionally, we review SCAI CS classification system to emphasise key considerations in the diagnosis and management of CS to further elucidate the stages of shock and care protocols.

Conclusions: There is a growing body of data to support the Implementation of a shock team. This has been based on a multidisciplinary standardised team-based approach that emphasises timely diagnosis, invasive haemodynamics, and appropriate use of MCS. This is not only feasible but may result in improved survival in all-comer patients with CS (as demonstrated in the literature). Additionally, scores and CS Stage classifications have been developed which now use demographic, laboratory, and haemodynamic markers to help stratify risk and guide clinical decision-making in patients with all types of CS. This has become a global focus and many efforts have emerged which help apply standardised multidisciplinary care in a coordinated regionalised approach. The result of these concerted efforts are not only a reduced practice variation, but importantly, there may be improved patient outcomes.

Euro20A-OP042
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Coronary angiography and PCI after TAVI: insights from a tertiary centre

GONÇALVES Mariana [1], GONÇALVES Mariana [1], DE ARAÚJO GONÇALVES Pedro [1], CAMPANTE TELES Rui [1], BRÍZIDO Catarina [1], FÉLIX OLIVEIRA Afonso [1], BRITO João [1], RAPOSO Luís [1], MESQUITA GABRIEL Henrique [1], GAMA Francisco [1], DE SOUSA ALMEIDA Manuel [1]

(1) Santa Cruz Hospital, Carnaxide, Portugal

Aims: To evaluate the incidence of myocardial infarction (MI), rate of invasive coronary angiography (ICA) and percutaneous intervention (PCI) after transcatheter aortic valve implantation (TAVI).

Methods and results: Between October 2007 and December 2018, 563 patients underwent TAVI in a tertiary centre and were included in this registry. Mean age was 82±7 years, 47% were male, 21% had previous history of heart surgery, 25% of previous PCI and 16.6% of MI. The mean EuroSCORE II was 5.5%±4.2. The number of patients undergoing elective PCI for TAVI was 11%. In a mean follow-up of 31.6±24.9 months, 9 (1.6%) patients experienced an acute coronary syndrome. From these, 4 (44%) underwent ICA and the other 5 (56%) were considered for medical therapy (mainly type 2 MI with recognised secondary causes). Another 8 patients underwent ICA in the setting of stable coronary artery disease from which 6 (75%) underwent PCI. Two patients required a second attempt on the same admission due to the inability to perform selective coronary angiography. Overall, 12 (2%) patients underwent ICA after TAVI, from which 33% had received an Edwards® (n=4), 42% CoreValve® (n=5), 17% Symetis® (n=2) and 1 Portico®. Median procedural time was (7/10) 89 min (IQ 99) and contrast dose 190 mL (IQ 147), mean fluoroscopy time 26±15 and effective radiation dose was 1656±1462 mGy. In one patient selective coronary angiography was not possible and in another only incomplete revascularisation was performed due to impossibility of delivering the stent through the CoreValve® struts.

Conclusions: In this population of 563 patients with a mean follow-up of 32 months, a strategy of previous guideline-guided revascularisation is associated with a low rate of acute MI (with no ST-elevation MI), repeated ICA and PCI after TAVI. Valve design may impact access to coronary arteries but since this occurrence is uncommon this feature may not be a priority in the choice of TAVI device.

TAVI - Tools, devices and techniques

Evolution of procedural outcomes after transcatheter aortic valve-in-valve implantation: 12 years of experience from a single high-volume centre

KITAMURA Mitsunobu [(1)], KITAMURA Mitsunobu [(1)], BANI HANI Amjad [(1)], ROTTA DETTO LORIA Johannes [(1)], DUMPIES Oliver [(1)], MAJUNKE Nicolas [(1)], DESCH Steffen [(1)], BORGER Michael [(1)], THIELE Holger [(1)], HOLZHEY David [(1)], ABDEL-WAHAB Mohamed [(1)]

(1) Heart Centre Leipzig at University of Leipzig, Leipzig, Germany

Aims: Transcatheter aortic valve-in-valve implantation (ViV) is a reasonable therapeutic option for high-risk patients with structural valve deterioration (SVD) of a degenerated surgical aortic valve (SAV). However, concerns of severe patient-prosthesis mismatch (PPM), iatrogenic coronary obstruction and cerebral embolisation remain after ViV. In this study, we sought to demonstrate the evolution of procedural outcomes after ViV over a period of 12 years at a single institution.

Methods and results: From 2007 to 2019, and out of 5466 transcatheter aortic valve implantation (TAVI) procedures, a total of 239 ViV procedures were performed. The degenerated SAV was an internally-mounted leaflet type in 161 patients (67%), an externally-mounted leaflet type in 62 (26%), a stentless valve in 12 (5%) and a rapid deployment valve in 4 (2%). Transcatheter heart valves (THVs) were successfully implanted in 228 patients (95%) with correct positioning of a single THV, and neither major complications nor in-hospital mortality. There were 5 (2.1%) in-hospital deaths due to left ventricular (LV) perforation (n=1), left coronary obstruction (n=1), vascular access complication (n=2), and intraprocedural occlusion of right internal carotid artery (n=1). At discharge, paravalvular leakage (PVL) >1+ was observed in 4 patients (1.7%), and 69 patients (29%) showed mean transprosthetic gradient of 20 mmHg or more. Severe PPM (iEOA <0.65 cm^2/m^2, or iEOA < 0.60 cm^2/m^2 if body mass index > 30 kg/m^2) was diagnosed in 47 patients (20%), and was more common after balloon-expandable than self-expanding THVs (33% vs 16%, p=0.005). Bioprosthetic valve fracture (BVF) was introduced in the last tertile of procedures (case 161-239), which was associated with a lower incidence of severe PPM (0% in ViV with BVF vs 21% in ViV without BVF, p=0.087). Coronary obstruction occurred in 2 patients (0.8%), and both patients had a stentless SAV with pericardial leaflets. Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction (BASILICA) was performed in 14 patients (all in tertile 3) with high-risk for coronary obstruction based on a shallow aortic root. In addition, 5 patients (2.1%) underwent chimney stenting after ViV. Hence, a total of 21 patients (8.8%) were at risk of potential coronary obstruction. Stroke after ViV was observed in 6 patients (2.5%) during the 1st and 2nd tertile of procedures (cerebral protection in 21%), while no cases of stroke were observed in tertile 3 (cerebral protection in 73%).

Conclusions: Short-term procedural outcomes after ViV have improved over time, and the introduction of ancillary procedures (such as BVF, BASILICA and cerebral protection) may have significantly contributed to this positive evolution. However, a considerable number of patients still suffer from severe PPM after ViV. Predictors of PPM and establishing indications for BVF should be addressed in future studies.

Euro20A-OP046
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Intentional leaflet laceration to prevent TAVI-induced coronary obstruction: first systematic single-centre European experience with the BASILICA technique

ABDEL-WAHAB Mohamed [1], ABDEL-WAHAB Mohamed [1], KITAMURA Mitsunobu [1], MAJUNKE Nicolas [1], DUMPIES Oliver [1], KRIEGHOFF Christian [1], ENDER Jörg [1], BORGER Michael [1], THIELE Holger [1], DVIR Danny [2], HOLZHEY David [1]

(1) Herzzentrum Leipzig, Leipzig, Germany; (2) Seattle University, WA, USA

Aims: Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) is a new transcatheter procedure which involves a catheter-directed electrified guidewire that lacerates the pre-existing aortic leaflet (native or failed prosthetic) immediately before transcatheter aortic vale implantation (TAVI) in patients at high risk for coronary obstruction. We report on the first systematic single-centre European experience with this emerging new technique.

Methods and results: Symptomatic patients with severe native aortic stenosis or failing aortic bioprostheses at high surgical risk and high risk for coronary obstruction were enrolled in this prospective single centre registry. Clinical events were judged according to the VARC-2 criteria. Multislice computed tomography (MSCT) was performed at baseline (for procedural planning and to assess the risk for coronary obstruction) and post-procedure (to confirm coronary patency and exclude hypoattenuated leaflet thickening). A total of 18 patients (age 78±6 years) with a EuroSCORE II of 12.2±6.3% and an STS score of 7.7±4.4% were included into this analysis. Severe stenosis of the prosthesis or native aortic valve was the main cause for treatment (56%), whereas the remaining patients were treated for either severe regurgitation (22%) or mixed disease (22%). The majority of patients had a failing surgical bioprothesis (n=15, 83%), one patient had failure of a self-expanding transcatheter heart valve and two patients had native aortic valve stenosis. Coronary height was less than 10 mm in all patients, and the mean virtual transcatheter heart valve to coronary distance was 3.7±0.8 mm. A cerebral embolic protection device was used in 17 patients (94%). Successful BASILICA traversal and laceration was achieved in all but one patient (94%) and in all but one leaflet (n= 19, 95%). Single leaflet BASILICA was attempted in 16 (left-only) and double leaflet BASILICA in 2 procedures. The majority of patients were treated with a self-expanding device (n=15/83%), whereas 3 patients (17%) were treated with a balloon-expandable device. Total procedure time was 109±43 min, BASILICA time was 31±25 min, and fluoroscopy time was 50.7±24.6 min. Early safety events within 30 days according to the VARC-2 definition occurred in 1 patient (5.5%). In this patient, a 29 mm balloon-expandable valve was implanted after successful laceration of the left coronary leaflet of a failed stentless surgical valve. After valve implantation, the right coronary artery was occluded. Recanalisation and percutaneous intervention was successful and the patient was discharged without sequelae. Freedom from emergency surgery, need for reintervention, life-threatening bleeding, vascular complications, acute kidney injury (stage 2 or 3) or stroke was 100%. Post-procedural MSCT scans showed coronary patency in all patients and no hypoattenuated leaflet thickening.

Conclusions: BASILICA in patients at high risk for coronary obstruction appears feasible, safe and effective when performed by an experienced team. The systematic use of cerebral embolic protection devices during BASILICA may prevent thromboembolic events. Larger studies with longer follow-up are necessary to elucidate the long-term outcomes of this emerging technique.

Euro20A-OP048
Abstract | Oral presentation

TAVI - Tools, devices and techniques

TAVI with LOTUS Edge: early European experience

ARMARIO Xavier [1], ARMARIO Xavier [1], MYLOTTE Darren [1], ROSSEEL Liesbeth [1], MCGRATH Brian [1]

(1) University Hospital Galway, Galway, Ireland

Aims: To evaluate the clinical outcomes of transcatheter aortic valve implantation (TAVI) with the recently released LOTUS EdgeTM system.

Methods and results: We performed a multicentre retrospective registry to generate early information on patients undergoing TAVI following commercial release of the LOTUS EdgeTM system. Novel features of this second-generation device include increased flexibility of the delivery catheter, enhanced visualisation of the locking mechanism and depth guard technology to reduce interaction of the valve frame and the LVOT. A new method of device deployment was also utilised for the first time. Participation in the registry was voluntary. All data were site-adjudicated according to VARC-2 definitions. A total of 280 consecutive patients undergoing LOTUS EdgeTM implantation from 17 participating centres were included. The mean age and STS score were 82±6,9 years and 5.0±5,5%, respectively. Most patients were treated under local anaesthesia (97.3%) via transfemoral access (98.9%). Valve pre- and post-dilatation were performed in 54.6% and 2.1%, respectively. In-hospital (1.4%, N=4) and 30-day (2.1%, N=6) mortality and 30-day (N=9, 3.2%) stroke rates were acceptable. Major vascular complications occurred in 1.8% and life-threatening/major bleeding in 3.6%. Moderate to severe paravalvular leak occurred in 1.0%. New permanent pacemaker was required in 24.3%.

Conclusions: Early experience with the LOTUS EdgeTM TAVR system demonstrated acceptable short-term mortality and stroke rates and an impressively low incidence of paravalvular leak. The requirement for new permanent pacemaker remain high but is reduced as compared to the predicate LOTUS device.

Euro20A-OP051
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Long-term outcome comparison of patients undergoing TAVI with balloon or self-expanding bioprostheses

COSTA Giuliano [1], COSTA Giuliano [1], BARBANTI Marco [1], PICCI Andrea [1], SGROI Carmelo [1], TAMBURINO Corrado [1]

(1) AOU Policlinico-Vittorio Emanuele, Catania, Italy, Catania, Italy

Aims: We sought to compare long-term (7-year) mortality and structural valve dysfunction of patients undergoing transcatheter aortic valve implantation (TAVI) with balloon- or self-expanding bioprostheses

Methods and results: Patients seen from June 2007 to December 2014 were included. They had a mean age of 80.7±5.3 years and a mean Society of Thoracic Surgery mortality score of 4.7±3.3%. Patients received either balloon- (26.7%) or self-expanding (73.3%) bioprostheses. After propensity score weighting adjustment, 288 patients were matched with a 1:1 ratio according the type of the transcatheter aortic valve (TAV) implanted. No difference was encountered in post-procedural mean aortic gradients between the two matched groups (10.1±4.5 vs 9.7±4.2 mmHg for balloon- and self-expanding TAV matched group, respectively, p=0.51). The overall survival estimate was 43.4% at 7 year. Patients receiving balloon-expandable TAV showed a higher survival at 7 years (hazard ratio [HR] 1.4, 95% confidence interval [CI] 1.0-1.9, p=0.05). Severe and moderate structural valve dysfunction (SVD) rates were similar between the two matched TAV groups at 7 years (1.4% vs 0.7% and 2.1% vs 2.8% for balloon- and self-expanding TAV matched group, respectively; p=0.57 and p=0.70, respectively).

Conclusions: Comparing patients undergoing TAVI with either balloon- or self-expanding first-generation TAV, balloon-expandable treated showed a higher survival with similar rates of SVD between the two matched groups at 7 years.

TAVI - Tools, devices and techniques

Risk and benefit of bioprosthetic valve fracture: a report from an international multicentre registry

BRINKMANN Christina [1], SCHOFER Joachim [1], TCHÉTCHÉ Didier [2], ABDEL-WAHAB Mohamed [3], WEBB John [4], WINDECKER Stephan [5], HILDICK-SMITH David [6], TARAMASSO Maurizio [7], CONRADI Lenard [10], RIEß Friedrich-Christian [9], WITT Julian [9], SATHANANTHAN Janarthanan [4], OLIVER Bhadra [10], MIURA Mizuki [7], PILGRIM Thomas [5], BEDOGNI Francesco [11], TESTA Luca [11], OOMS Joris [12], NICOLAS Van Mieghem [12], MYLOTTE Darren [8], WOLF Alexander [13], CHARBONNIER Gaetan [2]

(1) Medical Care Center Prof. Mathey, Prof. Schofer, Department of structural heart disease, Hamburg, Germany; (2) Clinique Pasteur, Toulouse, France; (3) Herzzentrum Leipzig, Leipzig, Germany; (4) St. Paul's Hospital, BC, Canada; (5) Inselspital, Universitätsspital Bern, Bern, Switzerland; (6) Sussex University, Brighton, United Kingdom; (7) Universitätsspital Zürich, Zürich, Switzerland; (8) Bon Secours Hospital Galway, Galway, Ireland; (9) Albertinen Krankenhaus, Hamburg, Germany; (10) Universitätsklinikum Hamburg-Eppendorf, Hamburg, Germany; (11) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy; (12) Erasmus Universiteit Rotterdam, Rotterdam, the Netherlands; (13) Elisabeth-Krankenhaus Essen, Essen, Germany

Aims: Prosthesis-patient-mismatch (PPM) after surgical aortic valve replacement (SAVR) increases mortality. Valve-in-valve transcatheter aortic valve implantation (VIV-TAVI) is often used to treat degenerated aortic bioprostheses (DAB). Bioprosthetic valve fracture (BVF) VIV-TAVI can reduce the incidence of PPM. The aim was to evaluate the risk and benefit of this procedure. Data was derived from an international multicentre registry.

Methods and results: Data of 72 patients (pts) with DAB who underwent BVF and VIV-TAVI were collected from 13 centres. PPM was calculated based on the true internal diameter (ID) of the DAB. BVF was performed with non-compliant balloons (NCB) sized 1 – 4 mm larger than DAB true ID. PPM after BVF was calculated based on the diameter of the completely inflated NCB. Transvalvular gradients were measured either haemodynamically or by echocardiography. VARC-defined device success, early safety composite, clinical efficacy after 30 days and specific BVF related periprocedural complications like aortic route rupture, ventricular septal perforation, balloon rupture leading to clinical consequences, cardiac tamponade, coronary obstruction, among others as well as reinterventions at follow-up were evaluated. Mean age was 76.5±8.2 years (42% male), mean STS prom score 4.9±3.1% and mean LogEuroSCORE I 22.4±12.8%. BVF was performed in 7 types of DAB (Sorin Mitroflow 31 %, Medtronic Mosaic 21 %, Edwards Magna 18 %, Edwards Perimount 22 %, St. Jude Epic 4 %, Edwards CE Standard 3 %, Sorin Pericarbon Freedom 1 %) with a mean duration after SAVR of 11.4±3.6 years. Degeneration mode was stenosis in 47 %, regurgitation in 13 % and mixed in 40%. Meantrue DAB ID was 19.2±2.0 mm (range 16 – 25 mm), max/min gradients were 62.3/37.2 (± 20.1/13.1). Moderate or severe PPM was present in 59.4 % after surgical valve replacement. VIV-TAVI was performed with balloon-expandable (Edwards SAPIEN) in 25% and self-expanding transcatheter heart valves (THV) in 75% (Medtronic Evolut 89%, (NVT Allegra 6 %, Boston Scientific Acurate Neo 2 %, Abbott Portico 2 %). BVF was performed with NCB either prior (13 %) or after (87 %) TAVI. In relation to the true ID of the DAB the NCB was oversized by a mean of 2.8±1.1 mm. Mean transvalvular gradient was reduced by VIV-TAVI with BVF from 37.2±13.1 mmHg to 12.9±6.5 mmHg and the incidence of moderate to severe PPM from 59.4 % to 19 %. In pts with TAVI prior to BVF the haemodynamic peak to peak gradient was 38.5±18.0 mmHg at baseline, 21.9±12.5 mmHg after TAVI (p=0.0001), and 6.9±6.1 mmHg after BVF (p<0.0001 vs TAVI without BVF). Device success was 86.1 %, in 11 % a gradient ³20 mmHg was the reason for failure. VARC-2-defined periprocedural and 30-day-complication rate was 4.2 % (3 pts): 1 pt died after balloon rupture in the presence of severe LVOT- and aortic root calcification, 2 pts had ventricular septal perforation after BVF without clinical consequences. Two pts needed a second TAVI 3 and 6 months after BVF because of severe valvular regurgitation. In both pts BVF was performed after TAVI.

Conclusions: BVF can significantly reduce the residual gradient and eliminate PPM after SAVR in the majority of pts, which may improve long-term outcome. The procedural risk seems to be acceptable, although more data needs to be collected in particular on longer-term follow-up, because severe THV dysfunction, which was observed 3 to 6 months after BVF in 2 pts, is of concern.

Euro20A-OP057
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Early experience of nurse led management of patients undergoing TAVI

FRANZA Davide [1], FRANZA Davide [1], DASTIDAR Amardeep [1], DORRINGTON Toni [1], BOHIN Rachel [1], YEAROO Ibrahim [1], HONEYANDS Benjamin [1], OBEIDALLA Abubaker [1], TURNER Mark [1], DORMAN Stephen [1], JOSHI Nikhil [1]

(1) Bristol Royal Infirmary, Bristol, United Kingdom

Aims: The aim of the project was to describe early experience and learning of transition from anaesthetic lead management of sedation to a nurse led management in patient undergoing TAVI in a large tertiary centre.

Methods and results: We retrospectively analysed patients from our TAVI database who had undergone nurse-led TAVI (53). We collected data with respect to changes in the aspects of care that we transitioned to nurse led service. We also collected periprocedural data, outcomes including length of stay, complications, pacemaker rates and in hospital mortality. Results: A total of 210 numbers of TAVIs were undertaken between January 2019 to December 2019 and 53 were managed by a trained nurse. The average age of patients undergoing nurse led TAVI was 84 yrs (female 38%). The valve type used was Edwards S3/Ultra 75% cases (n=40), Medtronic Evolut 17% (n= 9) and Abbott Portico 8%(n=4). The procedure was uncomplicated in a majority of cases (96%) with MACE of 4% (1 death and 1 patient needing emergency vascular repair), 13% (7 patients) required PPM. There were no periprocedural MI or stroke. None of the patients needed further advanced input from anaesthetic. For transition period, in-house nurse led intensive training programme was developed for periprocedural care to be standardised. The transition from anaesthetic led to nurse led sedation provided abundant learning opportunities. First, from a team of 3 anaesthetic staff members, we could transition to 1 extra nursing staff who was trained with basics of sedation, analgesia prescribing and basic airway management. We devised a standardised protocol which included paracetamol IV, fentanyl, midazolam and antibiotics. Efficiency was significantly improved as evidenced by shorter procedure time, and furthermore, length of patient stay was reduced.

Conclusions: Nurse-led sedation during TAVI procedures is feasible, safe, efficient and likely to streamline patient care pathways and improve cost effectiveness.

Euro20A-OP060
Abstract | Oral presentation

TAVI - Echocardiography, Tricuspid / Pulmonary valve - Echocardiography

Long-term outcomes in patients with severe tricuspid regurgitation undergoing TAVI

BRENNAN Paul [(1)], BRENNAN Paul [(1)], COLLINS Patrick [(1)], COBURN Jaimie [(1)], SANTOS Angelo [(1)], NZEWI Onyekwelu [(1)], JOHNSTON Nicola [(1)], OWENS Colum [(1)], JEGANATHAN Reuben [(1)], SPENCE Mark S [(1)], MANOHARAN Ganesh [(1)]

(1) Royal Victoria Hospital, Belfast, United Kingdom

Aims: Concomitant tricuspid regurgitation (TR) is frequently encountered in patients undergoing transcatheter aortic valve implantation. Several groups have reported 1-year mortality rates of around 33% in patients with moderate or severe concomitant TR but outcomes of patients with isolated severe TR aren't well described. We aimed to assess pre-procedural characteristics and outcomes for all patients with severe TR undergoing TAVI in our hospital.

Methods and results: Baseline characteristics were retrospectively analysed using the National Institute for Cardiovascular Outcomes Research (NICOR) database and Northern Ireland Electronic Care Record (NIECR). Kaplan Meier survival analysis was used to assess median long-term survival. 1033 consecutive patients had TAVI between February 2008 and December 2018 (mean age 81.7±6.8 years, female 53.5% (n=553), mean EuroSCORE II 8.4±7.9%). A total of 54% patients (n=556) had no/trace TR, 37% (n=383) mild/mild-moderate TR, 8% (n=82) moderate/mod-severe TR. Severe TR was seen in 1% (n=12) patients (mean age 83.5±4.5 years, female=67%, mean EuroSCORE II 19.9±14.5%). Of the 12 pts with severe TR, 83% (n=10) had atrial fibrillation (AF), 33% (n=3) had impaired left ventricular systolic function (LVSF), 42% (n=5) had impaired right ventricular systolic function (RVSF) and 33% (n=4) had co-existing moderate or severe mitral regurgitation (MR). A raised estimated pulmonary artery systolic pressure (PAP) was observed in 42% (n=5) patients and a history of COPD was seen in 33% (n=4) patients. Renal impairment was common in this patient group with a mean creatinine clearance of 33.3±13.7 ml/min. Transfemoral TAVI under local anaesthesia was performed in 92% (n=11) patients. Stroke, new permanent pacemaker requirement, major vascular injury and/or cardiac tamponade were not observed in any patients with severe TR during the periprocedural period. Persistent severe TR on pre-discharge TTE was observed in 67% (n=8) patients, with the remaining 33% (n=4) showing an improvement of at least 1 TR grade. All patients with severe TR survived to discharge with a median length of stay of 5 days (range 1-31). In pts with severe TR, the 30 day and 1-year mortality were 0% and 33% (n=4) respectively. A total of 58% (all-cause n=7 [cardiovascular mortality n=4]) pts died at any time during follow-up and the median survival estimate was 2.3 years (95% CI: 1.2-3.5), with 2 patients, to date, surviving >5 years. The patients that died during follow-up were older than those still alive (85±5 years vs 82±4 years) and of similar EuroSCORE II risk (19±17% vs 21±13%). AF was observed in 71% (n=5) of the 7 patients that died during follow-up compared to 29% (n=2) in the 5 still alive. The combination of severe TR and at least moderate MR was seen in 4 patients in whom 3 died during follow-up. Impaired LVSF and RVSF occurrence was no higher in the patients that died during follow-up, nor was COPD. A total of 42% (n=5) patients were readmitted with heart failure (HF) at 1 year. Infective endocarditis was not observed in this patient group.

Conclusions: TAVI in patients with severe TR can be performed safely with good short-term outcomes, however 1 yr and long-term mortality are high. Despite this, a select few do survive >2 years post-TAVI and perhaps better, more detailed patient selection for TAVI, by excluding those with AF or MR >moderate, could benefit some of these unfortunate high-risk patients with severe TR. A larger study will help define these risks further.

Euro20A-OP065
Abstract | Oral presentation

TAVI - Vascular access and bleeding

Routine use of ultrasound-guided vascular access management to minimise vascular and bleeding complications in a very high-risk TAVI population

NICOLINI Elisa [1], NICOLINI Elisa [1], PIVA Tommaso [1], MAOLO Alessandro [2], TERRACCIANO Francesco [1,3], BELTRAME Mirko [1], SCHICCHI Nicolò [1], MUCAJ Andi [1], ANGELOZZI Andrea [1], GABRIELLI Gabriele [1]

(1) Ospedali Riuniti Torrette Di Ancona, Province of Ancona, Italy; (2) Ospedale Generale Provinciale, Province of Macerata, Italy; (3) Università degli Studi della Campania Luigi Vanvitelli, Metropolitan City of Naples, Italy

Aims: To demonstrate feasibility of ultrasound-guided femoral artery access management strategy and its efficiency to minimise vascular and bleeding complications in a high risk TAVI cohort.

Methods and results: This was a single-centre prospective cohort study, including all patients who underwent a TAVI procedure from September 2017 to December 2019. An accurate pre-interventional screening using multidetector computed tomography of iliac-femoral arteries was performed. We analysed: lumen diameters and area of common femoral and iliac artery, SFAR ratio, pattern of calcification at the puncture site subdivided in four quadrant and described as follow: none or calcification spot on posterior wall (<25% of the circumference), calcification extended to medial and/or lateral wall (>25% but <75%), level of femoral bifurcation and of inferior border of epigastric artery and their correspondence to femoral head, depth of femoral artery, extent and complexity of atherosclerosis. According to these features and using anatomic landmarks, we created a coordinate of ideal entry site. The femoral access was obtained without contrast use. A final digital subtraction angiography was made through the left radial artery, to evaluate adequate haemostasis and assess vascular patency. Our outcomes were access-site-related major and minor vascular complications, life-threatening, major and minor bleeding and the need for packed red blood cell transfusion. Definitions were based on the VARC-2 criteria. Results: The study cohort included 290 patients: median age was 83 years, with 56,6% being women, predicted mortality was 7,2% by EuroSCORE II and 8±4% by STS score, diabetes 28%, chronic renal failure 59%, history of peripheral vascular disease 36%, obesity 23,4% with 13% of morbid obesity, dialysis 4,1% and 24,8% of urgent TAVR. We implanted: Evolute R and Pro (46,9%), SAPIEN3 (35,3%), Acurate Neo (15,8%) and Portico (2%). According to CT imaging, we identified an high rate of vascular and bleeding complications predictors: 37% of patients had common femoral artery diameter < 6,5 mm, median SFAR of 1,01±0,16 with 22% of patients having a SFAR > 1,05; in 23% of cases femoral bifurcation was judged high, the distance between the inferior border of epigastric artery and femoral bifurcation was < 3 cm in 48% of cases, with a small target zone for puncture. Calcifications on lateral and or medial quadrant were present in 41,5% of cases of which 13% had calcifications in both quadrants. In 31,8% of the patients the common femoral artery depth was > 4 cm. Even though these are high-risk features, no access site-related major vascular complications were observed and 5 minor vascular complications (1,7%) occurred. In 4 cases, patients were women, with severe chronic renal disease and with a small femoral artery (minimal diameter 5,7±0,2 mm, SFAR > 1,05). The proportion of major bleeding (4,6%) and access-related transfusion was very low (4,5%). In reference to major bleeding, 1 case was access-related due to a self-limited retroperitoneal haematoma occurred after 3 days in a patient taking anticoagulant therapy.

Conclusions: A pre-specified and accurate pre-interventional CT screening combined with a routine use of ultrasound vascular access management were seen to be feasible and associated with a very low rate of access-related vascular and bleeding complications in a high risk population.

Euro20A-OP069
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Real-world experience with the SAPIEN 3 Ultra: a propensity matched analysis from the USA

NAZIF Tamim [1], DAVID Daniels [4], GEORGE Isaac [1], JAMES McCabe [3], KANEKO Tsuyoshi [8], WANG John [7], RODRIGUEZ Evelio [5], KRISHNASWAMY Amar [2], KAPADIA Samir [2], MAKKAR Rajendra [6], LEON Martin [1]

(1) Columbia University, NY, USA; (2) Cleveland Clinic - Main Campus, OH, USA; (3) University of Washington, WA, USA; (4) Sutter Health, CA, USA; (5) Saint Thomas West Hospital, TN, USA; (6) Cedars-Sinai Medical Center, CA, USA; (7) MedStar Union Memorial Hospital, MD, USA; (8) Brigham and Women's Hospital, MA, USA

Aims: The SAPIEN 3 Ultra (ULTRA) is a new-generation balloon-expandable transcatheter heart valve (THV) with an enhanced outer sealing skirt intended to reduce paravalvular leak (PVL). Limited data are available on the haemodynamic performance of the ULTRA THV.

Methods and results: The STS/ACC TVT RegistryTM was queried for transcatheter aortic valve replacement (TAVR) procedures performed with the SAPIEN 3 (S3) or ULTRA THV between January 2018 and October 2019. Non-transfemoral arterial access was excluded, as was the use of a 29 mm THV, since the ULTRA was not available in this size. A propensity score matched analysis was performed with 1:1 matching of 26 covariates using a logistic regression model. Missing baseline values were imputed with the Markov chain Monte Carlo method. Echocardiographic and clinical outcomes were evaluated at hospital discharge and 30 days, respectively. From an analysis population of 59,142 patients, all 803 ULTRA patients were matched with 803 S3 patients. The matched ULTRA and S3 recipients were similar with respect to important baseline characteristics, including age (79.3 vs 79.6 years, p=0.47), male sex (46 vs 46%, p=1.0), and STS score (4.7 vs 4.8, p=0.45). Baseline echocardiographic variables were also similar, including aortic valve mean gradient (43.1 vs 43.1 mmHg, p=0.99), aortic valve area (0.72 vs 0.74 cm^2, p=0.16), and left ventricular ejection fraction (58.4 vs 58.2%, p=0.76). Almost 99% of patients received a 23 or 26 mm THV, and only 1.2% received a 20 mm THV. The use of conscious sedation was more frequent among ULTRA patients (72.4 vs 63.0%, p<0.01), and the ULTRA was associated with shorter procedure time (79.3 vs 83.6 min, p=0.03), shorter fluoroscopy time (13.8 vs 14.9 min, p=0.04), and less contrast volume (78.9 vs 92.8 mL, p<0.01). Major procedural complications, including annulus rupture, coronary obstruction, cardiopulmonary bypass, and conversion to open surgery were extremely rare (<1% combined) and similar between groups. At 30 days, there were no between-group differences (ULTRA vs S3) in important clinical outcomes, including all-cause mortality (1.5 vs 1.6%, p=0.76), cardiovascular mortality (0.7 vs 0.9, p=0.62), stroke (1.3 vs 2.1%, p=0.27), major vascular complications (0.9 vs 1.3%, p=0.47), or pacemakers (6.6 vs 6.6%, p=0.95). Site-reported, pre-discharge echocardiograms were available in 77% of patients. ULTRA and S3 patients had similar aortic valve mean gradients (12.2 vs 11.8 mmHg, p=0.15), whereas ULTRA patients had larger aortic valve areas (1.86 vs 1.75 cm^2, p<0.01). Freedom from any PVL was more frequent with ULTRA (91.9 vs 80.5%, p<0.01). The ULTRA also resulted in significantly less mild PVL (8.1 vs 18.9%, p<0.01) and was associated with no moderate or severe PVL.

Conclusions: In this propensity matched analysis from the TVT Registry, the balloon expandable SAPIEN 3 Ultra and SAPIEN 3 valves had similar procedural and 30-day clinical outcomes, but ULTRA was associated with less paravalvular regurgitation.

Euro20A-OP071
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Transfemoral implantation of the Portico transcatheter heart valve using the FlexNav Delivery System is safe in high or extreme risk patients with horizontal aortic anatomy: a post hoc analysis from the IDE FlexNav Delivery System study

CHEHAB Bassem [1], CHEHAB Bassem [1], BEDOGNI Francesco [2], YONG Gerald [3], GARRETT JR Harvey Edward [4], GROH Mark [5], ASCH Federico [6], JILAIHAWI Hasan [7], SHARMA Rahul [8], FONTANA Gregory P. [9], MAKKAR Raj [10]

(1) Cardiovascular Research Institute of Kansas, KA, USA; (2) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy; (3) Fiona Stanley Hospital, WA, Australia; (4) Baptist Memorial Hospital Memphis, TN, USA; (5) Mission Hospital, NC, USA; (6) MedStar Health Research Institute, DC, USA; (7) NYU Langone Health, NY, USA; (8) Stanford University Medical Center, CA, USA; (9) Los Robles Regional Medical Center, CA, USA; (10) Cedars-Sinai Medical Center, CA, USA

Aims: Increased aortic root angulation (AA) presents a significant anatomic challenge in transfemoral TAVR that may increase the risk of procedural complications and lead to post-procedural aortic regurgitation. The FlexNav™ Delivery System with its lower profile, increased flexibility and enhanced lubricity is designed to overcome challenges related to tortuous, calcified vessels and horizontal aortic anatomy. We evaluated the impact of increased AA on procedural and short-term clinical outcomes following TAVR with the self-expanding Portico™ Transcatheter Aortic Valve and FlexNav Delivery System.

Methods and results: *Post hoc* analyses were performed on symptomatic (NYHA class ≥II), severe aortic stenosis patients at high or extreme risk for surgical aortic valve replacement enrolled in the IDE FlexNav Delivery System study; a prospective, multicentre, open-label study arm of the PORTICO IDE trial (NCT02000115). Eighty (80) high risk and 20 extreme risk patients (mean age 85.2 years, 60% female, mean STS score 5.0%) who underwent transfemoral Portico valve implantation using the FlexNav Delivery System at 23 sites across the United States, Australia and Europe between November 7, 2018 and June 14, 2019 were included. Aortic root angulation (AA) was evaluated using preprocedural core-lab assessed multi-slice CT with subjects separated into two groups based on the mean AA (mean 47.8°± 8.47°); normal AA group<48° (n=49) and horizontal aorta (HA) group ≥48° (n=51). Procedural and short-term clinical outcomes were adjudicated by an independent Clinical Events Committee according to Valve Academic Research Consortium 2 criteria. Mean transvalvular gradients, aortic valve area and paravalvular leak was assessed using TTE and analysed by an independent echo core lab at 30 days. Except for kidney disease and pre-existing right bundle branch block (both p=0.02) which occurred more frequently in normal AA subjects and a higher rate of moderate or severe tricuspid regurgitation in HA subjects (p=0.03), all demographic, clinical characteristics and echocardiographic-derived anatomical parameters were similar between groups at baseline. Procedurally, no differences in technical device success (defined as successful vascular access, delivery and deployment of a single Portico valve and successful retrieval of the FlexNav Delivery System), pre-balloon aortic valvuloplasty, resheathing, post-dilatation or final implant depth were reported between groups (all p≥0.10). Total procedure time tended to be shorter in HA subjects (42.4 vs 49.7 minutes; p=0.09); with no reported cases of valve-in-valve in HA subjects (0% vs 6.1%; p=0.11). Rates of major vascular complications (8.2% vs 5.9%), life-threatening bleeding (4.1% vs 3.9%), new permanent pacemaker (11.4% vs 17.8%), and moderate-to-severe paravalvular leak (6.8% vs 6.1%) were comparable between normal AA and HA subjects at 30-days (all p≥0.07). No instances of death, disabling stroke, trans ischaemic attack or acute kidney injury (stage 2 or 3) were observed. At 30 days, aortic valve area was similar between groups (1.85±0.37 vs 1.80±0.36 cm^2; p=0.50), while mean transvalvular gradient was higher in the HA group (5.98±2.55 vs 7.29±3.29 mmHg; p=0.03).

Conclusions: The FlexNav Delivery System with its low insertion profile and high flexibility allows accurate and safe transfemoral Portico valve placement in high and extreme risk subjects with challenging horizontal aortic anatomy that does not lead to adverse short-term clinical outcomes.

Euro20A-OP074
Abstract | Oral presentation

Mitral valve replacement and repair - CT / MRI imaging

Left ventricular and systolic dimension determines anatomic suitability for transcatheter mitral valve implantation

CONRADI Lenard [1], MODINE Thomas [3], DUNCAN Alison [2], DUMONTEIL Nicolas [4], BLANKE Philipp [5]

(1) University Heart Center Hamburg GmbH, Hamburg, Germany; (2) Royal Brompton Hospital, London, United Kingdom; (3) CHR Lille, Lille, France; (4) Clinique Pasteur, Toulouse, France; (5) University of British Columbia, BC, Canada; (6) Abbott, MN, USA

Aims: A common exclusion for transcatheter mitral valve implantation (TMVI) is a small predicted neo-left ventricular outflow tract (LVOT). Simulation of the neoLVOT is time-consuming, requires multi-detector computerised tomography (MDCT), specialised software, and computer models of the prosthesis. Measurements that do not require neoLVOT simulation may provide a simpler approximation of TMVI anatomic suitability. This study evaluates several MDCT-derived anatomic measurements for their ability to accurately differentiate between patients eligible for TMVI and those excluded for anatomic reasons.

Methods and results: Between January 2016 – September 2019, a total of 496 patients were submitted for screening in the Tendyne™ TMVI (Abbott, Santa Clara, CA, USA) Expanded Clinical Study and had MDCT anatomical measurements performed by an independent Core Laboratory. All subjects who met all study eligibility criteria and were deemed clinically appropriate for participation in the study were included in this analysis: of 386 subjects meeting all study criteria, 121 had annular dimensions outside the ranges provided in the manufacturer's recommendations and were therefore excluded from the primary analysis. The remaining 265 subjects comprised the primary analysis population: 153 (57.7%) underwent TMVI, while 112 (42.3%) were excluded from the study for anatomic reasons. Receiver operating characteristic (ROC) curves were constructed for 12 MDCT-measured anatomic variables of interest to identify those that differentiated between patients treated with TMVI versus those excluded due to anatomic concerns. Of the 12 MDCT variables, left ventricular end systolic diameter (LVESD) was the most accurate differentiator, with an area under the curve of 0.909 ($p<0.0001$). In the primary analysis cohort, 97.4% (147 of 151) of patients treated with TMVI had LVESD >40 mm, corresponding to 75.0% (147 of 196) of all screened patients with LVESD >40 being deemed anatomically suitable. Conversely, 93.8% (60 of 64) of patients with LVESD <40 mm who were screened failed for anatomic reasons.

Conclusions: This analysis demonstrates the feasibility of using a simple yet accurate MDCT-based screening method to assess preliminary anatomic suitability for TMVI with the Tendyne system, across all available valve sizes. Of the subjects meeting study eligibility criteria and possessing annular dimensions within the manufacturer's recommended ranges, 97.4% of treated subjects had LVESD of >40 mm, and 75.0% of all patients with LVESD >40 mm were screen passed. Notably, this approach does not require neoLVOT simulations or access to valve-specific computerised models. Future studies to determine whether LVESD measured by transthoracic echocardiogram might determine preliminary anatomic eligibility for TMVI with Tendyne prior to proceeding to MDCT are ongoing. These screening guidelines may not apply to patients with severe mitral annular calcification, as these patients were not included in this analysis.

Euro20A-OP076
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Vascular closure devices in TAVI: MANTA vs ProGlide in a propensity-matched population

SÁ MENDES Gustavo [(1)], MENDES Gustavo [(1)], OLIVEIRA Afonso [(1)], CAMPANTE TELES Rui [(1)], ARAÚJO GONÇALVES Pedro [(1)], BRITO João [(1)], MESQUITA GABRIEL Henrique [(1)], RAPOSO Luis [(1)], GONÇALVES Mariana [(1)], ALMEIDA Manuel [(1)]

(1) Santa Cruz Hospital, Carnaxide, Portugal

Aims: Vascular complications increase morbidity and mortality in transcatheter aortic valve implantation (TAVI). A collagen plug-based closure device - MANTA® was recently introduced as an alternative to the suture-mediated ProGlide® vascular closure device (VCD). Data regarding the efficacy and safety comparing both VCD is scarce. The present study sought to compare the effectiveness of both devices.

Methods and results: Single centre retrospective analysis on prospectively collected data of 300 consecutive patients who underwent TAVI using MANTA® or ProGlide® since 2018. A 1:1 propensity-score matched population derived by a multivariate logistic regression model based on age, sex, body mass index, pre-procedural haemoglobin, EuroSCORE II, main access calcification and the sheath-to-artery ratio. The primary endpoint was the composite of major or life-threatening bleeding (VARC-2 definition), femoral artery stenosis/dissection, pseudoaneurysm and need for endovascular/surgical bailout intervention. The propensity score matching resulted in 129 matched pairs. The median age was 84 years old (IQR 80-87), 42% males with a median EuroSCORE II of 4.29% (IQR 3.05-6.24). There were no differences in the primary endpoint between MANTA ® and ProGlide® cohorts (3.9% vs 7.8%, p=0.287, respectively). The rates of the primary endpoint with the MANTA® device decreased with centre experience, with relatively steep learning curve effect concerning device success. Major or life-threatening bleeding (3.1% vs 5.4%, p=0.540) and pseudoaneurysm (0.8% vs 2.3%, p=0.622) occurred less frequently in MANTA® cohort, but the differences did not reach statistical significance. Endovascular (stent or balloon) or surgical rescue intervention (9.3% vs 5.4%, p=0.341) and femoral artery stenosis/dissection (6.2% vs 3.1%, p=0.376), were also similar rates. In ProGlide® cohort, to achieve VCD success (without primary endpoint events), 15.5% needed more than 2 devices, significantly different from MANTA ® (p<0,001).

Conclusions: In patients undergoing transfemoral TAVI, the MANTA® VCD showed a similar efficacy and safety compared to the ProGlide® device and it reduced significantly the need of additional VCDs for completion of haemostasis. These results were obtained despite a clear learning curve associated with MANTA.

2020 PCR e-Course Interventions for valvular disease

Euro20A-OP077
Abstract | Oral presentation

Mitral valve replacement and repair - Tools, devices and techniques

Characteristics and outcomes of patients with severe mitral regurgitation ineligible for TMVR

LUDWIG Sebastian [1], LUDWIG Sebastian [1], WEIMANN Jessica [1], KALBACHER Daniel [1], SEDIGHIAN Roya [1], SCHOFER Niklas [1], BHADRA Oliver [1], DEUSCHL Florian [1], SCHNEEBERGER Yvonne [1], LINDER Matthias [1], KÖLL Benedikt [1], WALDSCHMIDT Lara [1], SCHÄFER Andreas [1], SEIFFERT Moritz [1], SCHIRMER Johannes [1], WESTERMANN Dirk [1], SCHÄFER Ulrich [2], REICHENSPURNER Hermann [1], BLANKENBERG Stefan [1], CONRADI Lenard [1], LUBOS Edith [1]

(1) University Heart Center Hamburg GmbH, Hamburg, Germany; (2) Marienkrankenhaus, Hamburg, Germany

Aims: This study aimed to investigate the anatomical and clinical phenotypes as well as outcomes of patients ineligible for TMVR that received optimal medical therapy (OMT) only.

Methods and results: From 5/2016 until 12/2019 a total of 110 patients with severe MR and ineligible for surgery underwent screening for TMVR at our centre. Clinical and anatomical characteristics (echocardiography and MSCT) of patients, that were found ineligible for TMVR and were consecutively treated only by OMT (N=34), were analysed. Kaplan-Meier analysis were calculated for all-cause mortality after 6 months and 1 year. Median follow-up time was 407 (IQR 178, 944) days. Overall screen failure rate was 60.9%. Out of 67 patients ineligible for TMVR, 34 (50.7%) were consecutively treated by OMT. In these patients, anatomical reasons for screen failure were mitral annular calcification (MAC) (36.2%), small LV dimensions (36.2%), the predicted risk of LVOT obstruction (27.7%) and either too small or too large annular dimensions (each 19.1%). Median age of the patients in this subset was 77.5 years, 38.2% were male and median EuroSCORE II was 5.8 (3.3, 9.3). Of note, 29.4% of all patients had prior aortic valve replacement (SAVR or TAVR). Regarding echocardiography, median left-ventricular end-diastolic diameter was 52 (44, 59) mm and median ejection fraction was 53% (41%, 62%). Moreover, concomitant moderate or severe tricuspid regurgitation was present in 32.4%. Mitral annulus areas and inter-commissural diameters, as measured by MSCT, ranged from 4.83 cm^2 to 15.9 cm^2 (median 8.65 cm^2) and from 22.5 mm to 49.3 mm (median 34.5 mm), respectively. Extensive MAC was present in 48.0% of all patients in this group. All-cause mortality rates 6 months and 1 year after TMVR screening initiation were 21.2% and 39.3%, respectively. At latest follow-up, the overall rate of all-cause mortality was 44.1%.

Conclusions: Despite growing experience with TMVR, the subset of patients anatomically amenable to TMVR is still small and a substantial number of patients is eventually treated by OMT only. Mortality in these patients is high underlining an unmet need for adequate therapeutic alternatives in this substantial portion of patients with severe MR. TMVR devices adapting to broader annular size ranges with smaller ventricular profiles might fill this gap in the future.

Euro20A-OP079
Abstract | Oral presentation

TAVI - Vascular access and bleeding

Impact of vascular complications and their treatment on long-term prognosis after TAVI

LUNARDI Mattia [(1)], PIGHI Michele [(1)], PESARINI Gabriele [(1)], MARIN Federico [(1)], SCARSINI Roberto [(1,2)], KOTRONIAS Rafail [(2)], KHARBANDA Rajesh [(2)], BANNING Adrian [(2)], RIBICHINI Flavio [(1)]

(1) AOUI, VR, Italy; (2) Oxford University, Oxford, United Kingdom

Aims: Despite the extremely rapid technological improvement of transcatheter devices for the treatment of aortic stenosis, vascular complications (VC) are still the most frequent. The incidence of VC still comes to 15% of the overall procedures performed worldwide, and data about their management and impact on prognosis are limited to small registries. This study aims to report data from the FRIENDS (Finalized Research In ENDovascular Strategies) collaboration, a multi-centre experience on the incidence, the management strategies and the impact on long-term outcomes of VC following TAVI.

Methods and results: We analysed 1,074 consecutive patients who underwent transfemoral TAVI between 2010 and 2019. The primary endpoint was the survival free from MACCEs (Major Adverse Cardiovascular and Cerebral Events) (death, stroke, myocardial infarction and VC) at a minimum follow-up (FU) of 24 months. Adverse events were reported according to the Valve Academic Research Consortium 2 criteria. 103 patients out of 1074 (9,6%) had a VC (either minor or major), of those 95 underwent percutaneous repair (balloon PTA: 58; PTA + covered stent implantation: 37), while 8 required surgical treatment. Among the former, 9 procedures have been conducted in the iliac arteries, whereas the most addressed the femoral ones. None of the basal characteristics of the patients was identified as a predictor of VC. After 2 years of FU (mean 728±278 days), the primary endpoint was met in 92% of the patients presenting a VC treated with percutaneous repair, in 90% of those who underwent surgical repair, and in 85,4% of those without VC (p=0.44). Only 2 patients with previous percutaneous treatment for VC (2,1%), presented with ischaemia signs below the knee during FU (after 14 and 18 months respectively) successfully treated with conservative medical therapy.

Conclusions: Performing bail-out percutaneous angioplasty or placing a stent into iliac or femoral arteries after TAVI does not have an impact on survival and MACCE at long term FU, when compared to patients not presenting TAVI-related VC.

Euro20A-OP087
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Final results of the Frontier IV study with the PerQseal (Vivasure Ltd) fully absorbable patch based large-bore vascular closure device

GALLI Mario [2], GEUDENS Paul [1]

(1) Quarterback Consulting, Vosselaar, Belgium; (2) Azienda Ospedaliere Sant'Anna, Como, Italy

Aims: The current approaches to large-bore arterial closure have limitations. A new, fully absorbable, patch-based closure device, the PerQseal, offers a unique alternative to close large-bore arteriotomies created by 12-20 Fr introducer sheaths, such as those used in TAVI and endovascular aortic aneurysm repair (EVAR) procedures. The FRONTIER IV study was designed to determine the safety and clinical performance of the PerQseal large-bore vascular closure device.

Methods and results: The FRONTIER IV study assessed the safety and clinical performance of the PerQseal patch-based, fully absorbable large-bore vascular closure device. A 75-patient prospective, multicentred, non-randomised study was conducted across ten European centres. Patients undergoing a transfemoral procedure using large Introducer Sheaths, in the range of 12 Fr to 20 Fr, such as in TAVI and endovascular aneurysm repair procedures, were included. The analysis was conducted on all treated patients, without a roll-in cohort. Post-procedure follow-up assessments were at discharge, 1 and 3 months with ultrasound screening at 3 months. The primary outcome is the incidence of (peri-procedure to 1-month post-procedure) major vascular complications as defined by VARC-2 criteria. The secondary outcomes are the incidence of (peri-procedure to 1-month post-procedure) minor vascular complications and the device technical success rate. With the 75 patients enrolled and 84 closures completed (9 bilateral closures in EVAR cases), there was one procedure-related major complication, five device related minor complications, no late access site complications and no clinically significant haemodynamic changes on duplex ultrasound or CT angiogram.

Conclusions: The PerQseal large-bore closure device showed encouraging results regarding feasibility, safety and haemodynamic outcome for closing large bore femoral arteriotomies. Potential advantages compared to established closure techniques are the short learning curve and the ability to deploy the single device, per large arteriotomy, at the end of the procedure, a feature that may also be of benefit in emergent cases.

Euro20A-OP088
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Optimal sizing and implant depth of the Portico valve: OpTech results, a substudy of the Portico I trial

TARAMASSO Maurizio [1], TARAMASSO Maurizio [1], MAISANO Francesco [1], SONDERGAARD Lars [2], STEPHEN Worthley [3], RODES-CABAU Josep [4]

(1) Universitätsspital Zürich, Zürich, Switzerland; (2) Rigshospitalet, Copenhagen Municipality, Denmark; (3) GenesisCare, NSW, Australia; (4) University Institute of Cardiology and Respirology of Quebec, QC, Canada

Aims: To investigate the impact of sizing and implant depth on key procedural outcomes including permanent pacemaker implant (PPI) and occurrence of paravalvular leak (PVL) at 30 days and one year after implant with a Portico™ valve in patients with severe aortic stenosis. This is the first report of OpTech, a Portico I Sub-study.

Methods and results: OpTech study was performed on 277 subjects with evaluable pre-procedural multi-slice computer tomography scans and a final post-deployment aortogram. The sub-study imaging assessment was performed by an independent Core Lab (CL). All patients had a 30-day echocardiogram read by a separate CL. Patients with a prior pacemaker were excluded. At baseline, the mean age was 81.9 y (±5.9 y), 73% were female and mean STS score for mortality 6.0% (±4.6%). The Optech CL utilised a pre-specified sizing algorithm consistent with the manufacturer's sizing chart to determine each subject's optimal Portico valve size. Annular diameter, perimeter, area, sinus dimensions, eccentricity and calcium burden were consistently CL assessed. When the annular dimensions spanned 2 sizes, the larger size was recommended. The implanted valve in each subject was categorised as undersized (15.7%, n=39), optimally-sized (69.5%, n=173) or oversized (14.9%, n=37) compared to the result of the CL. Post-implant aortograms were CL assessed utilising a reference calibration to accurately measure the distance from the non-coronary cusp (NCC) and left coronary cusp (LCC) to left ventricular outflow tract (LVOT) end of the stent frame. At 30 days, valve sizing had no impact on all-cause mortality (p=0.63), CV mortality (p=0.56), occurrence of Myocardial Infarction (MI) (p=0.80), PPI (p=0.65) or greater than mild PVL (p=0.30). An eccentricity index of < 0.73 was measured in 15.5% of subjects (n=28). There was no significant impact of eccentricity index on risk for PPI, however more than mild PVL occurred in 7.1% at 30 days in the group with lower eccentricity index, while none occurred in the group with eccentricity index > 0.73 (p=0.02). LVOT and leaflet/annulus calcification volumes had no impact on the occurrence of PPI and more than mild PVL at 30 days. The implanters tend to underestimate implant depth (5.2 mm ± 2.5 mm) as compared to the calibrated CL technique (6.9 mm ± 3.6 mm). When divided into implant depth groups based on a CL assessed NCC depth of <3 mm (n= 60), 3-5 mm (n=49) and >5 mm (n=161), the occurrence of PPI at 30 days was significantly higher in the group with an implant depth >5 mm (p=0.01). When implanted at the advised implant depth (3-5 mm), the new PPI rate at 30 days was 6.3%. Implant depth was not a significant predictor for >mild PVL at 30 days. Implant depth did not impact mortality or MI rates at 30 days. At 1 year, there was a higher occurrence of all-cause mortality in patients with undersized valves (p=0.049). A multivariable analysis did not show sizing as an independent factor increasing the risk of mortality at 1 year, but it did at 2 years (p=0.02). Implant depth was not associated with greater all-cause or CV mortality at 1 or 2 years.

Conclusions: The OpTech sub-study shows that accurate sizing by CT could significantly improve survival at 2 years. Eccentric annuli (<0.73) appear to be at an increased risk for greater than mild PVL while an implant depth >5 mm appears to increase patient risk for a new PPI at 30 days. When Portico valve is implanted at an optimal depth (3-5 mm), implanters can achieve a new PPI rate of 6.3% at 30 days.

Euro20A-OP093
Abstract | Oral presentation

Mitral valve replacement and repair - Tools, devices and techniques

Implementation of the COAPT trial criteria in a real-world population undergoing MitraClip for secondary mitral regurgitation

ADAMO Marianna [1], ADAMO Marianna [1], LUPI Laura [1], FIORELLI Francesca [2], GIANNINI Cristina [2], BRANCA Luca [1], FIORINA Claudia [1], CHIARI Ermanna [1], PETRONIO Anna Sonia [2], METRA Marco [1], CURELLO Salvatore [1]

(1) Civil Hospital of Brescia, Brescia, Italy; (2) AOU PISA, PISA, Italy

Aims: Our objective was to investigate whether real-world patients undergoing MitraClip for secondary mitral regurgitation (SMR) and fulfilling the COAPT trial criteria have a better prognosis compared to those who did not have a COAPT-like profile.

Methods and results: One-hundred-ninety-nine patients underwent MitraClip for moderate-to-severe or severe (3+ or 4+) SMR at 2 Italian centres have been included. COAPT-like profile was defined as fulfilling all the following criteria: (i) left ventricular ejection fraction (LVEF) between 20 and 50%; (ii) left ventricular end systolic diameter (LVEDD) ≤70 mm; (iii) systolic pulmonary pressure (SPP) ≤70 mmHg; (iv) absence of severe right ventricular dysfunction; (v) absence of severe tricuspid regurgitation (TR); (vi) absence of haemodynamic instability. Primary endpoints were: 2-year death and 2-year composite endpoint including all-cause death and heart failure (HF) hospitalisations. Mean age was 74±11 years; 76% of patients were males, 56% had a COAPT-like profile. No significant differences have been observed between COAPT-like and no-COAPT-like group with respect to demographic features (age, gender), comorbidities (atrial fibrillation, coronary artery disease, renal insufficiency, hypertension, diabetes mellitus) and baseline risk profile (EuroSCORE II). Compared to patients with no-COAPT-like profile, those who fulfil COAPT criteria had less advanced symptoms (NYHA IV class: 38% in COAPT-like group vs 62% in no-COAPT-like group; p=0.001), less dilated ventricles (LVESD 60 mm vs 54 mm; p<0.001), higher LVEF (34% vs 29%; p<0.001), and lower SPP (47mmHg vs 51mmHg; p=0.023). Device success and number of clips deployed were comparable between the two groups. Cumulative incidence of all-cause mortality was lower in COAPT-like compared to no-COAPT like patients (29.1% vs 43.5%; Log rank p=0.017). Cumulative incidence of the composite endpoint at 2-year follow-up was also lower in COAPT-like compared to no-COAPT like patients (39% vs 60%; Log rank p=0.009). COAPT-like profile is associated with a lower risk of clinical events regardless of baseline demographic characteristics and comorbidities (HR 0.50; 95% CI: [0.31-0.81]; p=0.005).

Conclusions: More than half of a real-world population undergoing MitraClip for SMR met COAPT criteria. Patients who fulfil COAPT criteria had a better prognosis after the procedure compared to those with a no-COAPT-like profile.

Euro20A-OP098
Abstract | Oral presentation

TAVI - Echocardiography

Haemodynamic performances and clinical outcomes in patients undergoing valve-in-valve vs native TAVI

LECLERCQ Florence [1], MARIAMA Akodad [1], MEILHAC Alexandra [1], LEFEVRE Thierry [2], CAYLA Guillaume [3], LATTUCA Benoit [3], DUFLOS Claire [1], MACIA Jean-Christophe [1], GANDET Thomas [1], CHEVALIER Bernard [1], LECLERCQ Florence [1]

(1) Hôpital Arnaud De Villeneuve CHU MPT, Montpellier, France; (2) Institut Cardiologie Paris Sud, Massy, France; (3) CHU Nimes Caremeau, Nimes, France

Aims: Although valve-in-valve recently emerged has a less invasive treatment than surgery for patients with degenerated bioprosthesis, no data are available comparing results of valve-in-valve versus TAVI in native aortic stenosis. We aimed to compare haemodynamic performances and outcomes between patients undergoing valve-in-valve procedure versus TAVI for native aortic stenosis.

Methods and results: This bicentric study included all patients undergoing aortic valve-in-valve procedure for surgical bioprosthetic aortic failure between 2013 and 2017. All patients undergoing TAVI were included in the analysis during the same period. Valve-in-valve and non-valve-in-valve patients were matched with 1:2 ratio according to size, type of TAVI device, age (±5 years), sex and STS score. Primary endpoint was haemodynamic performance including mean aortic gradient and aortic regurgitation at 1-year follow-up. A total of 132 patients were included, 49 in the valve-in-valve group and 83 in the non-valve-in-valve group. Mean age was 82.8±5.9 years, 55.3% were female. Mean STS score was 5.2±3.1%. Self-expandable valves were implanted in 78.8% of patients (n=104). At 1-year follow-up, mean aortic gradient was significantly higher in valve-in-valve group (18.1±9.4 mmHg vs 11.4±5.4 mmHg; p<0.0001) and 17 (38.6%) patients of this group had a mean aortic gradient > 20 mmHg vs6 (7.8%) in the non-valve-in-valve group (p=0.0001). Incidence of ≥ grade 2 aortic regurgitation was similar in both groups (p=0.71). In the valve-in-valve group, new pacemaker implantation was less frequent (p=0.01) and coronary occlusions occurred only in the valve-in-valve group (n=2; 4.1%).

Conclusions: Valve-in-valve is an effective alternative to repeated cardiac surgery in patients with failed bioprosthesis. However, as 1-year haemodynamic performances seem better in native TAVI procedures, long-term follow-up should be assessed to determine the impact of residual stenosis on outcomes and durability.

Euro20A-OP102
Abstract | Oral presentation

TAVI - Tools, devices and techniques

First single-centre experience with the transcatheter LOTUS Edge aortic valve system after relaunch

GONSKA Birgid [1], GONSKA Birgid [1], BUCKERT Dominik [1], MÖRIKE Johannes [1], KEßLER Mirjam [1], ROTTBAUER Wolfgang [1]

(1) Ulm University, Ulm, Germany

Aims: The new-generation mechanically expandable Boston LOTUS Edge transcatheter aortic valve (BLE) is a fully repositionable device with early valve function in the deployment process and a unique Adaptive® seal to minimise paravalvular leak. Compared to its predecessor, the Boston LOTUS valve (BL), the BLE is now equipped with depth guard technology designed to reduce left ventricular outflow tract interaction during the deployment process and to lower permanent pacemaker implantation rates. Furthermore, the BLE has an improved delivery system for enhanced delivery and deployment of the valve.

Methods and results: We report on procedural results and in-hospital data of the first 100 patients treated with the BLE valve for severe aortic stenosis, implanted between March and October 2019. We compared these to the last 250 patients treated with the BL at our institution. We evaluated procedural success, post-procedural paravalvular aortic regurgitation and rate of permanent pacemaker implantation. The BLE was safely implanted in all patients and throughout the procedure, implantation depth was very well controlled. There was no intraprocedural depth with the BLE or BL. With the BLE there was no technical failure leading to conversion to surgery compared to two cases of technical failure with need for conversion to surgery with the BL (0% vs 0.8%, p=0.84). Periprocedural rate of stroke/TIA was low with 2% for BLE and 4.4% for BL (p=0.28). The cerebral protection device Claret Sentinel was used in 99% of patients treated with BLE and 35.2% of patients treated with BL. In patients with cerebral protection periprocedural rate of stroke/transient ischaemic attack was also not different (BLE 2.02% vs BLE 3.41%, p=0.56). There was no intraprocedural death in both groups. There was no valve embolisation after release of the valve and valve function was sufficient in all cases. With both valves no moderate or severe PVL occurred, there was a significantly higher rate of none/trace paravalvular aortic regurgitation in the group of patients treated with the BLE compared to the BL (97% vs 85%, p<0.01). Post-procedural permanent pacemaker implantation rate for the overall cohort was 27% for BLE and 38% for BL (p=0.05). Excluding patients with prior pacemaker (8 patients with BLE and 22 patients with BL) rate of new pacemaker implantation was significantly lower in patients with BLE compared to BL (29.4% vs 41.7%, p=0.04).

Conclusions: In patients with severe aortic stenosis, transfemoral aortic valve implantation with the BLE valve after its modification and relaunch was safe with excellent valve performance, especially in terms of paravalvular aortic regurgitation. New permanent pacemaker implantation was significantly lower with the BLE compared to its predecessor, the BL valve.

TAVI - Tools, devices and techniques

In-hospital and one-year outcome of valve-in-valve TAVI with the Portico system: a single-centre experience

GORLA Riccardo [(1)], GORLA Riccardo [(1)], BIANCHI Giovanni [(1)], DE MARCO Federico [(1)], CASENGHI Matteo [(1)], ACERBI Elena [(1)], BRAMBILLA Nedy [(1)], AGNIFILI Mauro Luca [(1)], TUSA Maurizio [(1)], TESTA Luca [(1)], BEDOGNI Francesco [(1)]

(1) Policlinico san donato, Metropolitan City of Milan, Italy

Aims: To assess in-hospital and 1-year outcomes of valve-in-valve transcatheter aortic valve-in-valve implantation (ViV-TAVI) with the Portico device.

Methods and results: This retrospective study included 49 consecutive patients, who underwent ViV-TAVI with a Portico (N=49) at our institution between 2016 and 2019. Overall, mean age of the study populations was 78.9±10.0 years, 53.1% were females, and time from surgery to valve degeneration was 9.1±3.4 years. Of these, 25 patients (51.0%) underwent the chimney technique (ChT). This group was characterised by a smaller stent internal diameter (ID) of the degenerated bioprosthesis (19.6±3.1 mm vs 21.1±1.9 mm; p=0.045), a lower height of coronary arteries on CT angiography (left main: 8.1±3.4 mm vs 11.7±4.4 mm, p=0.006; right coronary artery: 12.7±5.1 mm vs 16.4±5.2 mm, p=0.033) and a higher prevalence of Mitroflow bioprosthesis (68.0% vs 16.7%; p<0.001), compared to the non-ChT group. Implantation depth was greater in the chimney technique group both at the level of non-coronary (7.3±2.1 mm vs 5.4±1.2 mm; p=0.024) and left coronary (8.6±2.2 mm vs 5.9±1.4 mm; p=0.005) cusp, whereas no differences were evident regarding other procedural aspects. Postoperatively, mean aortic gradient, moderate paravalvular leak (PVL), and pacemaker implantation rates were overall 16.3±9.6 mmHg, 6.1%, and 10.2% respectively, with no differences between the ChT and non-ChT group. No cases of major vascular complications, stroke and in-hospital mortality were observed. Device success was overall 71.4% with no differences between the two groups, mainly affected by a 24.5% rate of patients (12/49) with post-procedural mean aortic gradient>20 mmHg. On univariate analysis, surgical bioprosthesis size (OR:0.59, p=0.015), stent ID (OR:0.67, p=0.013) and true ID (OR:0.56, p=0.009) were significant predictors of post-procedural mean aortic gradient>20 mmHg. These findings were confirmed also on ROC analysis; a surgical bioprosthesis size ≥23mm (AUC=0.72; sensitivity 70%, specificity 60%; p=0.022) and true ID≥17.15 mm (AUC=0.77; sensitivity 92%, specificity 50%; p=0.006) significantly predicted the absence of post-procedural mean aortic gradient>20 mmHg. At 1-year follow-up, all-cause mortality was 13.9% (5/36 patients), with one case of cardiovascular death due to heart failure.

Conclusions: ViV-TAVI with the Portico device was overall safe in both ChT and non-ChT patients with optimal moderate PVL and good survival rates both in-hospital and at 1-year follow-up. Post-procedurally, a mean aortic gradient>20 mmHg was not unfrequent and was predicted by the surgical bioprosthesis size; however, this finding did not seem to have a clinical impact on the study population at 1-year follow-up.

Euro20A-OP104
Abstract | Oral presentation

Mitral valve replacement and repair - Echocardiography

Recurrent mitral regurgitation after edge-to-edge mitral repair: predictor and aetiology

SUGIURA Atsushi [(1)], WEBER Marcel [(1)], TABATA Noriaki [(1)], OEZTUERK Can [(1)], NICKENIG Georg [(1)], SINNING Jan-Malte [(1)]

(1) UKB University of Bonn, Bonn, Germany

Aims: Little is known about risk factors and aetiology of recurrent mitral regurgitation (MR) in patients after transcatheter edge-to-edge mitral repair with the MitraClip system.

Methods and results: Among consecutive patients who underwent MitraClip repair from January 2011 to March 2019, we identified 240 patients who had MR ≤2+ at discharge and follow-up echocardiography within three years after the procedure. Recurrent MR was defined as MR ≥3+ during the follow-up. To investigate risk factors of recurrent MR, we conducted a Cox proportional hazard model. During the follow-up period (median 491 days), 38 patients had recurrent MR (≥3+). In the Cox proportional hazard model, higher LV end-diastolic volume index (adjusted-HR 1.01, 95% CI: 1.00-1.02, p=0.03), higher LV ejection fraction (adjusted-HR 1.05, 95% CI: 1.01-1.08, p=0.005), and residual MR =2+ (adjusted-HR 2.98, 95% CI: 1.50-5.95, p=0.002) were associated with an increased risk of recurrent MR. The association of LV ejection fraction was pronounced in patients with degenerative MR (adjusted-HR 1.07, 95% CI: 1.02-1.12, p=0.003). The association of residual MR =2+ was pronounced in patients with functional MR (adjusted-HR 5.02, 95% CI: 1.95-12.8, p<0.001). In patients with recurrent MR, a significant increase in antero-posterior annulus diameter was observed regardless of the baseline aetiology of MR (all associations, p<0.001).

Conclusions: Greater LV volume, higher LV ejection fraction, and residual MR at discharge were associated with the increased risk of recurrent MR after MitraClip use. The risk factors differed across the baseline aetiologies of MR. A significant increase of annulus diameter was observed regardless of the aetiology.

TAVI - Tools, devices and techniques

Quality of life after TAVI: single centre study

PICCIANI ANDREA [1], PICCIANI Andrea [1]

(1) ASL n.2 Lanciano Chieti Vasto, Province of Chieti, Italy

Aims: The objective of this study is to provide an overview of the quality of life (QoL) before and after TAVI, of the patients undergoing this procedure, at the U.O.S.D. Haemodynamics of the Chieti. Since QoL is a multidimensional concept, it is studied through items that include physical limitation, the frequency of symptoms, social limits, general well-being and the relative functional status.

Methods and results: The study was conducted in the Lanciano-Vasto-Chieti Local Health Authority at the U.O.S.D Haemodynamics in Chieti where a new interventional activity was implemented from 16 October 2017: TAVI. Patients with severe aortic stenosis who underwent TAVI for any access route and for any implanted prosthesis were included in the study. The study provided for the administration of a questionnaire: the Kansas City Cardiomyopathy Questionnaire 12 (KCCQ12), in two steps: 1) administration of the questionnaire by telephone, two weeks before the TAVI; 2) administration of the questionnaire by telephone two weeks after the TAVI implantation. The time span of the duration of the study is defined by the period between 16 October 2017 and 16 September 2019. For the study, 76 patients were selected who met the inclusion criteria. The sample consisted of 33 men (43.4%) and 43 women (56.6%) with an average age of 83.99 years. The statistical processing of the KCCQ-12 questionnaire data was performed by comparing the averages of the samples observed before and after the TAVI implantation. The statistical analysis was performed with the use of Student's T for paired data, a fundamental tool in comparing the scores of the averages obtained from each domain present in KCCQ12. The domains analysed are five, namely: 1) physical limitation; 2) the frequency of symptoms; 3) the quality of life; 4) social limitations; 5) and finally the total of the scores obtained respectively by the four domains. From the statistical analysis it can be observed that the averages of the post TAVI scores, compared to the pre scores, are higher in all domains. Furthermore, we can say with a 95% confidence interval that patients before implantation have an average score lower than the post-implantation score. Based on the analysis carried out, we can say that the quality of life has improved in patients who have performed TAVI in a statistically significant way.

Conclusions: The study focuses on changes in quality of life after the TAVI procedure, a topic that is gaining increasing importance in addition to standard clinical goals, such as survival and the NYHA functional class. The objective improvement of the quality of life is perceived already two weeks after the treatment, at the same time determining an indirect benefit in terms of economic and social costs. In conclusion, we can say that patients with severe symptomatic aortic stenosis who underwent TAVI, analysed with this study, found an improvement in their quality of life in a short time, in fact the minimal invasiveness of the procedure, is able to minimise the time post-operative recovery, the time of hospitalisation and rehabilitation, necessary instead in the case of more invasive interventions. The use of KCCQ12 in this pathology represents an important opportunity for future research in order to obtain a more complete picture of the QoL of these patients.

Euro20A-OP109
Abstract | Oral presentation

TAVI - CT / MRI imaging

Device selection in patients with borderline size aortic valve annulus undergoing TAVI

TALMOR-BARKAN Yeela [1,2], TALMOR-BARKAN Yeela [1,2], KORNOWSKI Ran [1,2], VAKNIN-ASSA Hanna [1,2], HAMDAN Ashraf [1,2], BARBASH Israel M [2,4], DANENBERG Haim [6], KONIGSTEIN Maayan [2,5], BAR Noam [3], BARSHESHET Alon [1,2], CODNER Pablo [1,2]

(1) Beilinson, Petah Tikva, Israel; (2) Sackler Interdepartmental Core Facility, Tel Aviv-Yafo, Israel; (3) Weizmann Institute of Science, Rehovot, Israel; (4) Sheba Medical Center, Ramat Gan, Israel; (5) Ichilov Hospital, Tel Aviv-Yafo, Israel; (6) Hadassah Medical Center, Mount Scopus, Sderot Churchill, Israel

Aims: Proper transcatheter heart valve (THV) selection for transcatheter aortic valve implantation (TAVI) is crucial to achieve procedural success. Borderline aortic annulus size (BAAS) is a common challenge during device selection and the most effective THV selection strategy for these patients remains unclear. Herein, we aim to evaluate the outcomes of TAVI in patients with BAAS according to THV size selection.

Methods and results: We performed a retrospective study including patients with severe aortic stenosis (AS) and BAAS, measured by multidetector computed tomography (MDCT), undergoing TAVI with self-expandable (SE) or balloon-expandable (BE) THV from the Israeli multicentre TAVI registry. BAAS was defined based on THV manufacturer sizing instructions; size cut-off ±1 mm for SE-THV and borderline range for BE-THV. TAVI outcomes were assessed according to the Valve Academic Research Consortium-2. Out of 1,166 patients with proper MDCT measurements, 539 patients (46%) had BAAS as defined for at least one THV type (SE or BE). In BAAS patients treated with SE-THV, large THV selection was associated with significantly lower rate of paravalvular leak (PVL), as compared with small THV (no PVL 34.0 vs 41.8%; mild PVL 60.0 vs 38.1%; mild-moderate PVL 4.3 vs 18%; moderate PVL 0% vs 1.8%; p=<0.05). In BAAS patients implanted with BE-THV no significant difference in PVL was noted between large and small THV selection. However, large BE-THV selection was associated with lower post-procedural transvalvular gradients compared to small THV (peak 17±7 mmHg vs 22±6.6 mmHg; mean 9.9±3.9 mmHg vs 12.1±1 mmHg; p=<0.05). Of note, mortality, new left bundle branch block, rate of new pacemaker implantation, stroke/transient ischaemic attack, annular rupture and coronary occlusion did not differ between groups.

Conclusions: BAAS is highly common among patients undergoing TAVI. Selection of large rather than small THV in these patients is associated with lower rates of significant PVL and better haemodynamic profile in patients implanted with SE and BE-THV, respectively, with no effect on procedural complications.

Euro20A-OP110
Abstract | Oral presentation

Mitral valve replacement and repair - Tools, devices and techniques

Percutaneous edge-to-edge mitral valve repair in patients hospitalised with cardiogenic shock: a nationwide analysis

ESTEVEZ-LOUREIRO Rodrigo [1], ESTEVEZ-LOUREIRO Rodrigo [1], PSOTKA Mitchell [4], YU Yang [3], PRILLINGER Julie [3], TANG Gilbert [2]

(1) Álvaro Cunqueiro Hospital, Vigo, Spain; (2) Mount Sinai Medical Center, NY, USA; (3) Abbott, CA, USA; (4) Inova Heart and Vascular Institute, VA, USA

Aims: This study is the first to provide nationwide population-based data on MitraClip use in patients hospitalised with cardiogenic shock.

Methods and results: United States Medicare administrative fee-for-service claims data were used to identify patients with an inpatient hospitalisation from 1/1/2014 to 3/1/2019 that included both a diagnosis of cardiogenic shock (ICD-9 785.51 or ICD-10 R57.0) and MitraClip procedure (ICD-9 35.97 or ICD-10 02UG3JZ). Patients with MitraClip placement ≤48 hours after hospital admission were excluded. Continuous Medicare enrolment was required ≥1 year prior to index and ≥30 days after hospital discharge, or until death or heart transplant. There were 315704 patients hospitalised with cardiogenic shock. Of these, 408 patients (76±10 years-old, 57% male) underwent MitraClip and met the inclusion/exclusion criteria. A prior diagnosis of heart failure was present in 72%, and 44% of patients had a prior myocardial infarction. Admission diagnosis was listed as heart failure, shortness of breath, or dyspnoea in 42% and acute coronary syndrome, chest pain, or angina in another 14%. Ventilation was used in 47% of patients (≥96 hours in 24%), IABP in 31%, Impella or TandemHeart in 8%, and ECMO in <3%. Diagnostic catheterisation was performed in 70%, while PCI was performed in 16% and CABG in <3%. These interventions were performed a median of 1 to 7 days prior to MitraClip. Approximately 10% of patients received haemodialysis during the same hospitalisation. The median hospital stay was 19 [IQR 14–28] days and median time from admission to MitraClip was 10 [IQR 6–16] days. Over three quarters of patients were hospitalised in the intensive care unit for a median of 9 [IQR 4–16] days. Complications were common in this critically ill population. During the index hospitalisation, new-onset renal failure occurred in 19% of patients, major bleeding in 38%, sepsis in 21%, and stroke in 6%. In-hospital mortality was 24% for the study cohort, versus 40% for the overall cardiogenic shock population in the same dataset. Among those discharged alive, only 18% of patients went home, with the remainder sent to rehab, hospice, or long-term care. From live discharge, 30-day and 1-year mortality rates were 17% and 45%, respectively. The 1-year all-cause and heart failure hospitalisation rates were 2.1 and 0.8 events/patient-year, respectively. Over the study period, MitraClip use increased from 0.1% to 0.3% of all cardiogenic shock hospitalisations.

Conclusions: The MitraClip may be used for some critically ill patients with cardiogenic shock and significant mitral regurgitation. Further study to guide selection and treatment of cardiogenic shock patients with MitraClip is warranted.

Euro2OA-OP113
Abstract | Oral presentation

TAVI - Vascular access and bleeding

Suture- or plug-based vascular closure: a randomised trial

VAN WIECHEN Maarten [1], VAN WIECHEN Maarten [1], TCHÉTCHÉ Didier [2], OOMS Joris [1], HOKKEN Thijmen [1], GHATTAS Angie [1], SIDDIQUI Saifullah [2], LAPERCHE Clémence [2], DAEMEN Joost [1], DUMONTEIL Nicolas [2], VAN MIEGHEM Nicolas [1]

(1) Erasmus MC, Rotterdam, the Netherlands; (2) Clinique Pasteur, Toulouse, France

Aims: Vascular complications after transcatheter aortic valve replacement (TAVR) are relevant and often associated with vascular closure device failure. Aim is to compare the efficacy and safety of a suture-based vascular closure device (VCD) vs a dedicated large bore plug-based VCD.

Methods and results: The MAnta™ vs Suture-based vascular closure after transcatHeter aortic valve replacement trial (MASH trial) is an international, two-centre randomised trial comparing the MANTA™ vascular closure device vs two ProGlides. A total of 210 consecutive patients undergoing TAVR at the Erasmus Medical Center in Rotterdam (NL) and Clinique Pasteur in Toulouse (France) were randomised in a 1:1 ratio. The composite primary endpoint consisted of access-site related major- or minor vascular complications at 30-days follow-up. Secondary endpoints include time to haemostasis and need for additional manoeuvres to achieve haemostasis. All events were classified according to VARC-2 definitions and were adjudicated by an independent clinical event committee. 210 patients (150 in the Netherlands, 60 in France) were included between October 2018 and January 2020.

Conclusions: MASH TAVI will be the first randomised trial to compare the incidence of vascular complications for two widely used large bore arteriotomy closure devices and will shed further light on how to minimise access site complications related to TAVR.

Euro2OA-OP114
Abstract | Oral presentation

TAVI - Adjunctive pharmacotherapy

Contrast-induced acute kidney injury in patients undergoing coronary angiography/PCI vs TAVI

PIGHI Michele [1], VENTURI Gabriele [1], PIGHI Michele [1], LUNARDI Mattia [1], PESARINI Gabriele [1], RIBICHINI Flavio Luciano [1]

(1) University of Verona, Verona, Italy

Aims: We aimed at investigating the possible impact of procedure type on contrast-induced acute kidney injury (CI-AKI) in a real-world population comprising patients undergoing coronary angiography/percutaneous coronary intervention (CAG/PCI) or TAVI.

Methods and results: Patients who underwent CAG/PCI or TAVI in our centre were retrospectively analysed in terms of baseline characteristics, procedural features, and pre/post-procedural serum creatinine (SCr) value. CI-AKI was defined as a relative increase in SCr concentration of at least 0.3 mg/dL within 72 hours after contrast-medium administration compared with baseline. Patients in dialysis were excluded. We analysed 1212 patients who underwent CAG/PCI (53,7%) or TAVI (46,3%). Patients who underwent TAVI were older, more hypertensive, anaemic (p<0,001), and had worse glomerular filtration rate (49,459±22,941 ml/min for TAVI patients vs 79,396±30,994 for CAG/PCI patients; p<0,001). However, CI-AKI occurrence was significantly lower in patients who underwent TAVI compared to CAG/PCI (6,6% versus 11,2%, p=0,005). At the multivariate analysis, the amount of contrast medium (p=0,017, OR 1,003, 95% CI: 1,000; 1,005), diabetes (p=0,049, OR 1,578, 95% CI: 1,002; 2,487) lower baseline glomerular filtration rate (p<0,001, OR 0,983, 95% CI: 0,975; 0,992) and the procedure type (p 0,001 OR 2,378, 95% CI: 1,410; 4,009) were independent risk predictors of CI-AKI. At a sub-analysis, after exclusion of patients undergoing CAG/PCI in emergency fashion, procedure type was still associated with CAG/PCI group (p=0,007, OR 2,27, 95% CI: 1,257-4,130).

Conclusions: The proportion of patients who developed CI-AKI was significantly lower in the TAVI group compared to CAG/PCI group despite a significantly higher-risk profile. The risk-benefit balance of contrast administration on the renal function in TAVI patients may be better than in patients with coronary artery disease thanks to haemodynamic effect following aortic valve replacement.

Euro2OA-OP121
Abstract | Oral presentation

TAVI - Tools, devices and techniques

CT characteristics and one-year clinical outcomes following TAVI with a supra-annular self-expanding valve with pericardial wrap from the FORWARD PRO study

WINDECKER Stephen [1], WINDECKER Stephen [1], VAN MIEGHEM Nicolas [2], BRECKER Stephen [3], MANOHARAN Ganesh [4], FIORINA Claudia [5], KORNOWSKI Ran [6], DANENBERG Haim [7], BRUSCHI Guiseppe [8], SCHOLTZ Werner [9], OPDAHL Anders [10], GRUBE Eberhard [11]

(1) University of Bern, Bern, Switzerland; (2) Erasmus Universiteit Rotterdam, Rotterdam, the Netherlands; (3) St George's Hospital, London, United Kingdom; (4) Royal Victoria Hospital, Belfast, United Kingdom; (5) Azienda Ospedaliera Spedali Civili di Brescia, Brescia, Italy; (6) Beilinson, Petah Tikva, Israel; (7) Hadassah University Hospital - Ein Kerem, Jerusalem, Israel; (8) Azienda Ospedaliera Ospedale Niguarda Cà Granda – Milano, Milano, Italy; (9) Herz- und Diabeteszentrum NRW - Ruhr-Universität Bochum - Bad Oeynhausen, Bad Oeynhausen, Germany; (10) Oslo Universitetssykehus-Ullevål Universitetssykehus – Oslo, Oslo, NORWAY; (11) University of Bonn, Bonn, Germany

Aims: The Evolut PRO system includes a new transcatheter aortic valve (TAV) system based on the Evolut R TAV. The Evolut PRO TAV has an outer pericardial wrap added to the lower inflow portion of the frame intended to minimise paravalvular leak. The FORWARD PRO study evaluated outcomes of the Evolut PRO system in patients with native AV stenosis or a failed (stenosed, insufficient or combined) surgical bioprosthetic AV in routine clinical practice.

Methods and results: The FORWARD PRO study is a multicentre, prospective, single-arm, interventional post-market study to evaluate the acute and long-term clinical performance and safety of the repositionable Evolut PRO system (23-mm, 26-mm and 29-mm valves, Medtronic, Minneapolis, MN, USA) among patients in routine practice at 39 centres in 14 countries in Europe. Patient eligibility was based on clinical indications and the Instructions for Use for the Evolut PRO system. A baseline cardiac MSCT per standard care was performed and anatomical parameters were centrally measured. All sites followed a standardised protocol for acquisition of echocardiographic endpoint data, and valve haemodynamics were centrally analysed by the Mayo Clinic Echocardiographic Laboratory (Rochester, MN, USA). Risk-based study monitoring was performed and included 100% review of patient consent documentation, primary and secondary-related endpoints and study-specific adverse events. An independent Clinical Events Committee reviewed all safety-endpoint-related adverse events. A total of 629 patients underwent attempted implant of the Evolut PRO valve. Baseline characteristics include mean age 81.7±6.1 years, STS PROM 4.7±3.4%, 33.4% frail, 14.9% required living assistance, 10.5% had a pacemaker or defibrillator and 20.1% had LVOT moderate or severe calcification. Most patients were implanted via the iliofemoral route (97.0%) and local anaesthesia was used in 80.1%. Embolic protection was used in 9.1% of patients. The primary endpoint of all-cause mortality at 30 days was 3.2% compared to a performance goal of 5.5%, p=0.004. The secondary endpoint of no or trace aortic regurgitation at discharge was present in 59.2% of patients and did not meet the prespecified performance goal of >67.1%. No, trace or mild aortic regurgitation was present in 98.2% of patients at discharge.

Conclusions: Native aortic valve characteristics from baseline CT screening, and the 1-year prespecified, clinical and echocardiographic outcomes from the largest prospective evaluation of the Evolut PRO TAV will be available.

Euro20A-OP122
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Impact of haemodynamics on clinical outcomes after self-expanding TAVR in failed surgical valves

HOLZHEY David [1], HOLZHEY David [1], REARDON Michael [2], TCHETCHE Didier [3], DAUERMAN Harold [4], KORNOWSKI Ran [5], CHEVALIER Bernard [6], POPMA Jeffrey [7], DEEB Michael [8]

(1) Herzzentrum Leipzig, Leipzig, Germany; (2) Houston Methodist Hospital, TX, USA; (3) Groupe CardioVasculaire Interventionnel, Toulouse, France; (4) The Robert Larner, M.D. College of Medicine at The University of Vermont, VT, USA; (5) Rabin Medical Center Golda Hasharon Campus, Petah Tikva, Israel; (6) Ramsay Générale de Santé, Institut Cardio-vasculaire Paris-Sud, Massy, France; (7) Beth Israel Deaconess Medical Center (BIDMC), MA, USA; (8) University of Michigan Hospital, MI, USA

Aims: Two trials, Valve in Valve (VIVA) in Europe and Expanded Use United States (EUS), evaluated the clinical and haemodynamic outcomes of patients with failing surgical aortic valves (SAV) that underwent transcatheter aortic valve replacement (TAVR) with the self-expandable platform. This analysis combines the two studies to further evaluate outcomes of TAVR in SAV.

Methods and results: The pooled analysis combines data from 202 patients in the VIVA trial and 226 patients from the EUS trial. VIVA was a prospective, observational, single arm, post-market multicentre study conducted at 23 sites in France, Germany, Israel and Italy. The TAV in SAV EUS study was a prospective, single arm, multicentre study. The primary safety outcome was all-cause mortality, and was analysed by SAV failure mode (regurgitation, stenosis, or a combination of both), by valve type (stented vs stentless), and by post-implant mean gradient (≥20 mm Hg). Overall, there were 239/428 (55.8%) males in the pooled dataset. Most patients were in NYHA class III/IV 336/424 (79.2%). The majority of failed SAVs were stented (87.1%) with 9.3% stentless valves and 3.5% homografts. Surgical valve failure was caused by aortic stenosis in 56.3%, regurgitation in 22.4% and combined in 21.3% of patients. Discharge mean gradients were higher for stented than for stentless SAVs by all failure modes, and highest to lowest for a stenotic versus combined versus regurgitation failure mode. The percent of patients with a discharge mean gradient ≥20 mm Hg was 37% and varied by SAV failure mode, being highest in patients with a stenotic surgical valve and higher in stented versus stentless valves. At 2 years, the overall rate of all-cause mortality was 71/428 (16.6%) and was significantly higher in patients with a discharge mean gradient ≥20 mm Hg (20.6%) compared to patients with a discharge mean gradient <20 mm Hg (10.1%; log-rank p=0.008). Predictors of elevated residual mean gradient and its impact on 2-year follow-up will be available at the time of the presentation.

Conclusions: The combined analysis of VIVA and EUS studies provides a large population for analysis of TAVR using the CoreValve and Evolut R self-expanding valves in failed SAVs, allowing for better understanding of the clinical and haemodynamic outcomes in these patients.

Euro20A-OP126
Abstract | Oral presentation

TAVI - Vascular access and bleeding

Quantifying post-procedural management of the vascular access site following TAVI to assess association with length of hospital stay: a clinical audit

MAHON Claire [(1)], MAHON Claire [(1)], STEVENS Melissa [(1)], MARTIN Lorelle [(1)], NAISMITH Carolyn [(1)], FAROUQUE Omar [(1)], HORRIGAN Mark [(1)]

(1) Austin Hospital, VIC, Australia

Aims: Transcatheter aortic valve implantation (TAVI) is the guideline recommended standard of care for aortic stenosis patients at high surgical risk. Large lumen catheters inserted via the femoral artery increase risk for vascular access site complications. Bleeding impedes early ambulation and increases length of stay (LOS). In this frail patient cohort, shorter LOS correlates with better outcomes. We aimed to quantify management of vascular access sites to determine the incidence of minor persistent bleeding following TAVI and its effect on LOS.

Methods and results: A retrospective chart review of 47 TAVI patients was undertaken between July 2018 and June 2019 capturing clinical and procedural variables including demographics, haemoglobin and platelet levels, anti-coagulation status and renal function at baseline. Procedural characteristics include sheath size, number of suture vascular closure devices deployed, procedure time, procedural anticoagulation and blood pressure during and after procedures. Post-procedural access site management was assessed by: 1) number of episodes of manual compression required during post-procedural care for management of persistent bleeding, 2) time to haemostasis, 3) the need for alternative strategies required to achieve haemostasis, and 4) time to ambulation post procedure. Results: The femoral artery was the primary access site at 98%. Additional episodes of manual compression were required for 62% of the cohort. However, time to haemostasis was difficult to assess due to incomplete documentation. Ambulation at Day 1 was achieved 40% of the time and 38% of the cohort were discharged by Day 3. We found 21% of patients were transfused with Packed Red blood cells (PRCs) which did not necessarily comply with the institutional guideline recommendations. Major vascular complications rates were uncommon: one patient required emergent vascular surgery and one patient had a pseudoaneurysm. Mortality at 30 days was zero. Other procedural complications included stroke (6%); and delirium (2%). Ultrasound guided vascular access was used 2% of the cohort. Since this audit, ultrasound guided vascular access has been routinely introduced at our institution. We will therefore expand future clinical audits to measure the impact of this. Overall, these results may explain prolonged ambulation and discharge times in this frail elderly cohort.

Conclusions: The incidence of vascular access bleeding has been quantified by this audit. High rates of minor bleeding and delayed ambulation rates has given the impetus for a redesign of procedural vascular protocols for TAVI and a review of the current documentation system. Systematic documentation improvement will aid data analysis to evaluate performance and facilitate improvement in procedural outcomes.

Euro2OA-OP127
Abstract I Oral presentation

TAVI - Tools, devices and techniques, Other valvular and structural interventions - Other

Results of TAVI procedures with use of underexpanded balloon-expandable prosthesis in patients with borderline aortic valve annulus

SALICHKIN Dmitrij [(1)], IMAEV Timur [(1)], AKCHURIN Renat [(1)], KOMLEV Aleksey [(1)], LEPILIN Peter [(1)], KOLEGAEV Aleksandr [(1)], KUCHIN Ivan [(1)], MARGOLINA Anna [(1)], MAKEEV Maxim [(1)]

(1) Russian Cardiology Research and Production Complex, Moscow, Russian Federation

Aims: Recently transcatheter aortic valve implantation (TAVI) has become the optimal choice procedure for patients with aortic stenosis. The last generation of transcatheter valves allows us to perform TAVI in a vast majority of patients. Patients with borderline aortic annulus size who have transition of aortic ring parameters (diameter, area and perimeter of ring) from a smaller to a larger size comprise the particular category of patients. The aim of this study was to analyse the results of TAVI with use of underexpanded balloon-expandable prosthesis in patients with borderline aortic valve annulus.

Methods and results: Among 310 patients who underwent TAVI in 2019 at cardiovascular department of National Cardiology Research Center, 38 (12%) patients had borderline aortic valve annulus were employed an underexpansion of balloon-expandable prosthesis approach. Clinicopathological profile sand hospital outcomes were analysed. 12 patients were included in group 1. 50 patients who underwent TAVI with nominal size prosthesis in the same period of time formed group 2. The main indication for underexpansion approach was oversizing more than 20%. Balloon underfilling volume was performed by scheme adopted from the John Webb algorithm. Preoperative status (clinical, echocardiographic and computed tomography profile) and hospital results were analysed. Results: Edwards SAPIEN XT was implanted in both groups. There were no differences in clinical and echocardiographic profiles between study groups. Preoperative mean values of maximal and mean pressure gradient were 88±28 and 54±19 mmHg vs 97±32 and 56±20 mmHg in group 1 and 2, respectively, $p<0,05$. Mean values of oversize percentage were 38%, 26% and 37% for 23, 26 and 29 prosthetic size respectively in study group and 16%, 15% and 12% for 23, 26 and 29 prosthetic size, respectively, in the control group. Technical success was achieved in all cases. There were no difference in pressure gradients at 5 day postoperatively with mean values of maximal and mean pressure gradient 19±7 and 10±4 mmHg vs 16±4 and 7±3 mmHg in group 1 and 2 respectively, $p<0,05$. There were not any significant differences in complication frequency between the groups. Complications in group 1 included 1 case of endarterectomy from vascular access site and 1 pacemaker implantation due to atrioventricular block. There were 2 vascular complication and 2 pacemaker implantations in the control group.

Conclusions: Underexpanding of the balloon-expandable transcatheter heart valve has no adverse effect on procedural and hospital outcomes and might be of certain value in reducing the risk of annular rupture in selected patients.

Euro2OA-OP128
Abstract | Oral presentation

TAVI - Echocardiography

Impact of baseline mitral and/or tricuspid regurgitation in patients with left ventricular dysfunction undergoing transcatheter aortic valve implantation

COBURN Jaimie [1], COBURN Jaimie [1], BRENNAN Paul [1], COLLINS Patrick [1], SANTOS Angelo [1], NZEWI Onyekwelu C. [1], JOHNSTON Nicola [1], OWENS Colum [1], JEGANATHAN Reuben [1], SPENCE Mark S. [1], MANOHARAN Ganesh [1]

(1) Royal Victoria Hospital, Belfast, United Kingdom

Aims: Registry data has shown that the presence of ≥ moderate baseline mitral regurgitation (MR) and/or moderate tricuspid regurgitation (TR) are recognised predictors of mortality following transcatheter aortic valve implantation (TAVI). We aimed to assess the impact of mild MR and/or TR on all consecutive patients that had TAVI in our institution between February 2008 and December 2018.

Methods and results: Baseline patient/echocardiographic characteristics were retrospectively analysed using the National Institute for Cardiovascular Outcomes Research (NICOR) database and Northern Ireland Electronic Care Record (NIECR). All patients were eligible for actuarial 1-year survival analysis. Kaplan-Meier survival analysis was used to assess long-term survival. Patients with ≥ moderate MR/TR were excluded from the mortality analysis. 1,033 consecutive patients had TAVI between February 2008 and December 2018 (mean age 81.7±6.8 years, male 46.5% (n=480), mean EuroSCORE 8.4±7.9%). Echo findings: 35.6% patients (n=368) had no/trace MR, 47.4% (n=490) mild/mild-moderate, 15.8% (n=163) moderate/mod-severe and 1.2% (n=12) severe MR, respectively. 54% patients (n=556) had no/trace TR, 37% (n=383) mild/mild-moderate TR, 8% (n=82) moderate/mod-severe TR and 1% (n=12) severe TR, respectively. Impaired left ventricular systolic function (LVSF) was observed in 27% (n=280) of patients (ejection fraction <50%). 1-year mortality was higher in patients with mild/mild-moderate MR compared to those with no/trace MR (11.6% vs 7.9%, p 0.07) but this did not meet statistical significance. The median survival for both groups was 5.1 years. 1-year mortality did not differ with respect to mild/mild-moderate TR and no/trace TR (10.7% vs 10.4%) and long-term median survival was similar (5.4 years vs 5.1 years). The combination of mild MR and TR (n=204) had a 1 year mortality of 11.8% compared to 8.9% for patients with no/trace MR/TR (n=583 (p 0.24)) and long-term median survival did not significantly differ (4.6 years vs 5.3 years, p 0.27). Patients with impaired LVSF had a significantly higher 1-year mortality when compared to those with preserved LVSF (16% vs 7.6%, p 0.001). When combined with both mild MR and mild TR (n=60), 1-year mortality increased further compared to patients with mild MR/TR and preserved LVSF (20% vs 8.8%, p 0.005). 5-year mortality was estimated at 67% compared to 46% with overall median survival estimates of 3.8 years vs 5.4 years (p 0.001) in these two respective patient groups.

Conclusions: The presence of mild MR and/or TR on their own showed a statistically insignificant trend towards worse short and long-term mortality in patients undergoing TAVI. The combination of mild MR, mild TR and reduced LVSF, however, resulted in significantly worse short- and long-term mortality.

TAVI - Tools, devices and techniques

Transcarotid vs transfemoral access during TAVR with complex femoral approach

LECLERCQ Florence [1], LECLERCQ Florence [1], CHOTTEAU Romuald [1], AKODAD Mariama [1], CAYLA Guillaume [2], ROBERT Pierre [1], MACIA Jean Christophe [1], DELSENY Delphine [1], SCHMUTZ Laurent [2], LATTUCA Benoit [2], GANDET Thomas [1]

(1) Universite Montpellier I - Faculty of Medicine, Montpellier, France; (2) CHU Nimes Caremeau, Nimes, France

Aims: While transfemoral way is the first line approach in patients undergoing TAVR, some anatomic characteristics as low vascular diameters, calcifications or tortuosity can make this access complex, and may make consider an alternative access as transcarotid route. The purpose of this study was to compare the outcomes of patients with complex femoral anatomy undergoing TAVR with transfemoral or transcarotid approaches.

Methods and results: All consecutive patients with complex femoral anatomy, undergoing TAVR via transfemoral or transcarotid approaches between 2015 and 2018 in our centre were included in this retrospective study. Complex anatomy assessed by CT scan was defined as diameter of the common femoral or iliac artery <6.5 mm with at least severe calcifications or severe tortuosity or by the presence of aortic aneurysm or aortic plaque with high-risk of embolism. The vascular approach was chosen according to the heart team decision. The primary endpoint was a combined endpoint including failure of the vascular access, mortality, major vascular complications, major bleeding, and stroke evaluated at 1-month follow-up. Secondary endpoints included procedural results and hospitalisation length. The study enrolled 131 patients including 51 transfemoral (39,2%) and 80 transcarotid (60,8%) approaches. The mean age was 81,8±6,3 in the transfemoral group vs 81,7±7,4 in the transcarotid group (p=1). Patients in the transcarotid group had a higher risk profile (STS score 7.7% vs 5.5% p=0.01), with a lower mean left ventricular ejection fraction (44% vs 53%; p≤0.001) and a higher incidence of coronary artery disease (n =42, 61% vs n=17, 38%; p=0.04) compared to patients in the transfemoral group. There were more women in the transfemoral group (n= 34, 66% vs n= 17, 31% in the transcarotid group; p =0.0001). In the transfemoral group, 16 patients (31.4%) reached the primary endpoint versus 11 patients (13,8%) in the transcarotid group, p=0.057. There were no significant differences in 30 day mortality (1.9% vs 2.5%; p=1), stroke rate (1.9% vs 2.5%; p=1) or total bleeding (13.7% vs 7.5%; p=0.38) between the transfemoral and the transcarotid group but rate of major vascular complications was higher in the transfemoral group (n=6, 11.8% vs n=1, 1.3% in the transcarotid group; p=0.019). Hospitalisation length was similar between the 2 groups (6.9±3.2 days in the transfemoral group vs 6.8±4.3 days in the transcarotid group; p =0.89) and no significant difference was found in radiation dose or contrast amount between the 2 strategies.

Conclusions: Despite a higher risk profile of the patients, the transcarotid approach during TAVR associated with complex femoral anatomy provides similar success rate and global safety that the transfemoral approach but was associated with a lower risk of major vascular complications. Carotid access could be considered as an interesting alternative approach in case of challenging femoral or aortic anatomy in patients undergoing TAVR.

Euro20A-OP134
Abstract | Oral presentation

TAVI - Tools, devices and techniques

Comparison of the SAPIEN 3 vs the ACURATE neo valve system: a propensity score analysis

STELLA Pieter [2], KOOISTRA Nynke [2], INTAN-GOEY Valent [2], ZIVIELLO Francesca [1], LEENDERS Geert [2], KRAAIJEVELD Adriaan [2], DOEVENDANS Pieter [2], VAN MIEGHEM Nicolas [1], VOSKUIL Michiel [2], STELLA Pieter [2]

(1) Erasmus MC, Rotterdam, the Netherlands; (2) UMC Utrecht, Utrecht, the Netherlands

Aims: Differences in clinical outcomes between the latest-generation balloon-expandable S3 and self-expanding NEO in a "real-world transfemoral TAVI population" are still unclear. We aimed to compare the outcomes of transfemoral ACURATE neo (NEO) and SAPIEN 3 (S3) patients in terms of device success and clinical safety outcomes using a propensity score analysis.

Methods and results: We compared up to 6 months clinical outcomes using a propensity score analysis (inverse probability of treatment weighting [IPTW]) to account for differences in baseline characteristics. A total of 345 patients underwent transfemoral TAVI with either NEO or S3 at two centres in the Netherlands. Composite device success and early safety endpoints were comparable between NEO and S3 (Device success: IPTW-adjusted OR: 0.35 [95%-CI: 0.12-1.18], and early safety: IPTW-adjusted OR: 0.51 [95%-CI: 0.19-1.38]). Six-months mortality was 5.3% vs 3.6%, stroke was 2.8% vs 3.3%, and pacemaker rate was 6.1% vs 8.6%, respectively with p=NS). Mean aortic gradient was lower in the NEO group (5.72±2.47 vs 9.05±3.48; p=<0.001), with a comparable rate of moderate or severe PAR (0% vs 2.1%; p=NS).

Conclusions: Device success and clinical safety outcomes were comparable for both valves. Up to 6-months follow-up clinical outcomes and mortality rate remained excellent. Mean aortic gradient was lower after ACURATE neo implantation.

2020 PCR e-Course Interventions for valvular disease

Euro2OA-OP135
Abstract | Oral presentation

TAVI - CT / MRI imaging

Coronary access after TAVR with a next-generation self-expanding bioprosthesis: insights from CT

ABDELGHANI Mohammad [1,2,3], ABDELGHANI Mohammad [1,2,3], LANDT Martin [3], TRABOULSI Hussein [3], BECKER Björn [3], RICHARDT Gert [3]

(1) Al Azhar University Hospital, Nasr City, Egypt; (2) Academic Medical Centre, Amsterdam, the Netherlands; (3) Segeberger Kliniken GMBH / Herz- und Gefäßzentrum, Bad Segeberg, Germany

Aims: Lower risk patients undergoing transcatheter aortic valve implantation (TAVI) endure a high cumulative risk of coronary events, but coronary access after TAVI can be challenging. Using post-TAVI multislice computed tomography (MSCT), we explored possible interference of the Medtronic Evolut R/Pro transcatheter heart valve (THV) frame with coronary access.

Methods and results: In 101 patients who received a single Evolut R/Pro device for native tricuspid aortic valve stenosis, MSCT (performed at a median of 30 days after TAVI) was used to assess the orientation of the elements of the THV frame relative to the ostium and possible interference with coronary access. The closest cell of the THV frame vertically-aligned with the coronary ostium was located: opposite the ostium in 58% and 63%; below the ostium in 22% and 30%, or above the ostium in 20% and 7% of left and right coronary arteries (LCA and RCA), respectively. The free sinus of Valsalva space between the THV frame and the coronary ostium was 0.45±0.17 cm and 0.44±0.17 cm for the LCA and RCA, respectively and showed a stepwise decrease with decreasing THV size ($p<0.001$). Bioprosthetic valve commissures were anti-anatomical (i.e. not aligned with native commissures) in 45 patients (47%), out of which the commissural post was overlapping a coronary ostium in 15 patients (16%). Two patients (2.0%) with 5−6 mm implantation depth had a possible interference of the paravalvular sealing skirt with coronary access.

Conclusions: After Evolut R/Pro implantation, a selective access to coronary ostia seems feasible in the majority of cases over a diamond at the same level of the ostium, but not uncommonly over a cell located below or above the ostial plane. In our cohort, potential interference with coronary access from the THV frame was mainly because of an anti-anatomical commissural post overlapping the coronary ostium. These findings have important implications on the choice of the catheter and the catheterisation techniques as well as possible improvements in THV design and implantation techniques to facilitate future coronary access.

Euro2OA-OP139
Abstract I Oral presentation

TAVI - Adjunctive pharmacotherapy

Invasive haemodynamic assessment and outcomes of patients with severe aortic stenosis with normal ejection fraction undergoing TAVI

ALLALI Abdelhakim [1], ALLALI Abdelhakim [1], KURNIADI Arief [1], MANKERIOUS Nader [1], LANDT Martin [1], KAUR Jatinderjit [1], ABDEL-WAHAB Mohamed [2], RALPH Toelg [1], RICHARDT Gert [1]

(1) Segeberger Kliniken GMBH / Herz- und Gefäßzentrum, Bad Segeberg, Germany; (2) Leipzig University, Leipzig, Germany

Aims: Our aim is to evaluate the clinical and invasive haemodynamic indices of patients with symptomatic severe aortic stenosis (AS) and normal ejection fraction and to evaluate their clinical outcomes following treatment with transcatheter aortic valve implantation (TAVI).

Methods and results: of 1052 patients treated with TAVI in the Heart Center Bad Segeberg between 2007 and 2017, 752 patients had a full pre-procedural right and left heart catheterisation and a complete 1-year follow-up. Of those, 386 with severe AS (indexed aortic valve area calculated with Gorlin equation (iAVA) ≤0.6 cm²) had a left ventricular (LV) ejection fraction ≥ 50% as evaluated by LV-angiogram. Based on invasive assessment, we identified three groups: 113 patients with normal flow, high-gradient (NF-HG: stroke volume index (SVI) ≥35 mL/m², mean gradient (MG) ≥40 mmHg), 190 patients with low-flow, high gradient (LF-HG: SVI<35 mL/m², MG≥40 mmHg) and 83 patients with paradoxical low-flow, low-gradient (PLF-LG: SVI<35 mL/m², MG<40mmHg). Compared with NF-HG patients, LF-HG and PLF-LG population was older (80 years [IQR: 77-83] vs 83 years [IQR: 79-86] vs 83 years [79-85]; p=0.010) and had higher incidence of atrial fibrillation (25.7% vs 42.6% vs 53%; p<0.001). The NT-pro-BNP levels were higher in patients with LF-HG and PLF-LG (955 pg/mL [IQR: 484-1935] vs 1746 pg/mL [IQR: 686-3388] vs 1648 pg/mL [IQR: 572-3339]; p<0.001). The invasive assessment revealed higher prevalence of pulmonary hypertension in LF-HG and PLF-LG compared with HF-HG group (mPAP≥25 mmHg in 54% vs 67.4% vs 66.3%; p=0.053). Thirty days mortality was not significantly different between the groups (2.7% vs 4.2% vs 1.2%; p=0.398). At one year, all-cause mortality was not significantly different between the groups (9.7% vs 10% vs 15.7%; p=0.335). Concerning clinical symptoms, significant amelioration of the New York Heart Association (NYHA) class was observed in all groups at 30 days compared with baseline. This amelioration remained significant at 1 year in surviving patients when compared with baseline functional status. A reduction in NT-pro-BNP levels was more pronounced in LF-HG and PLF-LG groups at 30 days as compared with baseline values (560 pg/mL [IQR: 321-914]; p value compared to baseline= 0.349 vs 880 pg/mL [IQR: 444-1964]; p value compared to baseline<0.001 vs 777 pg/mL [IQR: 410-1612]; p value compared to baseline= 0.095; p value between the three groups= 0.096). NT-pro-BNP levels at 1 year continued to decrease in NF-HG group (441 pg/mL [IQR: 304-1323]; p=0.154 compared to 30 days; p<0.001 compared to baseline), remained stable in LF-HG group (973 pg/mL [381-1538]; p=0.997 compared to 30 days; p<0.001 compared to baseline) and increased slightly in PLF-LG group (985 pg/mL [493-1552]; p=0.635 compared to 30 days; p=0.007 compared to baseline); p value between the groups=0.064.

Conclusions: In patients with severe symptomatic AS and normal ejection fraction, the presence of low-flow with or without high gradient in the invasive evaluation was common (70.7%). These patients are older and have higher incidence of atrial fibrillation with more pulmonary hypertension and higher NT-pro-BNP levels. Nevertheless, treatment with TAVI improved clinical and functional outcome.

2020 PCR e-Course Interventions for valvular disease

Euro20A-OP146
Abstract | Oral presentation

Mitral valve replacement and repair - Tools, devices and techniques

Six-month and one-year outcomes with the novel PASCAL transcatheter valve repair system for patients with mitral regurgitation from the multicentre, prospective CLASP study

WEBB John [1], KAR Saibal [2], MAKKAR Raj [3], KIPPERMAN Robert [4], SPARGIAS Konstantinos [5], O'NEILL William [6], NG Martin [7], FAM Neil [8], RINALDI Michael [9], SMITH Robert [10], LIM Scott [11]

(1) St Pauls Hospital, BC, Canada; (2) Los Robles Regional Medical Center, CA, USA; (3) Cedars-Sinai Medical Center, CA, USA; (4) Morristown Medical Center, NJ, USA; (5) Hygeia Hosptial, Athens, Greece; (6) Henry Ford Hospital, MI, USA; (7) Royal Prince Alfred Hospital, NSW, Australia; (8) St. Michael's Hospital, ON, Canada; (9) Sanger Heart & Vascular Institute, NC, USA; (10) The Heart Hospital Baylor Plano, TX, USA; (11) University of Virginia Health System Hospital, VA, USA

Aims: Transcatheter mitral valve repair has emerged as a viable option for treating mitral regurgitation (MR). We report results from the multicentre, prospective, single arm CLASP study with the PASCAL transcatheter valve repair system (Edwards Lifesciences, Irvine, CA).

Methods and results: 109 patients with clinically significant MR deemed candidates for transcatheter repair by the local heart team were treated in the CLASP study. The study evaluated safety, performance, clinical and echocardiographic outcomes and included an independent clinical events committee and echocardiographic core lab. The primary safety endpoint was a composite MAE rate at 30 days of cardiovascular mortality, stroke, MI, new need for renal replacement therapy, severe bleeding, and re-intervention for study device-related complications. Results: Mean age was 76 years, 54% male, 57% NYHA Class III/IV, 100% MR grade ≥3+ with 62% functional, 31% degenerative, 7% mixed aetiology. Successful implantation was achieved in 95% of patients. At 30 days, the MAE rate was 8.3% including one cardiovascular mortality due to cardiogenic shock as a result of severe bleeding at the contralateral arterial access site for haemodynamic monitoring further complicated by disseminated intravascular coagulation, one stroke, and one conversion to mitral valve replacement surgery. In paired analysis, 88% of patients were in NYHA Class I/II ($p<0.001$), MR grade was ≤1+ in 79% of patients and ≤2+ in 96% of patients. Significant improvements in 6 MWD (+27 m, $p<0.001$) and KCCQ (+16 points, $p<0.001$) were observed. The six-month data will be available for presentation. In addition, we report one-year follow-up of the first 62 patients (ITT): 93% one-year survival rate (Kaplan-Meier estimate), no stroke, no late reintervention, one late MI. In paired analysis, MR grade was ≤1+ in 82% of patients and ≤2+ in 100% of patients. 88% of patients were in NYHA Class I/II ($p<0.001$), 6 MWD improved by 21 m ($p=0.124$) and KCCQ improved by 13 points ($p<0.001$).

Conclusions: This study demonstrates the PASCAL transcatheter valve repair system is safe and resulted in remarkable MR reduction with 100% of patients achieving MR ≤2+, and ~ 80% MR ≤1+, sustained at one year. Results show a high survival rate, low complications, and sustained improvements in functional status, exercise capacity, and quality of life at one year in patients with clinically significant, symptomatic MR. The CLASP IID/IIF pivotal trial is underway.

TAVI - Tools, devices and techniques

Does transient left ventricular dysfunction peri-aortic valve intervention truly exist?

ALDALATI Omar [1,2], ALDALATI Omar [1,2], CABACA Anna Rita [1,2], MARTIN Katherine [1], BYRNE Jonathan [1], ESKANDARI Mehdi [1,2], MONAGHAN Mark [1,2], WENDLER Olaf [1,2], SHAH Ajay [1,2], MACCARTHY Philip [1,2], DWORAKOWSKI Rafal [1,2]

(1) King's College Hospital, London, United Kingdom; (2) King's College London, London, United Kingdom

Aims: Previous research demonstrated transient left ventricular dysfunction (TLVD) after aortic valve intervention (surgical or transcatheter). The definition of TLVD and its clinical relevance is not established. We aimed to: 1) test the hypothesis that TLVD after TAVI is a true phenomenon. 2) define TLVD. 3) evaluate its clinical relevance among TAVI patients.

Methods and results: We recruited TAVI patients and studied the LV contractility utilising a load-independent invasive modality - the pressure-volume loop (PVL) studies (baseline measurements and force-frequency relationships (FFR) with incremental pacing) - with the following stages: Stage 1: The objective was to invasively characterise the LV in AS (ejection fraction (EF) >50%) through a comparison to controls and heart failure patients. Stage 2: The objective was to test the primary hypothesis. We based TLVD definition and sample size calculation on the work of Dekker et al. (a drop in LV end-systolic pressure-volume relationship (ESPVR) post-intervention). We examined the hypothesis that a 40% incidence of TLVD is no less than 10% (the required sample size is 22 cases). Stage 3: We correlated the invasive indices of contractility to serial biomarkers, NYHA class and 6-minute walk test. Clinical outcomes (hypertensive crisis (HC), acute heart failure syndrome (AHFS) and survival) were censored up to one-year post-TAVI, and we assessed their association with TLVD. Results: Stage 1: Twenty-six (26) aortic stenosis (AS), 15 controls (Ctrl) and 12 heart failure (HF) patients were recruited. The HF group had the lowest EF, Starling contractility index (SCI), and pre-load recruitable stroke work (PRSW). SCI dropped more in AS and HF groups compared to the Ctrl with FFR (β coefficient = 1.12 (0.47) for Ctrl Vs AS, p =0.007; β coefficient = -1.6 (0.53) for HF vs Ctrl, p =0.003). Stage 2: Twenty-four (24) AS patients completed the protocol. Post-TAVI, EF and PRSW dropped significantly, and the diastolic profile worsened. With FFR, cardiac output had a more blunted response post-TAVI (β coefficient = 0.237 (0.08) for pre- vs post-, p =0.005). 58% (14/24) met the criterion of TLVD (the null hypothesis was rejected). They showed a blunted SCI response to FFR pre-TAVI (β coefficient = 0.633 (0.3) for no-TLVD vs TLVD, p =0.049). Stage 3: TLVD patients were more symptomatic (NYHA class ≥3, 65% vs 10%, p =0.013) and walked less (in meters, 135 vs 280, p =0.037). ST2 (ug/L, 16 (IQR 7) Vs 24.8 (IQR 12), p =0.006) and NT-proBNP (ug/L, 1411 (IQR 1438) vs 5141 (5111), p =0.048) were different at baseline. In-hospital hypertensive crisis (15%) and one-year mortality (9%) and AHFS admissions (15%) were not different between the groups. Baseline NT-proBNP correlated negatively with SCI (Spearman's R, -0.41, p =0.017) and PRSW (Spearman's R, -0.459, p =0.007). Finally, we observed that SCI (pre-TAVI) at critical heart rate (CHR, defined with incremental pacing) was a significant predictor of mortality: SCI at CHR hazard ratio = 1.126 (95% CI: 1.029 to 1.233, p =0.010).

Conclusions: 1) TLVD peri-TAVI is a true phenomenon and occurs at an intrinsic myocardial level; patients who develop TLVD are more symptomatic. 2) Cardiac biomarkers are likely to identify these patients pre-TAVI. 3) Invasive contractility indices during stress (pacing) are of prognostic value.

Euro20A-OP004
Abstract | PCR's Got Talent

TAVI - Tools, devices and techniques

Acute transcatheter aortic valve performance: update on a multicentre quantitative regurgitation assessment of 2,321 valves implanted in the "real-world"

MODOLO Rodrigo [1,2], MODOLO Rodrigo [1,2], KAWASHIMA Hideyuki [2], WANG Rutao [7], TAO Ling [3], VAN MIEGHEM Nicolas [4], ONUMA Yoshinobu [5], SINNING Jan-Malte [6], DE WINTER Robbert [2], SERRUYS Patrick [5]

(1) Hospital das Clínicas da Unicamp, State of São Paulo, Brazil; (2) Amsterdam UMC - Locatie VUmc, Amsterdam, the Netherlands; (3) Xijing Hospital, Shaanxi, China; (4) Erasmus Universiteit Rotterdam, Rotterdam, the Netherlands; (5) National University of Ireland Galway, Galway, Ireland; (6) Universitätsklinikum Bonn Medizinische Klinik und Poliklinik I, Bonn, Germany; (7) Radboud Universiteit, Nijmegen, the Netherlands

Aims: Regurgitation following transcatheter aortic valve implantation (TAVI) impacts all-cause mortality. Thus far, no quantitative comparison of regurgitation amongst multiple commercially available transcatheter heart valves (THV) has been performed. We sought to assess the acute regurgitation following TAVI comparing different implanted THV.

Methods and results: Aortograms from a multicentre cohort of consecutive 4,099 TAVI from The Netherlands, Brazil, Canada, Germany, Japan, Italy, Denmark, Sweden, France and China were evaluated in this pooled analysis. The quantitative method for assessing aortic regurgitation after TAVI is based on time-density curves derived from videodensitometry in the aortic root and in the left ventricle outflow tract. The ratio of the area under these two curves represents the quantification of the regurgitation in percentage. A total of 2,321 (56.6%) were considered analysable by an independent academic core lab using videodensitometry. Valves evaluated with videodensitometry were: Acurate (n=115), Centera (n=11), CoreValve (n=532), Direct Flow Medical (n=21), Evolut Pro (n=95), Evolut R (n=295), Inovare (n=4), Lotus (n=546), Lotus Edge (n=3), SAPIEN XT (n=239), SAPIEN 3 (n=397) and Venus-A Valve (n=63). For the main analysis only valves with more than 50 procedures (8 types) were used. Lotus valve had the lowest mean regurgitation (3.5±4.4%), followed by Evolut Pro (7.4±6.5%), SAPIEN 3 (7.6±7.1%), Evolut R (7.9±7.4%), SAPIEN XT (8.8±7.5%), Acurate (9.6±9.2%), Venus-A Valve (11.2±11.5%) and CoreValve (13.7±10.7%, ANOVA p-value<0.001). The only valves that statistically differed from all their counterparts were Lotus (as the lowest regurgitation) and Venus-A and CoreValve (the two highest, that did not differ only between each other). The proportion of patients presenting a moderate or severe regurgitation followed the same ranking order: Lotus (2.2%), Evolut Pro (5.3%), SAPIEN 3 (8.3%), Evolut R (8.8%), SAPIEN XT (10.9%), Acurate (11.3%), Venus-A Valve (20.6%) and CoreValve (30.1%) – chi-square p-value <0.001.

Conclusions: In this pooled analysis stemming from daily clinical practice, the Lotus valve showed to have the best immediate sealing. This analysis reflects the objective evaluation of regurgitation by an academic core lab (non-sponsored) in a real-world cohort of patients using a reproducible and quantitative technique.

TAVI - Echocardiography

The impact of severe aortic annular calcification on paravalvular leak after TAVI

SOULAIDOPOULOS Stergios [(1)], SOULAIDOPOULOS Stergios [(1)], DRAKOPOULOU Maria [(1)], SYNETOS Andreas [(1)], STATHOGIANNIS Konstantinnos [(1)], OIKONOMOU George [(1)], TOSKAS Pantelis [(1)], XANTHOPOULOU Maria [(1)], TOUTOUZAS Konstantinos [(1)], TOUSOULIS Dimitrios [(1)]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: Paravalvular leak (PVL) remains a frequent complication after transcatheter aortic valve implantation (TAVI) and seems to affect short- and long-term survival. The aim of this study was: 1) to identify anatomical predictors of PVL after TAVI and 2) assess the impact of PVL on cumulative survival.

Methods and results: Patients with severe and symptomatic aortic stenosis (effective orifice area [EOA] ≤1 cm^2) referred for TAVI at our institution were consecutively enrolled. Prospectively collected demographic, laboratory and echocardiographic data were retrospectively analysed. Patients were stratified into two groups according to the presence of PVL after TAVI and were followed up postoperatively with clinical and echocardiographic assessment. Primary clinical endpoint was all-cause mortality, as defined by the criteria proposed by the Valve Academic Research Consortium 2. In total, 291 patients were included (male: 50.2%, mean age: 80±7.6 years) in our study. Of these, 165 (56,8%) presented at least mild PVL after TAVI (mild: 85,5%, moderate: 13.3% and severe: 1.2%). The median follow-up period was 27.3 (min. 0, max 113 months). Two patients with severe PVL were excluded from the analysis. In the follow-up period, there was no significant difference regarding all-cause mortality between patients with and those without PVL after TAVI, independently from the degree of PVL (log rank: 0.018, p=0.991). Nevertheless, among patients with PVL after TAVI, patients with PVL and preserved EF (≥50%) presented better survival rates in the follow-up period compared to patients with PVL and impaired left ventricular systolic function (EF<50%) before TAVI (log rank: 4.985, p=0.026). Severe aortic annulus calcification, the presence of a bicuspid aortic valve and aortic root angulation, as assessed by computed tomography (CT), were found to associate with PVL after TAVI in univariate analysis. In the multivariate analysis, severe aortic annulus calcification was found to be the only independent predictor of mild or moderate PVL after TAVI (Exp[B]: 1.540, 95% confidence interval: 1.067- 2.224, B= 0.432, p=0.021).

Conclusions: The presence of mild to moderate PVL was associated with worse survival outcomes in patients with reduced left ventricular systolic function. Severe aortic annulus calcification assessed by CT-scan, was found to be the only independent predictor of PVL after TAVI.

TAVI - Tools, devices and techniques

Safety and efficacy of TAVR in patients with severe, symptomatic aortic stenosis aged 90 years or older

ZADROZNY Magda [1], ZADROZNY Magda [1], JOCHHEIM David [1], THEISS Hans [1], BRAUN Daniel [1], MEHILLI Julinda [1], MASSBERG Steffen [1], HAUSLEITER Jörg [1], DESEIVE Simon [1]

(1) LMU, Munich, Germany

Aims: In the aging western societies, an increasing prevalence of severe, symptomatic aortic stenosis (AS) is observed. The aim of this study was to examine the safety and efficacy of transcatheter aortic valve replacement (TAVR) in patients aged 90 years and older.

Methods and results: All consecutive patients who underwent TAVR for severe, symptomatic AS in our institution between January 2013 and December 2017 were included in this analysis. Procedure related mortality (<30 days) was defined as primary endpoint. Mortality rates at one year, device failure and procedural complications were defined as efficacy and safety secondary endpoints according to the Valve Academic Research Consortium II criteria. Procedural data were collected prospectively and post-interventional examinations and treatments were done as in clinical routine of our institution. Patients were contacted per telephone for a follow-up 30 days after hospital-discharge and one year after the procedure. If adverse events occurred after hospital-discharge, documentation from other hospitals was requested. Transfemoral aortic valve replacement was performed in conscious sedation and every kind of valves used in clinical routine were implanted, which include non-balloon expandable (CoreValve, Medtronic, Minneapolis, MN, USA and Lotus Valve System, Boston Scientific, MA, USA) or balloon-expandable (Edwards SAPIEN XT and S3, Edwards Lifesciences, Irvine, CA, USA) prostheses. Suture-mediated vascular closure systems (one Prostar XL or two ProGlide systems, Abbott Vascular Inc., Santa Clara, CA, USA) were used for closing after puncture. After TAVR either dual antiplatelet therapy with ASS (lifelong) and clopidogrel (for at least 3 months) or oral anticoagulation (if indicated by comorbidities) was recommended. The study population (n=1,891) consisted of 1,766 patients younger than 90 years and 125 patients aged 90 or older. Procedure-related mortality within 30 days (4.0% vs 3.6%, p=0.8) was similar in both groups. The rates of device failure were numerically but not significantly higher in the elderly patients (4.9% vs 2.7% p=0.15), driven by more paravalvular regurgitation >°I (4.0% vs 1.5%, p=0.048). All other procedural complications including strokes, major bleedings and the need for permanent pacemaker implantation were comparable. Estimated survival rates at 1 year were 78.55% (95% CI: 71.4 and 86.4) in the elder and 85.0% (95% CI: 0.83 and 0.87, p=0.03) in the younger patients.

Conclusions: In this analysis, TAVR procedure was found to be equally safe and feasible in patients aged 90 years or older compared to younger patients. Differences in 1-year survival appear to be patient-related rather than procedure-related. Regarding the overall 1-year survival rate of nearly 80% in those patients, TAVR should not be withheld from carefully selected patients with severe, symptomatic AS at higher age.

Other valvular and structural interventions - Other

Does pre-TAVI coronary artery disease revascularisation reduce the risk for future revascularisation? The experience of a single high-volume TAVI centre

GHATTAS Angie [1], GHATTAS Angie [1], SIDDIQUI Saif [1], LAPERCHE Clemence [1], DE BIASE Chiara [1], AGUDZE Edem [1], DOMUNTEIL Nicholas [1], TCHETCHE Didiere [1]

(1) Clinique Pasteur, Toulouse, France

Aims: To investigate the significance of coronary revascularisation pre-TAVI utilising the SYNTAX II score for risk stratifying patients and differences in outcome between patients who underwent revascularisation pre-TAVI and those who did not have revascularisation.

Methods and results: Patients who underwent TAVI between January 2016 and December 2017 in a single high-volume centre were retrospectively analysed. All patients underwent coronary angiograms pre-TAVI. The angiograms were reviewed with SYNTAX II score being calculated for patients with underlying coronary artery disease. Patients who underwent percutaneous revascularisation were compared with those patients who had no planned pre TAVI revascularisation and patients with no underlying coronary artery disease (CAD). Patients were followed up to January 2020. Primary outcomes were: all-cause mortality, myocardial infarction requiring revascularisation, and revascularisation for stable angina symptoms. Follow-up was completed by analysing the hospital records for outcomes and any further intervention. Patients who were not reviewed in hospital or were out of area, had their follow-up completed by contacting the primary physician. Statistical analysis was performed by Graph Prism 2018. Normally distributed data are described as mean ± standard deviation and were analysed using parametric testing. Non-normally distributed data are described as median and interquartile range and analysed using non-parametric testing. Non-parametric data were analysed using a Wilcoxon t-test for independent data. Between January 2016 and December 2017, 1081 patients had a TAVI procedure, (55% male, age 85±9). Non-clinically significant coronary artery disease was present in 540 patients (50). Moderate to severe coronary artery disease was angiographically assessed and documented in 541 patients pre-TAVI (50%), with 81 patients having had a CABG previously (7.5%). However, only 283 patients (26%) patients had percutaneous revascularisation (SYNTAX II score 29 [14-43]) pre-TAVI, with 9.8% receiving multivessel PCI leading to complete revascularisation (SYNTAX II score 36 [18-55]). Non-revascularised patients with underlying coronary artery disease had SYNTAX score of 25 (12- 37). The SYNTAX score was significantly higher in revascularised patients compared to non revascularised patients, p=0.03. During the follow-up period, mean 35±7.8 months, 12% of patients were lost to follow-up. There were 23 all-cause mortalities and 11 myocardial infarctions in the complete cohort (1.1%) of which 5 occurred in patients who had previous CAD and 6 in patients with no previous documented CAD, p=0.7. All patients were successfully treated percutaneously. There were no patients treated percutaneously for stable angina post-TAVI during our follow-up period.

Conclusions: SYNTAX II score could be used to risk stratify patients pre-TAVI. Partial or complete revascularisation pre-TAVI in patients with a high SYNTAX score should be considered. Myocardial infarction is infrequent post-TAVI. In our cohort, there was no difference in the post-TAVI MI rates between those patients who were percutaneously revascularised pre-TAVI and those who were not. It is interesting that there were no revascularisations for stable angina post-TAVI in this large cohort.

TAVI - Tools, devices and techniques

Impact of transcatheter heart valve design on patient-prosthesis mismatch in patients undergoing TAVI with small aortic annulus: a retrospective multicentre study

VOIGTLÄNDER Lisa [1], VOIGTLÄNDER Lisa [1], KIM Won-Keun [2], SINNING Jan Malte [3], MAURI Victor [4], GOßLING Alina [1], LINDER Matthias [1], RENKER Matthias [2], SUGIURA Atsushi [3], SCHMIDT Tobias [4], SCHOFER Niklas [1], WESTERMANN Dirk [1], HAMM Christian [2], NICKENIG Georg [3], ADAM Matti [4], REICHENSPURNER Hermann [1], BLANKENBERG Stefan [1], CONRADI Lenard [1], SEIFFERT Moritz [1]

(1) University Heart Center Hamburg GmbH, Hamburg, Germany; (2) Kerckhoff-Klinik GmbH, Bad Nauheim, Germany; (3) University Hospital of Bonn, Bonn, Germany; (4) University Hospital of Cologne, Cologne, Germany

Aims: Patient-prosthesis mismatch (PPM) after transcatheter aortic valve implantation (TAVI) is associated with increased mortality and morbidity rates and has a high prevalence in patients with small aortic annulus. This large multicentre analysis aimed (i) to determine the incidence of PPM in patients with a small aortic annulus undergoing TAVI and (ii) to compare outcome and haemodynamic performance of different THV designs in this patient population.

Methods and results: Data from 8,500 consecutive patients who underwent TAVI for the treatment of severe aortic stenosis between May 2012 and April 2019 at four German centres were retrospectively evaluated. A small aortic annulus was defined as MDCT-derived annulus area <400 mm^2. PPM was defined as indexed effective orifice area ≤0.85 cm^2/m^2. Haemodynamic and echocardiographic performance and early clinical outcomes were assessed. A small annulus was found in 994 (11.7%) patients who were included in this analysis. 93.8% of these patients were female, median age was 82.9 [79.5-86.2] years. TAVI was performed with self-expanding supra- (Evolut: 16.3%; ACURATE neo: 40.5%), balloon-expandable and self-expanding intra- (SAPIEN-3: 27.1%; Portico: 10.7%), and mechanically-expandable infra-annular THV (Lotus: 5.4%). Median annulus area was 368.1 mm^2 [343.4-382.9] and larger in patients treated with balloon-expandable intra-annular THV (376.0 mm^2 [351.9-386.0]; p<0.001). PPM after TAVI was detected in 34.6% of patients with a small aortic annulus. The incidence was higher after balloon-expandable intra-annular (53.5%) or mechanically-expandable infra-annular (36.7%) compared to self-expanding intra- and supra-annular THV implantation (Portico: 19.8%, Evolut: 23.9% and ACURATE neo: 29.4%, p<0.001). Accordingly, residual mean transvalvular gradients were higher in patients with balloon-expandable intra-annular (12.8 mmHg [IQR 9.0-16.0]) and mechanically-expandable infra-annular (12.0 mmHg [IQR 9.8-15.9]) compared to self-expanding intra- and supra-annular devices (Portico: 9.0 mmHg [IQR 7.0-11.0]; Evolut: 7.0 mmHg [IQR 5.0-10.0] and ACURATE neo: 9.0 mmHg [IQR 6.0-12.0], respectively (p<0.001). Paravalvular regurgitation: moderate was more common after implantation of self-expanding (Evolut: 4.9%, ACURATE neo: 7.2%; Portico: 5.7%) vs balloon-expandable devices (1.5%; p=0.005). All-cause mortality was 9.7% at 12 months and similar among all groups.

Conclusions: In this large contemporary multicentre patient population, PPM after TAVI was common in patients with a small aortic anatomy. Self-expanding supra- or intra-annular THV demonstrated superior haemodynamics in these patients at risk. However, this was seen at the cost of higher rates of residual paravalvular regurgitation.

TAVI - Tools, devices and techniques

Impact of early hospital discharge on clinical outcomes after TAVI

BÆKKE Pernille [(1)], BÆKKE Pernille Steen [(1)], JØRGENSEN Troels Højsgaard [(1)], SØNDERGAARD Lars [(1)]

(1) Rigshospitalet, Copenhagen Municipality, Denmark

Aims: To evaluate the risk of all-cause mortality, permanent pacemaker implantation and re-hospitalisation from discharge to 90-day post-procedure among patients with planned short hospital stay (fast track) compared to patients with planned longer hospital stay (standard approach).

Methods and results: A single-centre study, including all-comers patients with severe, symptomatic aortic stenosis, who underwent transfemoral transcatheter aortic valve implantation (TAVI) between August 2011 and 2017 at Rigshospitalet, Denmark. In August 2015, procedural anaesthesia changed from general to local, and simultaneously an early discharge program was introduced. Patients were allocated to two groups, depending on whether the date of procedure was before or after August 2015. Furthermore, the two study populations were propensity score matched according to baseline characteristics. A total of 914 patients underwent TAVI during the study period. After propensity score matching, 334 pair of patients were eligible for analysis. After the index procedure, the median total length of hospital stay was 3 days (IQR: 2 – 4) for patients in the fast track group compared to 6 days (IQR: 4 – 8) for those in the standard approach group ($p<0.0001$). There was no difference in all-cause mortality between groups at 30-day (1.2 % vs 1.2 %, $p=1.00$) or 90-day post-procedure (2.8 % vs 3.3 %, $p=0.69$). Likewise, there was no difference in the all-cause mortality rate after discharge and within 90-day post-procedure between groups (0.05 deaths per patient-year in the fast track group vs 0.08 deaths per patient-year in the standard approach group, $p=0.31$). There was a trend towards lower risk of permanent pacemaker implantation in the fast track group at 30-day (15.1 % vs 21.9 %, $p=0.06$), which became statistically significant at 90-day post-procedure (15.1 % vs 23.2 %, $p=0.02$). Among patients who had a permanent pacemaker implantation within 90-day after the procedure, more patients in the fast track group received it after their index admission (21.3 % vs 8.1 %, $p<0.0001$). There was no difference in the rate of permanent pacemaker implantation after discharge and within 90-day post-procedure between groups (0.17 permanent pacemaker implantations per patient-year in the fast track group vs 0.11 permanent pacemaker implantations per patient-year in the standard approach group, $p=0.26$). There was no difference in the rate of re-hospitalisation between groups between discharge and 90-day post-procedure (2.41 re-hospitalisations per patient-year in the fast track group vs 2.38 re-hospitalisations per patient-year in the standard approach group, $p=0.86$). The median number of days from discharge to the first re-hospitalisation was 14 days (IQR: 6 – 40) in the fast track group compared to 17 days (IQR: 7 – 38) in the standard approach group ($p=0.73$).

Conclusions: Early discharge in an all-comers patient population with severe, symptomatic aortic stenosis undergoing transfemoral TAVI is a safe and non-inferior alternative to longer hospital stay with regards to all-cause mortality, late permanent pacemaker implantation and re-hospitalisation.

TAVI - Vascular access and bleeding

Clinical results of transfemoral TAVI with endovascular therapy

AMANO Tatsuya [(1)], AMANO Tatsuya [(1)]

(1) New Tokyo Hospital, Chiba, Japan

Aims: Background: Transfemoral (TF)-transcatheter aortic valve implantation (TAVI) is considered to have better clinical outcomes than non-transfemoral (non-TF)-TAVI. In our institution, we have been actively implementing TF-TAVI in combination with endovascular therapy (EVT) even for cases with narrow lower-limb arteries. However a systematic evaluation of this approach is not available, hence we investigated the success rate of transcatheter protheses valve delivery and the occurrence of lower-limb ischaemia during follow-up in patients who underwent EVT in the iliac to femoral regions.

Methods and results: Of 435 patients who underwent TF-TAVI at our institution from December 2013 to November 2019, 51 patients underwent EVT in the iliac to the femoral regions during the perioperative period. The study objectives were death from any cause, amputation, and target lesion revascularisation during follow-up period. Results: the average age of 51 patients who underwent EVT in the iliac to the femoral regions was 83 years (± 14 years), among whom 13 were men and the average Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score was 8.8%. Of the 51 patients, 33 were treated with a balloon-expandable valve and 18 were treated with a self-expanding valve. The size of the sheath used for treatment was 14 Fr in 19 patients, 16 Fr in 18 patients, 18 Fr in 12 patients, and 20 Fr in 2 patients. There were no cases in which TF-TAVI was discontinued or changed to non-TF-TAVI. Revascularisation was performed before TAVI in 3 cases, before valve placement on the day of TAVI in 21 cases, and after valve placement on the day of TAVI in 27 cases. Of the 51 patients, 35 were stented (14 covered stents), and 16 underwent balloon angioplasty. Over a median of 450 days of follow-up, target lesion revascularisation was performed in three patients (at 3, 8, and 332 days after TAVI, respectively), and amputation was performed in none of the patients. Death was confirmed in eight patients.

Conclusions: TF-TAVI with EVT is feasible and associated with low TLR rates.

TAVI - Tools, devices and techniques

Machine learning-based prediction model of hospital length of stay after TAVI

GOMES Bruna [1], GOMES Bruna [1], REICH Christoph [1], KONSTANDIN Mathias [1], LEUSCHNER Florian [1], KATUS Hugo [1], MEDER Benjamin [1]

(1) Heidelberg University, Heidelberg, Germany

Aims: This study aims to establish predictive models for length of hospital stay (LoS) in patients undergoing transcatheter aortic valve implantation (TAVI) using a machine learning approach.

Methods and results: A total of 426 consecutive patients undergoing elective TAVI between February 2014 and June 2016 was randomly split in training and testing sets (75:25). Exclusion criteria included intra-hospital mortality. A LoS cut-off was set at 9 days, representing the mean length in days at our centre. After a 4-fold cross-validation and hyperparameter tuning on the training set, the best models were tested on the independent test cohort. Models included neural networks, support vector machines and random forests. All patients underwent a complete clinical, echocardiographic, computer tomographic and laboratory evaluation at baseline, as well as a thorough annotation of procedural course, whereas a total of 81 baseline and procedural features were included. Main evaluation metric comprised the calculation of ROC AUC curves. Performance of the support vector machine was highest (AUC 0.76), followed by the random forest (AUC 0.71) and by a neural network model (AUC 0.63) in predicting a longer LoS. Applying an Extreme Gradient Boosting, a decision tree model, the 10 highest feature importance were extracted. Among post-procedural features: antibiotic use longer than 1 day, infection, Troponin T and leucocyte counts at third day post-TAVI. Among baseline features: mean gradient pressure pre-TAVI, septal thickness, left ventricular end-diastolic diameter and creatinine value, female gender and the New York Heart Association functional class.

Conclusions: Machine learning has the potential to improve patient selection and risk management for interventional cardiovascular procedures. Larger, multicentric and prospective studies are needed to confirm these results.

TAVI - Tools, devices and techniques

Preventative chimney stenting during valve-in-valve TAVI for degenerated Mitroflow bioprostheses: 12-month clinical follow-up

NERLA Roberto [1], NERLA Roberto [1], CASTRIOTA Fausto [1], MICARI Antonio [1], MICCICHÈ Eligio [1], CREMONESI Alberto [1]

(1) Humanitas Gavazzeni, Province of Bergamo, Italy

Aims: To evaluate the clinical outcome of preventative coronary stenting using the "chimney" technique during valve-in-valve TAVI for degenerated Mitroflow bioprostheses.

Methods and results: Main clinical and procedural data of all "valve-in-valve" (VIV) TAVI procedures to treat degenerated Mitroflow bioprostheses at our institution (2016-2018) were prospectively collected. Patients were judged at high risk of coronary occlusion according to a multi-variable evaluation of anatomical aortic root features (i.e., sinus width and height, coronary height, use of supra-annular TAVI device) and coronary protection was used. Among them, preventative stenting according to the previously described "chimney" technique was performed at operator's discretion at the end of the procedure. All patients underwent clinical follow-up at 30 days and at 12 months from the procedure. During the reference period, 36 patients (age 78±7 years, 61% males) underwent VIV TAVI for Mitroflow degeneration. A supra-annular TAVI device was used in most patients (Evolut R: 17/36, 47.2%; ACURATE neo: 5/36, 13.9%), while a Lotus valve was used in 14 patients (38.9%). Twenty patients (55.5%) were judged at high risk for coronary occlusion; of them, 8 patients received a preventative chimney stenting. Patients judged at low risk of coronary occlusion (n=16, 44.4%) showed a higher EuroSCORE II (11.4±9.9 vs 6.2±3.3, p=0.04). Among them, one non-cardiac death (i.e., sepsis) was reported at 1-month follow-up, with no further events at 1-year assessment. In the high-risk group, patients who did not receive preventative stenting showed an early post-procedural myocardial infarction due to coronary occlusion 2 hours after the TAVI procedure which was successfully treated with emergency PCI. Two more cardiovascular events were reported at 12-month follow-up (global rate 3/12, 25%) in the high-risk subgroup which did not undergo preventative stenting (i.e., 1 sudden death; 1 death due to worsening heart failure). No cardiovascular events were reported at 12 months in patients who received preventative "chimney" stenting. No patients required coronary angiography during this follow-up time.

Conclusions: Valve-in-valve procedures carry a significant risk of coronary occlusion when performed in anatomically unfavourable aortic roots with high-risk degenerated bioprostheses like Mitroflow. This is the first series showing 1-year clinical outcomes of a preventative "chimney" stenting in patients at high risk of coronary occlusion. In spite of a number of limitations to be assessed in future studies (i.e., the need for coronary re-access), chimney stenting should be preferred to a conservative approach when performing VIV TAVI in unfavourable aortic roots with degenerated Mitroflow bioprostheses.

TAVI - Tools, devices and techniques

Predictors of haemodynamic performance in patients with aortic stenosis and small annulus undergoing TAVI with self-expandable valves

CHIARITO Mauro [1], CHIARITO Mauro [1], REGAZZOLI Damiano [1], CANNATA Francesco [1], PAGNESI Matteo [2], MIZUKI Miura [3], ZIVIELLO Francesca [4], PICCI Andrea [5], REIFART Jorg [11], DE MARCO Federico [6], BEDOGNI Francesco [6], ADAMO Marianna [7], CURELLO Salvatore [7], TELES Rui [8], TARAMASSO Maurizio [3], BARBANTI Marco [5], TAMBURINO Corrado [5], STEFANINI Giulio [1], MANGIERI Antonio [9], GIANNINI Francesco [9], PAGNOTTA Paolo Antonio [1], MAISANO Francesco [3], KIM Won-Keun [11], VAN MIEGHEM Nicolas M [4], COLOMBO Antonio [9], REIMERS Bernhard [1], LATIB Azeem [10]

(1) Humanitas Research Hospital, Metropolitan City of Milan, Italy; (2) San Raffaele Hospital, Metropolitan City of Milan, Italy; (3) University Heart Center Zurich, Zürich, Switzerland; (4) Erasmus University Medical Center, Rotterdam, the Netherlands; (5) Azienda Ospedaliera "Policlinico Vittorio Emanuele", Province of Catania, Italy; (6) Policlinico san donato, Metropolitan City of Milan, Italy; (7) Spedali Civili Di Brescia, Province of Brescia, Italy; (8) Hospital de Santa Cruz, Lisbon, Portugal; (9) Maria Cecilia Hospital Del Gruppo Villa Maria, Province of Ravenna, Italy; (10) Montefiore Medical Center, NY, USA; (11) Kerckhoff-Institut, Bad Nauheim, Germany

Aims: Aortic annular size is recognised as one of the most relevant anatomical features that could influence haemodynamic and clinical outcomes after transcatheter aortic valve implantation (TAVI). *Post hoc* analysis of pivotal trials comparing TAVI with surgery in patients with small aortic annulus showed that TAVI offered better haemodynamic results and a reduced risk of developing severe prosthesis-patients mismatch (PPM), especially with self-expandable valve (SEV) implantation. However, no direct comparisons of the performance of currently available SEVs in this subgroup of patients are available.

Methods and results: In this registry, we compared the haemodynamic and clinical outcomes of four commercially available SEVs in patients affected by aortic stenosis with a small aortic annulus undergoing TAVI. This registry retrospectively enrolled all patients with small annulus (CT-scan annular perimeter lower than 72 mm or area lower than 400 mm^2) treated with currently available self-expandable valves (n=859; Evolut R-EvR=397; Evolut PRO-EvPRO=84; ACURATE neo-NEO=201; Portico-POR=177) at 9 European centres between June 2011 and October 2018. In the present sub-analysis, we performed multivariable backward logistic regression analyses to assess the presence and the impact of predictors of high post-procedural mean gradient, severe PPM, and moderate to severe para-valvular leak (PVL). The multivariable analysis identified annular perimeter (OR -0.21, 95% CI: -0.38- -0.03, p=0.023), preprocedural mean gradient (OR 0.08, 95% CI: 0.04-0.13, p<0.001), and severe left ventricular outflow tract calcification (OR 2.52, 95% CI: 0.43-4.61, p=0.019) as independent predictors of high post-procedural mean gradient. Severe annular calcification was the only independent predictors of severe PPM (OR 0.27, 95% CI: 0.01-0.53, p=0.049). Severe LVOT calcification (OR 0.45, 95% CI: 0.23-0.67, p<0.001), preprocedural left ventricular ejection fraction (OR -0.01, 95% CI: -0.02- -0.01, p=0.015), and severe annular calcification (OR ---0.27, 95% CI: -0.44- -0.09, p=0.004) were identified as independent predictors of moderate to severe PVL.

Conclusions: This study suggests that in patients with aortic stenosis and small aortic annulus treated with transcatheter SEV implantation haemodynamic performances are influenced by several anatomical and echocardiographic features. Identification of these predictors could lead to a further optimisation of transcatheter treatment of patients with aortic stenosis and small aortic annulus.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Tricuspid regurgitation: current outcomes and initial experience with bicaval systems

AMAT-SANTOS Ignacio J. [(1)], APARISI Álvaro [(1)], SANTOS-MARTINEZ Sandra [(1)], RODRIGUEZ-GABELLA Tania [(1)], SERRADOR Ana [(1)], REDONDO Alfredo [(1)], ARNOLD Roman [(1)], DELGADO ARANA Jose Raul [(1)], CARRASCO-MORALEJA Manuel [(1)], BALADRON Carlos [(1)], PASTOR Gemma [(1)], SAN ROMÁN Alberto [(1)], AMAT-SANTOS Ignacio J. [(1)]

(1) University Clinical Hospital of Valladolid, Valladolid, Spain

Aims: Moderate-to-severe tricuspid regurgitation (TR) has been associated with a greater mortality in comparison to mild insufficiency. On the other hand, roughly less than 18% of severe-TR are referred to tricuspid valve surgery. In the current era, technology has brought us the opportunity to treat those deemed to be at high risk for surgical valve replacement with the development of different tricuspid transcatheter valve interventions (TTVI). We aimed to appraise the current situation and management of TR in our centre

Methods and results: Moderate to severe TR was screened in all patients who underwent transthoracic echocardiography in our institution in the first semester of 2018 in order to determine its incidence. Patients were classified according to the aetiology of TR and followed up for 1 year to determine the management and outcomes of the disease. Results: a total of 97 patients (2.7%) presented TR ≥2+ across 3620 consecutive patients assessed in the echocardiography unit. Of these, TR was severe in 41.7%, massive in 17.7%, and torrential in 2.1%. Mean age was 75.9±11.2 years, 65% were women and the most common aetiology was secondary TR. The echocardiography determined a mean size of the tricuspid annulus (4-chamber view) of 48.29± 9.24-mm, with an estimated tricuspid annular plane systolic excursion (TAPSE) of 16.9±4.2 mm. Mean systolic pulmonary artery pressure was 53.6±14 mmHg and mean left ventricular ejection fraction was 54.2±13.3%. The mean follow-up time was 323.9±101.4 days with 37.1% of the patients requiring hospital admissions mainly due to heart failure (58.3%). A total of 13 patients (13.5%) died. Of those with recurrent HF decompensation, three patients underwent surgical treatment with one in-hospital death, two patients underwent bicaval valve implantation (CAVI) as compassionate therapy after approval by competent authorities, including Tricento® (NVT) and TricValve® (Products & Features) systems. One more patient underwent MitraClip implantation in tricuspid position. The first case was a 58-year woman with history of mitral mechanical prosthesis (Carbomedics n.25 valve) implanted 11 years before and functional severe TR in New York Heart Association (NYHA) class III-IV and multiple hospital admissions. She had right ventricular dilation with a preserved function. Percutaneous Tricento was performed and the patient was discharged 24-hour after a successful procedure. At 30-days the patient presented NYHA class I, improvement of 6-minute walk test from 408 to 475 m, and reduction of TR to moderate degree. The second case was a 74-year woman with surgical mitral (Carbomedics n.25) and aortic (ATS n.18) valve replacement 8 months before. At that time, TR was moderate but after surgery severe TR was developed leading to several re-admissions. Hence, compassionate CAVI with TricValve was decided. The patient underwent a successful procedure and was discharged 3 days later. At 30-day the patient improved its functional status to NYHA class II, 6-minute walk test improved from 158 to 239 m, and TR persisted as severe but there was a reduction of pulmonary hypertension from 68 to 49 mmHg.

Conclusions: TR is associated with a midterm high mortality rate both with medical and surgical treatments. Potential prognostic benefit of bicaval transcatheter prosthesis for the treatment of TR requires longer term studies, but systematic analysis suggest safe and effective procedural and short-term outcomes.

TAVI - Echocardiography

Impact of mitral stenosis in TAVI recipients: clinical and echocardiographic perspective

SANTOS-MARTINEZ Sandra [1], HINOJOSA Williams [1], SANTOS-MARTINEZ Sandra [1], MUÑOZ-GARCIA Erika [2], AVANZAS Pablo [3], RIVERO Fernando [4], REDONDO Alfredo [1], GARCIA-GOMEZ Mario [1], SERRADOR Ana [1], GUTIERREZ Hipólito [1], CAMPO Alberto [1], GOMEZ Itziar [1], RODRIGUEZ-GABELLA Tania [1], SAN ROMAN Jose A [1], AMAT-SANTOS Ignacio J. [1]

(1) University Clinical Hospital of Valladolid, Valladolid, Spain; (2) Hospital Universitario Virgen de la Victoria, Málaga, Spain; (3) HUCA, Oviedo, Spain; (4) Hospital de La Princesa, Madrid, Spain

Aims: Rheumatic mitral stenosis (MS) often precede in time to aortic stenosis (AS) whereas degenerative MS can occur simultaneously due to common pathways. We aimed to analyse the impact of these baseline conditions on outcomes following transcatheter aortic valve implantation (TAVI).

Methods and results: Between January 2008 and January 2018,1,391 consecutive patients with diagnosis of severe AS underwent TAVI in 4 institutions. Comparison according to the need for prior mitral commissurotomy (PMC) and to the degree/aetiology of MS at the time of TAVI, was performed. Central echocardiographic assessment was performed. Results: mean age was 80.1±7 years, 53.2% were women, and Log EuroSCORE was 16.4±12%. Thirty-seven patients (2.6%) had undergone PMC a median of 9.3 (IQR:3.1-13.3) years before TAVI. This subgroup developed more vascular complications and worse NYHA class but with similar mortality. Additionally, 75 patients (5.4%) presented concomitant MS when TAVI was performed, being moderate-severe in 1.8%. Three patients developed severe MS immediately after TAVI due to low implantation and one was successfully treated with a SAPIEN 3 valve in a mitral annular calcification. Patients with moderate-severe MS developed a significant increase of mean transmitral gradient and pressure half-time after TAVI (+1.4±0.4 mmHg and +11.1±2.4 ms, respectively, $p<0.001$). Although degenerative MS was more frequent (60%), most moderate-severe MS cases were of rheumatic aetiology (53.3 vs 22.2%, $p=0.006$). MS severity or aetiology were not associated with the 3-year mortality rate.

Conclusions: TAVI was associated with a significant increase in MS severity in patients with baseline moderate-severe MS but neither this, nor the MS severity or aetiology were associated with an increase in the mortality rate at 3-year follow-up. Balloon-expandable valves in the mitral position could be an alternative for progressive MS after TAVI thanks to anchoring between the mitral ring and the TAVI stent frame.

TAVI - Adjunctive pharmacotherapy

TAVR for residual lesion after "healed" infective endocarditis of the aortic valve – feasibility and safety multicentre study

SANTOS-MARTINEZ Sandra [1], SANTOS-MARTINEZ Sandra [1], ALKHODAIR Abdullah [2], NOMBELA-FRANCO Luis [3], SAIA Francesco [4], MUÑOZ-GARCIA Antonio J. [5], GUTIERREZ Enrique [6], REGUEIRO Ander [7], JIMENEZ-DIAZ Victor A. [8], RIVERO Fernando [9], SATHANANTHAN Janarthanan [2], CARRASCO-MORALEJA Manuel [1], WEBB John [2], SAN ROMAN Jose A [1], AMAT-SANTOS Ignacio J. [1]

(1) University Clinical Hospital of Valladolid, Valladolid, Spain; (2) St. Paul's Hospital, BC, Canada; (3) Hospital Clínico San Carlos, Madrid, Spain; (4) S. Orsola Hospital, bologna University, Bologna, Italy, Bologna, Spain; (5) Hospital Universitario Virgen de la Victoria, Málaga, Spain; (6) Gregorio Marañón Hospital, Madrid, Spain; (7) Hospital Clínic i Provincial de Barcelona, Barcelona, Spain; (8) Álvaro Cunqueiro Hospital, Vigo, Spain; (9) Hospital de La Princesa, Madrid, Spain

Aims: Patients with aortic valve (AV) infective endocarditis (IE) presenting valve dysfunction despite successful antibiotic treatment are often rejected for cardiac surgery due to high operative risk. The use of transcatheter aortic valve replacement (TAVR) following IE currently is not recommended. We aimed to evaluate the safety and mid-term efficacy of TAVR for the treatment of residual AV lesion following IE.

Methods and results: Multicentre retrospective study across 10 centres, gathering all baseline, in-hospital, and 1-year follow up characteristics of patient with healed AV-IE treated with TAVR. Matched comparison according to age, gender, euroSCORE, chronic kidney disease, left ventricular ejection fraction, prosthesis type, and valve-in-valve procedure was performed with a cohort of patients free of prior IE treated with TAVR (46 pairs). From a total of 2,897 patients treated with TAVR, 54 (1.8%) presented prior AV-IE with residual valvular lesion and healed infection. They had higher rate of multivalvular disease and greater surgical risk scores. Also, they harboured more often a valvular prosthesis (50 vs 7.5%, p<0.001). The in-hospital and 1-year mortality rates were 5.7% and 13.7%, respectively, and were comparable to the control cohort. The 1-year III-IV aortic regurgitation rate was 25.9 % (vs 11.1% in the matched cohort, p=0.289). Only one case presented IE recurrence (1.8%) but 18% complicated with sepsis at 1-year follow-up and 43% were re-admitted due to heart failure.

Conclusions: TAVR is a safe alternative for the treatment of AV residual damage after successfully healed AV-IE. The risk of IE recurrence was low and mortality rate did not differ from global TAVR candidates, but >50% presented complications requiring re-admission in the follow up.

TAVI - Echocardiography

Self-expandable transcatheter heart valves for the treatment of aortic stenosis: clinical outcomes and haemodynamic matched comparison

AMAT-SANTOS Ignacio J. [1], VERA-VERA Silvio [1], NOMBELA-FRANCO Luis [2], SANTOS-MARTÍNEZ Sandra [1], MORENO Raúl [3], JIMENEZ-DIAZ Victor A. [4], RODRÍGUEZ-GABELLA Tania [1], CASTRO-MEJIAS Alex [2], BAZ Jose Antonio [4], GALEOTE Guillermo [3], GÓMEZ Itziar [1], SAN ROMÁN Jose A. [1], AMAT-SANTOS Ignacio J. [1]

(1) University Clinical Hospital of Valladolid, Valladolid, Spain; (2) Hospital Clínico San Carlos, Madrid, Spain; (3) University Hospital La Paz, Madrid, Spain; (4) Hospital Álvaro Cunqueiro, Vigo, Spain

Aims: Aortic self-expandable (SE) transcatheter heart valves (THV) are particularly useful for patients with aortic stenosis and small/tortuous vessels, small annuli, or low coronary ostia. However, the growing range of SE devices raises the question of whether the haemodynamic and clinical outcomes are comparable amongst them. We aimed to analyse their haemodynamic behavior and describe the clinical outcomes.

Methods and results: All patients treated with the 4 different SE THVs available in our setting in 4 institutions were gathered. Baseline and follow-up clinical data were collected and echocardiographic tests were blindly centrally analysed. Patients were compared according to valve type and a 1:1 matched comparison was performed according to degree of calcification, aortic annulus dimensions, left ventricular ejection fraction, and body surface area. A total of 514 patients were included (Evolut R/Pro: 217, ACURATE neo: 107, ALLEGRA: 102, Portico: 88). Surgical risk scores and the degree of valve calcification were comparable in the unmatched population. No differences were observed regarding post-THV regurgitation rate of any degree. In particular, the rate of moderate or severe aortic regurgitation for each pair were: Evolut vs ACURATE (1.4 vs 1.4%, p=0.999); Evolut vs Portico (1.8 vs 1.8%, p=0.999); Evolut vs ALLEGRA (3.1 vs 6.3%, p=0.687); ACURATE vs Portico (1.4 vs 2.8%, p=0.999); ACURATE vs ALLEGRA (1.4 vs 5.4%, p=0.999); and Portico vs ALLEGRA (5.4 vs 3.6%, p=0.999). The only pair presenting differences in mean aortic gradint post-THV was ACURATE vs ALLEGRA (8.5±4 vs 6.7±2.8, p=0.001). Regarding main clinical outcomes, the in-hospital mortality (2.7%) was comparable. ACURATE neo presented lower rate of permanent pacemaker (10.5% vs >20% all others, p≤0.001) that persisted after matching compared to Evolut R/Pro and Portico. Also, the rate of valve embolisation was significantly higher with ALLEGRA (5.8%) than with the others (p<0.001).

Conclusions: A matched comparison of four SE THV did not show differences regarding residual aortic regurgitation but residual mean gradients were lower with ALLEGRA than with ACURATE. However, ALLEGRA device presented the highest rate of valve embolisation. No differences were found in terms of in-hospital mortality. ACURATE neo presented significantly lower need for permanent pacemaker although further analysis according to baseline conduction disturbances is warranted.

TAVI - Tools, devices and techniques

Chimney stenting for coronary occlusion during TAVR: insights from the chimney registry

ROSSEEL Liesbeth [1], MYLOTTE Darren [1], BAGUR Rodrigo [2], SINNING Jan-Malte [3], LATIB Azeem [4], PETRONIO Anna Sonia [5], TCHÉTCHÉ Didier [6], DIGNE Franck [7], MAKKAR Raj [8], DVIR Danny [9], LEFEVRE Thierry [10], MERCANTI Federico [1], NEYLON Antoinette [1,10], NICKENIG Georg [3], GRUBE Eberhard [3], HILDICK-SMITH David [11], TAVANO Davide [12], WOLF Alexander [13], COLONNA Giuseppe [14], MITOMO Satoru [12], ANGELILLIS Marco [5], DE BIASE Chiara [6], ADAMO Marianna [15], NEJJARI Mohammed [7], SCHÄFER Ulrich [16], AMABILE Nicolas [17], ACHKOUTY Guy [17], YOON Sung-Han [8], FINKELSTEIN Ariel [18], JONES Tara [9], CHEVALIER Bernard [10], PIAZZA Nicolo [19]

(1) University Hospital Galway, Galway, Ireland; (2) London Health Sciences Centre, ON, Canada; (3) Heart Center Bonn, Department of Medicine II, University Hospital Bonn, Bonn, Germany; (4) Unit of Cardiovascular Interventions, IRCSS San Raffaele Scientific Institute, Milan, Italy; (5) Cardiothoracic and Vascular Department, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy; (6) Clinic Pasteur, Toulouse, France; (7) Haemodynamic Department, Centre Cardiologique du Nord, Saint Denis, France; (8) Smidth Heart Institue, Cedars-Sinai Medical Center, Los Angeles, USA; (9) Division of Cardiology, Department of Medicine, University of Washington Medical Centre, Seattle, USA; (10) Institut Cardiovasculaire de Paris, Massy, Paris, France; (11) Sussex Cardiac Centre, Brighton and Sussex University Hospitals NHS Trust, Brighton, United Kingdom; (12) IRCCS MultiMedica, Metropolitan City of Milan, Italy; (13) Department of Interventional Cardiology, Elisabeth Hospital Essen, Essen, Germany; (14) Cardiology, Vito Fazzi Hospital, Lecce, Italy; (15) Cardiac Catheterization Laboratory, Cardiothoracic Department, Spedali Civili of Brescia, Brescia, Italy; (16) Department of General and Interventional Cardiology, University Hospital Hamburg-Eppendorf, Hamburg, Germany; (17) Department of Cardiology, Institut Mutualiste Montsouris, Paris, France; (18) Tel Aviv Medical Center and Tel Aviv University, Tel Aviv, Israel; (19) McGill University Health Centre, QC, Canada

Aims: Coronary artery occlusion (CAO) during transcatheter aortic valve replacement (TAVR) is a rare but devastating complication. The aim of this study is to determine the safety and efficacy of chimney stenting, a bail-out technique for the treatment of established CAO or prevention of obstruction in impending CAO.

Methods and results: In the International Chimney Registry, patient and procedural characteristics and data on outcome are retrospectively collected of patients that underwent chimney stenting during TAVR. Sixteen centres have contributed 60 cases among 12,800 TAVR procedures (0.5%). Chimney stenting was performed for two reasons: (1) due to a new complete and established (e)CAO (N=25, 41.6%), or (2) when CAO was partial with an impending (i)CAO (N=35, 58.3%). The majority of cases (86.6%) had one or more risk factor for CAO. More than two thirds (N=42, 70.0%) of this cohort had a VIV procedure for a failed surgical bioprosthesis. Upfront coronary artery protection was performed in 44 cases (73.3%), more commonly in iCAO cases (91.4% vs 48.0%, p<0.01). Total procedural mortality occurred in 3 patients (5.0%). Myocardial infarction, cardiogenic shock and resuscitation all occurred more frequently in eCAO as compared to iCAO (52.0 vs 0.0%, p<0.01; 52.0 vs 2.9%, p< 0.01; 44.0 vs 2.9 %, p<0.01, respectively). The absence of upfront coronary protection was the sole independent risk factor for the combined endpoint of death, cardiogenic shock, or myocardial infarction at multivariate analysis. During a median follow-up time of 612 days (IQR: 405 to 842), two cases of stent failure were reported (1 in-stent restenosis, 1 possible late stent thrombosis) after 157 and 374 days.

Conclusions: Chimney stenting is an infrequently used technique during TAVR and appears to be an acceptable bail-out technique for CAO. Clinical event rates appear to be higher among those with eCAO and among those without upfront coronary artery protection. This study represents the first report on patients undergoing chimney stenting during TAVR. However, questions regarding optimal antithrombotic regimen, frequency and impact of late chimney stent failure and the obstacle for future coronary re-access remain open for which extended study of a larger population with systematic follow-up is required.

TAVI - Vascular access and bleeding

The efficacy of direct visualisation of MANTA using ultrasound-navigated technique following large-bore arteriotomy

MORIYAMA Noriaki [(1)], MORIYAMA Noriaki [(1)], LAINE Mika [(1)]

(1) Helsinki University Central Hospital, Helsinki, Finland

Aims: Previously, the efficacy of ultrasound-navigated MANTA deployment (US-MANTA) technique was reported following transfemoral transcatheter aortic valve replacement (TF-TAVR) in comparison to conventional use of MANTA without ultrasound. The aim of this study is to assess the relationship between visibility with US-MANTA technique and the incidence of MANTA closure failure leading to vascular complication.

Methods and results: Consecutive patients who underwent TF-TAVR with US-MANTA technique from November 2018 to October 2019 were evaluated. MANTA deployment failure was defined as access site complications related to the MANTA device leading to major or minor vascular complication based on Valve Academic Research Consortium-2. In 280 patients, 249 patients (88.9%) with successful visualisation and 31 patients (11.1%) with failed visualisation were identified. With increased case experience, significantly increased success rate of visualisation was observed (first 70 cases: 81.4%, and last 70 cases: 95.7%, $p<0.05$). MANTA failure was significantly less frequent in patients with successful visualisation in comparison to those with failed visualisation (2.0% vs 16.1%, $p<0.001$, and major vascular complication: 1.2% vs 9.7% and minor vascular complication: 0.8% vs 6.5%, respectively). Successful visualisation (OR: 0.09, 95% CI: 0.02 to 0.43) was identified as an independent predictor of significantly less frequent MANTA failure by multivariate analysis.

Conclusions: US-MANTA technique displayslearning curveeffect with achieving appropriate visibility. In an unselected population, successful direct visualisation of MANTA is associated with more secure haemostasis following TF-TAVR requiring a large-bore arteriotomy as compared to implanting with failed visual control.

Mitral valve replacement and repair - Tools, devices and techniques

Relative survival and excess mortality after percutaneous mitral valve repair. An insight from the Mitra Swiss registry

BIASCO Luigi [1,2], BIASCO Luigi [1,2], KLERSY Catherine [3], GAEMPERLI Oliver [4], JEGER Raban [6], FRANCESCO Maisano [7], PRAZ Fabien [14], TARAMASSO Maurizio [7], WINDECKER Stephan [14], PEDRAZZINI Giovanni [8]

(1) Università della Svizzera italiana, Lugano, Switzerland; (2) Azienda Sanitaria Locale Torino 4, Cirie, Italy; (3) Fondazione I.R.C.C.S. Policlinico San Matteo, Province of Pavia, Italy; (4) Klinik Hirslanden, Zürich, Switzerland; (5) Federal Statistical Office of Switzerland, Neuchatel, Switzerland; (6) University Hospital of Basel, Basel, Switzerland; (7) University Hospital of Zürich, Zürich, Switzerland; (8) Fondazione Cardiocentro Ticino, Lugano, Switzerland; (9) Lausanne University Hospital, Lausanne, Switzerland; (10) Klinik Im Park, Zürich, Switzerland; (11) Hôpitaux Universitaires de Genève (HUG), Geneva, Switzerland; (12) University hospital, Bern, Switzerland; (13) Kantonsspital luzern, Luzern, Switzerland; (14) University of Bern, Bern, Switzerland

Aims: To provide a long term cause-specific survival analysis in a national cohort of patients with functional mitral regurgitation (FMR) treated with edge-to-edge percutaneous mitral valve repair (PMVR) while adjusting for underlying expected mortality risk as estimated by the national Swiss mortality data. Clinical correlates associated with excess mortality are also identified.

Methods and results: All FMR patients enrolled between 2011 and 2017 in the Mitra Swiss registry (479 pts) with a mean age of 74.7±9.42 years were evaluated. Relative survival (RS) was computed and plotted up to 5 years after implant using the Swiss mortality tables, stratified by age, sex and calendar period. A Poisson regression was used to model EM as a function of age, sex, pre-implant RV/RA gradient, calendar period, ischaemic vs non-ischaemic aetiology and acute procedural success. In order to provide a cause-specific survival analysis, we evaluated outcomes of patients with FMR enrolled in the national Mitra Swiss registry by applying a relative survival approach. This statistical method relates observed survival in a cohort of interest to an age and sex matched group derived from the general population. This estimates net survival probability of the patients, i.e. the survival if CHF and the associated FMR were the only causes of death. Excess mortality, defined as mortality after correcting for deaths estimated from the background population, can also be calculated. After PMVR an excess mortality of +13% (95% CI,17%-9%), +21% (95% CI,27%-16%), +33%(95% CI,41%-36%), +37%(95% CI,46%-38%) and +38%(95% CI,50-37%) at each time point without differences over the entire follow up (p=0.481). Age group, sex, RV/RA gradient calendar period, ischaemic vs non ischaemic were not associated with excess mortality while a clear association was recognised with acute procedural success (p=0.011).

Conclusions: In FMR patients treated with MC EM was observed up to 3 years with a plateau thereafter. Acute procedural success is the only determinant of EM with a 65% lower EM as compared to procedural failures. Failure to account for non-cardiovascular death may underestimate PMVR efficacy.

TAVI - Vascular access and bleeding

Safety and efficacy of protamine administration for the prevention of bleeding complications in patients undergoing TAVI

AL-KASSOU Baravan [1], AL-KASSOU Baravan [1], KANDT Julian [1], LOHDE Luisa [1], SHAMEKHI Jasmin [1], SEDAGHAT Alexander [1], TABATA Noriaki [1], WEBER Marcel [1], SUGIURA Atsushi [1], FIMMERS Rolf [1], WERNER Nikos [1], GRUBE Eberhard [1], TREEDE Hendrik [1], NICKENIG Georg [1], SINNING Jan-Malte [1]

(1) UKB Universitätsklinikum Bonn, Bonn, Germany

Aims: Bleeding and vascular complications are the most frequent procedure-related complications following TAVI. Several studies have shown increased mortality rates in patients with major bleedings. In patients undergoing cardiac surgery, protamine administration for heparin reversal has become standard care, as it has shown to reduce the risk of bleedings. Data regarding the efficacy and safety of protamine administration in TAVI patients is scarce. The aim of this study was to evaluate whether protamine administration after TAVI reduces bleeding rates, and whether this might affect the outcome.

Methods and results: Our study cohort included 873 consecutive patients undergoing TAVI with next-generation transcatheter heart valves, of whom 677 (77.5%) received protamine for heparin reversal. Standard access management included vessel preclosure with one Prostar or two ProGlide devices, manual compression, and if necessary, percutaneous transluminal angioplasty (PTA) or implantation of a covered nitinol stent-graft. The indication for protamine administration was left to the discretion of the operator. The primary endpoint of the study was a composite of 30-day all-cause mortality, life-threatening as well as major bleeding. Key secondary end points included one-year all-cause mortality and VARC-2 defined stroke and myocardial infarction at 30 days. The mean age of our study population was 81 (±6.1) years; 50.2% were of female gender. The primary endpoint of the study occurred less frequently in the protamine administration group (3.2%) as compared with the control group (8.7%, p=0.03). This result was mainly driven by lower rates of life-threatening and major bleeding in the protamine group (0.1% vs 2.6%, p=0.003; 1.0% vs 4.1%, p=0.008, respectively). Accordingly, a red blood cell transfusion was needed more frequently in the control cohort than in the protamine group (11.7% vs 7.2%, p=0.05). Furthermore, protamine administration resulted in a significantly shorter hospital stay (11.1±5.8 vs 12.7±7.8 days, p=0.05). In the overall cohort, VARC-2–defined stroke was observed in 1.9% and myocardial infarction in 0.2% of patients, with no significant difference between the groups (p=0.08, p=1.0, respectively). In multivariate analysis, only protamine administration (OR: 0.24 [95% CI: 0.10-0.58], p=0.001) and acute kidney injury (OR: 5.82 [95% CI: 2.02-16.77], p=0.001) were independently associated with the primary end point.

Conclusions: Protamine administration resulted in significantly lower rates of life-threatening and major bleeding complications as compared to patients without heparin reversal. Patients with protamine administration had significantly shorter hospital stays (delta 1.6 days). Occurrence of stroke and myocardial infarction was not increased by protamine administration.

TAVI - Tools, devices and techniques

Fluid-structure interaction analysis of TAVR thrombosis formation with 29mm Edwards SAPIEN 3

TSENG Elaine [1,2], WANG Zhongjie [1,2], XUAN Yue [1,2], DVIR Danny [3], YE Jian [4], GUCCIONE Julius [1,2], GE Liang [1,2], TSENG Elaine [1,2]

(1) UCSF Medical Center, CA, USA; (2) San Francisco VA Medical Center, CA, USA; (3) University of Washington, WA, USA; (4) St. Paul's Hospital, BC, Canada

Aims: Transcatheter aortic valve replacement (TAVR) devices are equally effective in treating intermediate-, high-, and prohibitive-risk patients with severe symptomatic aortic stenosis. Subclinical leaflet thrombosis (SLT) occurred frequently in TAVR bioprosthetic aortic valves which is associated with increased rates of TIAs and strokes or TIAs. However, the factors affecting the post-TAVR thrombosis are not fully understood. A better understanding of SLT might offer a potential opportunity for further improvement in valve haemodynamics and clinical outcomes.

Methods and results: The commercial 29 mm Edwards SAPIEN 3 valve (Edwards Lifesciences, Inc, Irvine, Calif) underwent high-resolution micro-computed tomography scanning to develop a precise 3-dimensional geometric mesh of the stent and valve. Leaflet material properties were obtained from surgical bioprostheses, and stent material properties were based on cobalt-chromium. Patients' pre-TAVR CT angiography (CTA) images were contoured with MeVisLab and imported into LS-DYNA. The stent was first crimped and deployed into patient's ascending aorta and validated by post-TAVR CT images. Using fluid-structure interaction simulation, the blood residence time (BRT) was examined over the entire cardiac cycle using LS-DYNA software. Patient-specific FSI simulations were conducted on both the patient with and without SLT. In each patient-specific model, regions of flow stagnation with long BRT was observed in the distal side of the TAV leaflets. BRT and leaflet wall stress were different between the SLT and non-SLT TAVR patients.

Conclusions: Our study demonstrated that flow stagnation could contribute to TAVR SLT formation. The FSI models developed based on TAVR CT images may potentially be used in the future for prediction of SLT.

Mitral valve replacement and repair - Tools, devices and techniques

TMVR of functional mitral regurgitation – an updated meta-analysis

NOUTSIAS Michel [1], NOUTSIAS Michel [1], NOUTSIAS Michel [1], MATIAKIS Marios [1], SEDDING Daniel [1], RIGOPOULOS Angelos [1]

(1) Mid-German Heart Center, Department of Internal Medicine III (KIM III), Division of Cardiology, Angiology and Intensive Medical Care, University Hospital Halle, Martin-Luther-University Halle-Wittenberg, Halle (Saale), Germany

Aims: Moderate-to-severe or severe functional mitral regurgitation (FMR) is associated with higher rates of hospitalisation and increased mortality in heart failure (HF). Transcatheter mitral valve repair by MitraClip® implantation (TMVrMC) may effectively reduce severe MR, and is associated with symptomatic improvement. However, the long-term clinical effects of this procedure are not well defined. Here, we analysed outcomes for rehospitalisation and survival in HF patients with moderate-to-severe or severe FMR treated by either medical treatment (MT) only versus TMVrMC+MT by meta-analysis.

Methods and results: By systematic search of bibliographic databases, we evaluated publications comparing HF patients with FMR treated by MT only versus treatment by MT combined with TMVrMC. Studies with a minimum of 25 enrolled patients and a follow-up period of at least 12 months were deemed eligible for this meta-analysis. We identified n=7 studies enrolling 2,884 HFrEF patients, divided into two study arms: TMVrMC+MT (n=1,618), versus FMR patients receiving MT only (n=1,266). At 12 months, there was a significant reduction in all-cause mortality favouring TMVrMC+MT (OR: 0.65; CI 95% 0.53-0.79), compared with the MT only patients. At 24 months, a significant reduction of all-cause mortality in the TMVrMC+MT patient group (OR: 0.54; CI: 95%: 0.43-0.67; p<0.001) was calculated. TMVrMC+MT was associated with significantly lower rates of unplanned re-admissions for heart failure compared with MT only at 12 months (OR: 0.69; 95%; CI 0.53-0.89; p<0.001) and at 24 months (OR: 0.53; 95% CI: 0.39-0.71; p<0.001). In one publication, a survival benefit of TMVrMC+MT over MT alone was shown at 5 years post intervention (HR: 0.75; 95% CI: 0.69–0.94; p=0.012) after weighting for propensity score and controlling for age.

Conclusions: This meta-analysis on n=2,884 patients with moderate-to-severe or severe FMR reveals that TMVrMC+MT, as compared with MT alone, is associated with a significant reduction in rehospitalisation and improvement of survival up to 24 months after MitraClip implantation. However, the discordant results of 2 randomised controlled trials (MITRA-FR and COAPT) warrant further clarification, i.e. of the eligible FMR patient profiles who might benefit from TMVrMC+MT in terms of improvement of prognosis. These data imply additional evidence for TMVrMC in eligible HF patients with relevant FMR, which might be important for an update of the corresponding guidelines.

TAVI - CT / MRI imaging

Use of post-/preprocedural aortic regurgitation ratio versus preprocedural aortic valve calcium score to predict moderate-to-severe paravalvular leak requiring corrective measures after TAVR

MAS-PEIRO Silvia [(1)], MAS-PEIRO Silvia [(1)], UEBELACKER Roman [(1)], SEPPELT Philipp C [(1)], DE ROSA Roberta [(1)], MURRAY Marie-Isabel [(1)], ZEIHER Andreas M [(1)], VASA-NICOTERA Mariuca [(1)]

(1) University Hospital Frankfurt, Frankfurt, Germany

Aims: In patients undergoing transcatheter aortic valve replacement (TAVR), more-than-mild paravalvular leak (PVL) is associated to poor outcomes and may require corrective interventions. There is a crucial need to identify parameters allowing to predict such PVLs. We aimed at confirming the predictive value of post-/pre procedural aortic regurgitation ratio, and to compare its value with the use of an aortic valve calcium (AVC) score based on an individualised threshold.

Methods and results: Patients undergoing TAVR from March 2016 to June 2018 with available data on AVC derived from high-quality computed tomography (CT) and ARI ratio estimation based on peri-interventional haemodynamics were included. Corrective interventions were performed peri-interventionally based on PVL as assessed by angiography, and in three cases in which the valve did not fully expand. As per our previous work, an ARI ratio threshold <0.6 was used. 3mensio Structural Heart (Pie Medical Imaging) was used for calcification measures. AVC was measured from the aortic annulus plane to the leaflet tips. AVC score was based on the choice of an "individualised" threshold offered by the software, since it showed a better correlation than various fixed thresholds with visually-assessed categories: none, low, medium, or severe calcification. Complete CT, angiographic and haemodynamic data were available for 151 patients. Mean(±SD) age was 82±5.7, and 41.7% of patients were female. Mean perimeter-derived annulus was 25.3±3.2 mm. Fifty patients underwent a corrective intervention with post-dilation, and snaring was used in two patients. ARI ratio median was 0.78 (0.2-2.3). As expected, ARI ratios were significantly lower in patients who underwent post-dilation or snaring: 0.61 (0.2-2.2) vs 0.83 (0.2-2.3) ($p<0.0001$, Mann-Whitney test). ARI ratio was a predictor for PVL requiring corrective interventions after TAVR ($p=0.001$, logistic regression). AVC results were: none (n=4), low (n=36), medium (n=63), and severe (n=48). Median (min,max) AVC score was 401.3 (0-1896.5) mm^3. Median AVC in leaflets was: left coronary cusp 101 (0-725.2) mm^3, right coronary cusp 86.7 (0-629.4) mm^3, and non-coronary cusp 163.1 (0-892.8) mm^3. Median for LVOT was 6.7 (0-289.7) mm^3. AVC score was significantly higher in patients with PVL requiring corrective interventions: 529.3 (80.7-1896.5) mm^3 vs 351.3 (0-1637.5) mm^3 ($p<0.05$, Mann-Whitney test). In a logistic regression, AVC score showed a numerical trend; statistical significance was borderline ($p=0.051$). ARI ratio decreased with increasing AVC categories: none 1.11 (0.7-2.3), low 0.81 (0.2-1.5), medium 0.78 (0.4-1.8), and severe 0.71 (0.2-2.2). Using an ARI threshold of 0.6, AVC score was higher in patients below such threshold: 414.6 (74.0-1482.6) mm^3 vs 375.0 (0-1896.5) mm^3. However, this difference did not achieve significance.

Conclusions: Our study confirms, in a much larger population, the value of ARI ratio and an ARI ratio threshold of 0.6 to predict PVL requiring corrective measures after TAVR. AVC score was also associated to PVL requiring additional interventions, but a clear-cut predictive value could not be demonstrated. Moreover, only a non-significant numerical trend was observed for an association of ARI ratio with AVC score. Thus, ARI ratio appears to provide interventionists with a powerful predictive tool for PVL occurrence after TAVR, beyond the predictive value of preprocedural valve calcification derived from CT.

Mitral valve replacement and repair - Tools, devices and techniques

Impact of effective regurgitant orifice area on long-term outcome of secondary mitral regurgitation transcatheter repair

KARAM Nicole [1], KARAM Nicole [1], ORBAN Mathias [2], KALBACHER Daniel [3], BUTTER Christian [7], PRAZ Fabien [6], LUBOS Edith [3], BANNEHR Marwin [7], KASSAR Mohammad [6], PETRESCU Aniela [4], ILIADIS Christos [8], UNTERHUBER Matthias [5], THIELE Holger [5], PFISTER Roman [8], WINDECKER Stephan [6], LURZ Philipp [5], VON BARDELEBEN Stephan [4], HAUSSLEITER Joerg [2]

(1) Hospital European Georges Pompidou (Ap-Hp), Paris, France; (2) Großhadern (Klinik), Munich, Germany; (3) UKE, Hamburg, Germany; (4) Mainz University Hospital, Mainz, Germany; (5) Leipzig University, Leipzig, Germany; (6) University-Hospital of Bern, Bern, Switzerland; (7) Heart Center Brandenburg in Bernau/Berlin, Bernau, Germany; (8) University Hospital Cologne, Cologne, Germany

Aims: Conflicting data exists regarding the benefit of edge-to-edge transcatheter mitral valve repair (TMVR) in severe secondary mitral regurgitation (SMR). One of the explanations for the discrepancy is the difference in patients' baseline effective regurgitant orifice (ERO) between the studies. We aimed to assess the impact of ERO on TMVR outcome.

Methods and results: Using data from the EuroSMR (European Registry on Outcomes in Secondary Mitral Regurgitation) registry, we compared the characteristics and outcomes of SMR patients undergoing TMVR, according to their baseline ERO. Overall, 1,062 patients with severe SMR and ERO quantification by proximal isovelocity surface area method underwent TMVR in the participating centres, and were included in the study. Median age of the patients was 76.0 (IQR: 69.0 – 80.1) years, with 387 women (36.5%). Spline curve analysis was performed assessing the relation between ERO and mortality. This analysis revealed a flat curve, without identification of an optimal cut-off for ERO. Accordingly, an ERO < and ≥ 0.3 cm^2 was applied to evaluate the impact of ERO on mortality in this study. ERO was < 0.3 cm^2 in 575 patients (54.1%), and ≥ 0.3 cm^2 in 487 patients (45.9%). Overall, there was no difference between the two groups except for a lower proportion of men in the lower ERO group (60.7% vs 66.7%, for ERO < vs ≥0.3cm^2, respectively, p=0.050), and a more frequent ischaemic aetiology (54.9% vs 47.9%, p=0.031). Patients in the lower ERO group were more symptomatic with a higher proportion of patients having a NYHA class of III or IV at baseline (91.4% vs 86.9%, p=0.004. Their vena contracta diameters were smaller (6.5mm vs 7.0 mm, p<0.018). Notably, there was no difference in LVEF between the two groups (median LVEF 34.0 vs 33.2%, p=0.415). Post-procedural MR reduction of at least one grade was observed in 95.8% of patients (96.4% vs 94.6%, for ERO < vs ≥0.3cm^2, respectively, p=0.530). There was no difference in all-cause mortality at two-year follow-up according to baseline ERO (28.3% vs 30.0% for ERO < vs ≥0.3cm^2, p=0.585). Both patient groups demonstrated a significant improvement of at least one NYHA class (61.7% and 73.8%, p=0.002), resulting in a prevalence of NYHA class ≤II at 1-year follow-up of 60.0% and 67.4% for ERO < vs ≥0.3cm^2, respectively (p=0.05).

Conclusions: All-cause mortality at 2-years follow-up after TMVR does not differ if baseline ERO is < or ≥ 0.3cm^2, and both groups exhibit relevant clinical improvements. Accordingly, TMVR should not be withheld from patients with ERO <0.3cm^2 who remain symptomatic despite optimal medical treatment, if TMVR appropriateness was determined by an experienced team in dedicated heart valve centres.

TAVI - Vascular access and bleeding

Body mass index predicts biomechanical vascular closure device-related vascular complications after transfemoral transcatheter valve implantation

LUX Arpad [1,2], LUX Arpad [1,2], AKTAS Pinar [2], VEENSTRA Leo [1], KATS Suzanne [1], RASOUL Saman [3], HOF VAN 'T Arnoud [1,2,3], MAESEN Bart [1,2]

(1) Maastricht UMC+, Maastricht, the Netherlands; (2) Maastricht University, Maastricht, the Netherlands; (3) Zuyderland Medisch Centrum, Heerlen, the Netherlands

Aims: The prevention of vascular complications after transfemoral transcatheter aortic valve implantation (TF-TAVI) remains a challenging task and can be achieved with careful patient selection and application of state-of-the-art devices and protocols. Preventing these complications will improve patient outcomes, as it will reduce the occurrence of acute life-threatening events, and help to avoid prolonged hospitalisation. This analysis aimed to search for the independent predictors of access site complications after vascular closure with a dedicated biomechanical closure device.

Methods and results: A retrospective single-centre cohort study was performed with 230 aortic valve stenosis patients, who were admitted between 2017 and 2018 and underwent transfemoral percutaneous transcatheter valve implantation. Relevant medical history was collected with the help of the local business intelligence management team and manually from the electronic records. Abdominal aortic and iliofemoral tortuosity (angulation and the relation of true arterial length to the shortest distance between the puncture site and the renal arteries), degree of calcification and minimal vascular lumen diameters were quantified and measured using dedicated imaging software. Vascular complications were documented according to the VARC-2 criteria and diagnosis was based on or taken from available documentation. The study was approved by the local ethical committee. Closure with the biomechanical closure device was deemed completely successful in 164 patients (71.3%). Univariate analysis was performed with the available variables and BMI>30 kg/m^2 (OR 2.341 (p=0.008)), kidney function (OR 1.019 (p=0.015)) and unsuccessful MANTA closure (OR 4.228 (p<0.001)) were identified as potential predictors of post-procedural vascular access site complications. After performing multivariate analysis with the above mentioned variables, a BMI>30 kg/m^2 (OR 2.059 (p=0.037)), eGFR (OR 1.016 (p=0.047)) and unsuccessful access-site closure (OR 4.192 (p<0.001)) were identified as independent predictors of post-procedural access site complications. Surprisingly, the amount of iliofemoral and access-site calcification or arterial tortuosity and the minimal vessel diameter did not influence the occurrence of vascular complications.

Conclusions: In patients who were accepted for transfemoral aortic valve implantation, vascular properties do not influence the occurrence of access site complications. Obesity, however, predicts vascular complications even after seemingly successful vascular closure-device placements.

TAVI - Echocardiography

The impact of post-TAVI paravalvular leak in patients with pre-existing mitral regurgitation

COLLINS Patrick [1], COLLINS Patrick [1], BRENNAN Paul [1], COBURN Jaimie [1], BURNS Laura [1], NZEWI Onyekwelu [1], JOHNSTON Nicola [1], JEGANATHAN Reuben [1], OWENS Colum [1], SPENCE Mark [1], MANOHARAN Ganesh [1]

(1) Royal Victoria Hospital, Belfast, United Kingdom

Aims: Moderate-to-severe paravalvular leak (PVL) post transcatheter aortic valve implantation (TAVI) is associated with poor outcome. The long-term effects of PVL in patients with baseline mitral regurgitation (MR) remain unknown. We aimed to assess the effects PVL on MR grade post TAVI and their impact on outcome in patients undergoing TAVI at our centre between February 2008 and December 2018.

Methods and results: Baseline characteristics were retrospectively analysed using the National Institute for Cardiovascular Outcomes Research (NICOR) database and Northern Ireland Electronic Care Record (NIECR). MR and PVL were assigned grade 0 (none/trace), 1 (mild/mild-moderate), 2 (moderate/moderate-severe) and 3 (severe), respectively, based on availablle transthoracic echocardiogram (TTE) data. Total of 1,033 consecutive patients underwent TAVI (mean age 81.7±6.8 yrs, male 46.5%, mean EuroSCORE 2 8.4±7.9%, NYHA ≥ 2 = 99.2%). Preprocedural MR grade ≥ 1 was observed in 64.4% (n=665), with 27.1% (n=280) having a left ventricular ejection fraction (LVEF) less than 50%. Patients with MR grade ≥ 1 had a significantly higher rate of atrial fibrillation compared to those with grade 0 (36.2% vs 23.1%, p<0.0005), were more symptomatic (≥NYHA2 90.2% vs 84.2%, p 0.004) and more commonly had left ventricular systolic dysfunction (LVEF<50% 33.1% vs 21.4%, p<0.0005). Post-procedural TTE data was available for 98.5% (n=1017) of patients. Grades 0, 1 and 2 PVL were observed in 69.2% (n=704), 28.6% (n=291) and 2.2% (n=22) patients, respectively. Grade 3 PVL was not observed in any predischarge TTE. Post TAVI MR grade assessment showed no change in 47.9% (n=487), improved by at least 1 MR grade in 33.1% (n=337) and worsened in 19% (n=193) of patients. The presence of ≥ grade 1 PVL (n=313) was associated with a significantly higher rate of post-procedural MR deterioration of at least one grade compared to those with grade 0 PVL (27% vs 15%, p<0.0005). 1-year mortality was observed in 10.2% (n=104) of patients with available pre-discharge TTE data. On univariate analysis, post-procedural ≥ grade 1 PVL was associated with increased 1 year mortality (p=0.01). With respect to 1-year mortality, post-procedural ≥ grade 1 MR was not predictive (p=0.09) but ≥ grade 2 MR was (p=0.02). The 1-year mortality was worse in patients with a combination of both ≥ grade 1 PVL and ≥ grade 2 MR (n=45) compared with those with less PVL/MR (20% vs 9.8%; p=0.03). Actuarial 2-year mortality was also higher at 28% compared to 17% for the two respective patient groups but this did not reach statistical significance (p 0.12). Long-term median survival estimates did not differ significantly be-tween the two groups (4.6 years vs 5.3 years, p 0.24), respectively.

Conclusions: PVL after TAVI was associated with worsening of baseline MR grade. The combination of ≥ grade 1 PVL and ≥ grade 2 MR was associated with higher mortality after TAVI.

Mitral valve replacement and repair - Tools, devices and techniques, Tricuspid / Pulmonary valve - Tools, devices and techniques

Transcatheter mitral and tricuspid valve repair improves physical capacity in chronic heart failure assessed by activity tracking devices

DOLDI Philipp [1], DOLDI Philipp [1], STOCKER Thomas [1], HERTELL Helene [1], ORBAN Mathias [1], BRAUN Daniel [1], ROESLER Diana [1], MENNER Stephanie [1], NAEBAUER Michael [1], MASSBERG Steffen [1], HAUSLEITER Joerg [1]

(1) Klinikum Großhadern, Munich, Germany

Aims: Severe mitral regurgitation (MR) and tricupid regurgitation (TR) are independent predictors of increased mortality in chronic heart failure patients. MR and TR contribute to recurrent heart failure-related hospitalisations and have major impact on everyday activities. Especially in elderly patients with high perioperative risk, transcatheter edge-to-edge valve repair has been shown to be an effective approach. However, evaluating the clinical benefit after intervention can be a challenging task. Therefore we used physical activity tracking devices to evaluate real everyday life physical capacity.

Methods and results: We prospectively analysed a cohort of 167 patients (median age 79 years, 49% female, NYHA ≥III 89.9%, median NTproBNP 2,614,pg/ml) suffering from severe MR and/or severe TR undergoing transcatheter mitral valve repair (TMVR), transcatheter tricuspid valve repair (TTVR) or combined transcatheter mitral and tricuspid valve repair (TMTVR). All patients were equipped with activity tracking devices to the wrist for 1-week out-of-hospital activity tracking prior the intervention (baseline, BL) and again for follow-up (FU) assessments (1. FU: median 47 days, 2. FU: median 197 days). We analysed 25,472 hours of activity tracking in all patients. The main outcome was defined as changes in continuous physical activity (CPA), measured in mean steps/day. Secondary outcomes were defined as mean changes in NYHA class, NT-proBNP levels and resting heart rate. Throughout the whole study population, CPA significantly increased by 18.5% between BL and 1.FU (3,575 steps/d to 4,238 steps/d; p=0.005). At second follow-up CPA levels maintained significantly higher than BL with a total increase of 23.6% (3,575 to 4,419 steps/d, p=0.001). Accordingly, there were significant improvements in NYHA Class (3.0 to 2.0, p<0.001) and NT-proBNP levels (5,052 pg/ml to 4,208 pg/ml, p=0.026) between BL and 1. FU. In addition, there was a significant decrease in resting heart rate (61.3 bpm to 59.6 bpm, p=0.037). This improvement of the secondary outcomes was further increased at 2. FU. Analysing all groups of treatment separately, a significant improvement of CPA was measured in all three subgroups between BL and 2. FU. (TTVR: 3,286 steps/d vs 4,157 steps/d, p=0.008; TMVR: 3,922 steps/d vs 4,652 steps/d, p=0.04; TMTVR: 3,461 steps/d vs 4,606 steps/d, p=0.02).

Conclusions: Out-of-hospital activity tracking with analysis of CPA showed not only symptomatic and clinical improvement of patients after transcatheter valve repair, but also suggests a major improvement of mobility and functional status.

TAVI - Tools, devices and techniques

A novel haemodynamic parameter predicts effective outcome during self-expanding TAVI

PYKÄRI Jouni [1], VASANKARI Tuija [1], YLITALO Antti [1], PORELA Pekka [1], PAANA Tuomas [1], MALMBERG Markus [1], JUHO Koskinen [1], TERO Koivisto [1], SAVONTAUS Mikko [1]

(1) University of Turku, Turku, Finland

Aims: Haemodynamic measurements can be used to evaluate paravalvular leak (PVL) during transcatheter aortic valve implantation (TAVI) procedures. We hypothesised that the occurrence of a significant decrease in invasive aortic pressure after annular contact by a self-expanding TAVI device indicates effective annular sealing. This parameter could be used to recognise optimal outcome during implantation.

Methods and results: 38 patients (mean age 81 years) undergoing TAVI procedure with a self-expandable Evolut R or Evolut Pro (Medtronic) valve prosthesis were included in this study. Invasive continuous aortic pressure waveforms were recorded during valve implantation and analysed afterwards. Patients were classified into two groups regarding aortic pressure changes after valve prosthesis achieved annular contact. Decrease in aortic pressure during valve expansion was defined by a decrease of systolic pressure by 20 mmHg or 25% in 10-30 seconds after annular contact. Primary endpoint was the need for valve post-dilatation due to significant PVL as determined by the primary operator. Pressure decrease was seen in 71% (27/38) of patients. Between these two groups, post-dilatation was performed more often in the group which aortic pressure did not decrease during valve implantation, 14.8% (4/27) vs 54.5% (6/11) (p=0.019). Echocardiography was performed preoperatively, immediately after valve implantation, at discharge and at one month. One-month echocardiography demonstrated 21.1% (8/38) more than none/trace PVL (7 mild, 1 moderate), with no statistical difference between the two groups.

Conclusions: During TAVI procedure with a self-expanding device, a decrease in aortic pressure after annular contact is associated with an increased probability of good haemodynamic outcome as demonstrated by a lower risk for valve post-dilatation. This parameter could be used as a marker for optimal valve positioning during the implantation procedure.

TAVI - Tools, devices and techniques

Risk factors for permanent pacemaker implantation in patients receiving a balloon-expandable transcatheter aortic valve prosthesis

DROPPA Michal [1], RUDOLPH Tanja K. [2,3], BAAN Jan [4], NIELSEN Niels-Erik [5], BAUMGARTNER Helmut [6], VENDRIK Jeroen [4], BARANOWSKI Jacek [5], BRAMLAGE Peter [7], THOENES Martin [8], WÖHRLE Jochen [9], GEISLER Tobias [1]

(1) University Hospital Tübingen, Tübingen, Germany; (2) Cologne University, Cologne, Germany; (3) Clinic for General and Interventional Cardiology/Angiology, Heart and Diabetes Center NRW, Bad Oeynhausen, Germany; (4) Academic Medical Centre, Amsterdam, the Netherlands; (5) Linköping University Hospital, Linköping, Sweden; (6) University Hospital Münster, Münster, Germany; (7) IPPMed – Institut für Pharmakologie und Präventive Medizin GmbH, Cloppenburg, Germany; (8) Edwards Lifesciences Nyon, Nyon, Switzerland; (9) University of Ulm, Ulm, Germany

Aims: Permanent pacemaker implantation (PPI) is a widely recognised untoward event associated with TAVI (incidence 5–20%). Smaller registries have identified several variables associated with PPI. The aim of the present analysis was to validate patient- and transcatheter aortic valve implantation (TAVI)-related procedural variables associated with PPI.

Methods and results: A retrospective analysis of patients from six, European centres undergoing transfemoral (TF) TAVI with the Edwards SAPIEN 3 prosthesis. Baseline variables and preprocedural electrocardiogram characteristics and CT-scans were taken into account. Data for 1,745 patients were collected; 191 (10.9%) required PPI after TAVI. Baseline variables pulmonary hypertension (OR 1.64; 95% CI: 1.01–2.59), QRS duration >117 msec (2.58; 1.73–3.84), right bundle branch block (RBBB; 5.14; 3.39–7.72), left anterior hemi block (1.92; 1.19–3.02) and first-degree atrioventricular block (AVB, 1.63; 1.05–2.46) were significantly associated with PPI. RBBB (8.11; 3.19–21.86) and first-degree AVB (2.39; 1.18–4.66) remained significantly associated in a multivariate analysis. Procedure-related variables included access site (TF; OR 1.97; 95% CI: 1.07–4.05), implanted valve size (29 mm; 1.88; 1.35–2.59), mean implantation depth >30% (3.75; 2.01–6.98) and Vmax below the median (1.80; 1.03–3.19). Patients receiving PPI had longer intensive care unit durations and later discharges. Acute kidney injury stage 2/3 was more common in patients with PPI until discharge (15.2 vs 3.1; p=0.007) but was not statistically significant thereafter. Further differences in outcomes at 30 days did not reach significance.

Conclusions: A number of variables were associated with PPI, which will aid pre- and post-procedural patient management and prevent adverse long-term outcomes.

Mitral valve replacement and repair - Tools, devices and techniques

Mitral regurgitation in acute heart failure: under-appreciated, under-treated and under-resourced

VICTOR Kelly [1], VICTOR Kelly [1], STYLIANIDIS Vasileios [1], BANGASH Fatima [2], HANCOCK Jane [1], MONAGHAN Mark [2], BYRNE Jonathan [2], REDWOOD Simon [1], MCDONAGH Theresa [2], CARR-WHITE Gerald [1], PRENDERGAST Bernard [1]

(1) Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom; (2) King's College London, London, United Kingdom

Aims: We hypothesised that a significant number of heart failure (HF) patients have moderate or more mitral regurgitation (MR), remain symptomatic despite optimal medical therapy, and may be candidates for transcatheter mitral valve repair (TMVR). Our objectives were to determine: (1) the proportion of patients presenting with acute HF who have an ejection fraction (EF) of 20-50% and moderate or more MR, (2) the proportion of these who remain symptomatic despite optimal medical therapy and, 3) the proportion of this sub-group who may be candidates for TMVR techniques according to current guidelines.

Methods and results: We interrogated a large database of patients presenting with acute HF to two London-based tertiary centres. All patients underwent detailed echocardiography with MR assessed using an integrative multiparametric approach. Symptomatic progress and clinical outcomes (including mortality) were tracked using a combination of electronic care records, national registry data and UK Office of National Statistics (ONS) mortality data. Potential suitability for transcatheter mitral valve repair was determined by application of the COAPT trial echocardiographic exclusion criteria and adjudication of surgical risk (EuroSCORE II >6% = high-risk). Over a five-year period (Jan 2012 – Dec 2017), 1,884 patients presented with acute HF. Of this cohort, 237 (12.6%) had moderate or more MR and an EF of 20-50%. Mortality amongst patients with moderate or more MR was 29.9% at one year (compared to 26.9% for those with less than moderate MR, p=0.058). Following stabilisation on maximally tolerated optimal medical therapy, 84 patients remained symptomatic with moderate or more MR and an EF 20-50%. Of these, 14 met COAPT echocardiographic exclusion criteria (left ventricular end systolic dimension >70 mm, severe right ventricular systolic dysfunction and pulmonary artery systolic pressures >70 mmHg) and 37 were not considered high surgical risk (EuroSCORE II >6%), suggesting that 33 should be considered for transcatheter repair techniques according to current international guidelines. Extrapolating these data to the population of England (56 million) suggests a provisional requirement of approximately 2,083 transcatheter repair procedures per year for the acute heart failure cohort alone (compared with an overall number of 124 procedures performed in England in 2019).

Conclusions: A substantial proportion of acute HF patients remain symptomatic with moderate or more MR despite optimal medical therapy. Many of these are potential candidates for transcatheter mitral valve repair according to current international guidelines. Timely referral, specialist imaging and multidisciplinary Heart Team assessment are essential to improve clinical outcomes for this high-risk group.

Mitral valve replacement and repair - Echocardiography

Acute reduction of mitral regurgitation by transcatheter edge-to-edge therapy and impact on long-term survival

GEYER Martin [(1)], GEYER Martin [(1)], KELLER Karsten [(1)], TAMM Alexander R [(1)], BACHMANN Kevin [(1)], BORN Sonja [(1)], KREIDEL Felix [(1)], RUF Tobias F [(1)], BEIRAS-FERNANDEZ Andres [(1)], MÜNZEL Thomas [(1)], VON BARDELEBEN Ralph Stephan [(1)]

(1) University Medical Center Mainz, Mainz, Germany

Aims: While symptomatic and prognostic benefit after transcatheter edge-to-edge repair for functional mitral valve regurgitation was proven, evidence on long-term outcome is limited. Studies examining a potential correlation between the extent of peri-interventional reduction of mitral regurgitation and long-term prognosis are scarce.

Methods and results: Overall, 627 patients (47.0% females, 57.4% functional etiology) treated with interventional edge-to-edge repair (primarily combined procedures excluded) by March 2018 in our centre were enrolled in a retrospective monocentric analysis (median follow-up time 462 days [IQR 142-945]). Survival status was available in 96.7%. Of those, survival was 97.6% at discharge, 75.7% after 1 year, 54.5% after 3 years, 37.6% after 5 years and 21.7% after 7 years. Median follow-up time due to March 2018 for the long-term follow-up was 462 (IQR 142-945) days. Echocardiographic assessment of mitral regurgitation at discharge (available in 98.0%) showed the following results: Grade 0/no: 7.6%, 1/mild: 64.1%, 2/medium: 24.3%, 3/severe 3.8%. A higher grade of residual mitral regurgitation could be correlated to a decreased long-term survival; yet, hazard ratios failed to be significant (HR for MR: mild: 1.24 [95% CI: 0.63-2.46; p=0.053], medium: 1.57 [95% CI:0.78-3.20; p=0.209], severe: 1.89 [95% 0.78-4.55; p=0.158]). When mitral valve grades post intervention were pooled (no/mild vs medium/severe) and adjusted for risk factors, a lower grade of residual mitral regurgitation was predictive for improved survival (HR 1.59 [95% CI: 1.03-2.45; p=0.037).

Conclusions: In a large retrospective monocentric analysis with a long-term follow-up after edge-to-edge therapy for mitral regurgitation, we found evidence that – besides relatively high survival rates overall – a lower grade of residual mitral regurgitation is correlated to higher survival rates. Nevertheless, our data could not demonstrate a significant influence of each single grade of further MR-reduction – thus, comorbidities could play the key role regarding long-term prognosis of these patients.

Mitral valve replacement and repair - Tools, devices and techniques

Long-term outcome after transcatheter mitral valve repair by edge-to-edge therapy in a large monocentric cohort study with a follow-up up to seven years

GEYER Martin [1], GEYER Martin [1], KELLER Karsten [1], BORN Sonja [1], BACHMANN Kevin [1], TAMM Alexander R [1], RUF Tobias F [1], KREIDEL Felix [1], BEIRAS-FERNANDEZ Andres [1], MÜNZEL Thomas [1], VON BARDELEBEN Ralph Stephan [1]

(1) University Medical Center Mainz, Mainz, Germany

Aims: Edge-to-edge repair is an established form of transcatheter mitral valve repair (TMVR). Whereas symptomatic and prognostic benefit for functional mitral valve regurgitation has been shown, data on long-term outcome is still rather limited.

Methods and results: In a retrospective monocentric analysis, we gathered in-hospital and long-term survival of patients after transcatheter edge-to-edge repair. 627 patients (47.0% females, 57.4% functional etiology, primarily combined procedures excluded) who underwent therapy until March 2018 were enrolled. Of those, survival status was available in 96.7%. While 97.6% were discharged alive, survival was 75.7% after 1 year, 54.5% after 3 years, 37.6% after 5 years and 21.7% after 7 years. COPD (HR 1.70 [95% CI: 1.08-2.67], p=0.022), renal insufficiency (HR 2.59 [95% CI: 1.74-3.86], p<0.001), coronary artery disease (HR 2.16 [95% CI: 1.36-3.43], p=0.001), history of myocardial infarction (HR 1.98 [95% CI: 1.34-2.91], p=0.001) as well as a higher logistic EuroSCORE I (HR 1.03 [95% CI: 1.02-1.04], p<0.001) could all be identified to be predictive of a higher 1-year mortality. Interestingly, in-hospital survival increased over the years with increasing centre experience (OR 0.73 [95% CI: 0.57-0.93], p=0.010).

Conclusions: In a large longitudinal monocentric cohort with long follow-up, we could document relatively high survival rates at discharge and after one year after transcatheter edge-to-edge repair. Along with higher implantation numbers, periinterventional survival increased over the years. Long-term mortality was mainly determined by cardiac and non-cardiac comorbidities.

TAVI - Tools, devices and techniques

Left ventricular outflow tract calcification in patients undergoing TAVR

OKUNO Taishi [1], OKUNO Taishi [1], ASAMI Masahiko [1], HEG Dik [2], LANZ Jonas [1], PRAZ Fabien [1], HAGEMEYER Daniel [1], BRUGGER Nicolas [1], GRÄNI Christoph [1], HUBER Adrian [1], SPIRITO Alessandro [1], STORTECKY Stefan [1], WINDECKER Stephan [1], PILGRIM Thomas [1]

(1) Inselspital, Universitätsspital Bern, Bern, Switzerland; (2) Clinical Trials Unit, Bern, Switzerland

Aims: In patients undergoing transcatheter aortic valve replacement (TAVR), presence of left ventricular outflow tract (LVOT) calcification has been suggested to confer an increased risk of adverse clinical outcome. We aimed to systematically assess the importance of LVOT calcification on clinical outcome and device performance with contemporary transcatheter heart valve (THV) systems.

Methods and results: In a retrospective analysis of a prospective single-centre registry, LVOT calcification was assessed in a semi-quantitative fashion and categorised into mild, moderate and severe. Among 1,635 patients undergoing TAVR between 2007 and 2018, 650 patients were found to have LVOT calcification (39.8%). LVOT calcification was categorised as moderate or severe in 407 patients (24.9%). Patients with none/mild versus moderate/severe LVOT calcification were comparable with regards to age, sex, and Society of Thoracic Surgeons (STS) risk scores. Patients with moderate/severe LVOT calcification had significantly higher incidence of aortic root rupture (2.3% vs 0.2%, p<0.001), bail-out valve-in-valve implantation (2.9% vs 0.8%, p=0.004), and residual moderate or severe aortic regurgitation (11.1% vs 6.3%, p=0.002). At 30 days, comparable rates of mortality, disabling stroke, or permanent pacemaker implantation were observed as a function of presence or absence of moderate/severe LVOT calcification. At 1 year, patients with moderate/severe LVOT calcification were at increased risk of all-cause mortality (15.4% vs 11.6%, p=0.048). In a multivariate analysis, moderate/severe LVOT calcification did however not emerge as an independent predictor of all-cause mortality at 1 year (adjusted HR=1.16, 95% CI: 0.77 to 1.74, p=0.472). Balloon-expandable valves conferred a higher risk of aortic root rupture in the presence of moderate/severe LVOT calcification (4.0% vs 0.4%, p=0.002) as compared to other valve designs. There was no significant interaction of valve design/generation and LVOT calcification with regards to the occurrence of bail-out implantation of a second valve and moderate or severe aortic regurgitation at discharge.

Conclusions: Moderate or severe LVOT calcification confers an increased risk of aortic root rupture, residual aortic regurgitation, and implantation of a second valve. The risk of residual aortic regurgitation is consistent across valve designs and generations.

TAVI - Vascular access and bleeding

Plug-based vs suture-based vascular closure after TAVI: initial experience from a single high-volume centre

DUMPIES Oliver [1], DUMPIES Oliver [1], CRUSIUS Lisa [1], KITAMURA Mitsunobu [1], WILDE Johannes [1], MAJUNKE Nicolas [1], KIEFER Philipp [1], DESCH Steffen [1], THIELE Holger [1], HOLZHEY David [1], ABDEL-WAHAB Mohamed [1]

(1) Herzzentrum Leipzig, Leipzig, Germany

Aims: Vascular and bleeding complications are common after transcatheter aortic valve implantation (TAVI) and are associated with worse clinical outcomes. The plug-based MANTA vascular closure device (VCD) is a novel option to achieve haemostasis for large-bore arterial access sites. We aimed to compare vascular and bleeding complications between the plug-based MANTA VCD and the established suture-based ProGlide VCD in a single-centre registry.

Methods and results: From February to September 2019 a total of 578 patients underwent transfemoral TAVI at the Heart Center Leipzig of the University of Leipzig. During this time period, the plug-based VCD was gradually introduced into clinical practice. Eventually, access site closure was performed using the plug-based VCD in 195 patients (33.7%) and the suture-based VCD in 383 patients (66.3%). We assessed vascular and access site-related complications as well as bleeding events according to the Valve Academic Research Consortium (VARC) II definition. Baseline clinical and access-site related characteristics did not significantly differ between both groups. Overall vascular complications occurred less frequently in the plug-based VCD group (10.7% vs 19.0%, p=0.011) driven by a significantly lower rate of major vascular events (2.0% vs 6.5%, p=0.025), while the rate of minor vascular events did not significantly differ between both groups (8.7% vs 12.5%, p=0.194). Access site-related complications were significantly less frequent in the plug-based cohort (10.7% vs 16.6%, p=0.048). In addition, the plug-based VCD was associated with significantly lower rates of major (0.5% vs 4.4%, p=0.009) and life-threatening bleeding (0% vs 2,3%, p=0.032). Minor bleeding events were not significantly different (4.10% vs 6.79%, respectively, p=0.194). All-cause mortality at 30 days was low and not significantly different between both groups (1.5% vs 1.5%, respectively, p=0.97).

Conclusions: The large-bore plug-based MANTA VCD significantly reduced vascular and access-site complication rates as well as severe bleeding events after transfemoral TAVI compared to the suture-based ProGlide system in this single-centre early-experience cohort study. These findings need to be confirmed in an adequately powered randomised clinical trial.

TAVI - Tools, devices and techniques

Temporal trends in cerebrovascular events following TAVI

LINDER Matthias [(1)], LINDER Matthias [(1)], VOIGTLÄNDER Lisa [(1)], LUDWIG Sebastian [(1)], WALDSCHMIDT Lara [(1)], WEIMANN Jessica [(1)], REICHENSPURNER Hermann [(1)], BLANKENBERG Stefan [(1)], WESTERMANN Dirk [(1)], SCHOFER Niklas [(1)], CONRADI Lenard [(1)], SEIFFERT Moritz [(1)]

(1) Universitätsklinikum Hamburg-Eppendorf, Hamburg, Germany

Aims: Large registries demonstrated a consistent decrease in mortality and periprocedural complications after TAVI over time. However, despite procedural improvements and efforts to prevent cerebrovascular events, periprocedural stroke rates remained unchanged. Recently, low-risk trials demonstrated a first decrease in stroke rates. We evaluated temporal changes in the incidence of stroke after TAVI in a large real-world dataset.

Methods and results: A total of 2,191 consecutive patients undergoing TAVI at a single-centre between 2008 and 2017 were retrospectively analysed. The population was divided into an early group (n=1,094) and a late group (n=1,097) according to procedure date. Primary outcome was stroke at 30 days, clinical outcomes were adjudicated according to the Valve Academic Research Consortium-2 criteria. Median age was 81.3 (76.5 – 85.0 years) and 50.4% were female. Patients of the late group had less comorbidities (peripheral artery disease [27.9% vs 35.6%], chronic pulmonary disease [17.0% vs 25.4%], prior malignancy [21.5% vs 29.4%], p<0.001) reflected in a lower Society for Thoracic Surgeons Predicted Risk of Mortality Score (5.5% vs 7.3; p<0.001). Risk factors for a cerebrovascular event, e.g. atrial fibrillation, CHADS-VASC score and prior stroke, were similar between the two groups. Procedural aspects differed with regard to transfemoral access (82.5%; vs 45.3% p<0.001), valve-in-valve procedures (5.4% vs 3.3%; p=0.022), use of a resheathable devices (26.4% vs 1.5%; p<0.001) and cerebrovascular embolic protection (18.4% vs 0.6%; p<0.001). The incidence of the primary outcome of all strokes was lower in the late group (2.6% vs 5.5%; p<0.001); likewise, disabling strokes (1.7% vs 3.4%; p=0.021) and non-disabling strokes (0.9% vs 2.1%; p=0.034) were reduced. 30-day all-cause mortality (5.4% vs 9.2%; p<0.001) and VARC combined 30-day safety (15.0% vs 21.7%; p<0.001) were lower while VARC-defined device success was higher in late patients (95.2% vs 86.1%; p<0.001).

Conclusions: This analysis demonstrates for the first time a significant temporal decrease in the incidence of periprocedural strokes after TAVI in a real-world patient cohort. Both, reduced baseline risks and complication rates and procedural refinements may have contributed to this effect. These results support the expansion of TAVI to selected low-risk patients in clinical routine.

TAVI - Tools, devices and techniques

Infective endocarditis following SAPIEN 3 balloon-expandable versus Evolut R self-expandable TAVR: data from a nationwide analysis

DEHARO Pierre [1], DEHARO Pierre [1], CUISSET Thomas [1], SAINT ETIENNE Chrstophe [2], BOURGUIGON Thierry [2], FAUCHIER Laurent [2]

(1) APHM HOPITAL LA TIMONE ADULTES, MARSEILLE, France; (2) Cardiologie, CHU Tours, Tours, France

Aims: Transcatheter aortic valve implantation (TAVI) is an alternative to surgical aortic valve replacement (AVR) in aortic stenosis (AS). Infective endocarditis (IE) in patients with prosthetic heart valves is associated with significant morbidity and mortality. Data on the incidence, risk factors, and outcomes of IE after TAVI are conflicting. We aimed to compare the characteristics and outocmes following IE in balloon expandable (BE) versus self expandable (SE) TAVI a nationwide level.

Methods and results: We recently published the largest comparison of SAPIEN 3 BE vs Evolut R SE TAVR extracted from the French administrative hospital-discharge database. Based on the French administrative hospital-discharge database, the study collected information for all patients with aortic stenosis treated with either SAPIEN 3 or Evolut R in France between 2014 and 2018. Among 31,113 patients undergoing TAVR (20,397 [65.6%] SE and 10,716 [34.4%] BE) and followed-up for 11.6±12.5 months, a total of 719 patients with first IE post-TAVR were identified (BE 75.5%, SE 24.5%; yearly incidence 2.5% versus 2.1%, adjusted hazard ratio 1.18 95% CI: [confidence interval] 0.99-1.40, p=0.07). The timing between TAVR and IE was not different between groups (BE 10.0 [8.8-11.1] months versus SE 9.4 [8.2-10.6] months, p=0.52). In the BE group, streptococcus IE was more frequent (30.8% versus 18.2%; p=0.001) and coagulase-negative staphylococcus IE was less frequent (10.9% versus 19.3%; p=0.004) than in the SE group, whilst there were no significant differences for other causative micro-organisms. SE and BE recipients had a non-different rate of stroke/systemic embolism (18.6% versus 14.2%, adjusted odds ratio: 1.07, 95% CI: 0.95-1.21, p=0.29). Surgical replacement of the transcatheter valve (BE 1.1%, SEV 0.6%; p=0.40) and 30-day mortality at the time of IE episode (BE 21.9%, SE 20.0%; p=0.62) were not different between groups. After a mean follow-up of 7.0±8.9 months, 35.9% and 34.7% of the BE and SE recipients, respectively, had died (hazard ratio 1.03 95% CI: 0.77-1.38, p=0.84).

Conclusions: In conclusion, except for a lower rate streptococcus IE in SE than in BE, the characteristics of IE post-TAVR, including timing, embolic complications, early or late mortality did not differ according to valve type in our large analysis comparing SAPIEN 3 vs Evolut R TAVR. Those results emphasise the need for improvement in IE prevention and early detection in post TAVR patients.

Mitral valve replacement and repair - Tools, devices and techniques

Mitral annular dimension can predict optimal outcome when using MitraClip NTR and XTR

KREIDEL Felix [1], KREIDEL Felix [1], RUF Tobias [1], TAMM Alexander [1], DIESTELMEYER Simon [1], MUENZEL Thomas [1], VON BARDELEBEN Stephan [1]

(1) Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Mainz, Germany

Aims: In March 2018, the 3rd-generation of the MitraClip (MC) system (Abbott Med., USA) was introduced into clinical practice. Next to the standard size MC-NTR, an enlarged version of the MC - the MC-XTR - became available for clinical use. Until now there is no published evidence on what anatomic features device selection should be based on. The present single-centre study aimed to retrospectively evaluate whether the concept of measuring the mitral annular diameters proved to be reasonable concept with respect to achieving an optimal MR reduction without creating mitral stenosis.

Methods and results: From March 2018 until February 2019 207 patients (pts.) were treated with the MC system at our institution. 19 pts. were treated after previous surgical or interventional mitral valve therapy, and in 7 pts. a simultaneous combination therapy was undergone. All other pts. (n=181) were taken for further analysis. Initially no recommendation for device selection existed, with pt. number 12 measurements of mitral annular dimensions were taken into account although no explicit cut-off values for anteroposterior or intercommissural diameter were used. Basic transthoracic echocardiographic parameters were retrospectively collected. Of the 181 pts. (mean age 79±7 years, 49.5% men), 70 pts. (38, [MS2] 9%) had MR of primary (degenerative) origin, 95 pts. (52,8%) had MR of secondary (functional) origin, and in 16 pts. (8,9%) MR was found to be of mixed aetiology. Of the 175 pts. for whom discharge echo information was available, MR was reduced to ≤ grade 2 in 171 pts. (97.7%), of whom 145 pts. (83%) had MR ≤ grade 1. Pts. after single MC-NTR and single MC-XTR implantation were discharged with ≤ grade 1 in 79.6% and 86% respectively. The mean transmitral pressure gradient (TMPG) at discharge for single NTR, single XTR and pts. receiving >1 MC was 3.7±1.7 mmHg, 2.7±1.2 mmHg and 3.1±1.1 mmHg, respectively. In 26 pts. (14.4%) the mean TMPG at discharge was ≥ 5 mmHg. Of these, 11 pts. received a single MC-NTR, 4 received a single MC-XTR, and 11 received 2 MC. Mitral annular dimensions differed significantly between pts. receiving a single NTR vs a single XTR. The anteroposterior diameter was 33.6±4.5 mm vs 38.9±5.6 mm, respectively (p=0.002), the intercommissural diameter 35.2±3.3 mm vs 39.2±3.6 mm, respectively (p<0.001), and the annular area was 9.5±1.7 cm^2vs 12.3±2.6 cm^2, respectively (p<0.001). For both, the single MC-NTR and the single MC-XTR group pts. with TMPG ≥ 5 mmHg at discharge were found to have significantly smaller anteroposterior and intercommissural annular diameters than pts. who had TMPG <5 mmHg (MC-NTR: anteroposterior diameter 29.6±4.4 mm vs 34.7±3.9 mm, intercommissural diameter 33.3±2.7 mm vs 35.7±3.3 mm; MC-XTR: anteroposterior diameter 32.4±4.2 mm vs 39.6±5.3 mm, intercommissural diameter 34.5±6.7 mm vs 39.7±2.9 mm). ROC analysis identified a cut-off value for an anteroposterior diameter of less than 32.9 mm in single use of MC-NTR and an anteroposterior diameter of less than 36.4 mm for MC-XTR to predict a gradient of ≥ 5 mmHg at discharge.

Conclusions: In this single-centre experience use of the 3rd-generation MC was associated with high success rates for both MC-NTR and -XTR. The introduction of measuring the annular diameter proved to be feasible and to guarantee for a low rate of MC-XTR associated mitral stenosis. Cut-off values of mitral annular dimensions may help in predicting high gradients after edge-to-edge therapy for both device.

TAVI - Vascular access and bleeding

Secondary access in minimalist TAVI: a study on radial or femoral artery

FÉLIX-OLIVEIRA Afonso [(1)], FÉLIX-OLIVEIRA Afonso [(1)], CAMPANTE TELES Rui [(1)], BRITO João [(1)], GONÇALVES Mariana [(1)], ALBUQUERQUE Francisco [(1)], RAPOSO Luís [(1)], MESQUITA GABRIEL Henrique [(1)], NOLASCO Tiago [(1)], ARAÚJO GONÇALVES Pedro [(1)], SOUSA ALMEIDA Manuel [(1)]

(1) Hospital Santa Cruz (Centro Hospitalar de Lisboa Ocidental, EPE), Carnaxide, Portugal

Aims: The use of the radial artery (RA) as an ancillary access has been proposed for contemporary minimalist TAVI. Improved patient comfort and decreased bleeding risk are theoretical advantages. However, its use has been limited due to concerns regarding the performance of bail-out interventions on femoral main access. In our centre, RA has been progressivelly introduced and bail-out interventions are performed using balloon angioplasty or staged stent deployment through rescue contralateral femoral artery. This study aimed to describe the safety and efficacy using RA as a secondary access.

Methods and results: Single centre cohort study of consecutive patients undergoing transfemoral TAVI (TF-TAVI) between 2018 and 2019. RA access was progressively introduced during the study period, therefore a retrospective analysis with 1:1 propensity-score (PS) matched population was derived based on age, female sex, BMI, EuroSCORE II, pre-procedure haemoglobin, vascular closure device of the main access and sheath-to-femoral artery (SFa) ratio. A total of 250 matched patients (125 radial vs 125 femoral) were included. Median age was 84 (IQR 80-87), median ESII 4.2 (IQR 3.0-6.2) and 43.2% were male. The variables used in the PS were successfully balanced. The primary endpoint was the occurrence of major or life-threatening bleeding (VARC-2 definition) and secondary endpoint was successful percutaneous bail-out intervention (balloon and/or stent) on the main access. In the RA group, left side was used as the preferred approach (n=115, 92%). The event rate of the primary endpoint was low in both groups (RA – 7 patients, 5.6% vs FA – 5 patients, 4.0%, p=0.77). The incidence of the secondary endpoint was also low (RA – 9 patients, 7.2% vs FA – 10 patients, 8.0%, p=1.000). Of note, among patients in the RA group who needed a bail-out intervention, a balloon angioplasty was successfully performed in 4 patients and a stent was deployed in 5 patients. In the 5 patients requiring a femoral artery stent, a staged procedure was performed with balloon angioplasty from the RA followed by stent deployment through rescue contralateral femoral artery access. One patient in the RA required vascular surgery on the femoral main access while vascular surgery was not performed in the FA group. Therefore, the success rate of percutaneous bail-out intervention was 88% for radial (8/9) and 100% with femoral artery (10/10).

Conclusions: In our cohort of consecutive TAVI patients, the use of the RA as a secondary was safe and effective in managing vascular complications. The pros and cons of RA vs FA should be further tested in randomised clinical trials in minimalist TAVI.

TAVI - Echocardiography

Predictors and prognostic impact of early ejection fraction recovery in patients with aortic stenosis and reduced ejection fraction after TAVI

SILVA Cláudia [1], SILVA Cláudia [1], BRIZIDO Catarina [1], TRABULO Marisa [1], FREITAS Pedro [1], BRITO João [1], RIBEIRAS Regina [1], CANADA Manuel [1], ANDRADE Maria João [1], HORTA Eduarda [1], REIS Carla [1], OLIVEIRA Afonso [1], NOLASCO Tiago [1], GONÇALVES Pedro [1], TELES Rui [1], ALMEIDA Manuel [1], MENDES Miguel [1]

(1) Hospital Santa Cruz, Lisbon, Portugal

Aims: Patients with severe aortic stenosis (AS) and reduced left ventricular ejection fraction (LVEF) have a dismal prognosis compared with patients with preserved LVEF. Transcatheter aortic valve implantation (TAVI) has shown favourable results in this setting. This study aims to determine predictors of early LV ejection fraction (LVEF) recovery after TAVI and its subsequent prognostic impact.

Methods and results: Prospective single-centre registry including 96 consecutive patients (mean age 81±7 years, 43% female, median EuroSCORE II 5.3 % [IQR 3.6–8.0]) with severe AS and LV dysfunction (LVEF<50% assessed by biplane Simpson's method) who underwent TAVI between January 2015 and April 2019. A retrospective analysis defined early LVEF improvement as an absolute increase in LVEF ≥10% at discharge, in comparison to baseline LVEF. Survival analysis (Cox regression hazards model and Kaplan-Meier) was performed at a median follow-up of 20 months (IQR 13-28). Univariable and multivariable analysis were performed to determine independent predictors of lack in LVEF recovery. The median interval between TAVI and pre-discharge TTE was 4 days (IQR 2–5). Early LVEF recovery occurred in 43% (n=41) of the patients (R-group) and did not occurr in 57% (n=55; no-R group). Mean LVEF before TAVI was 40±9% in the R-group and 37±9% in the no-R group (p=0.083). The univariable analysis identified male sex, baseline indexed LV diastolic volume >75 ml/m^2, relative wall thickness (RWT) <0.42, and systolic pulmonary artery pressure (SPAP) >50 mmHg as associated with a reduced likelihood of LVEF improvement after TAVI. By multivariate analysis, indexed LV diastolic volume >75 ml/m^2 (HR 5.174, 95% CI: 1.115-24.010; p=0.04) and RWT <0.42 (HR 3.754, 95% CI: 1.00-14.083; p=0.05) were independent predictors of absent early LVEF recovery. A total of 23 deaths occurred – 8 on the R group and 14 on the no-R group (HR 0.30, 95% CI: 0.30-1.74, log-rank p=0.47).

Conclusions: Augmented left ventricle volume independently predicted the lack of early recovery of LVEF after TAVI, suggesting that patients without LV dilatation, may not have intrinsic myocardial disease but just afterload mismatch which could explain the rapid improvement of LVEF. However, and given a possible lack of statistical power, LVEF recovery was not associated with improved survival in this cohort.

Mitral valve replacement and repair - Tools, devices and techniques

Mortality predictors after edge-to-edge TMVR for secondary mitral regurgitation

KARAM Nicole [1], KARAM Nicole [1], ORBAN Mathias [2], KALBACHER Daniel [6], BUTTER Christian [8], PRAZ Fabien [5], LUBOS Edith [6], BANNEHR Marwin [8], KASSAR Kassar [5], PETRESCU Aniela [4], ILIADIS Christos [7], UNTERHUBER Matthias [3], THIELE Holger [3], PFISTER Roman [7], WINDECKER Stephan [5], LURZ Philipp [3], VON BARDELEBEN Stephan [4], HAUSLEITER Jörg [2]

(1) Hospital European Georges Pompidou (Ap-Hp), Paris, France; (2) Klinikum Großhadern, Munich, Germany; (3) Leipzig University, Leipzig, Germany; (4) Universitätsklinikum Mainz, Mainz, Germany; (5) University of Bern, Bern, Switzerland; (6) UKE, Hamburg, Germany; (7) University Hospital Cologne, Cologne, Germany; (8) Heart Center Brandenburg in Bernau, Bernau, Germany

Aims: Conflicting data exists regarding the benefit of edge-to-edge transcatheter mitral valve repair (TMVR) in severe secondary mitral regurgitation (SMR). We aimed to assess the mortality predictors after TMVR.

Methods and results: Using data from the EuroSMR (European registry on outcomes in secondary mitral regurgitation) registry, we assessed the mortality rates at one and two years, as well as the mortality predictors. Overall, 1,062 patients with severe SMR and ERO, quantified by proximal isovelocity surface area method, underwent TMVR in the participating centres, and were included in the study. Median age of the patients was 76.0 (IQR: 69.0 – 80.1) years, with 387 women (36.5%). Overall, 943 patients (89.4%) were in NYHA class III or IV at the time of the procedure. They presented with atrial fibrillation in 686 patients (64.7%), a prior stroke in 98 patients (9.2%), and a chronic pulmonary disease in 174 patients (16.4%). Regarding surgical risk, median EuroSCORE II was 6.7% (IQR: 3.9 – 11.9%). The aetiology of SMR was ischaemic in 515 patients (51.6%). Median ERO was 0.28 cm^2 (IQR: 0.20-0.39). Median LVEF was 34.0% (IQR: 25.0 – 44.0%) with a median LV end-diastolic volume of 170 ml (IQR: 123 – 225 ml) and end-systolic volume of 110 ml (IQR: 70.0 – 160.0 ml). Post-procedural MR reduction of at least one grade was observed in 95.8% of patients. At one year, improvement by at least one NYHA class was observed in 65.4% of patients. Estimated all-cause mortality rates at one year and two years were 24.0% and 29.1%, respectively. Predictors of mortality on multivariate analysis were age (HR 1.23; 95% CI: [1.23-1.46] per 10-years increase, p=0.16), presence of diabetes (HR 1.39; 95% CI: [1.04-1.86], p=0.03), increase in left ventricular end-diastolic volume (HR 1.34; 95% CI: [1.10-1.64], p=0.004), prior myocardial infarction (HR 1.72; 95% CI: [1.28-2.32], p<0.001), and renal failure (HR 0.75; 95% CI: [1.08-1.67], p=0.007), while effective regurgitant orifice was not associated with outcome (HR 0.57; 95% CI: [0.22-1.45], p=0.23).

Conclusions: In this study on 1062 patients undergoing TMVR for SMR, overall two-year mortality was 29.1% with most of the death occurring within the first year. Mortality predictors were age, diabetes, prior myocardial infarction, renal failure and increased left ventricular end-diastolic volume. Those parameters should be taken into account when considering TMVR in the setting of SMR.

Mitral valve replacement and repair - Echocardiography

Acute haemodynamic effects following TMVR in patients with proportionate and disproportionate functional mitral regurgitation

RAJANI Prina [1], DAVIES Allan [1], RAJANI Prina [1], CONNOLLY Lauren [1], VAZIR Ali [1], DUNCAN Alison [1], SMITH Rob [1]

(1) Royal Brompton & Harefield Nhs Foundation Trust, London, United Kingdom

Aims: The contrasting results of two recent randomised controlled trials evaluating the benefit of transcatheter mitral valve repair using the MitraClip system versus optimal medical therapy in functional mitral regurgitation (FMR) introduced the concept of "disproportionate MR": where the degree of MR is out of proportion to left ventricular dilatation. We hypothesised that patients with disproportionate MR would have greater acute haemodynamic reductions in peak and mean left atrial pressure (LAP) during the MitraClip procedure compared to those with proportionate MR.

Methods and results: Consecutive patients at a single-centre undergoing MitraClip for FMR were retrospectively recruited for analysis from 2018 (when periprocedural invasive LAP measurements were routinely recorded) until the end of 2019. LAP measurements were recorded during the MitraClip procedure after the insertion of the guide catheter into the left atrium, before insertion of the first MitraClip, and following completion of the case prior to removal of the guide catheter. All patients had undergone preprocedural transthoracic echocardiography, where severity of MR was quantified using effective regurgitant orifice area (EROA) and LV dilatation was measured as left ventricular end-diastolic volume (LVEDV) indexed to body surface area. Patients with an EROA >30mm^2 and indexed LVEDV <96ml/m^2 were considered for the purposes of the analysis to have disproportionate severe mitral regurgitation. We identified 34 patients with FMR and invasive LAP measurements for analysis (median age 76 years (IQR 67-82 years, 22 males). The median EROA was 31mm^2 and median indexed LVEDV was 82.5ml/m^2. A total of 12 patients had both an EROA > 30mm^2 and an LVEDVi < 96ml/m^2 (disproportionate MR). Compared to These patients had a significantly larger reduction in both peak LA pressure (12.3mmHg vs 4.8mmHg; p=0.025) and mean LA pressure (5.3mmHg vs 2.3mmHg; p=0.043) compared to the remaining 22 patients. During a median follow-up of 7 months, there were no observed differences in mortality (p=0.218).

Conclusions: Our analysis provides novel intra-procedural evidence that patients with severe and disproportionate FMR achieve greater acute haemodynamic improvements with significant reduction in the peak and mean LAP compared to FMR patients without disproportionate FMR. These findings would need to be evaluated in an expanded cohort, powered to assess for differences in clinical endpoints such as exercise capacity, hospitalisation for heart failure and mortality.

TAVI - Tools, devices and techniques

Valve durability and outcomes of TAVR compared to SAVR in patients with severe symptomatic aortic stenosis and less-than-high-risk for surgery – a propensity score matched analysis of the TAVIK registry

SCHYMIK Gerhard [1], SCHYMIK Gerhard [1], ALATAKI Sofia [1], BRAMLAGE Peter [1], SCHMITT Claus [1], TZAMALIS Pangiotis [1]

(1) Medical Clinic IV – Department of Cardiology, Municipal Hospital Karlsruhe, Karlsruhe, Germany; (2) Institute for Pharmacology and Preventive Medicine, Cloppenburg, Cloppenburg, Germany

Aims: This study aimed to investigate the rate of severe structural valve deterioration (SVD) and long-term outcomes of patients with severe symptomatic aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR).

Methods and results: Propensity score matched analysis of patients who underwent TAVR (n=216) and SAVR (n=216) between 2008 and 2012. Long-term echocardiographic parameters and clinical outcomes were assessed more than 6 years after TAVR/SAVR. The rate of severe SVD was 10.5% vs 4.5% in the TAVR and SAVR groups, respectively, but the difference was not statistically significant (hazard ratio [HR] 2.5; 95% confidence interval [CI] 0.7–8.3; p=0.159). This was largely driven by higher rates of mean transprosthetic gradient ≥40 mmHg (7.0% vs 3.4%; p=0.327) and aortic regurgitation (4.7% vs 0%; p=0.058). TAVR patients had lower survival rates at 6 years than SAVR patients (40.7% vs 59.6%, respectively, p<0.001, HR 2.15; 95% CI: 1.45–3.20). Rates of cardiovascular events (14.4% TAVR vs 18.2% SAVR, HR 0.8; 95% CI: 0.4–1.3; p=0.347) and permanent pacemaker implantation (PPI; 16.0% TAVR vs 9.2% SAVR, p=0.234) were similar between the two groups.

Conclusions: In conclusion, incidence of moderate and severe SVD was not statistically different between TAVR and SAVR. The rate of moderate or severe aortic regurgitation was significantly higher in the TAVR group with predominant use of first-generation valves. Re-intervention rate was low in both groups. Survival rate was lower after TAVR, probably because of higher frailty index, but the incidence of cardiovascular events, PPI and SVD was similar in both groups.

TAVI - Tools, devices and techniques

Experience of implantation of new-generation self-expandable TAV in patients with low surgical risk

HERNANDEZ-MATAMOROS Harol [1], HERNANDEZ-MATAMOROS Harol [1], JURADO-ROMAN Alfonso [1], GONZALVEZ-GARCIA Ariana [1], GALEOTE-GARCIA Guillermo [1], JIMENEZ-VALERO Santiago [1], MORENO-GOMEZ Raul [1], MARTIN-POLO Lorena [1], LOPEZ-SENDON Jose Luis [1,2], PLAZA-PEREZ Ignacio [2], GONZALEZ-DAVIA Rosa [3]

(1) University Hospital La Paz, Madrid, Spain; (2) Infanta Sofia University Hospital, San Sebastián de los Reyes, Spain; (3) Infanta Cristina Hospital nursery, Parla, Spain

Aims: In recent years there has been a great expansion of transcatheter aortic valve implantation (TAVI). With the increase in operator experience, technical advances in the new-generation of transcatheter heart valve and the simplification of the procedure, TAVI can be considered a therapeutic alternative in patients with low surgical risk (LSR). The aim of this study was to describe the mid-term results of implantation of the latest-generation self-expandable supra-annular prosthesis in patients with LSR.

Methods and results: Retrospective analysis of patients with severe aortic stenosis of LSR, rejected for surgery by the Heart Team, submitted to TAVI with the ALLEGRA (A) and ACURATE neo (ACT) valves between January 2017 and November 2019 in our centre. The variables were evaluated according to the VARC-2 definitions. We analysed 134 patients (61% women, 81.4±6.4 years) with symptomatic severe aortic stenosis (valvular area: 0.68±0.2 cm^2, maximum gradient: 77±25.4 mmHg and mean gradient: 44.3±15.2 mmHg) with LSR (EuroSCORE II 3.39±2.4) treated with transfemoral TAVI (A (n=70) and ACT (n=64). Successful implant defined by residual gradient < 20mmHg and less than severe aortic insufficiency, was 96.2%. Predilatation rate was 74.8% and post-dilatation rate was 31.7%. Periprocedural complications included: cardiac tamponade (n=2, 1.4%), need for a second valve due to inadequate position (n=3, 2.23%), major vascular complications (n =9, 6.5%), pacemaker implantation (n=15, 12.4%), stroke (n=7, 5.2%) and total mortality (n=5, 3.6%). After a follow-up of 8±5.1 months, the rate of hospital readmissions was 10.4% (5.22% of cardiovascular cause), stroke 1.8% and total mortality 3.7% (1.4% mortality cardiac).

Conclusions: New designs of self-expanding prostheses are safe and effective for the treatment of symptomatic severe aortic stenosis in patients with LSR.

Mitral valve replacement and repair - Echocardiography

Anatomic predictors of outcome after transcatheter edge-to-edge mitral valve repair for secondary mitral regurgitation

ORBAN Mathias [1], ORBAN Mathias [1], STOLZ Lukas [1], BRAUN Daniel [1], ORBAN Martin [1], STOCKER Thomas [1], MEHR Michael [1], KARAM Nicole [2], MASSBERG Steffen [1], NABAUER Michael [1], HAUSLEITER Joerg [1]

(1) LMU Munich, Munich, Germany; (2) Hospital European Georges Pompidou (Ap-Hp), Paris, France

Aims: Preprocedural echocardiographic predictors of outcome are not well defined in patients undergoing transcatheter edge-to-edge mitral valve repair (TMVR) for severe SMR. We sought to identify predictors of acute procedural failure (APF), recurrence of mitral regurgitation (MR) and long-term outcome in patients undergoing TMVR for secondary mitral regurgitation (SMR).

Methods and results: We retrospectively analysed echocardiograms of patients treated with TMVR for severe SMR for more than 25 echocardiographic parameters of the mitral valve (MV). Left and right heart anatomy were analysed at baseline. We identified predictors of APF (defined as MR grade ≥ 3+ immediately post-procedural), MR recurrence, and combined long-term outcome (mortality, MR recurrence and repeat intervention) in addition to NYHA functional class. Between 2009 and 2019, 330 patients with SMR underwent TMVR. MR was reduced to ≤ MR 2+ in 95.5% of patients. Mean follow-up was 19.0±16.7 months. Multivariable logistic regression revealed age (odds ratio [OR]=0.94, p=0.027), MV opening area (OR=0.37, p<0.01), and anterior basal leaflet angle (OR=0.86, p<0.001) as predictors of APF. Systolic pulmonary artery pressure (OR=1.07, p=0.013) was the only predictor of MR recurrence. Multivariable COX regression identified left ventricular ejection fraction (hazard ratio [HR]=0.97, p<0.01), vena contracta (HR=3.06, p=0.029), estimated glomerular filtration rate (HR=0.98, p<0.001), and critical preprocedural state (HR=2.24, p=0.033) as predictors of long-term outcome of TMVR.

Conclusions: In contrast to previous surgical studies, anatomical MV parameters predict acute procedural failure of TMVR, but not MR recurrence or long-term outcomes. TMVR is an effective therapy for SMR over a wide range of anatomic MV variations.

TAVI - CT / MRI imaging

Valvular and left ventricular outflow tract calcification as predictors of residual aortic regurgitation after implantation of self-expanding supra-annular aortic prosthesis

HERNANDEZ-MATAMOROS Harol [1], HERNÁNDEZ-MATAMOROS Harol [1], JURADO-ROMAN Alfonso [1], GONZALVEZ-GARCIA Ariana [1], GALEOTE-GARCÍA Guillermo [1], JIMENEZ-VALERO Santiago [1], MORENO-GOMEZ Raul [1], MARTIN-POLO Lorena [1], LOPEZ-SENDON Jose Luis [1], PLAZA-PEREZ Ignacio [2], GONZALEZ-DAVIA Rosa [3]

(1) University Hospital La Paz, Madrid, Spain; (2) Infanta Sofia University Hospital, San Sebastián de los Reyes, Spain; (3) Hospital Infanta Cristina, Parla, Spain

Aims: Aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI) is a recognised predictor of worse clinical evolution. The presence of calcium both at the valvular and subvalvular level is one of the main determinants of this complication. The objective of this study was to determine the value of valvular and left ventricular outflow tract (LVOT) calcification as predictors of residual AR and need for post-dilation after the implantation of two new different types of self-expanding supra-annular valves (ACURATE neo and ALLEGRA-NVT).

Methods and results: A retrospective analysis of patients with TAVI implantation (ACURATE neo or ALLEGRA devices) was carried out between January 2017 and November 2019. Quantification of valvular calcium and LVOT was performed using computed tomography (CT). The association of the calcium score measured by CT with the need for post-dilatation of the valve and residual AR after implantation was analysed. We analysed 136 patients with an average age of 81 years and 61% women, of whom 71 received an ALLEGRA prosthesis and 65 patients an ACURATE neo. The average calcium score in the TAC was 2753.9±1404.3. Predilation was performed in 74.8% of the cases and post-dilatation in 34.9%. The calcium score was higher in patients who required post-dilation, although statistical significance was not reached (no post-dilation: 2,557.3±1,478.3 vs post-dilation: 3,070.42±1,263.66, p=0.53). The calcium score was significantly higher in patients with moderate/severe AR (3089.5±1425 vs 2397.47±1241, p=0.54).

Conclusions: The calcium score measured by CT can predict the occurrence of moderate or severe residual AR after the implantation of self-expanding supra-annular prostheses and may be an indicator of the need for post-dilatation.

TAVI - Tools, devices and techniques

A single-centre experience with the second-generation ACURATE neo transcatheter bioprosthesis

HASHIM Hashim M S [(1)], VITHANAGE Thamal [(1)], IBRAHIM Abdalla [(1)], BAIG Kamran [(1)], GUNARATHNE Ashan [(1)], VARCOE Richard [(1)], JADHAV Sachin [(1)], HENDERSON Robert [(1)]

(1) Nottingham University Hospitals NHS Trust - City Hospital Campus, Nottingham, United Kingdom

Aims: The ACURATE neo valve is a self-expanding, supra-annular second-generation transcatheter valve. It's top-down deployment enables accurate positioning and haemodynamic stability. We present a single-centre experience with the second-generation ACURATE neo transcatheter bioprosthesis (Symetis/Boston, Ecublens, Switzerland).

Methods and results: Retrospective collection of clinical, procedural and in-hospital outcome data from 61 patients receiving the ACURATE neo valve in a single-centre in the United Kingdom. 61 consecutive implants were performed between January 2016 and December 2018. The mean age was 81.2±6.7 years. Indications for procedures were aortic stenosis (83.6.%), mixed aortic valve disease (16.4%), and failing aortic valve bio- prostheses (0.0%). All procedures were performed under local anaesthesia and conscious sedation using transfemoral access. The valve was implanted successfully in 98.4% of procedures. Predilatation occurred in 78.7% procedures. The mean aortic gradient post implantation was 8.6±5.0 mm/Hg and aortic valve area 1.9±0.7 cm^2. Paravalvular leak post procedure was mild or less in 96.7%. Procedural related death occurred in 0%. Complications were not common and included cardiac tamponade in 3.3%, acute kidney injury in 8.2%, stroke in 0%, coronary occlusion 0%, annular rupture 0%, conversion to sternotomy in 0%. A permanent pacemaker was implanted in 4.9% of patients.

Conclusions: This study represents a single-centre experience of the use of ACURATE neo valve. The use of this valve resulted in very good outcomes comparable with the SAVI TF registry. The complication rate was very low however there was a higher rate of acute kidney injury compared to previous studies.

TAVI - Tools, devices and techniques

Temporal trend in TAVI. Spanish TAVI registry analysis

JIMENEZ-QUEVEDO Pilar [1], JIMENEZ-QUEVEDO Pilar [1], MUÑOZ-GARCÍA Antonio [2], TRILLO-NOUCHE Ramiro [3], DEL VALLE Raquel [4], DE LA TORRE HERNÁNDEZ Jose Maria [5], SALIDO Luisa [6], GUTIERREZ Enrique [7], PAN Manuel [8], SÁNCHEZ-GILA Joaquín [9], NOMBELA-FRANCO Luis [1]

(1) Hospital Clínico San Carlos, Madrid, Spain; (2) Hospital Universitario Virgen de la Victoria, Málaga, Spain; (3) Complejo Hospitalario Universitario de Santiago de Compostela, Santiago, Spain; (4) Hospital Universitario Central de Asturias, Oviedo, Spain; (5) Hospital Universitario Marqués de Valdecilla, Santander, Spain; (6) Hospital Ramón y Cajal, Madrid, Spain; (7) Gregorio Marañón Hospital, Madrid, Spain; (8) Hospital Universitario Reina Sofia, Córdoba, Spain; (9) Hospital Universitario Virgen de las Nieves. Hospital General, Granada, Spain

Aims: The primary endpoint of this study was to present the in-hospital all-cause mortality in the Spanish TAVI registry from its beginning until 2018. Secondary endpoints included other in-hospital clinical events, 30-all-cause mortality, and to evaluate the temporal trend of this registry.

Methods and results: All consecutive patients included in the Spanish TAVI registry have been analysed. In this temporal analysis, the population was divided into those patients treated before 2014 (cohort A: 2009-2013) and patients treated between 2014 and 2018 (cohort B). From August 2007 to June 2018, 7,180 patients were included. The mean age was 81.2±6.5 years and 53% were women. Logistic EuroSCORE was 12% (8-20). Transfemoral access was used in 89%. In-hospital and 30-day all-cause mortality were 4.7% and 5.7%, respectively. Regarding the temporal analyses during the hospital phase, the rates of myocardial infarction, stroke, need for pacemakers, tamponade, coronary obstruction and vascular complications were similar between both groups. However, in cohort B a reduction in the need for conversion to surgery and valve malposition were observed. In addition, the implant success rate was increased from 93% to 96% (p<.001). In-hospital and 30-day all-cause mortality was significantly lower in cohort B, ([OR = 0.65; 95% CI: 0.48-0.86; p=0.003] y [OR = 0.71; 95% CI: 0.54-0.92; p=0.002], respectively).

Conclusions: Temporal trend analysis of the Spanish TAVI registry showed a change in patient clinical profile and an improvement in both in-hospital clinical outcome and 30-day all-cause mortality in patients treated more recently.

TAVI - Tools, devices and techniques

Safety of shortening post-procedural hospitalisation to 24 hours in patients undergoing transfemoral TAVI with CoreValve/Evolut self-expandable devices

COSTA Giuliano [(1)], COSTA Giuliano [(1)], BARBANTI Marco [(1)], PICCI Andrea [(1)], SGROI Carmelo [(1)], TAMBURINO Corrado [(1)]

(1) AOU Policlinico-Vittorio Emanuele, Catania, Italy, Catania, Italy

Aims: To evaluate safety of next-day discharge (NDD) among patients undergoing transfemoral transcatheter aortic valve implantation (TF-TAVI) with CoreValve/Evolut self-expandable devices and eligible for an early discharge (<72 hours).

Methods and results: We retrospectively analysed consecutive patients, who underwent TF-TAVI with CoreValve/Evolut self-expandable devices from July 2007 to December 2019 and were discharged alive from our institution. A total of 398 patients were discharged within 72 hours from the procedure, with a mean age of 80.9±5.7 years and an intermediate estimated surgical mortality risk. Among these, we compared NDD patients (n=112, 28.1%) with those discharged later, and accounted for confounding variables through a propensity matching adjustment. Next-day discharge strategy steadily increased over two-year time periods (3.4%-26.4%, p<0.05). After adjustment, no differences in all-cause mortality (0.0% vs 0.9%, for NDD and no-NDD matched groups respectively, p=0.32), major stroke (0.0% vs 0.9%, for NDD and no-NDD matched groups respectively, p=0.32), permanent pacemaker implantation (PPI) (0.9% vs 0.0%, for NDD and no-NDD matched groups respectively, p=0.32) and rehospitalisation for heart failure (0.0% vs 0.9%, for NDD and no-NDD matched groups respectively, p=0.32) rates were encountered at 30 days.

Conclusions: Shortening post-procedural hospitalisation to 24 hours in patients undergoing transfemoral transcatheter aortic valve implantation with self-expandable devices and eligible for an early discharge was demonstrated to be a safe strategy.

TAVI - Tools, devices and techniques

Preparatory valvuloplasty with an hourglass-shaped balloon to facilitate TAVI in bicuspid aortic valve stenosis

ZHAO Zhengang [(1)], ZHAO Zhengang [(1)], LI Xi [(1)], FENG Yuan [(1)], CHEN Mao [(1)]

(1) West China Medical School, West China Hospital, Sichuan University, Sichuan, China

Aims: Transcatheter aortic valve implantation (TAVI) has been increasingly performed in the bicuspid aortic valve (BAV) with the expansion of the technology into relatively younger patients, however, technical challenges remain and procedural results are suboptimal owing to the unfavourable valvular anatomies. The study aim was to assess the safety and effectiveness of using a geometrical hourglass-shaped balloon for preparatory valvuloplasty prior to self-expandable TAVI in BAV.

Methods and results: The study was conducted at a large TAVI centre in China. Patients with symptomatic aortic stenosis who were referred for TAVI were evaluated for the eligibility for inclusion. Briefly, the inclusion criteria are: 1) Sievers type 0 or type 1 BAV as determined by multislice computed tomography (MSCT); 2) moderate or severe leaflet calcification; 3) anatomically suitable for transfemoral TAVI using a self-expandable device. Key exclusion criteria are: 1) indeterminate aortic valve morphology on MSCT; 2) high risk of coronary obstruction; 3) maximal ascending aortic diameter ≥ 50 mm. The hourglass-shaped balloon has a narrowing in the centre, and the proximal and distal bulbs are 4.5 or 5 mm larger than the waist in diameter. For the dilatation of stenotic BAV leaflets, the waist of the balloon self-centres and locks at the stenotic valve orifice (the narrowest part), and the distal bulb hyperextends the leaflets upward and outward against the sinus wall. By conforming into the native anatomy, the balloon can reshape the body of BAV leaflets without being restricted at the orifice level. The selection of balloon size was based on MSCT-measured aortic root dimensions. The principle was that the nominal balloon diameter at any of the levels should not exceed 1.1-fold of the diameter of the corresponding root structures. Valve sizing was based on aortic annulus dimension unless there was predictable excessive oversizing relative to supra-annular structures even after desired valvuloplasty. From May to October 2019, 30 patients with severely stenotic BAV were enrolled. Seventeen (56.7%) patients had a type-0 BAV and the remainder had a type-1 BAV. Aortic valvuloplasty was successful in all patients. Rapid ventricular pacing was required in only 36.7% of the patients during balloon inflation. The aortic valve area increased from 0.45±0.16 cm² to 0.72±0.26 cm² ($p<0.001$) following valvuloplasty. Aortic regurgitation worsened by an average of 0.8±1.0 grade after valvuloplasty, however, there was only 1 (3.3%) patient requiring immediate valve implant due to acutely worsened aortic regurgitation. TAVI device success was achieved in all patients except 1 (3.3%), who required a second prosthesis. There were no procedural deaths, emergency surgery, or other severe adverse events. There were no patients with moderate or severe aortic regurgitation after TAVI.

Conclusions: Preparatory valvuloplasty with the hourglass-shaped balloon before self-expandable TAVI in BAV appears to be safe and is associated with encouraging procedural results. Future studies are needed to validate these findings and demonstrate its advantages over conventional cylindrical balloons.

TAVI - Tools, devices and techniques

Early haemodynamic and structural impact of TAVR in pure aortic regurgitation

AURIGEMMA cristina [1], AURIGEMMA Cristina [1], BURZOTTA Francesco [1], GRAZIANI Francesca [1], MENCARELLI Erica [1], PARAGGIO Lazzaro [1], ROMAGNOLI Enrico [1], PEDICINO Daniela [1], LEONE Antonio Maria [1], LAEZZA Domenico [1], TRANI Carlo [1]

(1) Fondazione Policlinico Universitario A. Gemelli, Metropolitan City of Rome, Italy

Aims: Patients with severe aortic regurgitation are treated by surgery and have variable left-ventricular "reverse remodelling" after intervention. Transcatheter aortic valve replacement (TAVR) might be considered in selected aortic regurgitation patients. In our study we have evaluated the haemodynamic and structural impact of TAVR in patients with pure aortic regurgitation.

Methods and results: Consecutive aortic regurgitation patients who underwent TAVR in our institution were identified. Left heart catheterisation before and after TAVR and complete echocardiographic assessment before TAVR, after (24-72 hours) TAVR and at follow-up (3-12 months) were systematically performed. Haemodynamic and echocardiographic parameters were compared before and after TAVR. Twenty-two patients with severe AR, high surgical risk and advanced heart damage were treated by TAVR using mainly self-expandable prostheses. The procedure was successful in 21 patients (95.5%). An immediate haemodynamic impact of the TAVR procedure was documented by different parameters and included significant decrease in left ventricle end-diastolic pressure (from 26.2 to 20.1 mmHg, p=0.012). Significant reduction in left ventricle size (left ventricle end-diastolic diameter: 60.0±8.0 mm vs 54.6±8.1 mm, p=0.002) and mass (left ventricle max indexed: 163.2±58.8 g/m^2 vs 140.2±45.6 g/m^2, p 0.004) as well as a sharp reduction in systolic pulmonary arterial pressure (48.3±17.6 vs 32.9±7.8 mmHg, p<0.0001) was documented at 24-72 hours. Furthermore, patients with baseline moderate-to-severe mitral and tricuspid regurgitation showed a significant, early valvular regurgitation reduction. All favourable changes persisted at follow-up. More pronounced left ventricle end-diastolic diameter reduction was predicted by baseline left ventricle end-diastolic diameter (p=0.019).

Conclusions: In patients with severe aortic regurgitation, TAVR determines a profound impact on heart remodelling, which is early detectable and durable.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Two-year experience with TTVR

MEHR Michael [1], MEHR Michael [1], ORBAN Mathias [1], STOCKER Thomas [1], BRAUN Daniel [1], NÄBAUER Michael [1], MASSBERG Steffen [1], HAUSLEITER Jörg [1]

(1) Klinikum Großhadern, Munich, Germany

Aims: We sought to investigate two-year outcomes after compassionate transcatheter tricuspid valve repair (TTVR) with the edge-to-edge MitraClip device (Abbott Structural Heart, Santa Clara, CA, USA) for high grade symptomatic tricuspid regurgitation (TR).

Methods and results: We investigated two-year results of 69 consecutive patients who were deemed ineligible for cardiac surgery and who underwent TTVR at our centre between 2016 and October 2017. Clinical and echocardiographic outcomes were prospectively collected and retrospectively analysed. At baseline, patients (age 77±11 years) showed significant signs of heart failure (NYHA functional class III/IV 97.1%). 28% had an LVEF ≤40%, 22% had a prior left heart valve intervention, pulmonary hypertension was present in 16%, and 37% had a pacemaker or ICD. Age and comorbidities resulted in an elevated estimated risk for mortality in cardiac surgery (EuroSCORE II 8.8% [IQR 4.0-9.6%]). A successful procedure with a TR reduction to grade ≤ 2+ was achieved in 91% by placement of 2±1 tricuspid clips. Concomitant treatment of severe TR and mitral regurgitation was performed in 63% of patients. After a mean follow-up of 805±263 days exact all-cause mortality was 49%. One patient underwent heart transplant, and one left ventricular assist device implantation, respectively. Re-TTVR for recurrence of high grade TR was performed in 3 patients. At 2 years, 55% of surviving patients were in NYHA functional class I/II ($p<0.001$) and TR was durably reduced to a degree ≤ 2+ in 91% ($p<0.001$; EROA 0.26±0.15cm²; vena contracta 7.3±3.4mm). Unplanned hospitalisation for heart failure had occurred in 20%. Procedural failure was associated with increased mortality as indicated by Kaplan-Meier analysis (log rank rest, $p=0.048$).

Conclusions: TTVR achieved a durable reduction of TR at 2-year follow-up, which also translated in a clear benefit to clinical symptoms, even though long-term mortality remained high.

TAVI - Tools, devices and techniques

Anatomy of supra-aortic branches and the use of cerebral protection devices

CUBERO-GALLEGO Hector [1], DEL VALLE Raquel [1], CUBERO-GALLEGO Hector [1], DIAZ Rocio [1], AVANZAS Pablo [1], PASCUAL Isaac [1], HERNANDEZ-VAQUERO Daniel [1], MORIS Cesar [1]

(1) Hospital Universitario Central de Asturias, Oviedo, Spain

Aims: Cerebral protection devices have been shown to capture debris in 99% of patients undergoing transcatheter aortic valve replacement (TAVR). The device marketed in Europe has a distal filter designed for arterial diameters of 6.5-10 mm (for placement in the LCCA) and a proximal filter for diameters of 9.0-15 mm (for brachiocephalic trunk). In the US, there is an additional size marketed for LCCA of 5-7 mm and with the same reference for the proximal filter. The aim of this study is to identify the proportion of patients referred for TAVR with supra-aortic branches anatomy compatible with CPD positioning.

Methods and results: This was a prospective registry, which included 33 patients referred for transfemoral TAVR, who had previously undergone computed tomography angiography to assess supra-aortic branches. Computed tomography with volumetric and multiplanar reconstruction of the supra-aortic branches (right subclavian artery, brachiocephalic trunk, right common carotid, and LCCA) was performed. The following data were collected: type of aortic arch; degree of tortuosity of the right subclavian artery–brachiocephalic trunk; degree of calcification; and diameters of the brachiocephalic trunk and the LCCA. Twenty-eight patients had a type 1 bovine arch and 5 patients have a type 2. According to the instructions for the use of the SENTINEL Cerebral Protection System (Boston Scientific, Marlborough, MA, US), which consists on a dual system filter basket; 36% of the patients did not meet the anatomical criteria for its use: 7 patients (21%) due to a LCCA diameter <6.5 mm, 1 patient due to a brachiocephalic trunk >15 mm, and 4 patients (12%) for severe tortuosity that contraindicates the use of this device. In addition, 6 patients showed significant calcification of the origin of the brachiocephalic trunk and/or the LCCA which could make deployment of the device difficult.

Conclusions: This is a real-world registry, which shows that 36% of patients referred for TAVR would not be candidates for the placement of the cerebral protection device with the dual system filter basket according to the indications for the use of the device. Notably, 58% of them would meet the specifications of the smaller filter, not marketed in Europe.

Other valvular and structural interventions - Other

Stroke risk during modern balloon aortic valvuloplasty procedures assessed using transcranial Doppler

WILLIAMS Timothy [1], WILLIAMS Timothy [1], COCKBURN James [1], PARKER Jessica [1], HILDICK-SMITH David [1]

(1) Royal Sussex County Hospital, Brighton, United Kingdom

Aims: To investigate the overall stroke risk presented by balloon aortic valvuloplasty in patients with severe aortic stenosis by assessment using transcranial Doppler. To also investigate how multiple balloon inflations affect the risk of stroke using transcranial Doppler.

Methods and results: 38 patients undergoing balloon aortic valvuloplasty during a TAVI procedure were investigated using intraprocedural transcranial Doppler (TCD) focused on bilateral middle cerebral arteries. High intensity transient signals (HITS) detected by TCD represent embolic phenomena and can be a marker of stroke risk. HITS during BAV were counted by TCD at each stage of the procedure, including differentiating between multiple inflations. BAV procedures were performed by the same operators, with the majority using a Z-med balloon (from 20-25 mm diameter) and rapid ventircular pacing in all cases via a Safari guidewire in the left ventricle. HITS were detected at all stages of the BAV procedure. The mean total number of HITS detected during all procedures was 174 (range 10 to 410). Of 38 patients included, 2 patients only underwent 1 balloon inflation. 36 patients underwent 2 inflations, and of these 16 had a third inflation of the balloon. During balloon inflations the highest number of HITS were observed during the first inflation (mean 28; range 4 to 131), with fewer during the second inflation (mean 10; range 0-25), and fewer still during the third inflation (mean 6; range 0 to 20). Significant HITS were also seen when manipulating the catheter across the valve (mean 17), and with movement of the Safari wire when across the aortic valve (mean 25). 1 patients suffered a clinical stroke. The number of HITS was not correlated to the calcium score of the valve assessed using CT.

Conclusions: HITS occur during BAV procedure and can identify stages of the procedure which may produce more vulnerability to stroke. If repeat inflations during BAV procedures are required, the number of HITS reduces with each inflation with the greatest risk of emboli during the first balloon inflation. Care must be taken at all stages of the procedure, including valve crossing and wire manipulation, and these stages provide opporunity to cut down on the risk of stroke during BAV procedures. Finally, the valve calcium score does not correlate with HITS in this small study.

Other valvular and structural interventions - Other

The impact of age on long-term survival of patients undergoing surgical AVR

TANIGUCHI Tomohiko [(1)], TANIGUCHI Tomohiko [(1)], MORIMOTO Takeshi [(3)], KENJI Ando [(1)], KIMURA Takeshi [(2)]

(1) Kokura Memorial Hospital, Fukuoka, Japan; (2) Kyoto University Hospital, Kyoto, Japan; (3) Hyogo College of Medicine, Hyogo, Japan

Aims: In the current guidelines, surgical aortic valve replacement (AVR) is recommended in patients with severe aortic stenosis (AS) when patients are less than 75 years. The aim of this study was to examine clinical outcomes after surgical AVR stratified by age.

Methods and results: Among 3,815 consecutive patients with severe AS enrolled in the CURRENT AS registry between 2003 to 2011, the present study proportion was 1,163 patients who actually underwent surgical AVR in the initial AVR strategy. There were 579 patients ≤74 years, 295 patients 75-79 years, 212 patients 80-84 years, and 77 patients ≥85 years. Median follow-up period after surgical AVR was 1,290 days (interquatile range: 960 to 1,718 days). Patients ≤74 years were more often male, and they more often had bicuspid valve and haemodialysis. With increasing age, there were incremental increases in the prevalence of female, coronary artery disease, anaemia, and AS-related symptoms. Mechanical valves were implanted in 205 patients (35%) ≤74 years and in 51 patients (9%) ≥75 years. The size of mechanical valves was less than 21mm in 100 patients (49%) ≤74 years and 45 patients (88%) ≥75 years. After excluding patients with haemodialysis, the crude cumulative mortality after surgical AVR was significantly different between the 4 groups, and the cumulative incidences of all-cause death were similar in patients 75-79 patients and those 80-84 patients (3.3%, 6.1%, 5.2% and 11.3% at 1 year; 6.9%, 13.2%, 13.3% and 15.7% at 3 years, respectively).

Conclusions: Mechanical valves were implanted in about one-third of patients ≤74 years, and the size of mechanical valves was small in one-half of patients ≤74 years in the surgical AVR era. Postoperative mortality was favourable in patients ≤74 years compared to those ≥75 years. These findings have implications for decision making with regard to the choice of surgical or transcatheter AVR.

Mitral valve replacement and repair - Tools, devices and techniques

Ventricular arrhythmias in patients with functional mitral regurgitation and implantable cardiac devices: implications of mitral valve repair with MitraClip

BENITO-GONZÁLEZ Tomás [1], BENITO-GONZALEZ Tomas [1], FREIXA Xavier [2], GODINO Cosmo [3], TARAMASSO Maurizio [4], ESTEVEZ-LOUREIRO Rodrigo [5], PASCUAL Isaac [6], SERRADOR Ana [7], NOMBELA-FRANCO Luis [8], GRANDE-PRADA David [9], CRUZ-GONZALEZ Ignacio [10]

(1) Department of Cardiology, University Hospital of León, León, Spain; (2) Department of Cardiology, Cardiovascular Clinic Institute, Hospital Clinic, University of Barcelona, Barcelona, Spain; (3) Department of Cardiology, San Raffaele Hospital, Milan, Italy; (4) Heart Valve Clinic, University Hospital of Zurich, University of Zurich, Zürich, Switzerland; (5) Department of Cardiology, University Hospital Álvaro Cunqueiro, Vigo, Spain; (6) Heart Área, Hospital Universitario Central de Asturias, Faculty of Medicine, University of Oviedo, Instituto de Investigación Sanitaria del Principado de Asturias (ISPA), Oviedo, Spain; (7) Department of Cardiology. Biomedical Research Networking Center on Cardiovascular Diseases (CIBERCV), University Clinic Hospital of Valladolid, Valladolid, Spain; (8) Cardiovascular Institute, Hospital Clínico San Carlos (IdISSC), Madrid, Spain, Madrid, Spain; (9) Department of Cardiology, University Hospital Virgen de la Victoria, Málaga, Spain; (10) Department of Cardiology, University Hospital Clínico de Salamanca, Biomedical Research Networking Center on Cardiovascular Diseases (CIBERCV), Biomedical Research Institute of Salamanca (IBSAL), Salamanca, Spain

Aims: Limited information has been reported regarding the impact of percutaneous mitral valve repair (PMVR) on ventricular arrhythmic (VA) burden. The aim of this study was to address the incidence of VA and appropriate antitachycardia implantable cardiac defibrillator (ICD) therapies before and after PMVR.

Methods and results: We retrospectively analysed all consecutive patients with heart failure with reduce left ventricular ejection fraction, functional mitral regurgitation grade 3+ or 4+ and an active ICD or cardiac resynchroniser who underwent PMVR in any of the eleven recruiting centres. Only patients with complete available device VA monitoring from one year before to one year after PMVR were included. Baseline clinical and echocardiographic characteristics were collected before PMVR and at 12-month follow-up. 93 patients (68.2±10.9 years old, male 88.2%) were enrolled. PMVR was successfully performed in all patients and device success at discharge was 91.4%. At 12-month follow-up, we observed a significant reduction in mitral regurgitation severity, NT-proBNP and prevalence of severe pulmonary hypertension and severe kidney disease. Patients also showed a significant improvement in NYHA functional class and showed a non-significant trend to reserve left ventricular remodelling. After PMVR a significant decrease in the incidence of non-sustained ventricular tachycardia (VT) (5.0±17.8 vs 2.7±13.5, p=0.002), sustained VT or ventricular fibrillation (0.9±2.5 vs 0.5±2.9, p=0.012) and ICD antitachycardia therapies (2.5±12.0 vs 0.9±5.0, p=0.033) were observed.

Conclusions: PMVR was related to a reduction in arrhythmic burden and ICD therapies in our cohort.

TAVI - Vascular access and bleeding

Gender differences in the clinical and periprocedural characteristics and clinical outcomes after TAVI: 10-year real-life experiences of a tertiary Polish centre

DYRBUS Maciej [3], WILCZEK Krzysztof [1], CHODOR Piotr [2], HAWRANEK Michal [1], DYRBUS Maciej [3], ZEMBALA Michal [4], PYKA Lukasz [1], WLOCH Lukasz [2], ZEMBALA Marian [4], KALARUS Zbigniew [2], GASIOR Mariusz [1]

(1) 3rd Department of Cardiology, School of Medical Sciences in Zabrze, Medical University of Cardiology, Katowice, Zabrze, Poland; (2) Department of Cardiology, Congenital Heart Diseases and Electrotherapy, Medical University of Silesia, Silesian Center for Heart Diseases,, Zabrze, Poland; (3) Student Scientific Society, 3rd Department of Cardiology, School of Medical Sciences in Zabrze, Medical University of Cardiology, Katowice, Zabrze, Poland; (4) Department of Cardiac Surgery and Transplantology, Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland

Aims: Despite the establishment of multiple clinical and periprocedural factors influencing short- and long-term outcomes in patients treated with TAVI, the real-world data on the association between gender and outcomes after TAVI remain conflicting. The aim of this analysis was to evaluate the association of gender with the clinical and periprocedural characteristics along with in-hospital, short- and medium-term outcomes of patients treated with TAVI in a tertiary Polish centre during more than a decade.

Methods and results: Out of 451 consecutive patients who underwent TAVI due to severe aortic stenosis at our centre between 2008 and 2019, the detailed characteristics were available in 275. Women were significantly older (median age: 80 years; IQR 74-84) than men (median age: 77 years; IQR: 72-82) p<0.001. There were no significant differences between genders in the prevalence of cardiovascular risk factors, apart from median LVEF, which was significantly lower in men (46.0%) than in women (52.0%, IQR: 32.0-54.0; p<0.001). Almost one in two male patients underwent CABG before TAVI (49.3% vs 18.6% women, p<0.001). The median logistic EuroSCORE was 23.3% and did not differ between men (median 24.0%, IQR: 12.0%-36.9%) and women (22.1%, IQR: 13.4%-30.3%; p=0.67). In women, surgical cutdown was performed significantly more frequently than in men (38.7% vs 23.1%; p=0.03) but no differences in the vascular closure techniques were observed (p=0.11). Female patients significantly more frequently had the Boston ACURATE and Edwards SAPIEN valve implanted (respectively 35.6% and 19.8% in women vs 25.2% and 11.2% in men), while in men, Medtronic CoreValve was more frequently chosen (63.6% in men vs 44.7% in women; p=0.006). The implantation was successful in 95.0% of women and 98.5% of men (p=0.13), while bail-out surgical intervention was necessary in 1.8% of women (vs none in men; p=0.12). During the index hospitalisation, men significantly more frequently required implantation of a pacemaker due to conduction disturbances (20.0% vs 10.4%, p=0.03). There were no differences in the rate of periprocedural vascular complications between the groups, with exception of severe bleeding (in 16.2% of women vs 7.2% of men; p=0.03) and the necessity for blood transfusion (55.3% in women vs 35.4% in men; p=0.002). No differences were observed in the length of hospital stay (overall median: 7 days, IQR: 5-13; p=0.21) and moderate-to-severe paravalvular leak after TAVI (9.7% in men vs 6.0% in women; p=0.35). There were no significant differences in 30-day all-cause mortality (3.0% in women vs 1.4% in men; p=0.43). No differences in the all-cause mortality in 6-month (10.5% in men and 11.9% in women; p=0.44) and in 12-month follow-up (12.4% in men vs 13.1% in women; p=0.51) were observed.

Conclusions: Despite advanced age and high prevalence of CV risk factors, the overall short- and medium-term prognosis in patients treated with TAVI in our analysis of the real-world population remains relatively low. Although men had a slightly worse clinical baseline profile, their 30-day, 6-month and 12-month outcomes did not differ significantly to those of female patients.

Other valvular and structural interventions - Other

Black-box warning for rheolytic thrombectomy in patients with acute pulmonary embolism should be reconsidered: a six-year single-centre experience

KAYMAZ Cihangir [(1)], AKBAL Ozgur Yasar [(1)], KAYMAZ Cihangir [(1)], KESKIN Berhan [(1)], TANYERI Seda [(1)], TOKGOZ Hacer Ceren [(1)], HAKGOR Aykun [(1)], KARAGOZ Ali [(1)], TURKDAY Sevim [(1)], BAYRAM Zubeyde [(1)], OZDEMIR Nihal [(1)]

(1) KARTAL KOŞUYOLU YÜKSEK İHTISAS EĞITIM VE ARAŞTIRMA HASTANESI, Istanbul, Turkey

Aims: Although rheolytic thrombectomy has been used as a percutaneous technology providing a high efficacy with a reduced bleeding risk in patients with pulmonary embolism, there has been a controversy over this method based on a meta-analysis of anectotal reports. In this study we aimed to present our results from a six-year, single-centre experience on rheolytic thrombectomy in patients with pulmonary embolism at intermediate-high and high risk status.

Methods and results: Our study was based on the retrospective analysis of 53 patients overall (female 43.4%, age 57.8±18.7 years) with documented pulmonary embolism who underwent rheolytic thrombectomy using a dedicated technology. Bilateral rheolytic thrombectomy was utilised in 30 (56.6%) patients with a high bleeding risk due to recent major surgery or active intracranial, visceral or gastrointestinal bleeding. In 13 out of 53 patients, rheolytic thrombectomy was performed after failed iv tissue type plasminogen activator (t-PA) therapy and in 3 out of 53 patients after unsatisfactory result from ultrasound-assisted thrombolysis. The systematic work-up including multidetector computed tomography, echocardiography, biomarkers, and pulmonary embolism severity index and its simplified version (PESI, sPESI) were performed in all patients. Qanadli score was used as the computed tomographic measure of the thrombotic burden in the pulmonary arteries. Intermediate-high risk and high risk were noted in 48 and 5 patients, respectively. Failure in the placement of the catheter was experienced in one out of 53 attempts. Intrapulmonary artery infusion of adjuvant t-PA was needed in 16 patients (30.2%) with a dosage of 12.7±7.8 mg. Mean thrombectomy time was 300 (240-388 IQR) seconds. Regardless of the risk status, RT resulted in significant improvements in heart rate (108.1+17 vs 84.1+11.6 bpm), blood oxygen saturation % (89.4+9.2 vs 94.5+2.5), tricuspid annular planary systolic excursion (TAPSE) (1.7+0.3 vs 2.1+0.3 cm) and tissue systolic velocity (St) (10.4+2.1 vs 13.2+2 mm/sec), PA systolic pressure (56.9±14.1 vs 40.3±13.7 mm Hg), QS (23.6±6.3 vs 12.6±7.1), right to left ventricle diameter ratio (1.3±0.2 vs 0.9±0.2) and diameter of main pulmonary artery (30.2±3.9 vs 28.4±4.2 mm) ($p<0.001$ for all). The rheolytic thrombectomy induced short-term bradicardia or conduction disturbances during system activation and a gross haemoglobinuria responsive to saline hydration in all patients. Major and minor bleeding events, and in-hospital mortality rates were 9.4 %, 5.6% and 9.4 %, respectively. Post-discharge pulmonary embolism-related morbidity and mortality were not documented during follow-up period for median 815 (430–944) days.

Conclusions: Our experience reveals that rheolytic thrombectomy facilitates pulmonary arterial thrombolysis, recovery of pulmonary haemodynamics and right heart functions with acceptable rates of complications in patients with pulmonary embolism at high bleeding risk or active bleeding, regardless the baseline risk status.

TAVI - Vascular access and bleeding

Independent and simultaneous association between higher mortality rate and male gender or atrial fibrillation complications following TAVI

CHIKATA Yuichi [1], IWATA Hiroshi [1], DOI Shinichiro [1], FUNAMIZU Takehiro [1], OKAZAKI Shinya [1], TAMURA Harutoshi [3], HIGUCHI Ryosuke [2], TOBARU Tetsuya [4], TAKAYAMA Morimasa [2], DAIDA Hiroyuki [1]

(1) Juntendo University, Tokyo, Japan; (2) Sakakibara Heart Institute, Tokyo, Japan; (3) Yamagata University, Yamagata, Japan; (4) Kawasaki Saiwai Hospital, Kanagawa, Japan

Aims: The prognostic impact of men who have atrial fibrillation/flutter (AF) following TAVI has been rarely evaluated, despite that these have been independently demonstrated to be associated with increased risk of morbidity and mortality after TAVI. Therefore, this study aimed to assess and compare the prognostic impact of either or both of male gender and AF in patients who underwent TAVI.

Methods and results: A multi-centre registry TAVI database of three hospitals enrolled 730 patients who underwent TAVI between October 2013 and August 2018. Endpoints were set as all-cause and cardiovascular (CV) death in this study. Median follow-up and range were 423 and 0-1,812 days, respectively. Participants were divided into 4 groups by gender and with or without (+ or -) AF, such as female/AF (-) (n=370), male/AF (-) (n=188), female/AF (+) (n=127) and male/AF (+) (n=45). The mean and standard deviation (SD) of age were 84.1±5.3 years old, respectively. All-cause and CV mortality occurred in 74 (10.1%) and 30 (4.1%) patients, respectively. While NT-proBNP was higher and eGFR was lower in 2 groups with AF (+), surgical risk scores, logistic EuroSCORE, EuroSCORE II and STS scores were similar in 4 groups. Kaplan-Meier analyses demonstrated higher cumulative all-cause mortality in patients with either (male/AF (-) and female/AF (+) or both (male/AF (+) of male gender and AF, compared to neither of these (female/AF (-) (log-rank $p<0.001$ in all comparisons) and cumulative higher CV mortality in male/AF (+) group compared to female/AF (-) group (log-rank P: 0.01). Multivariate Cox proportional hazard analysis adjusted by age, EuroSCORE II, NYHA class, CKD and COPD showed significantly higher hazard ratios for all-cause mortality and CV mortality in male/AF (+) group (hazard ratio: 4.8, 95% confidence interval: 2.2-9.8, hazard ratio: 4.8, 95% confidence interval: 1.5-13.6, respectively) and when the female/AF (-) group was set as a reference.

Conclusions: Findings in this study indicate that male patients complicated by AF are associated with increased risk in all-cause and CV mortality rates (4.8 times higher risk compared to female patients without AF) in patients following TAVI.

Other valvular and structural interventions - Other

Clinical outcomes after TAVR in oldest-aged patients – insights from the RISPEVA registry

PEPE Martino [1], PEPE Martino [1], CORCIONE Nicola [2], BIONDI-ZOCCAI Giuseppe [3,8], MORELLO Alberto [2], BEDOGNI Francesco [4], TOMAI Fabrizio [6], IADANZA Alessandro [5], FERRARO Paolo [7], NESTOLA Palma Luisa [1], GIORDANO Arturo [2]

(1) Policlinico di Bari, Metropolitan City of Bari, Italy; (2) Pineta Grande Hospital Pronto Soccorso, Province of Caserta, Italy; (3) Sapienza University of Rome, Metropolitan City of Rome, Italy; (4) SAN donato milanese, Metropolitan City of Milan, Italy; (5) Policlinico Le Scotte, Siena, Italy; (6) European Hospital, Metropolitan City of Rome, Italy; (7) Casa di Salute "Santa Lucia", San Giuseppe Vesuviano, Napoli, Italy; (8) Mediterranea Cardiocentro, Napoli, Italy

Aims: Although refinements in valve design and delivery systems have led to a widespread diffusion of transcatheter aortic valve replacement (TAVR), the differential outcomes across the age spectrum of treated patients are still debated. The aim of this study was to evaluate in the large "Registro Italiano GISE sull'impianto di Valvola Aortica Percutanea (RISPEVA)" registry the clinical outcomes of the oldest-aged patients undergoing TAVR in comparison with their younger counterparts.

Methods and results: A total of 3,507 patients undergoing TAVR were stratified according to age: 1,381 were classified as oldest-aged (≥85 years), the remaining 2,126 constituted the younger cohort. Baseline, procedural features, clinical events at 30-days and complete follow-up (FU) (medium 368 days) were compared with unadjusted and propensity score (PS)-matched analyses. Endpoints of interest were death, cerebrovascular events, myocardial infarction, major bleedings, major vascular complications, and cardiogenic shock occurring at procedure time, 30-days and complete FU. In comparison with the younger cohort, the oldest-aged patients had lower body mass index (25±3 vs 26±4 kg/m^2; p<0.001), worse renal function (estimated glomerular filtration rate (eGFR) 45±16 vs 59±26 mL/min; p<0.001), higher mean aortic gradient (50±15 vs 47±15 mmHg; p<0.001), smaller aortic valve area (0.6±0.2 vs 0.7±0.2 cm^2; p<0.001), worse symptoms such as prior pulmonary oedema (16.1% vs 13.6%; p=0.040) and syncope (9.5% vs 5.7%; p<0.001), but less often present with diabetes mellitus (18.3% vs 26.8%; p<0.001), coronary artery (24.3% vs 27.5%; p<0.036) and peripheral artery (16.4% vs 20.1%;p=0.005) disease, prior cerebrovascular events (5.5% vs 7.9%; p=0.005), prior cardiac surgery (7.5% vs 17.9%; p<0.001), chronic obstructive pulmonary disease (14.8% vs 20.9%; p<0.001). These differences were no longer observed after PS. In the unmatched population, compared with the younger counterpart, oldest-aged patients at procedure time suffered a higher incidence of death (1.1% vs 0.5%; p=0.034) and cardiogenic shock (1.7% vs 0.7%; p=0.004). However, after PS matching, no differences in procedural complications were found between the 2 groups. In the unadjusted analysis, 30-days mortality in the oldest-age group was low but higher than in younger patients (4.2% vs 2.4%; p=0.007); this difference in disadvantage of the oldest-aged remained true at complete FU (19.6% vs 15.9%; p=0.014). After PS-matching, the oldest-aged population showed a higher mortality solely at 30-days (4.7% vs 2.4%; p=0.016), while the survival at complete FU was similar to that of younger patients (20.1% vs 18.0%; p=0.286). The incidence of non-fatal outcomes were essentially comparable between the 2 groups at both 30 days and complete FU, also after PS matching. At the multivariate logistic regression analysis, procedural adverse events such as major bleedings (adjusted odds ratio (aOR) 3.931; p=0.029), cerebrovascular events (aOR 9.819; p=0.003), and cardiogenic shock (aOR 16.872; p<0.001) were predictors of 30-day death only in the oldest-aged cohort.

Conclusions: Oldest-aged patients can safely undergo TAVR procedures, being not more exposed to procedural complications than younger patients; nevertheless they showed worse short-term mortality probably driven by reduced tolerance to complications. However, past the critical periprocedural phase, in the very elderly cohort the midterm survival was comparable to that of younger patients with similar risk profile.

Tricuspid / Pulmonary valve - Tools, devices and techniques

MitraClip XTR vs PASCAL transcatheter valve repair system for edge-to-edge repair of severe tricuspid regurgitation

LÖW Kornelia [1], LÖW Kornelia [1], ORBAN Mathias [1], MEHR Michael [1], GMEINER Jonas [1], MASSBERG Steffen [1], NÄBAUER Michael [1], HAUSLEITER Jörg [1], BRAUN Daniel [1]

(1) LMU Munich, Munich, Germany

Aims: Edge-to-edge repair of severe tricuspid regurgitation (TR) has been shown to be an effective and safe alternative treatment option for patients ineligible for cardiac surgery. Novel device developments even enable the treatment of patients with large coaptation gaps. Here, we compared the acute and short-term results of patients treated with the MitraClip XTR (Abbott Vascular) vs PASCAL (Edwards Lifesciences) system.

Methods and results: We retrospectively analysed 120 patients treated with edge-to-edge repair for severe TR from February 2018 to October 2019 at the Munich University Hospital, off-label on a compassionate-use basis. In 88 patients the MitraClip XTR system was used whereas in 32 patients the PASCAL system was applied. Concerning baseline characteristics, patients of the entire cohort were 76.8±6.9 years old and had an STS score of 6.3±5.7%. The aetiology of tricuspid regurgitation was functional in 82.5%, degenerative in 8.3% and mixed in 9.2% of patients. Notably, patients in the PASCAL group had a numerically larger coaptation gap (7.8±3.3 mm vs 6.2±2.6 mm, p=0.2) leading to a higher baseline degree of TR (3.7±0.5 vs 3.4±0.5, p=0.01). Procedural success (TR≤2) was achieved in 86.4% in the MitraClip XTR group and in 90.6% in the PASCAL group (p=0.75). In the XTR group 2.1±0.7 clips were implanted, while in the PASCAL group 1.8±0.6 devices were placed (p=0.14). The number of single-clip procedures did not differ between groups (15.6% in the PASCAL group vs 13.6% in the XTR group, p=0.8). Independent leaflet grasping was used in 85% of all PASCAL devices. Applying a four-grade scale for echocardiographic tricuspid regurgitation assessment, TR was reduced intraprocedurally from 3.4±0.5 to 1.7±0.8 in the XTR group and from 3.7±0.5 to 1.8±0.7 in the PASCAL group. At thirty-day follow-up, echocardiographic results remained stable with a mean TR grade of 1.8±0.8 in the XTR group and 1.8±0.8 in the PASCAL group. Reduction of TR was associated with an improvement in NYHA functional class from 3.1±0.4 to 2.1±0.6 in the entire cohort. Accordingly, six-minute walking distance improved from 211±116 to 270±127 meters. Concerning adverse events, we observed single leaflet device attachment (SLDA) in 11% (10/88 pts.) of patients treated with the XTR system within thirty-days following the procedure. In 5 out of these 10 patients we could identify leaflet tear as the cause of SLDA and presumably incomplete leaflet insertion due to large coaptation gaps in further 4 patients. In one patient clip dislocation occurred during emergent permanent pacemaker implantation shortly following the procedure. In contrast, we observed SLDA in 6% (2/32 pts.) of patients treated with the PASCAL system that were presumably due to incomplete leaflet insertion (p=0.5).

Conclusions: The recently launched PASCAL system appeared to be as efficacious as the Mitra-Clip XTR in treating patients with severe tricuspid regurgitation despite a higher baseline TR grade. The numerically lower rate of SLDA in the PASCAL group could be explained by a favourable design of the device for fragile tricuspid leaflets as well as the ability to perform independent grasping.

TAVI - Tools, devices and techniques

The effect of permanent pacemaker implantation following TAVI upon survival

DRAKOPOULOU Maria [1], DRAKOPOULOU Maria [1], SOULAIDOPOULOS Stergios [1], SYNETOS Andreas [1], STATHOGIANNIS Konstantinos [1], OIKONOMOU George [1], TOSKAS Pantelis [1], XANTHOPOULOU Maria [1], SIDERIS Skevos [1], TOUTOUZAS Konstantinos [1], TOUSOULIS Dimitrios [1]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: Transcatheter aortic valve implantation (TAVI) is often followed by conduction abnormalities, leading to a permanent pacemaker implantation (PPI). Preprocedural predictors as well as the clinical impact of PPI following TAVI are yet to be established.

Methods and results: Patients with severe and symptomatic aortic stenosis (effective orifice area [EOA]≤1cm^2) referred for TAVI at our institution were consecutively enrolled. Prospectively collected demographic, laboratory and echocardiographic data were retrospectively analysed. Patients were stratified into two groups according to the need for PPI after TAVI and were followed up post-operatively with clinical and echocardiographic assessment. Primary clinical endpoint was all-cause mortality, as defined by the criteria proposed by the Valve Academic Research Consortium 2. In total, 292 patients were included (male: 50.2%, mean age: 80±7.6years) in our study. Of these, 109 (37.5%) underwent PPI simultaneously or shortly after TAVI. The median follow-up period was 27.3 months. In this period, all-cause mortality showed no significant difference between patients with and those without PPI after TAVI (log-rank p=0.756), even after excluding patients with a pre-existing pacemaker from the analysis. Subgroup analysis also showed no difference in survival between patients with low ejection fraction (<50%) and those with preserved (≥50%) receiving a permanent pacemaker after TAVR (log-rank p=0.269). Taking into consideration factors that were found to associate to PPI in univariate analysis in a multivariate model, including pre-TAVI ejection fraction, pulmonary artery systolic pressure, mean left ventricular outflow tract (LVOT) diameter as assessed by computed tomography (CT) and New York Heart Association functional classification, it was found that mean LVOT diameter was the only independent predictor of periprocedural PPI (Exp[B]: 0.867, 95% confidence interval: 0.789-0.954, B= - 0.142, p=0.003] with lower LVOT dimensions being highly correlated to PPI. Pre-TAVI conduction abnormalities and the degree of aortic annulus calcification, as assessed by CT were not found to predict PPI after TAVI.

Conclusions: PPI following TAVI was not associated with survival at 27 months of follow-up, independently from pre-TAVI ejection fraction. Mean LVOT diameter was the only independent predictor of periprocedural PPI.

Mitral valve replacement and repair - Tools, devices and techniques

TMVR: what are the outcomes for ineligible patients?

ZANCANARO Edoardo [1], ZANCANARO Edoardo [1], BUZZATTI Nicola [1], DENTI Paolo [1], GODINO Cosmo [1], STELLA Stefano [1], AGRICOLA Eustachio [1], MONTORFANO Matteo [1], CASTIGLIONI Alessandro [1], DE BONIS Michele [1], ALFIERI Ottavio [1]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy

Aims: Transcatheter mitral valve replacement (TMVR) has emerged in recent years as a promising tool to treat mitral regurgitation, however its applicability in the real world is currently limited. The aim of the study is to assess the 1-year outcomes of patients refused TMVR in a high-volume mitral centre.

Methods and results: In-hospital data of all patients admitted to our department are prospectively collected. All patients screened for TMVR were retrospectively selected. Follow-up was done through out-patient visits and/or telephone calls. Only patients with available 1-year data are presented. 44 patients screened for TMVR had complete 1-year data. 31(70%) had been refused TVMR and left in medical therapy (MT), while 13 patients (30%) had been accepted and treated. The main reasons for exclusion were anatomy unfeasibility in 13 patients (42%), excessive comorbidities in 7(22%), MT to be optimised in 4(13%) and lack of symptoms in 2(6%). Refused compared to treated patients had median age 81 (76-86) vs 78 (71-82) years, primary mitral regurgitation in 74% vs 46% of cases, left ventricle ejection fraction 50±14% vs 41±10% and NYHA class III-IV in 42% vs 77% of cases. Treated patients received a Tendyne device in 7 cases and Tiara device in 6 cases with procedure overall success of 92%. At 1-year, 12 deaths were observed in the refused patients (all cardiac) while 5 deaths (2 cardiac) occurred in the TMVR group (overall survival 62±9% vs 75±12% respectively). Over 1-year follow-up 3(9%) and 0 patients underwent other mitral procedures in the refused and TMVR groups, respectively. Residual mitral regurgitation >1+ at 1-year was observed in 99% of excluded patients but in no TMVR case. NYHA class worsened in 80% of excluded patients and improved in 56% of cases in the TMVR group.

Conclusions: After a strict selection, a small proportion of patients are currently treated with TMVR with promising results. On the other hand, while the present study does not yet allow any direct comparison and must be considered only hypothesis generating, patients refused TMVR show very poor short-term outcomes. While there remains a need for further evidence, an expansion of TMVR applicability appears desirable.

TAVI - Vascular access and bleeding, Other valvular and structural interventions - Other

The South African SHARE-TAVI registry: readmissions, length of stay and locally relevant outcomes data in low TAVI volume centres

SCHAAFSMA Elizabeth [1,2], SCHAAFSMA Elizabeth [1,2], SCHERMAN Jacques [2], WEICH Hellmuth [3], NTSEKHE Mpiko [1,2]

(1) SA Heart Association, Johannesburg, South Africa; (2) University of Cape Town, Cape Town, South Africa; (3) Stellenbosch University, Stellenbosch, South Africa

Aims: SHARE-TAVI, a prospective multicentre observational registry captures data as part of funding approval processes for all South African TAVI patients to monitor VARC-2 endpoints and define local variations in clinical presentation and outcomes compared to international data. Funding resistance limits TAVI in South Africa and funders repeatedly request local data to examine clinical and cost-effectiveness of TAVI as SAVR is still often assumed to be superior here in both respects.

Methods and results: 1,329 potential TAVI patients evaluated at 11 private/3 state TAVI centres. Combined centres recorded 969 implants since the registry was established in 2014, with 267 implants in 2019, and volumes low due to restrictive funding. 3 centres can offer both balloon- and self-expanding implants. Patients comparable to similar registry and trial populations (GARY, SOURCE 3, & US CoreValve Pivotal): mean age 79.73±7.5yrs, 54.3% male, mean risk predictions 6.4±6.5% [STS-PROM], 22.48±14.8 [log EuroSCORE] & 6.6±5.8% [EuroSCORE 2]. Procedural success at 30 days (n=950) is independent of centre volume (mean 94.7%, range 93.3-98.2%), mean success for 2019 cohort is 98.1%, total periprocedural mortality 2.32% & 30-day mortality 4.74%. Permanent pacemaker implantation (PPI) perioperatively 5.2% and total of 7.4% PPI by 30 days. Transfemoral access 90.84%, mean vascular complications relatively high at 8.0%, with 9.3% recorded vascular complications in second-generation balloon-expandable implants, which made up 30% of SA implants in 2019. All-cause mortality of 9.84% (n=69/701) at 1-year compares favourably to published TAVI populations, non-cardiac mortality accounts for 30.4% (n=21/69) of all-cause mortality. Stroke at 1 year 3.99% (n=28/701). Mean ICU & mean total length of stay have decreased from (ICU 3.35 days, LOS 5.50 days) in 2016 to 2019 (ICU 2.40 days, LOS 4.48 days), with overall mean ICU 2.43±4.27 days and LOS 4.92±5.33 days. Under 12% (n=84/701) of patients have admissions in the first year post TAVI, 4.6%(n=32/701) are within 30 days, 72% of admissions in <30 days post index procedure are non-cardiac related, for wound seroma, pneumonia, or other causes (n=5,4,14 respectively). In the first year 33 of the 84 admissions (39.3%) were cardiac, the majority were arrhythmia-related (n=20) & resulted in 14 new PPIs. 9 of these patients had no history of arrhythmia at evaluation. Only 0.86% (n=6/701) admissions were heart failure-related, compared to 3.2% for TAVI and 6.5% for SAVR in the Evolut Low Risk Trial. 1 admission was for reintervention related to the TAVI valve. 68.4% of patients were in NYHA functional class III/IV at evaluation, whereas at 30 days & 1-year post-TAVI only 6.53% & 7.22% in NYHA III/IV.

Conclusions: Clinical effectiveness of TAVI in SA is similar to that reported in international data, despite the low volumes. Raised vascular complications signal funder resistance to newer generation devices due to perceived higher device costs is a concern. Procedural success is improving year-on-year and length of ICU and total hospital stays are decreasing over time, translating to increased cost-effectiveness for funders. New PPI are lower than reported internationally as are heart failure readmissions. This local data should improve the value proposition of TAVI cf. SAVR in the SA healthcare system and potentially decrease TAVI funding resistance. Patients anecdotally have reported great satisfaction with QOL improvement & return to independent living post-TAVI, which is supported by the improvement in NYHA functional class for the majority of patients.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Safety and efficacy of transcatheter tricuspid valve repair at short-term follow-up: a pooled meta-analysis

MONTALTO Claudio [1], MONTALTO Claudio [1], STICCHI Alessandro [2], CRIMI Gabriele [1], LARICCHIA Alessandra [3], KHOKHAR Arif [3], GIANNINI Francesco [3], COLOMBO Antonio [3], LATIB Azeem [4], MANGIERI Antonio [3]

(1) Fondazione I.R.C.C.S. Policlinico San Matteo, Province of Pavia, Italy; (2) Campus Bio-Medico, Metropolitan City of Rome, Italy; (3) Cotignola ospedale Santa Maria, Province of Ravenna, Italy; (4) Montefiore Medical Center Moses Division, NY, USA

Aims: New percutaneous devices are available to treat severe tricuspid regurgitation (TR). Nonetheless, evidence about safety and efficacy of a strategy of transcatheter tricuspid valve repair is sparse.

Methods and results: Twelve studies reporting outcomes of patients with significant tricuspid regurgitation and treated with percutaneous devices were included in this pooled meta-analysis. A total of 412 patients were treated with Abbott MitraClip (n=292; 70.9%), Edwards PASCAL (n=28; 6.8%), Edwards Cardioband (n=30; 7.3%), Mitralign Trialign (n=15; 3.6%) or Edwards FORMA (n=47; 11.4%); the longest follow-up available was considered. Studies that failed to report an outcome of interest were excluded from the final analysis. Assuming a high heterogeneity between studies, random effect statistics were reported; k indicates the number of studies combined. The incidence of TR graded 3-4/4 was 89% (95% confidence interval [CI] 0.78-1; I2 18%; k = 9) and 90% of patients were in New York Heart Association (NYHA) functional class 3 or 4 (95% CI: 0.80-0.99; I2 0%; k = 11). Baseline 6-minute walking test (6MWT) distance was 220 m (95% CI: 186-253 m; I2 77%; k = 5). At a median follow-up of 30 days the incidence of all-cause death was 0.08 (95% CI: 0.03-0.1; I2 42%; k = 7) and the proportion of subjects with TR 3-4/4 was 14% (95% CI: 3.9-24%; I2 64%; k = 6), significantly lower than baseline (odds ratio [OR] 0.02; 95% CI: 0.004-0.06; p<0.0001; I2 51%; k = 6). Patients treated with any device were less likely to be in NYHA functional class 3-4 (OR 0.06; 95% CI: 0.02-0.13; p<0.0001; I2 59%; k = 9; Figure 1) and experienced a significant improvement in 6MWT distance (mean difference: +49 m; 95% CI: 22-78 m; p=0.0005; I2 18%; k = 5).

Conclusions: In this pooled meta-analysis, a strategy of percutaneous repair of significant tricuspid regurgitation with current devices was safe and resulted in improved functional and echocardiographic outcomes at follow-up.

TAVI - Tools, devices and techniques

Valve-in-valve TAVI for failing aortic valve prostheses

JONES Katherine [1], JONES Katherine [1], KEARNEY Katherine [1], CARROLL James [1], KEMPTON Hannah [1], PHAN Justin [1], ARRIAGADA Alexis [1], BART Nicole [1], BARON David [1], MULLER David [1], ROY David [1]

(1) St Vincent's Hospital, NSW, Australia

Aims: Surgical bioprosthetic valves are increasingly utilised for younger patients. Therefore there is increasing need for long-term strategies in the event of valve failure as re-do sternotomy increases surgical risk. This study aims to retrospectively analyse outcomes of valve-in-valve (VIV) transcatheter aortic valve implantation (TAVI) in a single Australian centre.

Methods and results: All patients who underwent valve-in-valve TAVI between February 2014 and December 2019 at an Australian tertiary centre were examined in a retrospective cohort analysis. Valve characteristics, patient demographics, clinical data and outcomes were all analysed. 27 patients were included in the valve-in-valve cohort (age 76±11yrs, logistic EuroSCORE II 6.3±5.1). All patients had severe surgical bio-prosthetic failure (PERIMOUNT 13, Trifecta 3, Mosaic 5, Freestyle 4, Mitroflow 2) necessitating consideration of re-do surgery. Aortic regurgitation (AR) was the mechanism of failure in 20 patients (74%) with aortic stenosis (AS) or mixed AS/AR in 7 patients. Transfemoral access with Medtronic CoreValve/Evolut valve was performed for all patients. Coronary protection with provisional stent placement was used in 3 patients who had valve-to-coronary (VTC) distances <4mm (2 patients left main protection, 1 patient left main and right coronary artery protection). In all 3 cases stents were removed due to good coronary flow post valve-in-valve TAVI. For the AR group; pre- and post-replacement, left ventricular end diastolic diameters (LVEDD) were 53±10.12 and 48.5±10.47mm respectively. Stroke volume index was 42.2±19.91 ml/m^2 pre-TAVI and 38.28±8.66 ml/m^2 post-TAVI. The dimensionless index (DI) post VIV was 0.59+0.43. For the AS and mixed AS/AR group; Pre-TAVI DI and aortic valve area (AVA) were 0.27±0.11 and 0.77± 0.46 cm^2, respectively, post DI was 0.54± 0.13 with an AVA of 2.04± 1.07cm^2. There were no deaths, strokes or incidences of coronary obstruction in the entire valve-in-valve cohort. Permanent pacing was required in 2 patients (7.4%) (heart block), 1 patient (3.7%) required surgical closure of femoral access site, 1 patient (3.7%) had re-do surgical replacement due to valve malposition and ongoing severe AR.

Conclusions: Valve-in-valve TAVI offers a low risk alternative to redo sternotomy in surgical bioprosthetic valve failure with excellent outcomes and a short hospital stay for patients who would otherwise be offered re-do sternotomy.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Immediate outcomes of balloon pulmonary valvuloplasty in adult patients with congenital heart diseases in our practice

KHOLIKULOV Sardor [1], KHOLIKULOV Sardor [1], MIRMAKSUDOV Mirakhmadjon [2], YULDASHEV Nabijon [1], YULDASHOV Bakhtiyor [1], ATAMURADOV Bakhtiyor [1], MADRAKHIMOV Nodir [1]

(1) Republican specialised scientific-practical medical centre of cardiology, Tashkent, Uzbekistan; (2) Tashkent Medical Academy, Tashkent, Uzbekistan

Aims: Despite the availability of balloon pulmonary valvuloplasty in practice for more than two decades, its use only started 2 years ago in Uzbekistan. Efficiency and coverage of the procedure are increasing year by year and we have some data about immediate outcomes, which can be used to assess the efficiency of the procedure. The purpose of our study to assess the effectivity and safety of balloon pulmonary valvuloplasty (BVP) in adult patients with congenital heart diseases according to immediate outcomes.

Methods and results: There were 12 BVP procedures From January 2018 to December 2019 in our centre. All patients had isolated congenital pulmonary stenosis. The average age of patients was 25.6 years (from 20 to 45 years). 10 patients were female and 2 patients were male. All patients primarily underwent ECG and echocardiography, observed right ventricular hypertrophy and dilated right chambers. The efficiency of BVP procedure is assessed by decreasing pressure gradients (PG) and right ventricular systolic pressure (RVSP), increasing pulmonary artery systolic pressure (PASP). Baseline and post-valvuloplasty PASP and PG are measured by cardiac catheterisation. The procedure resulted in successful BPV (more than 50% reduction of baseline pressure gradient) in 9 (75%) patients, partially successful BPV (from 20% to 50% reduction of baseline pressure gradient) in 2 (16.7%) and unsuccessful BPV (less than 20% percent reduction of baseline pressure gradient) in 1 patient (8.3%). Right ventricular systolic pressure was reduced from 96.2 mmHg to 52.9 mmHg ($p<0.05$). There was reduction of PG from 87.3 to 46.3 mmHg ($p<0.05$). The average PASP was increased from 11.8 mmHg to 19.2mmHg ($p<0.05$). There were no procedural complications.

Conclusions: Balloon pulmonary valvuloplasty is the high effective method for treatment of congenital pulmonary stenosis. Efficiency of BVP can be assessed by decrease of RVSP and PG and increase of PASP.

TAVI - Tools, devices and techniques

Characteristics and outcomes of TAVI procedures of early-era and current-era experience in an Australian centre

CARROLL James [(1)], CARROLL James [(1)], KEARNEY Katherine [(1)], JONES Katherine [(1)], KEMPTON Hannah [(1)], PHAN Justin [(1)], ARRIAGADA Alexis [(1)], BART Nicole [(1)], BARON David [(1)], MULLER David [(1)], ROY David [(1)]

(1) St Vincent's Hospital, NSW, Australia

Aims: To compare the demographics, risk profiles, procedural techniques and outcomes in patients receiving TAVI in a single-centre between early-era (2008-2014) and current-era experiences (2015-2019).

Methods and results: 523 patients underwent TAVI between August 2008 and November 2019 in a single centre in Sydney, Australia. There were 124 procedures performed between 2008 and 2014 ("early era", EE), and 399 performed between 2015 and 2019 ("current era", CE). Pre-implantation haemodynamics were worse in the EE cohort, with mean AV gradient of 47mmHg (±17.4) compared with 40mmHg (±15.6) in the CE. The mean ejection fraction was similar; 56% in the EE cohort vs 58% for the CE cohort. The EE had a higher rate of previous coronary artery bypass with 18.5% versus 13.2%, higher rates of hypertension 51.6% vs 49.1% and a lower BMI 25.0 vs 27.6. Previous PCI occurred in 25.0% of the EE group vs 18.5% of the CE group. Previous balloon aortic valvuloplasty was completed in 20.2% of the EE group and 3.0% of the CE group. Only 2 cases (1.6%) in the EE group were for a failing surgical aortic bioprosthetic valve ("valve-in-valve") vs 25 (6.2%) in the CE cohort. A transfemoral approach was used 91.9% of the time in the EE cohort vs 98.1% in the CE cohort. In the EE group, a general anaesthetic was used 52.9% of the time vs 31.7% of the time in the CE group. In the EE group, CoreValves were used in 52.0% of TAVIs performed, with SAPIEN valves making up 48.0%. In the CE group 11.2% of valves were CoreValve, 57.3% were Evolut, 2.1% were ACURATE, 26.4% were SAPIEN and 2.8% were Lotus. Post-procedurally, the EE cohort had a lower AV mean gradient at 4 mmHg (±3.3) vs 9mmHg (±5.2) for the CE cohort. Post-procedurally in the EE cohort 53.5% of patients received dual antiplatelet therapy (DAPT), 35.2% a single antiplatelet (SAPT) and 11.3% no antiplatelet (NAPT). In the CE cohort, 56.2% received DAPT, 29.5% SAPT and 13.7% NAPT. In the EE cohort 27.8% received an anticoagulant (Clexane/NOAC/Warfarin) vs 27.5% in the CE cohort. Mean survival post implantation in EE cohort was 5.4 years. During the follow up period, 63 patients from the EE cohort (50.1%) and 47 patients from the CE cohort (11.8%) had died. There was no difference in 30-day or 12-month mortality between the EE and CE cohorts (2.4% v 1.3%; p=0.404 and 8.1% v 7.6%; p=0.841, respectively). In the EE cohort, 13 of the 124 patients already had a PPM or ICD device vs 48 of the 394 with data in the CE cohort. There was no significant difference in the requirement for pacemaker implantation within 30-days of TAVI. In the EE cohort, 10 (9.0%) patients required a pacemaker in the first 30 days after TAVI compared to 22 (6.4%) of CE patients (chi2 = 0.877; p=0.349).

Conclusions: Early era patients reflected a prohibitive and high surgical risk cohort. The Current era cohort saw different valves used, a higher rate of using the transfemoral approach and reduced use of a general anaesthetic. There was a trend towards reduced procedural mortality and pacemaker implantation in the current era TAVI cohort, reflecting improvements in technical proficiency, patient selection and TAVI devices. This is an important consideration in expansion of TAVI into lower risk cohorts.

TAVI - Adjunctive pharmacotherapy

Predictors and prognostic impact of nutritional changes after TAVR

SHIMURA Tetsuro [(1)], SHIMURA Tetsuro [(1)], YAMAMOTO Masanori [(1)], KANO Seiji [(1)], SAGO Mitsuru [(1)], TSUNAKI Tastsuya [(1)], KAGASE Ai [(2)], KOYAMA Yutaka [(2)], TSUJIMOTO Satoshi [(2)], SUZUKI Takahiko [(1)]

(1) Toyohashi Heart Center, Aichi, Japan; (2) Nagoya Heart Center, Aichi, Japan

Aims: Little is known about changes in nutritional status as an index of frailty on clinical outcomes after transcatheter aortic valve replacement (TAVR). This study aimed to assess the clinical impact of serum albumin changes from baseline to 1 year after TAVR.

Methods and results: Changes in serum albumin levels from baseline to 1 year after TAVR were evaluated in 1,524 patients who were classified as having hypoalbuminaemia (<3.5 g/dl) and normoalbuminaemia (≥3.5 g/dl) at each timepoint. The patients were then categorised into 4 groups: NN (baseline normoalbuminaemia, 1-year normoalbuminaemia: n=1119), HN (baseline hypoalbuminaemia, 1-year normoalbuminaemia: n=202), NH (baseline normoalbuminaemia, 1-year hypoalbuminaemia: n=121), and HH (baseline hypoalbuminaemia, 1-year hypoalbuminaemia: n=82). Clinical outcomes and late mortality (>1-year) were compared among the 4 groups. Independent associations with mortality among these groups were also assessed. The cumulative 3-year mortality significantly increased across the 4 groups (NN: 11.4%, HN: 10.7%, NH: 25.4%, HH: 44.4%, p<0.001). Multivariable Cox regression analysis revealed that the NH group had a higher mortality risk (hazard ratio [HR]; 2.80 and 3.53, 95% confidence interval [CI]; 1.71-4.57 and 2.06-6.06, p<0.001 and p<0.001, respectively), whereas the HN group had similar risk (HR; 1.16, 95% CI: 0.66-2.06, p=0.61) compared with the NN group. Baseline hypoalbuminaemia, low body mass index, liver disease, peripheral artery disease, and hospital readmission within 1 year were predictors of late hypoalbuminaemia (all p<0.05).

Conclusions: Serial albumin assessment may identify poor prognostic subsets in patients with persistent and late acquired malnutrition 1 year after TAVR.

TAVI - Echocardiography

Impact of arterial stiffness on prognosis and left ventricular mass regression after transfemoral TAVR

TANAKA Tetsu [(1)], TANAKA Tetsu [(1)], ASAMI Masahiko [(1)], NINOMIYA Kai [(1)], TOMII Daijiro [(1)], HORIUCHI Yu [(1)], YAHAGI Kazuyuki [(1)], TANAKA Jun [(1)], YOKOZUKA Motoi [(1)], KOMIYAMA Kota [(1)], AOKI Jiro [(1)], MIURA Sumio [(1)], TANABE Kengo [(1)]

(1) Mitsui Memorial Hospital, Tokyo, Japan

Aims: Increased left ventricular (LV) afterload in patients with aortic stenosis (AS) consists of both valvular and vascular afterload. Valvular afterload improves immediately after relief of AS, however the effect of vascular afterload induced by arterial stiffness on clinical outcomes after transcatheter aortic valve replacement (TAVR) remains unclear.

Methods and results: The present study is a single-centre, retrospective analysis of 121 consecutive patients undergoing transfemoral TAVR with preprocedural assessment of brachial-ankle pulse wave velocity (baPWV) between December 2013 and July 2018. We investigated the association between baPWV and 1-year composite outcome of all-cause death and heart failure hospitalisation. Furthermore, echocardiographic measurements including LV mass index and LV diastolic function at 1, 6 and 12-months after TAVR were assessed. The optimal baPWV cutoff level was set to 1,639 cm/s using the receiver operating characteristic curve. Baseline characteristics were comparable between high baPWV group (n=51) and low baPWV group (n=70). Kaplan-Meier curve described a significantly higher cumulative 1-year composite outcome in high baPWV group than that in low baPWV group (35% vs 10%; log-rank test, p=0.007). In multivariate analysis using Cox-proportional hazard model, high baPWV was an independent predictor for 1-year composite outcome (adjusted hazard ratio, 4.65; 95% confidence interval, 2.01 to 12.02; p=0.0002). Echocardiographic follow-up revealed that high baPWV group had lower LV mass index regression after TAVR than low baPWV group (-3.6±23.9 g/m^2 vs -15.3±24.1 g/m^2; p=0.01, -13.4±30.1 g/m^2 vs -26.4±28.0 g/m^2; p=0.02, respectively) at 1- and 6-month follow-up. The LV mass index regression at 12-month follow-up was still numerically low in high baPWV group. Additionally, E/e' at 1-, 6- and 12-month after TAVR in high baPWV group were higher than those in low baPWV group (23.0±8.2 vs 17.9±5.9; p=0.0002, 23.7±10.4 vs 19.5±8.1; p=0.02, 21.5±7.5 vs 18.1±6.5; p=0.02, respectively).

Conclusions: Higher baPWV could be associated with impaired clinical outcomes after TAVR. Furthermore, the residual arterial stiffness after the intervention may result in delayed reverse LV remodelling.

TAVI - Tools, devices and techniques

Horizontal aorta and transcatheter valve design: which is the enemy?

GALLO Francesco [1], GALLO Francesco [1], KHOKHAR Arif [1], MANGIERI Antonio [1], LARICCHIA Alessandra [1], DI STEFANO Daniele [2], MANFRINI Marco [1], PONTICELLI Francesco [1], MONTORFANO Matteo [2], COLOMBO Antonio [1], GIANNINI Francesco [1]

(1) Maria Cecilia Hospital Del Gruppo Villa Maria, Province of Ravenna, Italy; (2) San Raffaele Hospital, Metropolitan City of Milan, Italy

Aims: Performing TAVR in patients with a horizontal aorta (HA) is challenging and associated with low procedural success rates in first-generation self-expandable (SE) valves. Newer-generation higher-profile valves lack a steerable delivery system or stabilising arches and are not fully repositionable or retrievable prior to final deployment; factors which may affect valve alignment and deployment. Therefore, we hypothesised that TAVR prosthesis design would have an impact on procedural outcomes in patients with a HA.

Methods and results: We retrospectively collected data from all consecutive patients who underwent TAVR in a single high-volume centre, between March 2012 and December 2017. A range of second-generation higher-profile (HP) and lower-profile (LP) TAVR valves were implanted. Patients were split into groups based on the presence of a horizontal aorta (defined as an aortic angulation (AA) ≥48°; angle between the horizontal plane and the aortic annulus). The two groups were further split into those receiving high-profile or low-profile valves. The outcomes studied were procedural success (as defined by the Valve Academic Research Consortium-2 criteria) and post-procedure aortic regurgitation (AR), which was assessed via transthoracic echocardiography. Differences in baseline characteristics were evaluated using chi-squared analysis, and predictors of procedural performance evaluated using logistic regression analysis. 547 patients (mean age 82±5 years, 46.4% male, mean EuroSCORE II 9±2.1 and STS score 5.7±4.5) underwent TAVR implantation. A horizontal aorta (HA) was detected in 210 (38%) cases with 198 (36%) patients receiving an HP valve and 349 (64%) patients an LP valve. The presence of an HA had no impact upon device success or aortic regurgitation at univariate analysis (OR 1.04; 0.60-1.73 95% CI; p=0.929 and OR 0.73; 0.49-1.1 95% CI; p=0.736 respectively) (Figure 1). A significantly higher rate of permanent pacemaker implantation after TAVR was seen in patients with an HA anatomy who received an HP valve (32.9% vs 19%; p=0.018). HP valves compared to LP valves were associated with a lower rate of device success in both aortic anatomies (HA: 82.9% vs 91.2%; p=0.06 and NHA: 79.3% vs 93; p<0.001) and a higher rate of aortic regurgitation (AR) ≥ moderate, after the procedure (HA: 28% vs 17.9%; p=0.075 and NHA: 40.5% vs 18.5 % p<0.001). On multivariate analysis, LP valve was an independent predictor of higher device success (OR 2.98; 1.74-5.07 95% CI; p<0.001) and lower incidence of post-procedural AR ≥ moderate (OR 0.41; 0.27-0.61 95% CI; p<0.001) in the overall population (both HA and NHA patients). Limitations include the single-centre retrospective nature of this study with no blinded adjudication and inclusion of a heterogenous group of TAVR valve designs.

Conclusions: This is the first study evaluating the procedural performance of two different valve profiles with a predefined aortic angulation cut-off. The presence of a horizontal aorta had no impact upon device success but resulted in higher rates of pacemaker implantation with higher profile valves. In contrast valve design had a significant impact on procedural outcomes, with LP valves associated with higher device success and less post TAVR AR.

TAVI - Tools, devices and techniques

Post-TAVR coronary revascularisation guided by stress cardiac imaging and impact on cardiovascular events: a prospective pilot study

LATTUCA Benoit [1], LATTUCA Benoit [1], PRUNET Elvira [1], HUET Fabien [2], AKODAD Mariama [2], MANNA Federico [2], MACIA Jean-Christophe [2], SCHMUTZ Laurent [1], GANDET Thomas [2], CAYLA Guillaume [1], LECLERCQ Florence [2]

(1) CHU de Nîmes, Nîmes, France; (2) Hôpital Arnaud De Villeneuve CHU MPT, Montpellier, France

Aims: The prognostic impact of systematic revascularisation of asymptomatic coronary artery stenosis before transcatheter aortic valve replacement (TAVR) is still debated. The main objectives of this study were to evaluate the feasibility and the safety of a functional evaluation of coronary artery disease (CAD) followed by a selective ischaemia-guided percutaneous coronary intervention (PCI) after TAVR.

Methods and results: This prospective, bi-centric, one-arm, open-label trial included patients with severe aortic stenosis (AS) eligible for TAVR and with significant CAD defined as one or more coronary stenosis ≥70%. Patients with left main stenosis ≥50%, proximal left anterior descending artery (LAD) stenosis ≥90% or >class 2 Canadian cardiovascular society angina pectoris were excluded. Coronary revascularisation was not performed before TAVR and myocardial ischaemia was evaluated by stress cardiac imaging one month after the procedure using single-photon emission computed tomography myocardial perfusion imaging or stress echocardiography using dobutamine infusion. The primary endpoint was the composite of all-cause of death, stroke, major bleeding (Bleeding Academic Research Consortium (BARC) ≥3), major vascular complication (Valve Academic Research Consortium 2 criteria), myocardial infarction (MI) and hospitalisation for cardiac causes at 6 months following TAVR. Between June 2016 and March 2019, 71 patients were included with a complete follow-up in 66 patients. The mean age was 84±5.2 years and the mean EuroSCORE was 13±8.6. Stress cardiac imaging could be achieved in 70% (n=46) of the patients and the main causes to not perform it were patient refusal or secondary impaired medical condition. Significant myocardial ischaemia was observed in only 3 patients (4.5%), of whom 2 patients had successful PCI. The primary endpoint occurred at 6 months in 15 patients (23%) including death in 6 patients (9%), stroke in 3 patients (5%) and major bleedings in 3 patients (5%). Acute MI was observed in only 2 patients (3%) that had non-LAD proximal and severe coronary stenosis (≥90%). Hospital readmission (n=27, 41%) was mostly related to non-cardiac causes (n=18, 27%).

Conclusions: In patients scheduled to TAVR and with significant coronary disease, a strategy of selective ischaemia-guided coronary revascularisation after TAVR appears safe with a low rate of myocardial infarction and myocardial ischaemia requiring revascularisation during follow-up. However, the poor adherence of elderly patients to stress test could suggest performing PCI of proximal and severe coronary lesions. Large-scale and randomised trials are warranted to validate this strategy.

TAVI - Tools, devices and techniques

Real-world comparison of the latest-generation SAPIEN-3/Ultra and Evolut-Pro/Evolut R34 devices in patients undergoing TAVI. Insights from the ATLAS registry

KALOGERAS Konstantinos [1,2], KALOGERAS Konstantinos [1,2], KABIR Tito [2], JABBOUR Richard [3,4], KALANTZIS Charalambos [1], KATSIANOS Eustratios [1], NAKAMURA Sunao [5], MALIK Iqbal.S [3,4], DALBY Miles [2], VAVURANAKIS Manolis [1], PANOULAS Vasileios [2,3]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece; (2) Harefield Hospital, Uxbridge, United Kingdom; (3) Imperial College London, London, United Kingdom; (4) Hammersmith Hospital, London, United Kingdom; (5) New Tokyo Hospital, Chiba, Japan

Aims: To date, comparisons between the latest-generation transcatheter implanted aortic valves have been limited with respect to procedural and short-term outcomes. The balloon-expandable Edwards SAPIEN 3 (S3) and SAPIEN Ultra, and the self-expanding Medtronic Evolut PRO and Evolut-R 34mm valves represent the main volume of transcatheter aortic valve implantation (TAVI) procedures conducted worldwide. In the present study, we compared the periprocedural and one-year clinical outcomes between these last generation devices.

Methods and results: Consecutive patients from the ATLAS (Athens-Tokyo-London Aortic Stenosis) registry, who had undergone TAVI with either the S3/Ultra or Evolut-Pro/R 34mm device, in four centres were retrospectively studied. Patients receiving a 34mm Evolut-R device were included in the analysis, as the large self-expanding device for the Pro platform is not available yet. In-hospital procedural characteristics and outcomes, were recorded and compared among the two populations. Kaplan-Meier estimated 1-year all-cause mortality was compared between groups. In total, 692 patients (352 patients treated with S3/Ultra and 340 patients with Evolut-Pro/R34mm device) were included in the analysis. Baseline demographics (age, coronary artery disease risk factors, logistic EuroSCORE and aortic valve haemodynamics) were similar between the two groups with the exception of female gender (45.2% vs 33.2% for S3 and Evolut-Pro respectively, p=0.001) and previous myocardial infarction (MI), which was significantly less common in patients treated with the S3/Ultra (6% vs 12.7%, p=0.04). In terms of periprocedural and short-term outcomes, patients treated with the Evolut-Pro/R34mm device had significantly lower peak (25.4±3.6mmHg for S3/Ultra vs 14.9±0.6mmHg for the self-expanding valves, p=0.002) and mean gradients at discharge (10.7±0.3mmHg S3/Ultra vs 7.9±0.4mmHg Evolut PRO/R34, p<0.001). Conversely, the S3 demonstrated significantly lower rates of at least moderate residual aortic regurgitation (AR) post-operatively (0.3% vs 4.8% for S3 and Evolut-Pro/R34mm respectively, p=0.001). Interestingly, the rate of new permanent pacemaker (PPM) required after the implantation in pacemaker-free patients on baseline, was numerically higher for the S3/Ultra cohort compared to the self-expanding valve group (17.6% vs 11.7% respectively, p=0.054). As expected, the need for balloon post dilatation of the implanted prosthesis was less among the S3/Ultra patients (5.5% vs 26.1%, p=0.001). One-year Kaplan-Meier estimated survival was similar between the two groups (85.9% for S3 vs 90% for Evolut-Pro/R34mm, plog-rank=0.071). Hazard ratio for all-cause mortality (Pro/R34 vs S3/Ultra) after adjustment for gender and previous MI was similar between the groups (HR=0.73; 95% CI: 0.47 to 1.14, p=0.165).

Conclusions: Real life comparison of the latest-generation balloon expandable and self-expanding devices demonstrates similar 1-year all-cause mortality. The S3/Ultra platforms, as compared to the Evolut-Pro/R34mm, demonstrate less paravalvular leak, at the expense of higher transvalvular gradients. Long-term follow-up and future larger trials are required to establish any potential long-term difference in clinical outcomes and prognosis.

TAVI - Echocardiography

Survival in patients with low-flow, low-gradient aortic stenosis undergoing TAVR

DESEIVE Simon [(1)], DESEIVE Simon [(1)], STEFFEN Julius [(1)], BECKMANN Markus [(1)], ZADROZNY Magda [(1)], MEHILLI Julinda [(1)], THEISS Hans [(1)], MASSBERG Steffen [(1)], HAUSLEITER Jörg [(1)]

(1) Klinikum der Universität München, Munich, Germany

Aims: The aim of this analysis was to compare the survival rates of patients with four different types of severe aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR); patients with normal-flow normal-gradient (NFNG) AS, patients with normal-flow low-gradient (NFLG) AS, patients with preserved left ventricular function and low-flow low-gradient (paradoxical LFLG) AS and patients with reduced left ventricular function and low-flow low-gradient (classical LFLG) AS.

Methods and results: All patients undergoing transfemoral TAVR for severe AS at our centre between 2013 and 2016 with available echo imaging and an aortic valve opening area <1.0 cm² were included in this analysis (n=688, 51.5% female). Patients' mean age was 80.7±7.2 years and mean Society of Thoracic Surgeons (STS) score was 5.7±5.2. Patients were stratified into four groups based on the left ventricular ejection fraction (EF), stroke volume index (SVI) and mean aortic valve pressure gradient (dpmean). The first group served as control group and comprised all patients with NFNG AS (n=267, EF>50%, SVI>35ml/m², dpmean>40mmHg), the second group comprised all patients with NFLG AS (n=169, EF>50%, SVI>35ml/m², dpmean<40mmHg), the third group comprised all patients with paradoxical LFLG AS (n=129, EF>50%, SVI<35ml/m², dpmean <40mmHg) and the fourth group comprised all patients with classical LFLG AS (n=123, EF<50%, SVI<35 ml/m², dpmean<40 mmHg). Kaplan-Meier survival estimates after two years were 81.3% (95% CI: 76.4% and 86.5%) in the NFNG control group. Survival rates were numerically lower without statistical significance in the NFLG group (76.9% with 95% CI: 70.5% and 83.6%, p=0.26) and in the paradoxical LFLG group (74.1% with 95% CI: 66.5% and 82.5%, 0.22). The survival rate was significantly lower in the classical LFLG group (63.0% with 95% CI: 54.1% and 73.4%, p<0.01). The corresponding hazard ratio for mortality in the classical LFLG patients was 1.77 (95% CI: 1.19 and 2.63). When adjusted for the STS score to account for comorbidities, the results remained unchanged (multivariate hazard ratio 1.85 with 95% CI: 1.15 and 2.95, p=0.01).

Conclusions: This analysis revealed a 77% higher 2-year mortality of patients with classical LFLG AS when compared to NFNG AS patients, while patients with NFLG AS and paradoxical LFLG AS had no significantly higher 2-year mortality.

TAVI - Vascular access and bleeding

Obesity is a risk factor for procedural vascular and haemorrhagic complications after TAVI. Results from a multicentre registry on behalf of the Italian Society of Interventional Cardiology (GISE)

SERGIO Berti [1], BERTI Sergio [1], BEDOGNI Francesco [2], GIORDANO Arturo [3], PETRONIO Sonia [4], IADANZA Alessandro [17], BARTORELLI Antonio [6], REIMERS Bernard [5], INDOLFI Ciro [12], TRANI Carlo [6], ATTISANO Tiziana [15], SARDELLA Gennaro [8], BONMASSARI Roberto [16], MEDDA Massimo [11], TOMAI Fabrizio [10], TARANTINI Giuseppe [9], NAVARESE Eliano Pio [13]

(1) Ospedale del Cuore "Gaetano Pasquinucci", Province of Massa and Carrara, Italy; (2) Hospital San Donato Milanese, Metropolitan City of Milan, Italy; (3) Pineta Grande Hospital, Province of Caserta, Italy; (4) University of Pisa, Province of Pisa, Italy; (5) Humanitas Research Hospital, Metropolitan City of Milan, Italy; (6) Agostino Gemelli University Polyclinic, Metropolitan City of Rome, Italy; (7) Monzino Cardiology Center, Metropolitan City of Milan, Italy; (8) Sapienza Università di Roma, Metropolitan City of Rome, Italy; (9) University of Padua, Province of Padua, Italy; (10) European Hospital, Metropolitan City of Rome, Italy; (11) Sant'Ambrogio, Metropolitan City of Milan, Italy; (12) Università degli Studi di Catanzaro "Magna Graecia", Province of Catanzaro, Italy; (13) Salerno 2000 Srl, SA, Italy; (14) Nicolaus Copernicus University, Torun, Poland; (15) Salerno hospital, Salerno, Italy; (16) Trento, Province of Trento, Italy; (17) University of Siena, Province of Siena, Italy

Aims: Obesity is an established risk factor associated with worse cardiovascular outcomes. Initial evidence has suggested a potential favourable role of obesity in improving prognosis of patients undergoing transcatheter aortic valve implantation (TAVI), a phenomenon known as obesity paradox. The precise role of higher BMI in TAVI is however debated owing to scant evidence and the lower number of enrolled patients in previous studies. We aimed to assess the role of obesity by comparing procedural outcomes in patients with different BMI undergoing TAVI procedures.

Methods and results: RISPEVA, a large multicentre prospective database was queried for demographical, procedural and outcome data of patients undergoing TAVI stratified by their BMI. Patients were classified according to World Health Organisation criteria such as normal weight, overweight, or obesity according to their BMI (18.5 to 24.9 kg/m^2, 25.0 to 29.9 kg/m^2, and ≥30.0 kg/m^2, respectively). A total of 3,993 subjects were included. Among them 1,729 (43.3%) were normal weight, 1,534 (38.4%) overweight and 730 (18.28%) obese. As compared to normal BMI, obese patients had significantly higher rate of vascular complications (24.3% vs 17.1%, OR [95% CI], 1.27[1.05-1.53], p=0.01 and haemorrhagic complications (5% vs 4.2% OR [95% CI], 1.25[1.01-1.55], p =0.04). When BMI was analysed as continuous measure, a significant linear relation was identified between increased BMI and vascular complications, with 1.4% increased vascular complications per each unit change in BMI (p=0.01).

Conclusions: This large-scale analysis shows that obese patients as compared to normal weight subjects undergoing TAVI experience worse procedural prognosis owing to increased vascular and bleeding complications. There is linear relationship between increased BMIs and vascular complications, suggesting the potential of BMI as risk predictor of procedural complications after TAVI and the need for undertaking measures to normalise or reduce weight in higher risk obese subjects candidates for TAVI.

TAVI - Tools, devices and techniques

Complications of TAVI in Al-Najaf cardiac centre

JABBAR Ammar [1], JABBAR Ammar [1], AMBER Khalidk [1]

(1) Al-Najaf Cardiac Center, Najaf, Iraq

Aims: To evaluate immediate and short term outcomes of TAVI in Al-Najaf Cardiac Center.

Methods and results: 53 patients with symptomatic severe aortic stenosis, mean age of (72.9±5.6) years and (54.72%) males had high Society of Thoracic Surgeon (STS) score and underwent transcatheter aortic valve implantation procedure in Al-Najaf Cardiac Center between 2015 and 2019. The procedure was done under local anesthesia and conscious sedation via femoral approach, using both balloon-expandable and self-expanding valves. All patients were followed immediately post-procedure, during the period of hospitalisation and thereafter periodically for procedure- and valve-related complications. Immediate and short term mortality was 5.66%, with the majority occuring immediately after procedure due to severe paravalvular leak, annulus rupture and cholesterol embolisation. Major vascular complications, moderate-severe paravalvular leak and conduction abnormalities were 5.88%, 15.45% and 37.73%, respectively. Permanent pacemaker was needed for only two patients. We observed increased risk of pericardial effusion with balloon-expandable valves (p value=0.019). Occurrence of other complications did not significantly differ regarding type of valve.

Conclusions: This study showed favourable rate of survival with procedural success and complication rates similar to international registered results.

TAVI - Tools, devices and techniques

Initial single-centre experience with SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve

CAMMARDELLA Antonio Giovanni [(1)], CAMMARDELLA Antonio Giovanni [(1)], RANOCCHI Federico [(1)], LIO Antonio [(1)], NICOLÒ Francesca [(1)], PERGOLINI Amedeo [(1)], RUSSO Marco [(1)], MONTALTO Andrea [(1)], COMISSO Marina [(1)], BUFFA Vitaliano [(1)], MUSUMECI Francesco [(1)]

(1) Azienda Ospedaliera San Camillo Forlanini, Metropolitan City of Rome, Italy

Aims: To assess in-hospital and 30-day outcomes of TAVI procedures using SAPIEN 3 Ultra system.

Methods and results: from January 2019 to December 2019, 74 patients underwent TAVI performed with SAPIEN 3 Ultra. The mean age was 80.58±8.26 years, with the percentage of males 51.35%. The mean STS score was 4.72±1.78. There were 3 valve-in-valve procedures. Seven patients (9.4%) were operated using a transapical approach and the remaining patients with a transfemoral access. Balloon predilatation and post-dilatation were performed in 19 (25.6%) and 2 (2.7%) patients, respectively. In the transfemoral group, one patient (1.3%) died due to complications of cardiac tamponade and open-heart surgery. There were no cases of major stroke. We observed 3 cases (4%) of major vascular complications in transfemoral group. The rate of blood transfusions in transapical and transfemoral group was of 28.5% and 4.4%, respectively. There were 2 moderate (2.7%) paravalvular leaks. The incidence of post-operative pacemaker implantation was of 2.7%. Median length of hospital stay after TAVI was of 4 days in transfemoral group and 7 days in transapical group. At 30-day there was one case of sudden death at home and no cases of MI, strokes or new pacemaker implantation.

Conclusions: In our retrospective analysis, we observed good early outcomes and low rates of complications in our initial cohort of patients who underwent TAVI performed with SAPIEN 3 Ultra.

TAVI - Tools, devices and techniques

Comparative study of the haemodynamic performance of two latest-generation supra-annular self-expanding transcatheter aortic valves

GONZÁLVEZ-GARCÍA Ariana [1], GONZÁLVEZ-GARCÍA Ariana [1], HERNÁNDEZ-MATAMOROS Harold [1], JURADO-ROMÁN Alfonso [1], JIMÉNEZ-VALERO Santiago [1], GALEOTE Guillermo [1], MARTÍN-POLO Lorena [1], GONZÁLEZ-DAVIA Rosa [3], PLAZA Ignacio [2], MORENO Raúl [1], LÓPEZ-SENDÓN José Luis [1]

(1) University Hospital La Paz, Madrid, Spain; (2) Infanta Sofia University Hospital, San Sebastián de los Reyes, Spain; (3) Hospital Infanta Cristina, Parla, Spain

Aims: The ALLEGRA (A) and the ACURATE neo (ACT) are new-generation supra-annular self-expanding transcatheter aortic valves designed to obtain low gradients and highly effective valve orifice area. The aim of this study was to compare these devices after their implant in terms of haemodynamic performance.

Methods and results: We conducted a comparative retrospective study of patients with severe aortic valvulopathy who underwent transcatheter aortic valve implantation (TAVI) with A and ACT valves between June 2017 and November 2019 in our centre. The haemodynamic results were assessed with post-implantation angiographic images and a complete transthoracic echocardiographic examination before discharge. A total of 136 consecutive symptomatic patients (61.0% females; 81.5±6.5 years-old; EuroSCORE II 3.4±2.4) who underwent TAVI (A [n=71] vs ACT [n=65]) were included. There were no significant differences among groups in baseline clinical characteristics (except a trend towards a higher use of ALLEGRA prosthesis in valve-in-valve procedures (A: 5.6% vs ACT: 0%, p=0.09) nor in echocardiogram findings. No differences were observed regarding immediate procedure success, defined by residual gradient less than 20 mmHg and aortic regurgitation (AoR) lower than grade III or IV (A: 93% vs ACT: 93.8%; p=0.2). The rate of moderate or severe paravalvular AoR (grade III or IV) evaluated angiographically after the implant was similar in both groups (A: 4.2% vs ACT: 4.6%; p=0.9). Both prostheses showed similar haemodynamic profiles as assessed by peak aortic gradient (A: 15.7±9.97 mmHg vs ACT: 16.95±6.6 mmHg; p=0.4) and mean aortic gradient in echocardiography (A: 6.9±4.8 mmHg vs ACT: 7.6±3.3 mmHg; p=0.3).

Conclusions: In our study, both prostheses presented a similar haemodynamic performance at hospital discharge.

TAVI - Tools, devices and techniques

Comparison of clinical events of two new-generation supra-annular self-expanding transcatheter aortic valves

GONZÁLVEZ-GARCÍA Ariana [1], GONZÁLVEZ-GARCÍA Ariana [1], HERNÁNDEZ-MATAMOROS Harold [1], JURADO-ROMÁN Alfonso [1], JIMÉNEZ-VALERO Santiago [1], GALEOTE Guillermo [1], MARTÍN-POLO Lorena [1], PLAZA Ignacio [2], GONZÁLEZ-DAVIA Rosa [3], MORENO Raúl [1], LÓPEZ-SENDÓN José Luis [1]

(1) University Hospital La Paz, Madrid, Spain; (2) Infanta Sofia University Hospital, San Sebastián de los Reyes, Spain; (3) Hospital Infanta Cristina, Parla, Spain

Aims: In recent years, the number of transcatheter aortic valve implantations (TAVI) has increased exponentially due to the technological improvement of devices. The ALLEGRA (A) and the ACURATE neo (ACT) valves are two of the latest-generation supra-annular self-expanding transcatheter aortic prosthesis. The aim of this study was to compare the immediate and medium term results between both designs.

Methods and results: Comparative retrospective study of patients with severe aortic valvulopathy who underwent TAVI with A and ACT prosthesis between June 2017 and November 2019 in our centre. The clinical events were assessed in the follow-up. A total of 136 patients who underwent TAVI (A [n=71] vs ACT [n=65]) were recruited (61.0% females; 81.5±6.5 years-old; EuroSCORE II 3.4±2.4). There were no significant differences among groups in baseline clinical characteristics (except a trend towards a higher valve-in-valve rate with prosthesis A: 5.6% vs ACT: 0%, p=0.09). No differences were observed regarding haemodynamic performance nor in immediate procedure success, defined by residual gradient less than 20 mmHg and aortic regurgitation (AoR) lower than grade III or IV (A: 93% vs ACT: 93.8%; p=0.2). There was a lower rate of permanent pacemaker implantation with ACT valve [A: 18.2% (n=12) vs ACT: 5.3% (n=3); p=0.03]. After a mean follow-up of 7.6±5.2 months, there were no significant differences in the composite endpoint of cardiac death or stroke (A: 4.2% vs ACT: 3.1 %; p=1) nor in the rates of individual adverse events: overall mortality (A: 5.6% vs ACT: 1.5%; p=0.4), cardiac death (A: 1.4% vs ACT: 1.5%; p=1), stroke (A: 1.4% vs ACT: 1.5%; p=1) and acute myocardial infarction (A: 0% vs ACT: 0%; p=NS).

Conclusions: In our series, both prostheses showed similar clinical results. Nevertheless, ACT valve was associated with a lower rate of pacemaker implantation after procedure.

TAVI - Adjunctive pharmacotherapy

Incidence, clinical impact and predictors of thrombocytopaenia after AVR with transcatheter or sutureless heart valve

TIRADO-CONTE Gabriela [(1)], TIRADO-CONTE Gabriela [(1)], SALAZAR TRIVIÑO Carlos [(1)], MCINERNEY Angela [(1)], CRUZ UTRILLA Alejandro [(1)], JIMENEZ QUEVEDO Pilar [(1)], COBIELLA Javier [(1)], GONZALO Nieves [(1)], NUÑEZ Ivan [(1)], ESCANED Javier [(1)], NOMBELA-FRANCO Luis [(1)]

(1) Hospital Clínico San Carlos, Madrid, Spain

Aims: Thrombocytopaenia (TP) is a well described, but poorly understood, complication following surgical (SAVR) and transcatheter aortic valve replacement (TAVR). Higher incidence of TP has been described with surgical sutureless (S-SAVR) and transcatheter balloon-expandable valves (BEV) compared to stented and self-expanding valves (SEV), respectively. The aims of this study were to analyse the incidence of TP in patients undergoing TAVR or S-SAVR, and to identify predictors of TP and it's impact on short and mid-term outcomes in the whole cohort.

Methods and results: Patients with symptomatic severe aortic stenosis undergoing aortic valve replacement with sutureless or transcatheter heart valves (THV) in a single centre were included. Patients with baseline TP were excluded. Patients were classified according to the lowest platelet count measured post-procedure as follows; Group A: no/mild TP (≥100 x109/L), Group B: moderate TP (<100 to 50 x109/L) and Group C: severe TP (<50 x109/L). ROC curves for 30-day mortality were performed using nadir platelet count and percentage decrease in platelet count. Multivariable analysis was performed to estimate independent predictors of TP and 30-day mortality. A total of 760 (679 TAVR and 81 S-SAVR) patients were included. The incidence of moderate and severe TP was 28.8% and 4.2%, respectively. BEV had a lower incidence of moderate and severe TP (24.4% and 3.2%) compared with SEV (31.1% and 5.7%) p=0.023, and sutureless valve (45.7% and 6.2%) p<0.001. Thirty-day mortality was 37.5% in Group C and 3.1% in group A, p<0.001. Major vascular complications and life threatening/major bleeding were more frequent in group B and C (8.7% and 21.9%, and 18.7% and 41.9%, respectively) compared with group A (3.3% and 9.3%, p<0.01 for all comparisons). Time to platelet nadir was longer for those with 30-day mortality (3.5 [1.5-6] vs 2 [1-3] days, p=0.010). Percentage decrease in platelet count showed a greater area under the curve in the ROC analysis compared to nadir platelet count (AUC: 0.79 vs 0.71, p=0.03), with an optimal cut-off point of 46% decrease in platelet count. Percentage decrease in platelet count ≥46% and time to platelet nadir were among the independent predictors for 30-day mortality. Independent predictors of decrease in platelet count ≥46% were baseline platelet count, SEV-Portico THV and S-SAVR, intraprocedural major vascular complications and post-procedural aortic regurgitation.

Conclusions: In conclusion, our study showed that, in this combined TAVR and S-SAVR cohort, moderate-to-severe TP occurred in approximately one-third of patients and was related to a higher rate of in-hospital complications. While a drop in platelet count ≥46% best predicted short-term clinical outcomes, SEV and sutureless valve had the highest incidence of TP. Future work should aim to better understand the pathophysiology behind this complication in order to best treat these patients.

Mitral valve replacement and repair - Tools, devices and techniques

Interventional mitral valve reconstruction with MitraClip: a comparison between primary and secondary mitral regurgitation

TAGLIARI Ana Paula [1,2], TAGLIARI Ana Paula [1,2], MIURA Mizuki [1], SAVIC Vedran [1], SROMICKI Juri [1], TARAMASSO Maurizio [1], RUSSO Giulio [1], ZUBER Michel [1], GAVAZZONI Mara [1], POZZOLI Alberto [1], MAISANO Francesco [1]

(1) Universitätsspital Zürich, Zürich, Switzerland; (2) Universidade Federal do Rio Grande do Sul, RS, Brazil

Aims: To compare outcomes of interventional mitral valve reconstruction with MitraClip in primary and secondary mitral regurgitation in a high-volume centre.

Methods and results: Between May 2009 and January 2019, a total of 495 patients, 287 (58%) with primary and 208 (52%) with secondary mitral regurgitation were submitted for MitraClip implant. All patients were symptomatic despite optimised medical therapy for heart failure. MitraClip implant decision was taken by the institutional Heart Team. We excluded patients with mixed aetiology or concomitantly subject to other valvular interventions. The primary endpoint was defined as all-cause mortality. Secondary endpoints were cardiovascular mortality, rehospitalisation due to heart failure, and the composite endpoint, as well as technical success according to the Mitral Valve Academic Research Consortium definitions. The mean age was 75.4±10 years and 62% were male. Patients with secondary mitral regurgitation were significantly different from those with primary aetiology in many clinical aspects, like age (71.5±10 vs 78±9.7 years; p<0.001); male sex (68% vs 57%; p=0.019); previous coronary artery bypass grafting surgery (23% vs 6.6%; p<0.001); previous cardiac resynchronisation therapy (21.6% vs 1.4%; p<0.001); previous acute myocardial infarction (44% vs 10%; p<0.001); diabetes mellitus (23% vs 13%; p=0.004); New York Heart Association Class III or IV (72% vs 63%; p=0.048); baseline creatinine (140±76 vs 123±66 µmol/L; p=0.007); left ventricular ejection fraction (37±14% vs 58±11%; p<0.001); and left ventricular end-diastolic diameter (182±82mm vs 121±47mm; p<0.001). Technical success was high and with no significant difference according to mitral regurgitation aetiology (97.2% in primary vs 95.7% in secondary; p=0.498). The mean number of clips implanted was 1.96±0.8 in the primary group and 1.84±0.7 (p=0.095) in the secondary group. Non-adjusted outcomes, in a median follow-up of 446 days (IQR 796, range: 0-2926 days), were better in the primary group (all-cause death: 21% vs 40%, p<0.001; cardiovascular death: 13% vs 31%, p<0.001; heart failure rehospitalisation: 15.7% vs 28%, p=0.001, composite endpoint: 32% vs 53%, p<0.001). However, after adjustment for the baseline differences found, the type of mitral regurgitation (primary vs secondary) was not an independent predictor of outcomes (all-cause death: HR 0.87, 95% CI: 0.49-1.54; cardiovascular-death: HR 1.24, 95% CI: 0.62-2.51; heart failure rehospitalisation: HR 1.71, 95% CI: 0.86-3.39; composite endpoint: HR 1.24, 95% CI: 0.76-2.02).

Conclusions: In this very large comparison between patients with primary and secondary mitral regurgitation who underwent MitraClip implant, we found comparable technical success and mid-term adjusted outcomes, despite those with secondary mitral regurgitation having a significantly worse baseline clinical condition.

Other valvular and structural interventions - Other

Immediate outcomes of percutaneous transvenous mitral commissurotomy of patients with severe mitral stenosis in different age groups

ALI Muzaffar [(1)], ALI Muzaffar [(1)]

(1) Allama Iqbal Medical College, Lahore, Pakistan

Aims: To evaluate the immediate outcomes of percutaneous transvenous mitral commissurotomy (PTMC) for severe mitral valve stenosis.

Methods and results: This cross-sectional study was conducted from January 2015 to December 2015 at the Cardiology Department, Jinnah Hospital, Lahore, Pakistan. Included patients with severe mitral valve stenosis had mitral valve area (MVA) 1.0 cm and underwent PTMC with suitable valve morphology. All patients underwent PTMC using the transseptal antegrade technique, after informed consent was obtained. Echocardiography was performed in all patients before and after PTMC to assess the severity of mitral regurgitation. Patients were divided in two groups based on younger <35 years and older age (36-60 yares) and comparison was made to assess difference before and after intervention. Independent t-test and chi-square test was used to assess difference in severity of mitral stenosis before and after PTMC in different age groups with $p<0.05$ as statistical significance. A total of 60 subjects with severe mitral stenosis underwent PTMC. Mean age was 29.98±10.824 years. The younger group <35 years were 68.3% and 31.7% were older between 36-60 years. There were 88.3% female. Mean pre- and post-PTMC MVA was 0.83±0.133 and 1.53±0.383 cm ($t=2.172$ $p<.034$), respectively. Similarly mean pre- and post-PTMC MVPG was 27.20±6.802 and 12.88±6.3813 ($t=4.591$ $p<0.000$). The success rate of the PTMC was significantly higher among 10-35 years 87.8% than 36-60 years 52.7% ($X=8.979$, $p=0.003$).

Conclusions: PTMC is a safe and effective treatment for patients with severe MS who have suitable valve morphology especially at younger age.

TAVI - Tools, devices and techniques

Superior short-term haemodynamic outcomes when comparing TAVI to sutureless surgical AVR using a Perceval valve

KEMPTON Hannah [1], KEMPTON Hannah [1], KATHERINE Jones [1], JAMES Carroll [1], KATHERINE Kearney [1], NICOLE Bart [1], JUSTIN Phan [1], ALEXIA Arriagada [1], DAVID Baron [1], DAVID Muller [1], DAVID Roy [1]

(1) St Vincent's Hospital, NSW, Australia

Aims: Since the introduction of TAVI, there has been extensive comparison of TAVI and surgical aortic valve replacement (SAVR). Increasingly, data is emerging for non-inferiority of TAVI for indications beyond surgical risk profile. While newer generations of TAVI valves and increasing experience with their implantation has reduced complications and improved haemodynamic results, surgical valve technology has advanced to include sutureless valves, reducing surgical morbidity. The aim of this study was to compare the short-term haemodynamic outcomes between TAVI and the sutureless Perceval valve.

Methods and results: Data for all patients who underwent TAVI and SAVR with a Perceval valve were extracted from registries at a single-centre. This included all patients since establishment of the programs, TAVI since 2008 and Perceval since 2014. Data included patient demographics, valve characteristics and surgical outcomes. The primary outcome was the difference in peak and mean aortic valve gradient based on measurements on postoperative echocardiogram within 3 months. Secondary outcomes included length of stay, pre- and postoperative haemoglobin (Hb), and requirement for postoperative permanent pacemaker during the same admission. All generations of TAVI valve were included in the cohort. There were 522 patients in the TAVI and 42 patients in the SAVR cohort. The average age of the Perceval valve cohort was 73.7 years, compared to 83.6 years in the TAVI cohort. TAVI valves used in this cohort included CoreValve (21%), Evolut (43%), ACURATE (2%), SAPIEN (32%) and Lotus (2%). TAVI patients had a significantly lower postoperative peak and mean valvular gradient (16.7±7.2mmHg and 8.9±4.8mmHg) compared to the Perceval valve cohort (24.1±7.6mmHg and 13.5±4.3mmHg) ($p<0.005$). Within the TAVI cohort, CoreValve had a peak and mean gradient of 14.6±5.5mmHg and 7.9±3.6mmHg, Evolut a peak and mean gradient of 15.5±6.8mmHg and 8.2±4.6mmHg, ACURATE a peak and mean gradient of 22.0±10.7mmHg and 14.5±6.4mmHg, SAPIEN a peak gradient of 18.7±7.6mmHg and mean of 10.3±5.1mmHg and Lotus a peak gradient of 20.0±10.2mmHg and a mean gradient of 9.25±5.7mmHg. The self-expanding TAVI valves (CoreValve, Evolut, and ACURATE; 64%) had significantly lower peak and mean gradients compared to their balloon and mechanically expandable counterparts (15.4±6.5 v 18.9±7.7 and 8.3±4.4 v 10.3±5.2 respectively; $p<0.0001$). With regards to secondary outcomes, TAVI patients had a shorter length of stay (mean 10.1±11.6 days compared to 12.8±6.6 days), however this was not statistically significant ($p<0.07$). Patients who had a SAVR experienced a greater fall in their postoperative Hb than the TAVI cohort (mean Hb 97.4±12.4g/L compared to 106.9±15.5/L; a fall of 13.8±11.1g/L and 31.0±11.6g/L respectively), which was statistically significant ($p<0.005$). SAVR patients were significantly more likely than TAVI patients to require postoperative permanent pacemaker (14% v 6% respectively; $p=0.036$).

Conclusions: TAVI demonstrates lower peak and mean valvular gradients in the early postoperative period when compared to SAVR with the Perceval valve. The superior haemodynamic performance is most apparent in self-expanding valves. TAVI patients were less likely to require a pacemaker postoperatively, and had a smaller reduction in their haemoglobin compared to SAVR patients.

TAVI - Echocardiography

Long-term follow-up and durability of TAVI devices

KEARNEY Katherine [(1)], KEARNEY Katherine [(1)], JONES Katherine [(1)], CARROLL James [(1)], KEMPTON Hannah [(1)], BART Nicole [(1)], ARRIAGADA Alexis [(1)], BARON David [(1)], MULLER David [(1)], ROY David [(1)]

(1) St Vincent's Hospital, NSW, Australia

Aims: To review valve durability, haemodynamic outcomes and patient survival at greater than 4 years following transcatheter aortic valve implantation (TAVI).

Methods and results: In a retrospective cohort analysis, we examined all 523 patients who underwent TAVI between 2008 and 2019 at a single-centre. There were 116 patients between 2008 and December 2015 (mean age 83.6±11 years). Patient demographic data were consistent with high and prohibitive surgical risk cohort. The Medtronic CoreValve was used in 63 cases, and the Edwards SAPIEN or XT valve in 52 cases. Procedures were performed transfemorally in 107 cases, transapically in 7 and via direct aortic access in 1 case. Mean survival post implant was 6.3 years. Expected actuarial survival for general population survival in 2011 at age 83 was 6.6±2 years. 26 (22.2%) patients died during the follow-up period. For the patients who had medication data available, 17 (24.2%) were on anticoagulants (warfarin or NOAC), 21 (30%) were on a single antiplatelet and 40 (57%) were on dual antiplatelets. Follow up echocardiographic data was available for 13 patients at greater than 4 years post implant. In these patients, peak gradient was 20±10 mmHg, mean gradient 11±5 mmHg. 3 patients had no paravalvular leak, 5 patients had trivial PVL, 3 mild PVL and 1 moderate PVL. 1 patient underwent surgical aortic valve replacement after 4 years, because of concomitant severe mitral incompetence. For these patients, mean follow up duration was 5.7±1.6 years.

Conclusions: In a high and prohibitive surgical risk cohort, patient survival and device durability were excellent. In this high risk group, patient mortality was commensurate with actuarial survival for given age.

Mitral valve replacement and repair - Echocardiography

Prevalence and clinical impact of iatrogenic atrial septal defects after TMVR in long-term follow-up

PAUKOVITSCH Michael [1], TILMAN Stephan [1], SCHNEIDER Leonhard [1], ROTTBAUER Wolfgang [1], KEßLER Mirjam [1], MARKOVIC Sinisa [1]

(1) Department of Internal Medicine II, Ulm, Germany

Aims: To investigate prevalence and clinical impact of iatrogenic atrial septal defect after TMVR in long-term follow-up using transoesophageal echocardiography.

Methods and results: 43 patients, who had undergone TMVR between January 2017 and June 2018 at our university hospital, were enrolled in this prospective study. Study protocol entailed a minimum 12 months follow-up for each patient and included physical assessment as well as transthoracic echocardiography and transoesophageal echocardiography. Primary outcome measure was persistence of atrial septal defects in transoesophageal echocardiography. Secondary endpoint measure entailed recurrent mitral valve regurgitation after TMVR, New York Heart Association functional class, systolic pulmonary artery pressure and left atrial diameter. Median clinical follow up time was 20.9 months after TMVR. Persistent iatrogenic atrial septal defect was found in 43.2% of patients (N=19). Those patients were compared to the group of patients who had no evidence of persistent iatrogenic atrial septal defect in echocardiography (N=24; 55.8%). Both groups showed comparable rates of recurrent MR (5.3% vs 13.0%; p=0.46) after TMVR as well as sustained improvement of functional capacity measured with the New York Heart Association classification (2.2 vs 1.8; p=0.13) and 6 minute walk test (301m vs 311m; p=0.78). Echocardiographic parameters were similar in both groups except for left atrial diameter at follow-up and tricuspid regurgitation at baseline. While left atrial diameter at follow-up was considerably smaller in the group with persistent atrial septal defect (51.4±7.2 cm vs 57.4±6.1; p=0.02), grade of tricuspid regurgitation at baseline was higher in this group (1.9±0.7 vs 1.3±0.5; p<0.01). Comparison of baseline and follow up left atrial diameter did not show significant differences. (p=0,1).

Conclusions: Prevalence of iatrogenic atrial septal defects during 20 months follow-up was 43.2% and did not seem to impact clinical and functional parameters negatively. A reasonable explanation for the persistence of iatrogenic atrial septal defect after transseptal puncture with the 22 Fr catheter could not be determined in this study.

TAVI - Tools, devices and techniques

Radiologic and histologic calcification is uncommon after CoreValve bioprosthesis implantation through five years

SATO Yu [(1)], SATO Yu [(1)], JINNOUCHI Hiroyuki [(1)], SAKAMOTO Atsushi [(1)], KAWAKAMI Rika [(1)], MORI Masayuki [(1)], CORNELISSEN Anne [(1)], SURVE Dipti [(1)], ROMERO Maria [(1)], VIRMANI Renu [(1)], FINN Aloke [(1,2)]

(1) Cvpath Institute Inc, MD, USA; (2) University of Maryland, Baltimore County, MD, USA

Aims: Transcatheter aortic valve implantation (TAVI) for low-risk patients is warranted from early data from randomised controlled trials. However, the long-term data on durability of TAVI valves is limited and available only in extreme-, high- or intermediate-risk patients. One of the main causes of long-term bioprosthetic valve failure is leaflet calcification, the prevalence of which has been studied in clinical studies, but no large pathologic data of long-term valves are available. This study aims to evaluate the prevalence of leaflet calcification in TAVI valves removed at surgery or autopsy.

Methods and results: A total of 115 TAVI self-expanding prosthetic valves were received at CVPath Institute from April 2011 to January 2020. The cases were collected from 5 clinical trials (CoreValve US Pivotal Trial, CoreValve Continued Access Studies, CoreValve Expanded Use Study, the SURTAVI trial, and Evolut Low Risk). Ninety-two autopsy- and 23 surgical-explanted cases were received fixed in 10% neutral buffered formalin and examined by cardiovascular pathologists. The valve leaflets were radiographed and examined grossly and histologically. Each leaflet was cut longitudinally at 2 to 3 mm intervals with minimum of 4 to 5 sections per leaflet, (total leaflets examined 345) and stained with H&E, Movat pentachrome and von Kossa stain for calcification. Each parameter was given a score as previously described (Yahagi et al. Cath Cardiovasc Interv 2017). The duration of implantation was over 6 months in 42 cases and of these 33 cases were implanted for over 1 year. Eight of 115 cases (7%) showed leaflet calcification. Two cases were mild, and the others had minimum calcification, none was significant enough to cause valve dysfunction. The median age of these 8 cases was 86 years (Q1, Q3; 76-95), 50% were male, 7 cases had a history of hypertension, and 5 cases had chronic kidney disease. The median duration of implantation was significantly longer in cases with calcification than cases without calcification (926.5 days [Q1, Q3; 295.3-1413 days] vs 50.5 days [Q1, Q3; 12.8-403.3 days], p=0.0007) and no cases of calcification occurred before 6 months post valve implantation. Six cases showed extrinsic calcification and 2 cases showed intrinsic calcification. Extrinsic calcification occurred in the presence of thrombus and rarely within the neointima. The mean duration of implantation was longer in the cases with intrinsic calcification (1,223±349 days) than the cases with extrinsic calcification (807±619 days), but there was no difference in the age of the patients.

Conclusions: Calcification was uncommonly observed in CoreValves that have been implanted up to 5 years, and when it occurred it was minimal or mild without associated valve dysfunction and dependent on the duration of implantation. To our knowledge, this is the first study to report a detailed examination of histologic and radiographic valve calcification in a large number of cases implanted >6 months.

TAVI - Adjunctive pharmacotherapy

Optimal anticoagulation during TAVR, a single-centre high-volume registry analysis

AVINEE Guillaume [1], AVINEE Guillaume [1], SIDDIQUI SAIF [1], GHATTAS Angie [1], LAPERCHE Clemence [1], AGUDZE Edem [1], CHARBONNIER Gaetan [1], FERRARA Jerome [1], DUBOIS Daniela [1], DUMONTEIL Nicolas [1], TCHETCHE Didier [1]

(1) Clinique Pasteur, Toulouse, France

Aims: As most interventional cardiology procedures, TAVR is usually performed under parenteral anticoagulation. The aim of the study was to assess the optimal level of anticoagulation during TAVR procedures.

Methods and results: Since 2015 every TAVR performed in our centre has been included in a single-centre registry. The administration of unfractioned heparin is performed after successful vascular access and the activated clotting time is measured after crossing the valve. Three groups of patients were defined according to activated clotting time. Less than 200, 200 to 250 and greater than 250 seconds, respectively. Outcomes were defined according to the updated definitions of the Valve Academic Research Consortium. The primary endpoint was 30-day mortality. The secondary endpoints were bleeding, vascular complication, stroke, and transient ischaemic attack. From 2015 to 2018, 2,026 consecutive patients benefited from TAVR with proper activated clotting time measurement. Among them 501 had activated clotting time <200s, 852 were between 200-250s and 673 were >250s. Baseline characteristics were similar between groups. Overall mean age was 83.8 (± 5.8), 1020 (50.4%) were men, mean logistic EuroSCORE was 16.6 (± 10.2). The type of valve differed: EVOLUT self-expanding valve in 72.3%, 67.5% and 58.8%, respectively, p<0.0001, 75.1% of alternative valves were balloon expandable SAPIEN 3 valves. The heparin dose was 46.4±15.2, 46.2±12.7, 51.1±15.5, respectively (p<0.0001). The procedure durations were short and varied significantly between groups, respectively 45±17.6, 48.3±1.7 and 46.9±18.0 minutes, p=0.043). The primary outcome did not vary between groups, respectively occurring in 0.5%, 2.3% and 1.1% (p=0.216). Incidence of stroke was low and did not vary (overall incidence 1.2%). The rate of transient ischaemic attack was significantly higher in the activated clotting time <200 group vs the two others (pooled), respectively 1.9% vs 0.3% p=0.017 (p=0.032 after adjustment according to the type of valve and procedure duration). Bleeding complications did not vary significantly, neither did transfusion rates, respectively 8.9% and 12.2%. However, we observed a trend towards higher transfusion rates for higher activated clotting time levels, respectively 9.9%, 12.0% and 14.2%, which was not significant (p=0.281).

Conclusions: In our single-centre high-volume experience, different levels of activated clotting time had no significant impact on 30-day death, stroke and bleeding complications. Lower activated clotting time rates were associated with higher occurrence of transient ischaemic attack. Usual dose of 50UI/kg of unfractioned heparin seems to afford the best benefit risk ratio.

TAVI - Tools, devices and techniques

Patient-specific computer simulation in TAVI with the self-expanding Evolut R valve. The multicentre prospective TAVIguide study

EL FAQUIR Nahid [1], EL FAQUIR Nahid [1], DE BACKER Ole [2], BOSMANS Johan [3], RUDOLPH Tanja [4,7], BUZZATTI Nicola [5], LATIB Azeem [5], ADAM Matti [4], REN Ben [1,6], VAN MIEGHEM Nicolas [1], DE JAEGERE Peter [1]

(1) Erasmus MC, Rotterdam, the Netherlands; (2) Rigshospitalet, Copenhagen Municipality, Denmark; (3) University Hospital Antwerp, Edegem, Belgium; (4) University Hospital Cologne, Cologne, Germany; (5) San Raffaele Hospital, Metropolitan City of Milan, Italy; (6) Cardialysis, Rotterdam, the Netherlands; (7) Ruhr-Universität Bochum, Bochum, Germany

Aims: Optimal outcome after TAVI may become more important as TAVI shifts towards low-risk patients. Patient-specific computer simulation is able to provide prediction of outcome after TAVI. However, its clinical role and validation of accuracy have not been studied prospectively yet. Therefore, we aimed to assess the added value and predictive power of the TAVIguide software in clinical practice.

Methods and results: This concerns a prospective observational multicentre study including 80 patients with severe aortic stenosis treated with the Evolut R. Simulation was performed in 42 patients and no simulation in 38. A comparison between the valve size (D1) and target depth of implantation (DOI1) selected by the operator based on MSCT and those selected after availability of simulation results (D2 and DOI2) were the primary endpoints. The predictive power was examined by comparing the simulated and observed degree of aortic regurgitation (AR). D2 differed from D1 in 1/42 patients due to the predicted AR and change in valve type occurred in 2/42. In 39/42 patients D1 and D2 were similar. DOI2 differed from DOI1 in 7/42 patients (lower in 4/7 and higher in 3/7). In 16/42 patients, simulation affected the TAVI procedure; in 9/16 the operator avoided additional measures to achieve the target DOI (DOI1) and in 7/16 patients additional measures were performed. There was a trend for higher degree of predicted than observed AR (17.5 vs 12 ml/s, p=0.13).

Conclusions: Patient-specific computer simulation did not affect valve size selection but did affect the selection of the target DOI and the execution of TAVI to achieve the desired target DOI.

TAVI - Tools, devices and techniques

A novel supra-annular TAVI prosthesis sizing assessment in raphe-type bicuspid aortic valve disease: the Level of Implantation at the RAphe (LIRA) plane method

IANNOPOLLO Gianmarco [1], IANNOPOLLO Gianmarco [1,3], ROMANO Vittorio [1], BUZZATTI Nicola [1], ANCONA Marco [1], FERRI Luca [1], RUSSO Filippo [1], BELLINI Barbara [1], GRANADA Juan [2], CHIEFFO Alaide [1], MONTORFANO Matteo [1]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy; (2) Cardiovascular Research Foundation, NY, USA; (3) Maggiore, Metropolitan City of Bologna, Italy

Aims: Recent evidence shows that TAVI prosthesis anchoring occurs at the raphe-level, known as Level of Implantation at the RAphe (LIRA) plane, in raphe-type bicuspid aortic valve (BAV) disease. Supra-annular prosthesis sizing in BAV disease is a concept not reproducibly demonstrated and specific measurements are not standardised among operators. The purpose of this study was to evaluate the application of a novel supra-annular prosthesis sizing method (the LIRA plane method) to optimise TAVI prosthesis sizing in raphe-type BAV disease.

Methods and results: The LIRA plane method was applied to all consecutive patients with raphe-type BAV disease between November 2018 and December 2019 in our centre. We prospectively sized TAVI prostheses according to the manufacture recommendations based on baseline CT scan perimeters at the LIRA plane. Post-procedural device success defined according to Valve Academic Research Consortium–2 (VARC-2) criteria, was evaluated in the overall cohort. 20 patients were identified as having a raphe-type BAV disease at pre-TAVI CT scans. Mean patient age was 81±5.4 years and 70% were males; median Society of Thoracic Surgeons (STS) predicted risk of mortality score was 4.3 (3.0-6.5). Three different BAV anatomies (15 patients with BAV type 1 with calcific raphe, 2 patients with BAV type 1 with fibrotic raphe and 3 patients with BAV type 2) were implanted with different types of TAVI prostheses (13 ACURATE Neo, 6 CoreValve Evolut R/Pro,1 Lotus) sized prospectively according to the LIRA plane method. In all patients, there was a significant discrepancy between LIRA and virtual basal ring (VBR) measurements with LIRA plane perimeter smaller than VBR perimeter (mean perimeter LIRA 72.8±7.9 mm vs mean perimeter VBR 82.2±6.6 mm; $p<0.001$). The prostheses were sized according to the manufacture recommendations on the basis of the LIRA plane perimeter (diameter prosthesis implanted/diameter prosthesis according to LIRA plane =1)(DPI/DP LIRA=1) and significantly downsized according to the VBR perimeter (DPI/DP VBR 0.89; $p<0.001$). The median prosthesis size was 25 mm (23-27). Predilatation was frequently performed (85%) with a median balloon size of 20 mm (18-22), whereas post-dilatation was applied in 25% of the cases with a median balloon size of 23 mm (22-26). The LIRA plane method appeared to be highly successful (95% VARC-2 device success) with no procedural mortality, no valve migration, residual trivial/mild paravalvular leak with only 1 case of moderate regurgitation and low transprosthetic gradient (residual mean gradient of 8.2±2.9 mmHg) with no cases of mean gradient >20 mmHg pre-discharge.

Conclusions: Supra-annular sizing according to the LIRA plane method appeared to be safe with a high device success. The application of the LIRA plane method might optimise TAVI prosthesis sizing in patients with raphe-type BAV disease.

TAVI - Tools, devices and techniques

The prevalence of aortic valve disease and current practice of TAVI in different regions – a contemporary review

JIA Kaiyu [1], JIA Kaiyu [1], LI Yiming [1], HE Jingjing [1], JIA Yuheng [1], CHEN Mao [1]

(1) Sichuan University, Sichuan, China

Aims: The aim of this study was to assess the prevalence and aetiology of aortic valve disease (AVD), and to define the baseline characteristics and clinical outcomes of TAVI patients in under-developed, developing and developed parts of the world.

Methods and results: A systematic search was conducted in PubMed, Medline and Embase. Baseline characteristics (age, sex, STS score) and mortality of TAVI patients as well as AVD prevalence were pooled using meta-analysis. Data from 22 epidemiology studies were used. The pooled global prevalence of AVD was 1.8% (95% CI, 1.7% to 2.0%). Higher AVD prevalence in Asia (2.8%, 95% CI: 2.4% to 3.3%), Africa (3.0%, 95% CI: 1.0% to 5.0%) and South America (2.8%, 95% CI: 2.5% to 3.1%) were observed compared to North America (1.4%, 95% CI: 0.8% to 2.0%) and Europe (0.7%, 95% CI: 0.5% to 0.8%). Calcific aortic stenosis (AS) presents as the main form of AVD in Western worlds and some developed areas of Asia due to the aging demographics whereas rheumatic aetiology takes up a major portion of AVD diagnosed in Africa and South America. A total of 25 TAVI studies from 16 nationwide and cross-regional TAVI registries were identified. The pooled age of TAVI patients was 82.26 (95% CI: 82.22 to 82.30), male ratio was 47% (95% CI: 44% to 49%) and STS score was 6.01 (95% CI: 5.99 to 6.03). Age and sex ratio of TAVI patients were similar among different centres while STS score exhibited significant variations. Highest baseline STS score of 14.20(95% CI: 13.10 to 15.30) and lowest baseline STS score of 5.25 (95% CI: 5.21 to 5.30) were observed in South America and Europe, respectively. The pooled 30-day mortality was 5.9% (95% CI: 4.6% to 7.2%) and 1-year mortality was 16.7% (95% CI: 14.3% to 19.2%). Lowest 30-day mortality (2.5%, 95% CI: 1.4% to 3.5%) and 1-year mortality (9.0%, 95% CI: 7.6% to 10.4%) were observed in Asia. Highest 30-day mortality (9.1%, 95% CI: 6.3% to 11.8%) and 1-year mortality (21.5%, 95% CI: 17.6% to 25.5%) were observed in South America. TAVI patients in developed areas of North America, Europe and Asia were of lower risk and had lower mortality in comparison to under-developed areas of South America.

Conclusions: The global burden of AVD exhibited much diversity among regions of different socio-economic status and exerts a heavy impact on healthcare resources. The non-calcific aetiology and high-risk score pose as the main obstacles for TAVI dissemination and are responsible for the relatively high mortality in developing and under-developed areas.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Pulmonary haemodynamic profile predicts mortality after transcatheter tricuspid valve repair in chronic heart failure patients

STOCKER Thomas [1], STOCKER Thomas [1], ROMMEL Karl-Philipp [2], RUF Tobias [3], ONG Geraldine [4], FAM Neil [4], VON BARDELEBEN Ralph Stephan [3], LURZ Philipp [2], HAUSLEITER Jörg [1]

(1) Medizinische Klinik und Poliklinik I, Klinikum der Universität München, Ludwig-Maximilians-Universität, Munich, Germany; (2) Leipzig Heart Center, University of Leipzig, Leipzig, Germany; (3) Mainz University Hospital, University of Mainz, Mainz, Germany; (4) Division of Cardiology, St. Michael's Hospital, University of Toronto, Toronto, Canada

Aims: Severe tricuspid regurgitation (TR) is associated with increased mortality in chronic heart failure. Transcatheter tricuspid valve repair (TTVR) has been demonstrated to effectively reduce TR and improve heart failure symptoms. However, the haemodynamic impact of TTVR, as well as haemodynamic predictors for mortality after TTVR are largely unknown. This study has been designed to assess haemodynamic changes after TTVR and to evaluate the pulmonary haemodynamic profile of patients undergoing TTVR.

Methods and results: In this international, multicentre study, 236 patients (median age 78 years, 53% female) from 4 sites in Germany and Canada have been enrolled. At baseline, all patients suffered from right-sided heart failure (88% NYHA III or IV) due to severe TR and underwent TTVR (tricuspid edge-to-edge repair in 100%) in accordance to interdisciplinary Heart Team consensus. Diagnostic right heart catheterisation (RHC) was performed intra-procedurally before TTVR. RHC demonstrated median cardiac index of 2.2 l/min/m^2 (interquartile range, IQR 1.8 to 2.9 l/min/m^2), systolic pulmonary artery pressure (sPAP) of 45 mmHg (interquartile range, IQR, 37 to 57 mmHg), mean pulmonary artery pressure (mPAP) of 30 mmHg (IQR 24 to 36 mmHg), transpulmonary pressure gradient (TPG) of 10 mmHg (IQR 7 to 15 mmHg), and pulmonary vascular resistance (PVR) of 2.3 Wood units (IQR 1.7 to 3.4 Wood units). TTVR induced an immediate 19% reduction of the median right-atrial v wave (pre-TTVR: 21 mmHg, IQR 15 to 28 mmHg; post-TTVR: 16 mmHg, IQR 12 to 21 mmHg; $p<0.001$). In a Cox proportional regression model, we identified sPAP, mPAP, TPG, PVR, and right ventricular stroke work (RVSW) as significant predictors for mortality after TTVR (all $p<0.05$). Other haemodynamic measures including cardiac output, pulmonary artery pulsatility index (PAPi), right atrial pressure, and cardiac filling pressure (CFP) were not significant predictors for mortality after TTVR. All patients were stratified regarding the presence of pulmonary hypertension (PH; mPAP threshold: 25 mmHg). PH-positive patients were subsequently stratified into pre- or post-capillary PH as defined by receiver operating characteristic analysis of TPG (TPG threshold: 17.5 mmHg; 85% specificity for mortality). Accordingly, patients were grouped into PH-negative (mPAP <25 mmHg; 65 patients), post-capillary PH (mPAP ≥25 mmHg, TPG <7.5 mmHg; 126 patients) and pre-capillary PH (mPAP ≥25 mmHg, TPG ≥17.5 mmHg; 32 patients). Patients grouped into pre-capillary PH had a significantly increased median PVR, when compared to post-capillary PH (4.8 Wood units vs 2.3 Wood units, $p<0.001$). Patients with pre-capillary PH showed a significantly increased 1-year mortality after TTVR (logrank test $p<0.001$; Figure 1). However, TTVR induced symptomatic improvement also in patients with pre-capillary PH, when compared to all other patients (pre-capillary PH vs PH-negative and post-capillary PH). This was shown for an improvement in NYHA functional class (64% vs 65%, $p=0.91$) as well as improved median six-minute walk distance (42 m vs 39 m, $p=0.469$) between baseline and follow-up assessment.

Conclusions: Assessment of the pulmonary haemodynamic profile including pulmonary hypertension and transpulmonary gradient predicts 1-year mortality after TTVR and should be incorporated in the patient selection for TTVR.

Mitral valve replacement and repair - Tools, devices and techniques

Single-centre early experience using the PASCAL repair system for transcatheter treatment of mitral regurgitation in 50 consecutive patients

BESLER Christian [1], NOACK Thilo [1], VON ROEDER Maximilian [1], KITAMURA Mitsunobu [1], FLO FORNER Anna [1], BEVILACQUA Carmine [1], ENDER Joerg [1], BORGER Michael [1], THIELE Holger [1], LURZ Philipp [1]

(1) Heart Center Leipzig, Leipzig, Germany

Aims: Mitral regurgitation (MR) is common and recent data imply an ongoing need for less invasive treatment options to improve the morbidity and poor outcome of MR in older patients. The PASCAL transcatheter valve repair system (Edwards Lifesciences, Irvine, California) was recently introduced as a novel leaflet device for transcatheter mitral valve repair (TMVr). The present study sought to characterise the real-world performance of the PASCAL system outside of clinical studies and to provide a more detailed analysis of procedural aspects.

Methods and results: Treated patients had severe MR and New York Heart Association (NYHA) functional class ≥II despite optimal medical therapy. All patients were discussed within the Heart Team and an interventional approach for MR treatment was considered as the best treatment option due to increased surgical risk. Procedural details, success rate, impact on MR severity, and the effect on functional status after one month of follow-up are reported. Fifty patients (median age 78.0 [IQR 74.5-81.0], 52% female, log EuroSCORE 21.6 [IQR 13.2-30.2]) were treated with the PASCAL system between February and November 2019. Functional and degenerative MR was present in 68% and 24% of patients, respectively, with a mixed aetiology observed in 8%. Mean left ventricular ejection fraction and median left ventricular end-diastolic volume were 46±16% and 151 (IQR 107-217) ml, respectively. Concomitant moderate or severe tricuspid regurgitation (TR) was observed in 23/50 (46%) patients. A total of 75 PASCAL devices were implanted in 50 patients (1 device in 26 patients, 2 devices in 23 patients, 3 devices in 1 patient). Mean duration of the procedure significantly decreased from 78±24 min for the first 15 procedures to 60±20 min for the remaining procedures. Besides one major bleeding episode during femoral access, no adverse procedure-related events occurred. At discharge, MR was reduced by at least one grade in all but one patient in whom a complete dislodgement of the device was apparent. At 30 days follow-up, one patient died for progressive heart failure despite successful MR reduction with a discharge MR grade of 1. On echocardiography after one month, a single leaflet device attachment was present in one patient with recurrent MR 3+. MR reduction to grade 2+ was maintained in 43/48 (90%) and 1+ in 34/48 (71%) of patients with one-month follow-up. Median transvalvular gradient across the mitral valve increased from 1.1 (0.5-2.1) mmHg to 3.2 (2.6-4.0) mmHg, but remained ≤5 mmHg in all patients irrespective of the number of devices implanted. On follow-up, 35/48 (73%) patients reported an improvement in NYHA functional class and 37/48 (77%) patients were in NYHA functional class I or II. Mean 6MWD increased from 320±83 to 393±95 m in patients with mild TR, but remained unchanged in patients with moderate or severe TR. No significant change in NT-proBNP levels was observed.

Conclusions: TMVr using the PASCAL system showed feasibility and acceptable safety in this largest single-centre real-world analysis. The device effectively reduced MR of functional and degenerative aetiology and led to improvements in NYHA functional class and 6MWD after one month of follow-up. Future studies are needed to address the question which TMVr device is best suited to reduce MR in a given anatomical situation.

TAVI - Echocardiography

Refining threshold of patient-prosthesis mismatch among overweight/obese patients undergoing TAVR

FERRARA Jerome [1], FERRARA Jérôme [1], THERON Alexis [1], CUISSET Thomas [1], DEHARO Pierre [1], COLLART Frédéric [1]

(1) APHM Hopital La Timone Adultes, Marseille, France

Aims: Obese patients (BMI ≥30 kg/m²) seem to be protected from the consequences of patient-prosthesis mismatch (PPM) which defines the obesity paradox. It may be the consequence of PPM overestimation severity in this category but also in overweight patients (BMI ≥25 kg/m²) undergoing TAVR. PPM definition may need to be revised in this subset of population. Our purpose is: 1/ to confirm the overweight/obesity paradox (i.e., BMI ≥25 kg/m²) in a population with severe AS undergoing TAVR; 2/ to determine a new prognostic cutoff of indexed effective orifice area in this population.

Methods and results: Inclusion criteria: severe symptomatic AS treated with TAVR (balloon-expandable or self-expanding aortic valve). Primary endpoint: composite criterion of all-cause mortality and/or hospitalisation for congestive heart failure at one year. Secondary endpoints: all-cause mortality and hospitalisation for congestive heart failure at one year. Four hundred and seventy-seven patients were included from February 2015 to May 2018. Mean age was 82.12±5.96 years with a majority of male gender (50.52%). Mean BMI was 26.19±4.48 kg/m². Two hundred and sixty patients (54.5%) had a BMI ≥25 kg/m² including 94 patients (19.71%) with BMI ≥30 kg/m². PPM occurred in 161 patients (33.75%). Among patients with PPM, 96 patients (59.63%) had a BMI ≥25 kg/m² including 40 patients (24.84%) with BMI≥30 kg/m². The composite endpoint occurred in 11/96 patients (11.46%) in the overweight/obesity subgroup versus 16/65 patients (24.61%) in patients with BMI <25 kg/m² with a significant difference (HR=0.43 [95% CI: 0.20, 0.91], p=0.03). An iEOA ≤0.85 cm²/m² was not associated with the occurrence of the composite criterion in the overweight/obese subgroup (HR=1.47 [95% CI: 0.61; 3.48], p=0.38) while iEOA <0.65 cm²/m² was a predictor of outcomes (HR=3.28 [95% CI: 1.01,8.59], p=0.04) with 93% specificity and 93% negative predictive value.

Conclusions: The negative impact of PPM is alleviated once BMI ≥25 kg/m². This illustrates the "overweight/obesity" paradox and makes the current definition of PPM likely to be obsolete in this specific subset of population. We therefore suggest the iEOA cutoff of 0.65 cm²/m² as a new definition of PPM in overweight/obese patients.

TAVI - Tools, devices and techniques

The Symetis ACURATE neo transcatheter heart valve: results in an experienced centre

JIMÉNEZ Miriam [(1)], JIMÉNEZ FERNÁNDEZ Miriam [(1)], ALCALDE MARTINEZ Vicente [(1)], SÁNCHEZ GILA Joaquín [(1)], RIVERA LÓPEZ Ricardo [(1)], MOLINA NAVARRO Eduardo [(1)]

(1) Virgen de las Nieves, Granada, Spain

Aims: TAVI has been proved to be a valuable alternative to conventional surgical AVR; its use has hugely increased due to its high efficacy and safety profile. New catheter-based prostheses have been developed since the first devices trying to improve some imperfections, such as perivalvular leaks or rhythm disturbances. We report our experience with a second-generation of TAVI device; Symetis ACURATE Neo®.

Methods and results: From June 2017 until November 2019, 81 patients with severe symptomatic aortic stenosis underwent TAVR with Symetis ACURATE Neo bioprosthesis, which means 28% of all TAVI in our centre in this period.The device was chosen due to the presence of severe coronary artery disease, dilated or angled ascending aorta, low origin of coronary arteries or extremely narrow sinus of Valsalva, where the risk of coronary ostium occlusion is higher.We evaluate patient characteristics, procedure performance and results, complications related with TAVI, short- and mid-term clinical follow-up. Regarding patient baseline characteristics, the mean age was 81 and 58% of them were women. 46,9% suffered from diabetes mellitus and 81.48% from hypertension;11.1% had prior stroke and 23.5% prior ischaemic cardiomypathy. The mean aortic valve area was 0.74cm^2 with a mean transaortic gradient of 49mmHg and a prior LEVF of 55.78%. Most patients presented high or intermediate surgical risk, with a mean Logistic EuroSCORE of 11.1% and STS score of 4.64%. 63.8% of patients had a Charlson index of 6 or more (high frailty). All procedures were performed by transfemoral access. A small valve was used in 21%, medium in 47.4% and large in 31.6%. Prior valvuloplasty was performed in all cases and balloon post-dilatation was required in 8.8% in order to reduce perivalvular leak. Closure of vascular access was performed with Prostar® device in all cases. The procedure was successfully and safely performed in 98.8% of cases (a prosthesis migration occurred in one patient, requiring a second ACURATE device implantation). A great improvement of cardiac haemodinamics was immediately observed after implantation in all cases, with no significant residual gradient. Echocardiographic moderate and severe post-implantation aortic regurgitation was present in 17.3% and 1.2% without clinical impairment. Procedure-related complications were: 7 complete atrioventricular blocks, 12 new left bundle branch blocks and 2 major vascular complications (one severe femoral bleeding with secondary haemorragic shock requiring vascular surgery and one solved with stent implantation). The mean hospitalisation time was 8.11 days. No strokes, myocardial infarctions or deaths occurred during hospitalisation; one patient presented a massive pulmonary embolism solved with parenteral anticoagulation. 9 patients (11.1%) developed rhythm disturbances needing definite pacemaker implantation. A follow-up of 320±222 days was performed. During this period, we reported 2 strokes (2.5%), 6 readmissions due to heart failure (7.4%) and 3 major bleedings (3.7%). Cardiovascular and all-cause mortality at 30 days were 1.23% and 2.5%. At one year-follow up, cardiovascular and all-cause mortality were 7.4% and 11.1%.

Conclusions: Symetis ACURATE Neo remains a valuable alternative to other prostheses previously tested and widely used nowadays. It is a reliable device, offering predictable, effective, and safe results, not increasing perivalvular leaks or the need for pacemaker implantations when compared to similar devices.

Tricuspid / Pulmonary valve - Tools, devices and techniques

In-hospital clinical and echocardiographic outcomes of transcatheter tricuspid treatment: experience of three centres

ESTEVEZ-LOUREIRO Rodrigo [1], ESTEVEZ-LOUREIRO Rodrigo [1], PORTOLES Antonio [2], BENITO-GONZALEZ Tomas [3], DEL TRIGO Maria [2], CANEIRO Berenice [1], MONIVAS Vanessa [2], GARROTE-COLOMA Carmen [3], BAZ Jose Antonio [1], MINGO Susana [2], FERNANDEZ-VAZQUEZ Felipe [3]

(1) Hospital Álvaro Cunqueiro, Vigo, Spain; (2) Hospital Puerta de Hierro-Majadahonda, Majadahonda, Spain; (3) Hospital de León, León, Spain

Aims: To describe the early clinical and echocardiographic outcomes of a cohort of patients with symptomatic severe tricuspid regurgitation (TR) treated by means of transcatheter approach.

Methods and results: Registry of all consecutive patients treated by transcatheter tricuspid techniques in 3 Spanish centres between January 2017 and November 2019. Clinical and echocardiographic baseline, intraprocedural and pre-discharge data were collected with the use of a dedicated dataset. Procedural success was defined as patient alive at the end of the procedure, with the device successful implanted and delivery system retrieved, with a residual TR ≤2+ (unless caval device implanted). Mitral Valve Academic Research Consortium criteria were used to define adverse events during hospitalisation. During the study period data from 13 patients (mean age 73.6±8.4 years; 92.3% female) were collected. All patients suffered from functional TR. Likewise, 46.2% had history of prior left-sided surgical valve intervention. In 2 cases, a pacemaker lead was across the tricuspid valve. Patients included were at high surgical risk (mean EuroSCORE II 9.5% and STS PROM 12.7%). All patients were highly symptomatic (NYHA functional class IV 53.8%). TR and grade was 4+ in 100% of the population with a mean vena contracta of 1.1±0.3 cm and mean effective regurgitant orifice of 0.8±0.4 cm^2. A central jet was present in 69.2%. Mean pulmonary pressure pre-intervention was 50±20 mmHg. Regarding procedural data, MitraClip was used in 76.9% of cases, with 2 transcatheter replacements with GATE prosthesis, and 1 caval treatment with Tricento. More than one clip was used in 50%, with 70% implanted in central or antero-septal location. Procedural success was obtained in 61.5% of cases. Excluding caval procedures, in all cases but one TR could be reduced at least one grade (91.6%). No deaths and no conversion to surgery occurred during the hospital admission. Only 2 cases of infection and 1 case of acute kidney injury grade II or III were documented as adverse events. All patients could be discharged home after a mean of 10±9 days with 50% of patients in NYHA functional class ≤II.

Conclusions: transcatheter tricuspid treatment is safe and feasible. It is associated with early reduction in TR and clinical improvement.

TAVI - Tools, devices and techniques

Transaortic balloon expandable valve implantation and sutureless aortic valve replacement. A matched comparative registry in low-risk patients

VEIGA FERNANDEZ Gabriela [(1)], VEIGA FERNANDEZ Gabriela [(1)], DE LA TORRE HERNANDEZ Jose M [(1)], LEE Dae-Hyun [(1)], SAINZ LASO Fermin [(1)], GIL ONGAY Aritz [(1)], SERRANO LOZANO David [(1)], LOZANO GONZALEZ Manuel [(1)], GARCIA CAMARERO Tamara [(1)], ZUECO GIL Javier [(1)]

(1) Hospital Valdecilla, Santander, Spain

Aims: Patients with aortic stenosis may be treated with transcatheter or surgical approaches. Transaortic valve implantation (TAVI) has become an alternative to surgery in a wider range of patients. On the other hand, technological developments have led to a surgically less invasive option for aortic valve replacement which avoids the use of sutures, known as "sutureless" or rapid deployment aortic valves (SU-AVR). The aim of our study was to compare clinical and echocardiographic 1-year outcomes in matched low risk patients treated with TAVI or SU-AVR in our institution.

Methods and results: In the period 2014 to 2018, 74 patients underwent SU-AVR (50% INTUITY and 50% Perceval) and 215 TAVI (100% balloon expandable). After adjustment by surgical risk two groups of 74 patients each were obtained. Patients in TAVI group remained older (76.5± 10 vs 79.6±6.5 yrs; p=0.03) but surgical risks scores were equivalent (EuroSCORE II 2.1± 0.8 vs 2.3±1.4 and STS mortality 2.3±0.6 vs 2.5±0.9, p=0.3 for both). In-hospital stay was shorter in TAVI group (15±8 vs 9±7 days; p<0.001). Clinical outcomes at 12 months: death (6.7% with SU-AVR vs 4% with TAVI; p=0.4), cardiac death (4% vs 0%; p=0.08), myocardial infarction (2.7% vs 0%; p=0.1), stroke (6.7% vs 4%: p=0.4), admission for heart failure (9.4% vs 8.1%; p=0.7), bleeding BARC ≥2 (13.5% vs 6.7%; p=0.1) and major vascular complications (2.7% vs 5.4%; p=0.4). Echocardiographic outcomes at 12 months: perivalvular leak ≥II (12.1% with SU-AVR vs 6.7% with TAVI; p=0.2), mean gradient (11.3±5.6 mmHg vs 11.2±4.4 mmHg; p=0.9) and LVEF (57±9% vs 58±6%; p=0.4). The combined endpoint of death, infarction, stroke and perivalvular leak ≥II was met in 25.6% in SU-AVR group and 10.8% in TAVI group (p=0.03).

Conclusions: In comparable cohorts of patients in terms of low surgical risk, TAVI as compared with SU-AVR was associated to a lower risk of adverse events at 1-year follow-up. Perivalvular leak of at least moderate degree was non-significantly less frequent with TAVI.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Six-month results of the PASCAL transcatheter valve repair system for severe tricuspid regurgitation: a multicentre, observational, first-in-human experience

LURZ Philipp [1], LURZ Philipp [1], FAM Neil [2], KITAMURA Mitsunobu [1], BRAUN Daniel [3], HO Edwin [2], SUGIURA Atsushi [5], NICKENIG Georg [5], DAVIDSON Charles [4], NARANG Akhil [4], HAUSLEITER Joerg [3]

(1) Heart Center Leipzig, Leipzig, Germany; (2) Michaels, ON, Canada; (3) Klinikum der Universität München, Munich, Germany; (4) Bluhm Cardiovascular Institute, Chicago, USA; (5) Herzzentrum Bonn, Bonn, Germany

Aims: We recently reported the feasibility and safety of the PASCAL transcatheter valve repair system for severe tricuspid regurgitation (TR) with promising short-term results. We now report the 6-month outcomes.

Methods and results: Twenty-eight patients treated with the PASCAL repair system with a 6-month follow-up in compassionate use experience were included in this analysis. All patients presented with heart failure due to severe TR despite receiving guideline-directed medical therapy and were considered at high surgical risk by institutional heart teams. Procedural success was defined as the implantation of at least 1 device with post-procedural TR grade ≤2+, with no mortality or conversion to surgery. Major adverse cardiac and cerebrovascular events (MACCE) including all-cause mortality, rehospitalisation due to worsening heart failure symptoms and repeat tricuspid intervention were reported at 6-month follow-up. The mean age was 78±5 years, 17 (61%) were women, with a mean European System for Cardiac Operative Risk Evaluation II score of 4.1±3.7%. TR aetiology was functional in 86%, with the mean tricuspid annular diameter of 51±10mm, and the mean coaptation gap of 7.2±3.5mm. Procedural success was 79%, with 1.7±0.7 devices implanted per patient (86% in anterior-septal commissure and 54% in posterior-septal commissure). There were no intraprocedural complications. At 30-day follow-up, 88% patients were in NYHA I or II, with TR grade ≤2+ in 79%. At 6-month follow-up, MACCEs were 2 cardiac deaths (7.1%), both within the first 30 days due to sudden death (n=1) and terminal heart failure (n=1). 89% patients were in NYHA I or II, with TR grade ≤2+ in 89%. There was one single-leaflet device attachment within the first 30 days, which was managed conservatively. Six-minute walk distance improved by 87m from 238m to 328m at 6 months ($p<0.001$).

Conclusions: This first-in-human experience using the PASCAL transcatheter tricuspid repair system showed promising clinical outcomes with sustainable TR reduction at 6 months. These initial promising results need to be validated in prospective clinical trials.

TAVI - Tools, devices and techniques

Pacemaker implantation after TAVI: clinical and procedural risk factors and the paradox of the depth of valve implantation

GUERRA Elena [1], GUERRA Elena [1], DANIOTTI Alessandro [1], DE LEO Alessandro [1], FAVARO Luca [1], CALZOLARI Diego [1], SCANGIUZZI Claudio [1], CERNETTI Carlo [1]

(1) Ospedale Ca' Foncello, Province of Treviso, Italy

Aims: These days one of TAVI's complications is the appearance of a left bundle branch block and atrioventricular block, which can require the implant of pacemakers. The aim of the study is to evaluate characteristics and risk factors, which could help us understand the reason for a high percentage of pacemaker implants after undergoing TAVI. We can also identify possible predictors of high ventricular pacing at follow-up.

Methods and results: This is retrospective observational study. A database has been created for patients who have undergone TAVI procedure, delving into the follow-up of post-TAVI pacemaker patients (mean follow up 48 months). 604 consecutive patients underwent TAVI from July 2009 to July 2019. Patients already wearing a pacemaker before the TAVI were excluded. 529 patients were included, of whom 104 received an implant after the TAVI (complete AV-block 64%, LBB and bradycardia atrial fibrillation 12%, significant pause 15%, trifascicular block 2%, others 8%). Multivariate analysis confirmed the predictors of pacemaker implant recognised by literature (depth of valve implantation, relatively bigger native valve diameter and pre-TAVI right bundle branch block). Possible predictors of ventricular pacing include oversizing, QRS before TAVI and after TAVI. Meanwhile, the increase of implant depth seems to be related to the percentage of ventricular pacing at follow up (p=0,037). The Kaplan-Meier survival curves comparing the two sub-populations appear similar; around 50% of survivors at 48-month follow-up, showing no correlation between PM implants and mortality.

Conclusions: This study confirms the data regarding predictive factors of pacemaker implants diffused in literature. It shows that pacemaker implants are not linked to mortality and proposes possible predictive factors of ventricular pacing need in the long term. Lastly, it demonstrates that patients with a low valve implant who undergo a pacemaker implant have a higher possibility of recovering the normal atrioventricular conduction at follow-up.

TAVI - Vascular access and bleeding

Impact of a systematic Doppler ultrasound of femoral access for vascular complications screening in transfemoral TAVI

VAILLIER Antoine [(1)], VAILLIER Antoine [(1)], DEHARO Pierre [(1)], JAUSSAUD Nicolas [(1)], MORERA Pierre [(1)], PORTO Alizée [(1)], COLLART Frederic [(1)], CUISSET Thomas [(1)]

(1) PHM Hopital La Timone Adultes, Marseille, France

Aims: The last step of the transfemoral percutaneous TAVI procedure consists of identifying vascular complications (VC). Identification of VC is usually performed using an arteriography of the descending aorta and ilio-femoral arteries. However, this technique is invasive and requires contrast injection and radiation. Doppler ultrasound of femoral access is a non-invasive technique and does not require contrast injection and radiation but has never been evaluated in this indication. The purpose was to compare Doppler ultrasound and arteriography in VC screening of transfemoral TAVI.

Methods and results: All transfemoral TAVI performed between December 2017 and May 2019 in Timone hospital, Marseille, France were included in the analysis. The inclusion was prospective in the Doppler ultrasound group and retrospective in the arteriography group with matching to age, gender, and history of peripheral vascular disease. VC were defined by the VARC-2 criteria. The primary endpoint was the diagnostic performance of Doppler ultrasound and arteriography for the detection of periprocedural VC. The secondary endpoint was the impact of this technique in procedure simplification (duration of procedure, radiation dose and contrast volume) between Doppler ultrasound and arteriography. A total of 202 patients were included in the study (101 in each group). No differences were observed between the patients of 2 groups: mean age of the patients was 84±6.2years, EuroSCORE 2 was 4.4±4.2% and the minimal femoral artery diameter was 7.7±1.3mm. VC occurred in 22% with 8% of periprocedural VC and 14% of post-procedural VC (VARC-2 major: 8%, minor: 14%). Regarding the diagnostic performance of the Doppler ultrasound: the sensibility (Se) was 89 % (IC 95 %: 0.50-0.99), the specifity (Sp) was 97 % (IC 95 %: 0,91-0,99), the predictive positive value (PPV) was 80 % (95% CI: 0.44-0.96) and the negative predictive value (NPV) was 99% (95% CI: 0.93-0.99). For the arteriography, the Se was 88 % (IC 95 %: 0.47-0.99), the Sp was 100 % (IC 95 %: 0.95-1), the PPV was 100% (95% CI: 0.56-1) and the NPV was 99% (95% CI: 0.93-1). The duration of the procedure (92±25 min vs 114±34 min, p<0.001), the radiation dose (322±162 k vs 369±162 k, p=0.03) and contrast load (63±27cc vs 79±32 cc, p<0.001) were significantly lower in the Doppler ultrasound group.

Conclusions: Systematic Doppler ultrasound for periprocedural VC screening during transfemoral TAVI showed excellent diagnostic performance while allowing simplification and optimisation of the procedure.

Other valvular and structural interventions - Other

Mid- and long-term outcomes after TAVI with Edwards SAPIEN in the HPG23 Bergamo TAVI Registry ("BETTER")

VASSILEVA Angelina [1], VALSECCHI Orazio [1], VASSILEVA Angelina [1], CEREDA Alberto F. [1], CUGOLA Diego [1], TERZI Amedeo [1], VIGNONI Andrea [1], FIOCCA Luigi [1], CANOVA Paolo [1], BALESTRIERI Giulio [1], MERLO Maurizio [1], PIAZZA Isabelle [1], GUAGLIUMI Giulio [1], SENNI Michele [1]

(1) ASST Papa Giovanni XXIII, Province of Bergamo, Italy

Aims: "Better" (Bergamo TAVI registry) is a retrospective dataset collecting available clinical variables and outcomes of TAVI procedures performed at ASST-HPG23 Hospital in Bergamo (Lombardy, Italy). The study includes all TAVI procedures using Edwards SAPIEN from 2010 treating the highest risk patients to 2018 (treating intermediate surgical risk patients). Since the initial experiences, even in high-risk older patients with elevated comorbidities, results were characterised by favourable early and mid-term results.

Methods and results: Data from all Edwards SAPIEN valve implantations performed at HPG23 were retrospectively collected. 316 patients underwent Edwards SAPIEN implantation. All-cause mortality status was reported with mortality tracking achieved in 100% of patients thanks to the national data warehouse. Negative predictors of survival were estimated using a binary logistic regression. The mean age at implantation was 83±6 years, 60% were female, the mean ejection fraction 50±9% with the following risk score profiles: EuroSCORE -1 20±13, EuroSCORE -2 5.5±3, STS 3±1.4. The cohort is defined by a significant clinical burden of chronic illness: 13% had a previous stroke, 30% a previous myocardial infarction, 44% had peripheral vascular disease, 12.5% underwent a previous cardiac surgery, 45% had previous coronary artery revascularisation, 17% were diabetic on insulin. 15% suffered from at least CCS1 angina with a prevalent NYHA III class. 23% of patients underwent TAVI after PTA (bridge-to-decision/bridge-to-TAVI). There were a low number of complications taking into account learning curves: any stroke 1.9%, any bleeding complication 6.6%, any vascular complication 10% and 9.8% of pacemaker implantation after TAVI. The mean systolic peak gradient was 17±6 mmHg; the mean gradient was 9±3.6 mmHg. 89% of patients were alive at 1 year with a 30-day mortality of 2%. The mean overall survival was 6.1 years. Survival curves are beyond reported (see figures). Significant negative predictors of long-term survival were stroke (SE-β 0.085), ejection fraction below 40% (SE-β 0.31), PAD (SE-β 0.5).

Conclusions: The placement of Edwards SAPIEN valve in our cohort of patients, from early inoperable patients to the current intermediate-risk, showed excellent results with favourable mid- and long-term outcomes in terms of haemodynamics, low complication rate, and overall survival.

TAVI - Tools, devices and techniques

TAVR in nonagenarians: a systematic review and meta-analysis

DEMIR Ozan [1], DEMIR Ozan [1], CURIO Jonathan [2], PAGNESI Matteo [3], RAHMAN Haseeb [1], MITOMO Satoru [4], COLOMBO Antonio [5], PERENDERGAST Bernard [1], LATIB Azeem [6]

(1) St Thomas' Hospital, London, United Kingdom; (2) Charité – Universitätsmedizin Berlin, Berlin, Germany; (3) IRCCS Ospedale San Raffaele, Metropolitan City of Milan, Italy; (4) New Tokyo Hospital, Chiba, Japan; (5) Villa Maria Cecilia Hospital, Province of Ravenna, Italy; (6) Montefiore Medical Center: Einstein Campus, NY, USA

Aims: This study sought to evaluate procedural performance, safety and outcomes of transcatheter aortic valve replacement (TAVR) for the treatment of severe aortic stenosis in nonagenarian (≥ 90-years-old) patients by performing a systematic-review and meta-analysis.

Methods and results: We systematically searched MEDLINE via PubMed from 2008 to August 2019 for all studies of TAVR, screening for studies that stated specific outcomes for nonagenarian patients undergoing TAVR. The quality of the included studies was assessed using a 20-items checklist based on the STARD statement for the Standards for Reporting Diagnostic Accuracy studies and the STROBE statement for Strengthening the Reporting of Observational studies in Epidemiology. A weighted meta-analysis was conducted, calculating pooled estimate rates with 95% confidence intervals (CIs) using a binary random-effects model for dichotomous variables, and comparing non-dichotomous outcomes with a continuous random-effects model. Twenty-three studies, enrolling 78,858 patients met the inclusion criteria, from which 16,094 patients (20.4%) were nonagenarians, forming the study population. The mean age of the nonagenarians was 91.2±1.8 years and 53.4% of them were women. The mean Society of Thoracic Surgeons mortality risk score (STS-M) was 10.2±5.4. The mean left ventricular systolic function was 56.6±12.7%, prevalence of prior percutaneous coronary intervention was 26.2%, myocardial infarction was 15.4%, coronary artery bypass grafting was 16.4% and peripheral vascular disease was 25.2%. Transfemoral access route was the most commonly utilised (83.0%), followed by transapical (16.7%) and subclavian access (0.02%). Procedural success pooled estimate rates were 94.1% (95% CI: 91.7-96.6%; I2 = 95.2%, p<0.001 for heterogeneity) using weighted meta-analysis. Incidence of major vascular complications was 6.3% (95% CI: 2.7-9.8%; I2 = 76.6%, p<0.001 for heterogeneity) and that of at least moderate post-procedural paravalvular leak (PVL) was 7.5% (95% CI: 4.4-10.6%; I2 = 60.8%, p=0.003 for heterogeneity). At 30 days the incidence of stroke or transient ischaemic event was 2.8% (95% CI: 1.9-3.6%; I2 = 58.7%, p<0.001 for heterogeneity) and rate of permanent pacemaker (PPM) implantation was 12.6% (95% CI: 7.6-17.6%; I2 = 97.8%, p<0.001 for heterogeneity).The pooled meta-analysis estimate rate of periprocedural mortality was 5.4% (95% CI: 4.4-6.4%; I2 = 58.6%, p<0.001 for heterogeneity), 30-day mortality was 6.1% (95% CI: 4.7-7.4%; I2 = 71.4%, p<0.001 for heterogeneity) and 1-year mortality was 20.5% (95% CI: 15.9-25.1%; I2 = 93.2%, p<0.001 for heterogeneity).

Conclusions: TAVR in nonagenarians is safe and efficacious with high procedural success rates and favourable outcomes up to 1 year. Nonagenarians undergoing TAVR have surgical risk profile comparable with patients in inoperable and high-risk TAVR trials, however, as patients in these trials were noticeably younger, nonagenarians seem to be a selected cohort with reasonable comorbidities and age as a driving factor of operative risk. The number of nonagenarian patients is expected grow hence specific research to identify ideal candidates and techniques in this cohort is needed.

TAVI - Adjunctive pharmacotherapy

Impact of renin-angiotensin system inhibitors on outcomes after surgical or TAVR – a meta-analysis

RODRIGUEZ-GABELLA Tania [(1)], AMAT-SANTOS Ignacio [(1)], RODRÍGUEZ-GABELLA Tania [(1)], REDONDO Alfredo [(1)], SANTOS-MARTÍNEZ Sandra [(1)], GUTIÉRREZ Hipólito [(1)], SERRADOR Ana [(1)], HINOJOSA Williams [(1)], CATALÁ Pablo [(1)], CARRASCO-MORALEJA Manuel [(1)], SAN ROMÁN Alberto [(1)]

(1) University Clinic Hospital of Valladolid, Spain, Valladolid, Spain

Aims: To determine whether renin-angiotensin system inhibitor (RASi) prescription is associated with better outcomes after transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR).

Methods and results: We gathered from PubMed, Web of Science, and Google Scholar through August 2019 all comparative studies of RASi versus no-RASi prescription in patients undergoing TAVI/SAVR. Hazard ratios (HRs) with their confidence interval (CIs) of mortality were extracted from each study and combined study-specific estimates using inverse variance-weighted averages of logarithmic HRs in the random-effects model. We identified 6 eligible studies with a total of 21,390 patients (TAVI: 17,846; SAVR: 3,544) and included them in the present meta-analysis. The 6 were observational comparative studies (including 3 propensity-score matched and 3 cohort studies) of RASi versus no-RASi prescription. The analysis demonstrated that RASi prescription was associated with significantly lower mortality in the whole group of patients undergoing aortic valve intervention (HR, 0.64; 95% CI:0.47-0.88; p<0.001). However, subgroup analysis suggested differences according to the selected therapy, with TAVI showing better mortality rates if receiving RASi (HR=0.67; 95% CI:0.49-0.93) but not in SAVR group (HR=0.61; 95% CI:0.29-1.30). No funnel plot asymmetry was identified, suggesting minimum publication bias. Sensitivity analyses sequentially eliminating dissimilar studies did not substantially alter the primary result favoring RASI prescription.

Conclusions: These findings suggest a benefit in terms of mortality of RASi in patients suffering from AS treated with aortic valve replacement that might be particularly relevant following TAVI. Future randomised studies are warranted to confirm this relevant finding.

TAVI - Tools, devices and techniques

Fluoroscopy time as a new predictor of early safety after TAVI

CAFARO Alessandro [1], CAFARO Alessandro [1], IACOVELLI Fortunato [2], SPIONE Francesco [2], BURATTINI Osvaldo [3], TARSELLA Serena [2], PIGNATELLI Antonio [4], DE CILLIS Emanuela [2], BORTONE Alessandro Santo [2], CONTEGIACOMO Gaetano [5], TESORIO Tullio [3]

(1) Regional General Hospital "F. Miulli", Acquaviva delle Fonti, Italy; (2) Policlinico University Hospital, Metropolitan City of Bari, Italy; (3) "Montevergine" Clinic, Mercogliano, Italy; (4) "Mater Dei" Hospital, Metropolitan City of Bari, Italy; (5) "Anthea" Clinic, Metropolitan City of Bari, Italy

Aims: TAVI has become a validated percutaneous procedure for the treatment of advanced aortic valve disease. Increased operator experience and improved device systems have led to a worldwide trend toward the extension of TAVI to intermediate- and low-risk patients. The aim of our real-world study was to evaluate the impact of easily recordable risk scores and procedural parameters on early safety after TAVI.

Methods and results: From 2011 to 2019, 728 consecutive patients (339 males, mean age 80.84±5.82, 647 transfemoral access, 249 with diabetes, mean STS predicted risk of mortality 5.55±4.71%), admitted to three southern Italy heart centres to undergo TAVI were enrolled. Clinical data (eg. cardiovascular risk factors, age at TAVI, sex), risk scores (STS, EuroSCORE I, EuroSCORE II, Mehran score), fluoroscopy time (FT), total amount and type of contrast medium (CM), other procedural data as well as complications according to Valve Academic Research Consortium 2 (VARC-2) were recorded. Patients were categorised according to the VARC-2 early safety (ES) endpoint. ES occurred in 65 (8.93%) patients. Mean FT (37.1±33.8 vs 23.4±13.1 minutes, p=0.002), total amount of CM (197.1±98.0 vs 164.9±70.6 ml, p=0.016), and Yamamoto ratio (CM volume x serum creatinine/body weight) (2.81 vs 2.24, p<0.001) were higher in ES-patients. STS predicted risk of mortality (p=0.053), logistic EuroSCORE I (p=0.416), EuroSCORE II (p=0.193) and Mehran score (p=0.119) were not significantly related to ES at univariate logistic regression. At multivariate regression FT was the strongest predictor (p<0.001) but also CM osmolarity was significantly (p=0.007) related to ES. Conversely total amount of CM (p<0.001) and Yamamoto ratio (p=0.046) were related to ES at univariate regression analysis but lost their significance in multivariate regression model. FT was also related to acute kidney injury (p<0.001), transfusion rate (p=0.008) and to any bleeding (p=0,006) according to Bleeding Academic Research Consortium.

Conclusions: FT, an easily recorded parameter that indirectly indicates the duration of the procedure, is a strong predictor of ES after TAVI.

Mitral valve replacement and repair - Tools, devices and techniques

Haemodynamic outcomes and predictors of dyspnoea reduction in patients treated with transcatheter direct mitral valve annulopasty

GEYER Martin [(1)], GEYER Martin [(1)], KELLER Karsten [(1)], SOTIRIOU Efthymios [(1)], TAMM Alexander R [(1)], RUF Tobias F [(1)], KREIDEL Felix [(1)], BEIRAS-FERNANDEZ Andres [(1)], SCHULZ Eberhard [(1)], MÜNZEL Thomas [(1)], VON BARDELEBEN Ralph Stephan [(1)]

(1) University Medical Center Mainz, Mainz, Germany

Aims: Transcatheter direct annuloplasty is a relatively novel form of interventional mitral valve repair in anatomically suitable subsets of patients with severe mitral valve regurgitation. Up to now, knowledge about its influence on intracardial pressures, biomarkers as well as predictors for dyspnoea reduction is scarce.

Methods and results: For this retrospective monocentric analysis, 18 consecutive patients (77.0±7.4 years, 44.4% females, 94.4% functional aetiology) with all initially high-grade mitral regurgitation undergoing transcatheter direct annuloplasty (primarily combined procedures excluded) between December 2015 and April 2018 were enrolled. Echocardiographic parameters, clinical and periprocedural data, biomarker levels and clinical outcomes after a follow-up of 30 days were gathered and analysed. Procedural success (successful implantation of the device) was high (94.4%) and 30-day mortality low (5.6%). Procedures lead to significant improvement of mitral regurgitation (no up to mild grade: 72.2%) and dyspnoea (NYHA >=3 at 30 days: -43.8% compared to baseline, p=0.008) in the majority of the patients. Furthermore, left atrial volumes (-16.5%, p<0.001), left atrial (LAP: -32.3%, p=0.019; v-wave -31.7%, p=0.014) and systolic pulmonary arterial pressure (PAP: -15.8%, p=0.025) could be significantly reduced. Lower levels of PAP (p=0.022) as well as elevated high-sensitive Troponin I (p=0.034) at baseline could be associated to relevant dyspnoea-reduction at the time of follow-up.

Conclusions: Treatment by interventional direct annuloplasty results in relevant reduction of mitral regurgitation, left atrial volumes, PAP, LAP and dyspnoea level in anatomically suitable patients. Patients with lower baseline levels of PAP and higher Troponin-values might be prone to a higher probability of clinical benefit by the intervention.

Mitral valve replacement and repair - Echocardiography

Feasibility of an optimised 3D TEE guidance protocol implementing real-time multiplanar reconstruction for transcatheter direct mitral valve annuloplasty and results in a single-centre cohort

GEYER Martin [1], GEYER Martin [1], SOTIRIOU Efthymios [1], TAMM Alexander R [1], RUF Tobias F [1], KREIDEL Felix [1], SCHULZ Eberhard [1], MÜNZEL Thomas [1], VON BARDELEBEN Ralph Stephan [1]

(1) University Medical Center Mainz, Mainz, Germany

Aims: Transcatheter direct annuloplasty is a relatively novel treatment option for anatomically suitable subsets of patients with severe mitral valve regurgitation. Successful and safe implantation of the device's metal anchors in the mitral annulus tissue avoiding damage of adjacent structures (e. g. coronary sinus) is crucially dependent on optimal simultaneous fluoroscopic and echocardiographic visualisation.

Methods and results: We elaborated an optimised echo protocol based on real-time single-beat multiplanar reconstruction (MPR) for guidance of interventional direct annuloplasty procedures. In a monocentric retrospective study, we analysed the results of our first 16 consecutive patients (87.5%functional/6.3%degenerative/6.3%mixed pathology; two patients received a primarily combined therapy including edge-to-edge-repair) treated between December 2015 and Septemner 2017 with interventional direct annuloplasty for severe mitral regurgitation using this protocol. Safety and success of the procedure with improved echo guidance was high; only one device failure involving rooting out of anchors occurred. Periprocedural device time decreased continuously (starting from 3-5 to 1-2 hours, mean 140±55.1 min) using the MPR-based echo-protocol. Technical success rate was high (93.8%) without any serious cardiac related adverse events. Mitral regurgitation could be relevantly improved (starting from severe to mild-to-intermediate in mean/statistical "mean" 1.22±0.75) peri-interventionally.

Conclusions: Echocardiographic guidance of interventional direct annuloplasty using a real-time MPR-based protocol is feasible and safe. Optimised imaging might enable reduced implantation times and potentially increases safety.

Mitral valve replacement and repair - Tools, devices and techniques

ReClip for patients with recurrent severe mitral regurgitation after previous MitraClip

GAYED Mohamed [1], GAYED Mohamed [1], ELHAKIM Abuel Rahman [2], HAMADNAH Mohamed [3], KÖGLER Kai [2], BRACHMANN Johannes [3]

(1) REGIOMED Klinikum Sonneberg/Neuhaus, Sonneberg, Germany; (2) REGIOMED Klinikum Coburg, Coburg, Germany; (3) REGIOMED Klinikum Hildburghausen, Hildburghausen, Germany; (4) REGIOMED Klinikum Coburg, Coburg, Germany

Aims: The aim of the current study is to evaluate the 30-day primary results and procedure-related safety of ReClip in patients with recurrent severe symptomatic mitral regurgitation due to progress of the regurgitation after successful MitraClip implantation.

Methods and results: We retrospectively studied 228 patients registered in Regiomed Klinikum Coburg who had undergone MitraClip implantation in the period from April 2016 till May 2019. Five male patients (mean age 76.2 years old, (range 70-85); underwent re-clip. Baseline data, procedural outcome and complications were assessed to identify the results and safety. All patients were symptomatic, NYHA III with severe MR with previous MitraClip implantation. Four patients were discussed in Heart tTam and considered inoperable or high risk patient for mitral operation. One patient refused the operation. Three patients had primary MI and two patients secondary MR. Three patients had ejection fraction ≥50%, whereas two patients had EF between 30 and 50%. All patients had received MitraClip implantation successfully with improvements of MI to MI ≤II with a mean gradient of <5 mmHg. The 30-day mortality was zero. No procedure-related complications (clip embolisation or detachment, pericardial effusion were documented. One patient developed respiratory failure due to heart failure and was managed with intubation and mechanical ventilation.

Conclusions: ReClip is a safe procedure with very good primary results for patients with recurrent severe mitral regurgitation after MitraClip

Other valvular and structural interventions - Other

Percutaneous occlusion of paravalvular aortic leaks: a single-centre experience focused on intracardiac echocardiography

RIBEIRO Joana Maria [1], RIBEIRO Joana Maria [1], PAIVA Luís [1,2], TEIXEIRA Rogério [1,2], PUGA Luís [1], LOPES João [1], SOUSA José Pedro [1], DE CAMPOS Diana [1], SALEIRO Carolina [1], COSTA Marco [1], GONÇALVES Lino [1,2]

(1) Centro Hospitalar e Universitário de Coimbra - Hospital Geral, Coimbra, Portugal; (2) Faculdade de Medicina da Universidade de Coimbra, Coimbra, Portugal

Aims: Percutaneous paravalvular leak occlusion (PPVLO) has emerged as an alternative to cardiac surgery for patients with symptomatic paravalvular leaks. Intracardiac echocardiography (ICE) is an appealing alternative to transoesophageal echocardiography (TOE) for guidance of percutaneous structural interventions, but experience with ICE for PPVLO guidance is limited. We aim to describe our initial experience with an ICE-guided approach for guidance of aortic PPVLO and to assess the outcomes after aortic PPVLO.

Methods and results: We performed a retrospective analysis of all aortic PPVLOs performed in our centre. Our initial experience with PPVLO began with TOE guidance, and later we switched to ICE guidance. In all cases, preprocedural TOE was performed for anatomic characterisation and exclusion of intracardiac thrombus. All procedures guided by TOE were performed under general anaesthesia or deep sedation, and all procedures guided by ICE were performed under local anaesthesia. The retrograde approach was used systematically. In the ICE-guide cases, the ICE probe was advanced through a femoral venous access and sited in the right atrium. The primary endpoints were technical and procedural success. Secondary endpoints included procedure-related complications, mortality, hospital admission due to heart failure, and improvement in New York Heart Association (NYHA) functional class. Ten aortic PPVLOs were included. ICE was used to guide 40% of the aortic PPVLOs. Overall, technical and procedural success rates were 90% and 80%, respectively. ICE-guided PVLO was successful in all cases, and there were no procedure-related complications; in the ICE group technical and procedural success were achieved in 83 and 67%, respectively, and procedure-related complications occurred in 17% of the cases (1 patient). One patient in the TOE group, who had undergone unsuccessful PPVLO, died during index admission due to refractory heart failure. Median follow-up was 22 months (interquartile range, 3-33 months). Mortality during follow-up was 22% and hospital admission due to heart failure was 33%. Median NYHA class improved from 3 (IQR, 2.75-4.00) to 2 (IQR, 1.25-2.00) ($p<0.01$) after PPVLO.

Conclusions: In our initial experience with an ICE-guided approach for aortic PPVLO, technical and procedural success were achieved in all cases and there were no procedure-related complications.

Mitral valve replacement and repair - CT / MRI imaging

The incidence of silent cerebral embolic events in patients after MitraClip

CERVINKA Pavel [1,2], CERVINKA Pavel [1,2], KVASNAK Martin [1], RUPERT Stepan [1], CIHLAR Filip [1,2], CERVINKOVA Michaela [1]

(1) Masarykova nemocnice, Ústí nad Labem-Severní terasa, Czech Republic; (2) UJEP, Ústí nad Labem-Severní terasa, Czech Republic

Aims: Silent cerebral high-intensity transient signals (HITS) are present in the majority of patients (75-80%) undergoing TAVI. However, there is a lack of data on the rate of silent cerebral infarcts after percutaneous edge-to-edge procedure. The aim of this observational study was to assess clinically overt stroke and silent cerebral embolic lesions detected by diffusion-weighted magnetic resonance imaging (DW-MRI) in patients after MitraClip implantation.

Methods and results: 43 patients underwent MitraClip implantation at our institution within a period of May 2016 - December 2019. Of these, 22 patients (51%) underwent DW-MRI pre- (<24 hours) and post- (24-48 hours) edge-to-edge procedure. No patients showed a significant decline in post-neurocognitive function (as assessed by the Montreal Cognitive Assessment [MoCA] score) compared with baseline. DW-MRI detected 1 new silent cerebral lesion (5%) after MitraClip implantation.

Conclusions: The rate of silent (assessed by DW-MRI) cerebral embolic events after MitraClip implantation was very low in our observational study. Larger randomised trials including neuroimaging are needed to define the occurrence and consequences of cerebral damage during transcatheter treatment of mitral regurgitation. Future research is also needed to investigate the role of cerebrovascular protection devices during this procedure.

TAVI - Tools, devices and techniques

Impact of prior balloon valvuloplasty versus direct TAVI on myocardial injury: insight from the DIRECTAVI trial

LECLERCQ Florence [1], AKODAD Mariama [1], MARIN Gregory [1], CAYLA Guillaume [2], MACIA Jean-Christophe [1], GANDET Thomas [1], LATTUCA Benoit [2], SCHMUTZ Laurent [2], ALBAT Bernard [1], ROUBILLE François [1], LECLERCQ Florence [1]

(1) Hôpital Arnaud De Villeneuve CHU MPT, Montpellier, France; (2) CHU Nimes Caremeau, Nimes, France

Aims: Myocardial injury, defined by significant troponin elevation, was described as a predictive factor of short- and long-term mortality after TAVI and may be increased by balloon predilatation. We aimed to evaluate the impact of balloon predilatation on myocardial injury after TAVI performed with new-generation balloon-expandable prostheses.

Methods and results: The DIRECTAVI trial, an open-label randomised study, demonstrated non-inferiority of TAVI performed without predilatation (direct TAVI group) in comparison with systematic predilatation in patients undergoing TAVI with the Edwards SAPIEN 3 valve. High-sensitive troponin assessment was performed in all patients before and after the procedure. The incidence of myocardial injury defined by troponin elevation >15 upper limit reference after the procedure was the main endpoint. Secondary endpoints were adverse events at 1- month follow-up according to VARC-2 criteria. Pre- and post-procedure troponin were available in 211 of the 236 patients (89.4%) included in this study,104 (90.4%) in the balloon predilatation group and 107 (88.4%) in the direct TAVI group. Baseline characteristics were comparable between both groups. Mean age was 82 y±6.7 and 145 were male (61.4%). Myocardial injury occurred in 42 patients (19.9%), 13 (12.2%) in the direct TAVI group and 29 (27.9%) in the balloon predilatation group, p=0.004. Myocardial injury increased by 2.8-fold in the balloon predilatation group in comparison to the direct TAVI group (OR 2.8 IC 95% 1.4-5.8). Myocardial injury was associated with 1-month outcomes (p=0.03).

Conclusions: Predilatation significantly increased myocardial injury in patients undergoing TAVI with new-generation balloon-expandable valves. Myocardial injury was associated with 1-month outcomes. These results argue in favour of direct implantation of the SAPIEN 3 valve.

TAVI - Echocardiography

Haemodynamic performances and outcomes in patients undergoing TAVI in bicuspid versus tricuspid aortic valves with new-generation devices

CHOTEAU Romuald [(1)], CHOTEAU Romuald [(1)], LECLERCQ Florence [(1)], CAYLA Guillaume [(2)], MARIN Gregory [(1)], LATTUCA Benoit [(2)], MACIA Jean-Christophe [(1,2)], SCHMUTZ Laurent [(1,2)], ROUBILLE François [(1)], GANDET Thomas [(1)], AKODAD Mariama [(1)]

(1) Hôpital Arnaud De Villeneuve CHU MPT, Montpellier, France; (2) CHU Nimes Caremeau, Nimes, France; (3) PhyMedExp, Montpellier, France

Aims: TAVI in bicuspid aortic valves is considered as associated with less favourable results than in tricuspid aortic valves. We aimed to compare haemodynamic performances and outcomes between bicuspid versus tricuspid aortic valves in patients undergoing TAVI with new-generation devices.

Methods and results: All consecutive patients with bicuspid aortic valve undergoing TAVI with new-generation prosthesis (Edwards SAPIEN 3, Medtronic EvolutR and EvolutPro) in our centre between January 2015 and July 2019 were evaluated. A systematic review of the CT scan was performed in all patients to confirm the bicuspid aortic valve and the type defined as type 0, 1, or 2 according to Sievers' classification. Each patient with bicuspid aortic valve was matched with patients with tricuspid aortic valve according to predefined criteria, with a 1:2 ratio. Matching criteria were sex, age, body mass index, left ventricular ejection fraction, surface of the aortic annulus, size and type of device. Primary endpoint was haemodynamic performance of the prosthesis including mean aortic gradient and aortic regurgitation assessed by transthoracic echocardiography at 1-month follow-up. A total of 97 patients were enrolled, 35 (36.1%) in the bicuspid aortic valve group and 62 (63.9%) in the tricuspid aortic valve group. Mean age was 80.6±8.5 and 49 patients (50.1%) were female. Both groups were comparable at baseline except for age, with older patients included in the tricuspid aortic valve group (83.2±6.8 versus 76.7±9.3 in the bicuspid aortic valve group [p=0.0001]), and for mean aortic gradient before TAVI, higher in the bicuspid aortic valve group (53.9±16.4 mmHg versus 43.9±16.1 in the tricuspid aortic valvegroup group [p=0.0031]). Type 1 bicuspid aortic valve group was the most frequently observed (77.1%) and a majority of Edwards SAPIEN 3 valve were implanted (n=75, 77.3%). At 1-month follow-up, mean aortic gradient was similar in both group (10.2±4.0 mmHg in the bicuspid aortic valve group versus11.0±3.5 mmHg in tricuspid aortic valve group, p=0.3). There was no significant difference in aortic regurgitation ≥grade 1 between the 2 groups (p=0.4) at 1 month despite a higher rate of aortic regurgitation ≥grade 1 in the bicuspid aortic valve group at 72 hours (p=0.009). At 1-month follow-up, only 1 patient (2.9%) died from cardiac causes in the bicuspid aortic valve group and hospitalisation rate for cardiac causes was similar in both groups (n=4, 11.4% in the bicuspid aortic valve group versus n=2, 3.2%in the tricuspid aortic valve group;p =0.1). Stroke occurred in 1 patient in each group; p=0.8. Pacemaker implantation occurred in 8 patients (22.9%) in bicuspid aortic valve group and 16 patients (25.8%) in tricuspid aortic valve group; p=0.1 and regardless of the type of device.

Conclusions: Although BAV is considered to have less favourable anatomy for TAVI, our study showed similar favourable short term haemodynamic results and outcomes to those obtained in TAV with new-generation prosthesis.

TAVI - CT / MRI imaging

Myocardial fibrosis measured by multidetector CT predicts outcomes in TAVI

TALMOR-BARKAN Yeela [1,2], TALMOR-BARKAN Yeela [1,2], HAMMER Yoav [1,2], ABELOW Aryeh [1,2], ORVIN Katia [1,2], LEVI Amos [1,2], LANDES Uri [1,2], SHAFIR Gideon [1,2], VAKNIN-ASSA Hana [1,2], KORNOWSKI Ran [1,2], HAMDAN Ashraf [1,2]

(1) Beilinson, Petah Tikva, Israel; (2) Sackler Interdepartmental Core Facility, Tel Aviv-Yafo, Israel; (3) Weizmann Institute of Science, Rehovot, Israel

Aims: Myocardial fibrosis is associated with adverse cardiovascular events and can be assessed by the measurement of extracellular volume (ECV) fraction. MRI is the gold standard method for ECV fraction evaluation. Recent studies indicate that by using new techniques ECV can be measured by multidetector computed tomography (MDCT), which is a routine examination for the evaluation of TAVI candidates. We aimed to evaluate the feasibility of ECV measurement by MDCT in patients with severe aortic stenosis (AS) and the correlation between cardiac fibrosis and long term clinical outcomes after TAVI.

Methods and results: Seventy-five consecutive patients with severe AS and nineteen subjects without AS were prospectively recruited and underwent a pre-contrast and post-contrast MDCT for estimation of myocardial ECV fraction. Blood sample was obtained at the day of MDCT and the serum level of galectin-3 was measured by enzyme-linked immunosorbent assay. Echocardiography was performed to evaluate the extent of cardiac damage according to the staging classification published by Philippe Généreux at el. Patients with AS were significantly older (80.6 vs 57.2, $p<0.05$) and with more comorbidities. As expected, ECV fraction was higher in patients with AS compared to subjects without AS (40% vs 21.6%, $p<0.0001$). At baseline, ECV fraction was significantly correlated with functional class (FC), atrial volume, ejection fraction and AS echocardiographic staging classification ($R=0.34,0.34,0.42$, and 0.29 respectively; $p<0.01$ for all). In addition, we demonstrated a correlation between ECV fraction and clinical outcomes of stroke and FC at 6 months ($R=0.32$, 0.51, respectively; $p<0.05$ for all) and hospitalisations due to heart failure (HF) and FC at 12 months ($R=0.39$, 0.6, respectively; $p<0.05$ for all) after TAVI. Using combined clinical outcome of stroke, HF-hospitalisation and all-cause mortality at 12 months after TAVI, the area under receiver operating characteristic curve (ROC AUC) was 0.77. A trend for correlation between serum level of galectin-3 and ECV was also noted (Pearson $R=0.22$, $p=0.07$).

Conclusions: Cardiac fibrosis measured by MDCT can predict long term adverse events in TAVI patients, and is associated with the echocardiography staging classification published by Philippe Généreux at el. In the future, this novel technique can be used for risk stratification of TAVI candidates.

Mitral valve replacement and repair - Tools, devices and techniques

12-month outcomes post mitral valve repair via MitraClip in patients younger than 65 years

MOHAMMED Hassan [1,4], BUCK Thomas [1], PLICHT Björn [1], FARAH Ahmed [1], MOHAMMED Hassan [1,4], OHLOW Marc-Alexander [2,3], EL GARHY Mohammad [2,4]

(1) Klinikum Westfalen GmbH, Dortmund, Germany; (2) Zentralklinik Bad Berka, Bad Berka, Germany; (3) SRH Wald-Klinikum Gera, Gera, Germany; (4) Faculty Of Medicine - Minia University, Minya, Egypt

Aims: Percutaneous mitral valve repair via MitraClip® became a well-established interventional option for cases with severe mitral regurgitation (MR). However, this treatment is almost only limited to old-aged patients with high surgical risk. This study aimed at presenting the experience of two centres in 11 patients younger than 65 years with almost no surgical options due to high operative risk.

Methods and results: A retrospective clinical and echocardiographic study was conducted to evaluate 11 patients younger than 65 years from a total of 250 patients treated by MitraClip in Central Clinic Bad Berka, Germany and Westfalen Heart Center, Germany. Statistical analysis revealed the following data; the mean age of these patients was 56.9±4.1 years, male gender was 63.6%. High operative risk was estimated by Society of Thoracic Surgeons (STS) score (mean=8.65±3). All patients were refused by the cardiac surgery team, accordingly, patients were enrolled for MitraClip procedure. Severity of mitral regurgitation (MR) was detected by vena contracta (VC) in two perpendicular views (mean=9.7±1.9 mm). Transmitral mean pressure gradient (MPG) was 1.7±0.76 mmHg. 54.5% of patients had eccentric regurgitation jets and 18.2% had multiple jets. As regards etiological mechanisms of MR, 3 patients showed leaflet prolapse as the main etiological factor of MR and in another 4 patients, the cause of MR was mitral annular dilatation. Finally, 3 patients exhibited mitral leaflet thickening and/or retraction due to fibrosis and only one patient exhibited papillary muscle displacement leading to leaflet tethering as a reason for MR. Procedural success was achieved in all patients with 2 clips implanted in 81.8% of cases. Two grades or more reduction in severity of MR (MR grade ≤II) was accomplished in 72.2% of patients. Mean post-procedural MPG across the mitral valve remained within acceptable levels of 4.5±2.3 mmHg. During 12-month follow-up, all patients showed persistent symptomatic improvement and effective reduction of MR. No second intervention was required. Only one patient experienced procedure-related complications in the form of a large local haematoma. There was no procedure-related mortality during the first 30 days, however a single case of mortality was recorded during the first month and was attributed to septicaemia after exclusion of infective endocarditis. Another patient passed away during 12-month follow-up owing to advanced heart failure.

Conclusions: Percutaneous mitral valve repair via MitraClip in patients younger than 65 years provides reliable clinical and echocardiography outcomes at 1 year. Future studies should evaluate the outcomes of MitraClip in this population at a longer follow-up.

TAVI - Adjunctive pharmacotherapy

Late kidney injury after TAVI

ADACHI Yuya [(1)], ADACHI Yuya [(1)], YAMAMOTO Masanori [(1)], YAMAGUCHI Ryo [(1)], SHIMURA Tetsurou [(1)], SUZUKI Takahiko [(1)]

(1) Toyohashi Heart Centre, Toyohashi, Japan

Aims: The serial changes in kidney function in patients undergoing transcatheter aortic valve implantation (TAVI) is not fully elucidated. This study aimed to identify the predictive factors and prognosis beyond 1 year of late kidney injury (LKI) evaluated 1 year after TAVI.

Methods and results: We retrospectively reviewed 1,705 consecutive patients who underwent TAVI using data from the OCEAN (Optimised Catheter Valvular Intervention) Japanese multicentre registry. Late kidney injury (LKI) was evaluated one year after TAVI, defined as an absolute increase in serum creatinine level of at least 0.3 mg/dl, a relative increase of 50% from baseline measurement pre-TAVI, or progression to end-stage renal disease (ESRD). Patients were categorised with LKI or non-LKI groups. The baseline characteristics, procedural outcomes, and clinical outcomes were compared between patients in the LKI or non-LKI groups. We evaluated the association between incidence of LKI and long-term mortality, and predictors of LKI were investigated. LKI occurred in 245 patients (14.4%). Cumulative 4-year mortality showed significant differences between the LKI and non-LKI groups (34.8% vs 20.6%, p 0.001). By multivariate analysis, chronic kidney disease (odds ratio [OR]: 1.63; 95% confidence interval [CI]: 1.15 to 2.30; p 0.006), coronary artery disease (OR: 1.51; 95% CI: 1.13 to 2.01; p 0.005), acute kidney injury (OR: 2.84; 95% CI: 1.89 to 4.28; p<0.001), and heart failure readmission within 1 year (OR: 2.13; 95% CI: 1.31 to 3.44; p 0.002) were associated with the occurrence of LKI. In a multivariate Cox regression analysis, the LKI was an independent predictor of increased late cumulative mortality risk (hazard ratio, 1.94; 95% CI: 1.31–2.86; p 0.001).

Conclusions: The LKI determined at 1 year to be related to cardio-renal events was associated with increased risk of late mortality beyond 1 year following TAVI.

TAVI - Tools, devices and techniques

Predictors of paravalvular leak and low implantation in patients undergoing TAVI with Evolut-R device: comparison between Evolut-R 34 mm and Evolut-R 23/26/29 mm

GORLA RIccardo [(1)], GORLA Riccardo [(1)], DE MARCO Federico [(1)], BIANCHI Giovanni [(1)], BRAMBILLA Nedy [(1)], ACERBI Elena [(1)], AGNIFILI Mauro Luca [(1)], TUSA Maurizio [(1)], TESTA Luca [(1)], BEDOGNI Francesco [(1)]

(1) Policlinico san donato, Metropolitan City of Milan, Italy

Aims: To compare in-hospital outcome of patients undergoing transcatheter aortic valve implantation (TAVI) with Evolut-R 34mm vs 23/26/29mm as well as to identify predictors of paravalvular leak (PVL) and low implantation in these two populations.

Methods and results: This retrospective single-centre study included 359 patients with severe aortic stenosis, who underwent TAVI with Evolut-R 34mm (N=84, 23.4%) or Evolut-R 23/26/29mm (N=275, 76.6%) between 2016 and 2019 at our institution. Patients in the Evolut-R 34mm group were more frequently males (91.5% vs 37.1%; p<0.001), had lower STS score (4.7±3.9 vs 5.8±3.5; p=0.014), ejection fraction (48.5±13.1% vs 54.5±12.4%; p<0.001), and mean aortic gradient (34.4±14.7mmHg vs 46.1±15.4mmHg; p<0.001), compared to the Evolut-R 23/26/29mm group. On CT-angiography, the Evolut-R 34mm group showed significantly larger diameters of aortic annulus (27.4±1.6mm vs 22.9±2.2mm), ascending aorta (36.7±4.4mm vs 33.1±3.9mm), and left ventricular outflow tract (LVOT) (27.2±2.0mm vs 22.3±2.5mm) compared to the other group (all p<0.001). The finding of a horizontal aorta was more frequent in the Evolut-R 34mm group as well (aortic angulation: 53.6±10.8°vs 49.3±9.8°; p=0.001); on the other hand, calcium volume 800HU was comparable. During TAVI, predilatation and post-dilatation rates were not significantly different between the two groups. However, implantation depth and contrast volume were greater in the Evolut-R 34mm group, compared to the Evolut 23/26/29mm group (respectively, 8.2±3.4mm vs 5.1±2.1mm; p<0.001 and 170.4±75.1mL vs 148.5±67.5mL; p=0.017). Post-procedurally, ≥moderate PVL, device success, and pacemaker implantation rates were overall respectively 8.1%, 87.1%, and 18.9%, with no differences between the Evolut-R 34mm and Evolut-R 23/26/29mm group. In-hospital mortality (3.6%), and stroke rate (1.4%) were comparable as well. On multivariate analysis, aortic angulation (OR:1.07; p=0.004) and calcium volume 800HU (OR:1.003; p<0.001) were independent predictors of ≥moderate PVL. Of these, calcium volume 800HU was confirmed as significant predictor on ROC analysis limited to the Evolut-R 34mm (AUC=0.81, p=0.006) or the 23/26/29mm (AUC=0.72, p=0.003) population, whereas aortic angulation was predictive of ≥moderate PVL only in the Evolut-R 34mm group (AUC 0.73, p=0.043) at an optimal cutoff of ≥61°(71% sensitivity, 78% specificity). On multivariate analysis, body weight (OR 1.03; p=0.027), LVOT diameter (OR 1.34; p=0.001), and mean aortic gradient (OR 0.96; p=0.006) were found independent predictors of low implantation (i.e. implantation depth >6mm). Of these, LVOT diameter was predictive of low implant also on ROC analysis (AUC 0.76; p<0.001) with an optimal cutoff of ≥25 mm (sensitivity 71%, specificity 65%).

Conclusions: TAVI with Evolut-R 34mm and Evolut-R 23/26/29mm showed comparable results in terms of PVL, device success, PM implantation, in-hospital survival, and complication rates. Among independent predictors of low implantation and ≥moderate PVL, LVOT diameter and aortic angulation were crucial particularly in patients treated with Evolut-R 34mm, since horizontal aorta and large LVOT were more frequent findings in this population.

Mitral valve replacement and repair - Tools, devices and techniques, Tricuspid / Pulmonary valve - Tools, devices and techniques

Intermediate term follow-up of patients treated with valve-in-valve technique for the treatment of aortic, mitral and tricuspid structural valve deterioration

CODNER Pablo [1], CODNER Pol [1], VAKNIN-ASSA Hana [1], SHAPIRA Yaron [1], KATIA Orvin [1], RAM Sharoni [1], TALMOR Yeela [1], HAMDAN Ashraf [1], PERL Leor [1], SAGIE Alik [1], KOENOWSKI Ran [1]

(1) Beilinson, Petah Tikva, Israel

Aims: Percutaneous treatment of structural valve deterioration (SVD) in the aortic, mitral and tricuspid position is an established and evolving alternative to redo surgery. Herein we report our intermediate-term results of patients with SVD in the aortic, mitral and tricuspid valve position, in a wide range of patients with different and complex valve pathologies.

Methods and results: A total of 119 consecutive patients with symptomatic SVD treated using the valve-in-valve (ViV) technique treated from March 2010 to November 2018, were included in this analysis. ViV in the aortic position was performed in 66 patients (mean age 78.7±7.9; mean STS score 6.9±4.7). Self-expanding and balloon-expandable devices were used in 53 (80%) and 13 (19.7%) patients, respectively. Procedures were performed via the transfemoral, trans-subclavian and transapical route in 60 (91%), 4 (6%) and 2 (3%) of cases, respectively. Survival rates at 4-year follow-up were 65.2%. VinV procedure in the mitral position was performed in 42 patients (66.6% female), mean age 75.8±8.4, mean STS 8.8±3.2. All procedures were performed using the balloon-expandable device. The transapical route was used in all procedures until the year 2016 (16 patients). Since 2017 the transseptal route was used in all patients (N=26). Mean hospital stay 4.7±1.6 days. Survival rates at 3-year follow-up were 76.2%. A total of 12 patients (83.3% female) underwent tricuspid ViV. Mean age 64.4±10.6 years. Mean STS 6.2±3.1. The composite endpoint of device success was achieved in all patients. Mean hospital stay was 3.1±1.3 days. Survival rates at 2 years follow up were 87.5%.

Conclusions: The valve-in-valve technique for the treatment of a wide range of bioprosthetic valve deterioration modes of failure in different valve positions is associated with favourable clinical outcomes at intermediate and long term follow-up.

TAVI - Tools, devices and techniques

TAVI in patients with diverse concomitant aortic diseases: long-term outcomes

USEINI Dritan [(1)], USEINI Dritan [(1)], SCHLÖMICHER Markus [(1)], HALDENWANG Peter [(1)], BECHTEL Matthias [(1)], STRAUCH Justus [(1)]

(1) Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil GmbH Klinik für Herz- und Thoraxchirurgie, Bochum, Germany

Aims: Patients with concomitant aortic diseases (AD) who need TAVI treatment are frequent. They are likely to be classified as high interventional risk patients or patients who cannot undergo the transfemoral approach. Since the 'transfemoral first' strategy has been established, there is an evidence gap regarding the outcomes of such patients. We aim to evaluate early and long-term outcomes after transapical TAVI in patients with diverse AD.

Methods and results: In total, 55 consecutive intermediate risk (STS-score 6.6±3%) elderly patients (78.4±8 years) with symptomatic severe aortic stenosis and AD (porcelain aorta 36.4%, ascending aneurysm 14.5%, descending aneurysm 25.5%, type-B-dissection 3.6%, aortic thrombus 7.3%, Leriche-Syndrome 3.6%, aortic kinking 10.9%, aortic ulcer 1.8%, previous aortic intervention 20%, aortic elongation/tortuosity 3.6%) underwent transapical-TAVI treatment between January 2011 and November 2019 at our institution. We used the second- and third-generation self-expanding and balloon-expandable valves. The follow-up time was 92.6 patient years. All endpoint-related outcomes were adjudicated according to the Valve Academic Research Consortium-2. We analysed the outcomes globally for the entire cohort and compared them to the pathogenesis of the aorta: atherosclerotic/occluding aortic disease (A/OAD) (20 patients) (porcelain aorta, Leriche syndrome, aortic ulcer, and aortic thrombus), aortic morphologic diseases (AMD) (24 patients) (ascending aneurysms, descending aneurysms, kinking, type B dissection, elongation/tortuosity, previous aortic intervention), and combined aortic diseases (CAD) (11 patients). Additionally, we analysed the outcomes of patients with different STS risk scores (Society of Thoracic Surgery-Predicted Risk of Mortality score): lower risk score was defined as STS-score ≤6 (28 patients) and higher risk score as STS-Score >6 (27 patients). All valves were implanted successfully without embolisation, aortic dissection, annulus rupture, aortic perforation, or aortic injury. Moreover, 30-day mortality, all-stroke, and myocardial infarction of the entire cohort were 5.5%, 3.6%, and 0%, respectively. Postoperative paravalvular leakage ≥2 was 1.8%. The rate of the permanent pacemaker was 9.6%. The median survival time of the entire cohort was 24.9 months (95% CI: 17.569–32.303). The log-rank test showed no significant differences in the median survival time (months) between three study groups—17 (95% CI: 0–37.963) in CAD vs 34.3 (95% CI: 15.498–53.233) in AMD vs 29 (95% CI: 17.485–40.536) in A/OAD; p=0.910. The freedom from a composite of death, all-stroke, and myocardial infarction between three groups was also not significant (p=0.525). The higher risk patients had high significantly shorter median survival and freedom from a composite of death, all-stroke, and myocardial infarction compared to the lower risk patient collective:11.6 (95% CI: 0.625–22.570); p<0.0001 and 11.6 (95% CI: 1.103–22.092); p<0.0001, respectively. We registered no aortic syndrome scenarios.

Conclusions: The transapical TAVI seems to be a safe method and shows very promising early- and long- term outcomes without early or late aortic syndrome in patients with diverse AD, where the transfemoral TAVI as the first transcatheter alternative might be contraindicated or even not feasible.

TAVI - Echocardiography

Valve in valve transcatheter aortic valve replacement: echocardiographic and clinical outcome

RECCIA Matteo Rocco [1], RECCIA Matteo Rocco [1], NOTRISTEFANO Francesco [1], ANNUNZIATA Roberto [2], BERNARDINI Gaetano [2], NOTARISTEFANO Salvatore [1], SCLAFANI Rocco [1], VERDECCHIA Paolo [1], CAVALLINI Claudio [1]

(1) Ospedale Santa Maria della Misericordia, Perugia, Italy; (2) Università degli Studi di Perugia, Perugia, Italy

Aims: Transcatheter aortic valve replacement (TAVR) is increasingly used to treat failed surgical aortic bio-prostheses. Recently, FDA recommended this strategy for inoperable patients. While the short-term safety and efficacy of this procedure are well established, the long-term outcome is still undefined. Our study evaluated the long-term clinical outcome in patients undergoing TAVR for failed surgical aortic bio-prostheses.

Methods and results: Valve-in-valve procedures for failed surgical aortic bio-prostheses were performed in 47 consecutive patients, who were subsequently followed for a median of 4.0 years (range: 3.2-5.4 years). All patients underwent a further echocardiographic study at 3 years after TAVR. The cause of surgical failure had been stenosis in 30%, regurgitation in 49% and combined dysfunction in 21%. The time to failure was 8.9±3.3 years, with a lower durability of stented valves compared to stent-less (7±3.7 VS 10±1.9, p 0.007). We used a self-expanding valve for TEVR in 81% of patients, and a balloon expandable in 19%. Age of patients was 78.4±6 years and the mean Society of Thoracic Surgeons score was 9.9±4%. Stented valves were 27 (57%) and small valves (<21 mm) were the majority (57%). Mean trans-aortic gradient was reduced from 33.2 mmHg at baseline to 13.9 mmHg acutely after TAVI (p<0.001). The gradient remained stable at the 3-year follow-up (11.5 mmHg, p=ns vs baseline) with no more than trivial aortic regurgitation. Acutely after TAVR, patients in NYHA class III-IV dropped from 79% to 13% (p<0.001). After 4 years, the proportion of patients in NYHA class III-IV raised to 25% (p<0.001 vs post TAVR). The 5-year cumulative incidence of mortality or re-hospitalisation (Kaplan Meier estimate) was 35% without any differences across surgical valve types and dimensions.

Conclusions: These data suggest that the valve-in-valve procedure is associated with a good echocardiographic and clinical outcome over a relatively long-term span. Further studies are needed to investigate the relations between echocardiographic and clinical changes in these patients.

TAVI - Tools, devices and techniques

Metabolite profiles of bicuspid aortic stenosis in the setting of TAVR

XIONG Tian-Yuan [(1)], XIONG Tian-Yuan [(1)], LIAO Yan-Biao [(1)], CHEN Mao [(1)]

(1) West China Hospital, West China School of Medicine, Sichuan University, Sichuan, China

Aims: Patients with bicuspid aortic valve (BAV) have different clinical features from tricuspid aortic valve (TAV). This study aimed at exploring the metabolomics profile involved in bicuspid aortic stenosis prior to and after transcatheter aortic valve replacement (TAVR) in comparison with tricuspid morphology.

Methods and results: In this TAVR cohort, blood samples were acquired from the peripheral vein before valve deployment during the index procedure and on the 7th day after TAVR, which were then sent for untargeted liquid chromatography-mass spectrometry and gas chromatography-mass spectrometry detection. Besides comparisons between BAV and TAV, BAV patients were also divided into subgroups according to baseline haemodynamics (i.e. maximal transaortic velocity, Vmax) and post-procedural reverse left ventricular (LV) remodelling (i.e. the change in LV mass index from baseline, ΔLVMI) for further analysis. Metabolic differences between groups were identified by integrating univariate test, multivariate analysis and weighted correlation network analysis algorithm. A total of 57 patients were enrolled including 33 BAV patients. Compared with TAV, the BAV group showed alleviative arginine and proline metabolism represented by decreased expression of L-Glutamine both before and after TAVR. In BAV subgroup analysis, patients with baseline transaortic Vmax>5 m/s (n=11) or the 4th quartile of ΔLVMI at one-year follow-up (i.e. poorly-recovered LV, n=8) showed elevated arachidonic acid metabolism, represented by increased expression of arachidonic acid and leukotriene B4, compared with the subgroup of vmax <4.5 m/s (n=12) or the 1st quartile of ΔLVMI (i.e. well-recovered LV, n=8), respectively.

Conclusions: Distinctive metabolomics profiling was identified between BAV and TAV in the setting of TAVR. Essential molecules in the arginine and proline metabolism pathway might delay the fast progression of bicuspid aortic stenosis. Metabolites in the arachidonic acid metabolism pathway might be potential biomarkers to determine BAV patients who would suffer from worse baseline haemodynamic stress or compromised LV recovery post-TAVR.

TAVI - Tools, devices and techniques

A combination of hypoalbuminaemia and muscle weakness deteriorates clinical outcomes after TAVI

UCHIDA Yasuhiro [(1)], TAMENISHI Akinori [(1)], ICHIMIYA Hitoshi [(1)], WATANABE Junji [(1)], KANASHIRO Masaaki [(1)], ICHIMIYA Satoshi [(1)]

(1) Yokkaichi Municipal Hospital, Mie, Japan

Aims: Although the clinical outcomes of transcatheter aortic valve implantation (TAVI) have significantly improved, some patients still have a poor prognosis due to their intrinsic clinical risks. Therefore, it is important to identify patients at risk for mortality after TAVR. Both nutritional status and muscle strength reflect the degree of frailty and these disorders increase risk of mortality in elderly population. We assessed the hypokinesis that the combination of hypoalbuminaemia (hALB) and muscle weakness (MW) might predict future adverse events in patients undergoing TAVI.

Methods and results: We performed TAVI in 79 consecutive patients with symptomatic severe aortic stenosis between December 2015 and August 2019. HALB and MW were defined as serum albumin level <3.5g/dl, and grip strength <26.0kg in men and <18.0kg in women, respectively. The primary endpoint was all-cause mortality following TAVI. Nutritional status and muscle strength were classified into four groups: hALB+/MW+ (n=20), hALB+/MW- (n=6), hALB-/MW+ (n=39), and hALB-/MW- (n=14). During the follow-up, death from any cause occurred in 5 (25.0%) patients in hALB+/MW+ group, 6 (15.4%) in hALB-/MW+ group, and 1 (7.1%) in hALB-/MW- group. On Kaplan-Meier analysis, the proportion of survival was significantly lower in hALB+/MW+ group (log-rank p=0.03). After adjustment for confounding factors, the combination of hALB and MW remained an independent significant predictor of all-cause mortality on multivariate Cox proportional hazard analysis (hazard ratio 2.51 [95% confidence interval: 1.15 to 7.71, p=0.02)].

Conclusions: The combination of hALB and MW was significantly associated with clinical outcomes in patients undergoing TAVR. Therefore, assessment of nutritional status and muscle strength is crucial in clinical practice.

TAVI - Tools, devices and techniques, Other valvular and structural interventions - Other

Benchside testing of contemporary aortic valvuloplasty balloons

WILLIAMS Timothy [1], WILLIAMS Timothy [1], COCKBURN James [1], RENDON-MORALES Elizabeth [2], AVILES-ESPINOSA Rodrigo [2], HILDICK-SMITH David [1]

(1) Royal Sussex County Hospital, Brighton, United Kingdom; (2) Sussex University, Brighton, United Kingdom

Aims: Valvuloplasty balloons are used for standalone BAV procedures and as part of TAVI, their characteristics under inflation are important. We aimed to establish accurate sizing of valvuloplasty balloons during inflations for BAV procedures to demonstrate their compliance and sizing as a function of pressure.

Methods and results: An experimental set-up including a non-contact optical system was developed to allow assessment of balloon size at progressive inflation pressure, based on bright field microscopy. 3 commonly used valvuloplasty balloons (Z-med, Edwards, and True dilation) were suspended in a non-contact set up and inflated accurately using an indeflator to pressures commonly reached during manual inflation of balloons as per standard BAV procedural practice. Measurements were taken of balloon diameter for different sized balloons at incrementally increasing pressures. Results were that measurements were reproducible and accurate, and although all balloons were generally within tolerances given by manufacturers the actual measurements varied from those given in product characteristics. Z-Med and Edwards balloons measured smaller than manufacturer specifications at lower pressures, converging with manufacturer data only at higher pressures (above rated burst pressures in some cases). True dilation balloons were consistenly larger (by up to 1 mm) than stated manufacturer characteristics but displayed very flat changes in size with increasing pressure. Two commonly used balloons for predilation in TAVI (Edwards and Z-Med) had differences in diameter of up to 1.5 mm at the same inflation pressure for the same sized balloons. The Edwards balloons also demonstrated an interesting characteristic during first inflation where their diameter increased dramatically between 1 and 2 atmospheres of inflation pressure. There was very little variation in diameter between serial balloon inflations providing comfort that repeated inflations *in vivo* are reliable and safe.

Conclusions: This study demonstrates a bench side experimental set up to measure balloon size vs pressure of inflation, and reassures us that serial inflations are consistent and that balloons are reliable up to pressures above RBP. This has important implications for BAV procedures and the ranging scope of structural procedures moving forwards.

TAVI - Tools, devices and techniques

The ALSTER-TAVI all-comers registry: procedural and one-year clinical outcomes of self-expanding vs balloon-expandable contemporary TAVI valves

PAITAZOGLOU Christina [1,3], PAITAZOGLOU Christina [1,3], HANKE Thorsten [4], LASS Michael [4], NOACK Jan [1,3], GRÜNING Anna [1], FRERKER Christian [2], SCHMIDT Tobias [2], MEINCKE Felix [2], BERGMANN Martin W. [1,3]

(1) Cardiologicum Hamburg - Praxis Wandsbek, Hamburg, Germany; (2) Asklepios Klinik St. Georg, Hamburg, Germany; (3) Asklepios Klinik Wandsbek, Hamburg, Germany; (4) Asklepios Klinikum Harburg, Hamburg, Germany

Aims: Transcatheter aortic valve implantation (TAVI) has emerged as the standard treatment of aortic stenosis in the elderly. Both self-expanding and balloon-expandable valves are routinely used; we compared procedural and clinical outcome variables before and after a switch from the balloon-expandable Edwards SAPIEN 3 bioprothesis to the self-expanding Medtronic Evolut R- and Evolut Pro.

Methods and results: In this single centre all-comers registry we retrospectively investigated procedural and clinical outcomes of consecutively treated transfemoral TAVI patients. Patients were mainly (>90%) treated with the SAPIEN 3 from November 2014 to January 2017 (N=133) and from February 2017 to August 2018 mainly (>90%) with the Evolut R or Evolut Pro valve (N=124). All patients received a coronary angiography, transoesophageal echocardiography and computer tomography (CT) of the aortic annulus before implantation; sizing of the annulus and decision on valve size was based on Osirix MD-based aortic CT evaluation. Procedural data were collected retrospectively from the in-hospital electronical databases. Clinical follow-up data were extracted from the outpatient-clinic database, where patients were routinely checked after the TAVI procedure including transthoracic echocardiography (TTE). One year follow-up data were available for 115 (92%) of the Evolut R/Pro and 133 (100%) of the SAPIEN 3 patients. Baseline characteristics between the groups were comparable. EuroSCORE (Evolut 22.5±0.9% vs SAPIEN 3 22.08±0.9%, mean±SEM p=0.4) and mean age (82.3±0.5 vs 82.1±0.5, p=0.6) were similar. Valves implanted were (Evolut/SAPIEN3): 6/29% 23mm, 21/50% 26mm, 47/21% 29mm and 26/0% 34mm. Implantation of the Evolut valves was associated with a higher radiation dose area product (70.674±9.077 vs 35.770±2.345 mGy*cm^2, p=0.0001), higher rate of pre- and post implantation valve dilatations (pre- 49.2% vs 25.2% p=0.0001; post-dilatation 37.1 vs 16.5% p=0.0007) but similar procedure time (72.8±2.8 vs 75.2±3.8 min, p=0.3) and no difference in the amount of contrast used (151±6 vs 159.7±5.8 ml). Mean hospitalisation duration (10.6±0.4 vs 11±0.5 days, p=0.7) and in-hospital mortality rate (4.0%, vs 3.0%, p=0.7) were similar. In-hospital life threatening bleeding complications (4.8% vs 6.7%, p=0.5), disabling strokes (1.6% vs 1.5%, p>0.9) and permanent pacemaker implantation rate (16.1% vs 13.5%, p=0.6) were also comparable. We observed one periprocedural annulus rupture in the Evolut group (0.8%) and two in the SAPIEN 3 group (1.5%). The transvalvular gradient (max/mean) measured by TTE post procedure (14.3/8.1±0.6/0.4 vs 19.7/11.1±0.6/0.3 mmHg, p<0.0001) and after one year (15.3/8.4±0.7/0.4 vs 21.8/12.1±0.8/0.5 mmHg, p<0.0001) was significantly lower in the Evolut group. All-cause mortality rates after six (10.4 % vs 11.2 %, p=0.9) and 12 months (13.7% vs 17.2 %, p=0.6) were comparable. The heart failure hospitalisation rate (12.1 vs 12.7%) and total permanent pacemaker implantation rate (18.5 vs 15%) were also similar at one year.

Conclusions: Switching from the balloon-expandable SAPIEN 3 to the self-expanding EvolutR/Pro in a medium-size TAVI program (around 60 TAVI/year) was not associated with a difference regarding periprocedural events or one-year clinical outcomes. Implantation of the Evolut R/Pro was associated with a significantly lower transvalvular gradient at all follow-up assessments. Pacemaker implantation rates were high at around 15% of patients in both groups.

TAVI - Tools, devices and techniques

Final three-year clinical outcomes following real-world TAVI with a supra-annular self-expanding repositionable valve: results from the multicentre FORWARD study

VAN MIEGHEM Nicolas [1], VAN MIEGHEM Nicolas [1], WINDECKER Stephen [2], MANOHARAN Ganesh [3], BOSMANS Johan [4], BLEIZIFFER Sabine [5], MODINE Thomas [6], GRUBE Eberhard [7]

(1) Erasmus Universiteit Rotterdam, Rotterdam, the Netherlands; (2) University of Bern, Bern, Switzerland; (3) Royal Victoria Hospital, Belfast, United Kingdom; (4) University of Antwerp, Antwerp, Belgium; (5) German Heart Centre Munich / Deutsches Herzzentrum München, Munich, Germany; (6) Université de Lille, Lille, France; (7) University of Bonn, Bonn, Germany

Aims: Transcatheter aortic valve implantation (TAVI) with contemporary transcatheter valve systems is a proven alternative to surgery across the risk spectrum in elderly patients. Long-term clinical data with the Evolut R supra-annular platform are scarce but important in light of the risk and age creep with TAVI.

Methods and results: FORWARD is a multicentre, prospective, single-arm, observational post-market study that documented the safety and performance of the Evolut R system (23 mm, 26 mm and 29 mm valve sizes, Medtronic, Minneapolis, MN, USA) in standard practice at 53 centres in 20 countries on 4 continents. The Evolut R bioprosthesis is self-expanding and consists of a supra-annular porcine pericardial valve within a low-profile, conformable nitinol frame that can be partially repositioned during implant to assist with accurate placement. Eligible patients had symptomatic native aortic valve or surgical bioprosthesis stenosis and were considered at elevated risk for surgical mortality/morbidity based on Heart Team assessment. A clinical events committee adjudicated serious adverse events. A total of 1,040 patients underwent attempted Evolut R valve implant. Patients were elderly with a mean age of 81.8±6.2 years, more often women (64.8%), with a mean STS score of 5.5±4.5% and mean EuroSCORE II of 5.7±5.0%. Patients were symptomatic (72.0% had NYHA III/IV symptoms) and 34.2% were considered frail. By echocardiographic core laboratory analysis at 1 year follow up, 77.9% had none or trace, 20.9% had mild and 1.2% had > mild aortic regurgitation (AR). At 2 years, the all-cause mortality rate was 16.9% and cardiovascular mortality was 11.6%; disabling stroke rate was 3.3% and a pacemaker was implanted in 20.9% of patients.

Conclusions: The Evolut R valve was shown to have a good safety profile through 2 years in routine practice. The final 3-year clinical outcomes will be available at a later date. Additional analyses will focus on the impact of new pacemakers, patient prosthesis mismatch and more than trace AR on all-cause mortality.

TAVI - CT / MRI imaging

TAVI for low-flow low-gradient aortic stenosis: prognostic impact of aortic valve calcification

LUDWIG Sebastian [1], LUDWIG Sebastian [1], GOSSLING Alina [1], WALDSCHMIDT Lara [1], LINDER Matthias [1], BHADRA Oliver [1], VOIGTLÄNDER Lisa [1], SCHÄFER Andreas [1], DEUSCHL Florian [1], SCHIRMER Johannes [1], REICHENSPURNER Hermann [1], BLANKENBERG Stefan [1], SCHÄFER Ulrich [2], WESTERMANN Dirk [1], SEIFFERT Moritz [1], CONRADI Lenard [1], SCHOFER Niklas [1]

(1) University Heart Center Hamburg GmbH, Hamburg, Germany; (2) Marienkrankenhaus, Hamburg, Germany

Aims: We sought to evaluate the prognostic impact of aortic valve calcification (AVC) in patients with low-flow low-gradient aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI).

Methods and results: This retrospective single-centre analysis includes all patients undergoing TAVI for severe low-flow low-gradient AS (N=526), i.e. low-EF low-gradient AS (LEF-LG AS; n=290) and paradoxical low-flow low-gradient AS (PLF-LG AS; n=236), in whom AVC was quantified from contrast-enhanced multislice computed tomography images. AVCdensity was defined as calcium volume per annulus area. Patients were trichotomized according to sex-specific AVCdensity tertiles in both subgroups. All-cause mortality was assessed by Kaplan-Meier analyses and independent outcome predictors were determined by applying multivariable analyses. In both subgroups, patients with high AVCdensity had higher mean transvalvular gradients at baseline and higher rates of PVL after TAVI. In LEF-LG AS patients high AVCdensity was associated with lowest 1- and 3-year mortality (1 year: 24.9%, 3 years: 44.1%) after TAVI compared to those with moderate (40.0%, 61.7%) and low AVCdensity (40.2%, 56.3%) (p=0.041, p=0.029). In contrast, there was no difference in mortality rates between AVCdensity tertiles in patients with PLF-LG AS. According to multivariable analysis AVCdensity was independently protective against mortality in LEF-LG AS patients (HR 0.73 [0.60-0.88], p=0.0011), but not in those with PLF-LG AS (HR 0.91 [0.73-1.14], p=0.42).

Conclusions: AVCdensity is an independent predictor of survival in patients treated with TAVI for LEF-LG AS. In contrast, AVCdensity was not protective for TAVI patients with PLF-LG AS. Quantification of AVC may not only have diagnostic but also prognostic value, as it facilitates the selection of LEF-LG AS patients with a higher probability of beneficial outcome after TAVI.

Mitral valve replacement and repair - Echocardiography

Impact of periprocedural changes of left ventricle systolic function on long-term survival after transcatheter mitral valve repair

HAGNÄS Magnus [1,2], GRASSO Carmelo [2], CASTANIA Giuseppe [2], DI PASQUALE Francesco [2], MANGIAFICO Sarah [2], MILICI Annalisa [2], CAGEGGI Anna [2], SCANDURA Salvatore [2], CAPODANNO Davide [2], MÄKIKALLIO Timo [3], TAMBURINO Corrado [2]

(1) Department of Internal Medicine, Lapland Central Hospital, Rovaniemi, Finland; (2) Cardiac-Thoracic-Vascular and Transplant Department, Azienda Ospedaliero-Universitaria "Policlinico G. Rodolico-S. Marco", Catania, Italy; (3) Division of Cardiology, Department of Internal Medicine, Oulu University Hospital, Oulu, Finland

Aims: An acute impairment of left ventricle ejection fraction (LVEF) after surgical repair of mitral regurgitation, known as afterload mismatch, has been associated with increased all-cause mortality. Afterload mismatch after MitraClip procedure has been postulated to be a transient phenomenon. In this study we investigated how the changes of LVEF between admission and discharge effected the long-term outcome among patients who underwent MitraClip procedure for secondary (functional) mitral regurgitation.

Methods and results: This study is based on a single-centre, prospective, observational registry of patients who underwent MitraClip implantation for the treatment of symptomatic, moderate-to-severe mitral regurgitation. For these statistical analyses we included data on 201 of the 307 MitraClip procedures (65%) performed on patients with secondary mitral regurgitation between October 2008 and December 2017 with data on LVEF and 3-year follow-up. LVEF was assessed by expert echographers before the MitraClip procedure and before discharge. The patients were divided into groups according to the change of LVEF: improved (n=26), unchanged (n=152) and decreased (n=23). An periprocedural decrease in LVEF after MitraClip procedure was associated with an increased risk of all-cause death in a 3-year follow-up (hazard ratio 2.6, 95% confidence interval 1.33-5.15, p=0.005), when compared to patients with unchanged LVEF after adjusting for age, hypertension, diabetes, symptoms of heart failure according to NYHA-class and pre-procedure measurement of creatinine. The risk of all-cause death for the patients with decreased LVEF after MitraClip procedure was even higher among the 123 patients with low preprocedural LVEF (<35%) (hazard ratio 3.8, 95%, confidence interval 1.66-8.72 p=0.002), when compared to patients with unchanged LVEF, after adjusting for the same confounding factors. The 3-year survival was numerically highest in the group of patients with improved LVEF (21/26, 81%) compared to the group of patients with unchanged (106/152, 70%) and decreased LVEF (11/23, 48%).

Conclusions: A periprocedural decrease of LVEF is associated with worse long-term survival among patients who underwent a MitraClip procedure.

TAVI - Tools, devices and techniques

Long term safety of direct implantation of a self-expanding valve. Insights from the multicentre, randomised DIRECT trial

TOUTOUZAS Konstantinos [1], BENETOS Georgios [1], DRAKOPOULOU Maria [1], KARMPALIOTI Maria [1], STATHOGIANNIS Konstantinos [1], KOSMAS Elias [2], VOUDRIS Vassilis [2], MASTROKOSTOPOULOS Antonios [3], DANENBERG Haim [4], TOUSOULIS Dimitris [1], TOUTOUZAS Konstantinos [1]

(1) Medical School of Athens, Athens, Greece; (2) Onassis Cardiac Surgery Center, Kallithea, Greece; (3) Athens naval hospital, Athens, Greece; (4) Hadassah University Hospital - Ein Kerem, Jerusalem, Israel

Aims: Randomized studies have reported the efficacy and short-term safety of direct implantation without prior balloon aortic valvuloplasty (pre-BAV) of both self-expanding and balloon-expanding valves during transcatheter aortic valve implantation (TAVI) procedures. However, long term safety data comparing direct implantation with pre-BAV in self-expanding valves are lacking. In the present study we aimed to investigate whether direct implantation has an impact on long-term safety.

Methods and results: In DIRECT trial consecutive patients with severe aortic stenosis at 4 centres were randomised to undergo TAVI with the use of self-expanding prostheses, with (pre-BAV) or without predilatation (no-BAV). The primary endpoint was device success according to the VARC-2 criteria. Secondary endpoints included periprocedural mortality and stroke, new permanent pacemaker implantation, vascular complications and one-year mortality. Patients were further followed up clinically after one year with telephone interviews or clinical visits. All cause death and stroke were compared between the two groups using Kaplan-Meier plots. In total 171 patients were randomised in 4 centres. In the intention-to-treat analysis 86 patients were randomised to the pre-BAV group and 85 patients to the no-BAV TAVI group. The device success according to the VARC-2 criteria was non-inferior in the no-BAV group compared to the pre-BAV group (65/85 - 76.5% for no-BAV versus 64/86 - 74.4% for pre-BAV, mean difference=2.1%, 90% CI -8.9 to 13). In the no-BAV group 25 (29.4%) patients underwent post balloon dilatation and in the pre-BAV group 13 patients (15.1%) (p=0.03). Regarding short term safety endpoints no death was recorded in the first 30 days in any of the groups and there was only one stroke in the no-BAV group (log-rank p=0.31). The need for new permanent pacemaker implantation was also similar: (no-BAV n=22 patients-32.8% versus pre-BAV n=19 patients -27.5%, log-rank p=0.54) and there was no difference in the incidence of major vascular complications (no-BAV: n=3 patients-3.5%, pre-BAV: n=5 patients – 5.8%, log-rank p=0.49). In the long term follow up (mean 653±329 days, median 588 days, P25: 369, P75: 921), there were in total 11 deaths in no-BAV group and 7 deaths in pre-BAV (logrank p=0.44). Similarly, there was no difference in the incidence of stroke (2 in no-BAV group versus 1 in pre-BAV group, logrank p=0.55).

Conclusions: Direct transcatheter aortic valve implantation is non-inferior to the procedure with predilatation in self-expanding valve. Moreover, direct procedure has no impact on the long-term mortality.

Mitral valve replacement and repair - Adjunctive pharmacotherapy

Effect of post-procedural optimal medical therapy on long-term prognosis after transcatheter mitral valve repair

HAGNÄS Magnus [1,2], GRASSO Carmelo [2], DI SALVO Maria Elena [2], SARDONE Andrea [2], RAPISARDA Paola [2], MOTTA Gessica [2], PELLICCIA Matteo [2], RUBBIO Antonio Popolo [3], CAPODANNO Davide [2], TIMO Mäkikallio [1], CORRADO Tamburino [2]

(1) Department of Internal Medicine, Heart smithy, Lapland Central Hospital, Rovaniemi, Finland; (2) Cardiac-Thoracic-Vascular and Transplant Department, Azienda Ospedaliero-Universitaria "Policlinico G. Rodolico-S. Marco", Catania, Italy; (3) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy; (4) Division of Cardiology, Department of Internal Medicine, Oulu University Hospital, Oulu, Finland

Aims: Optimal medical therapy (OMT) for mitral regurgitation (MR) and heart failure is highly recommended in the current treatment era; however, the impact of OMT on survival after MitraClip has been poorly characterised among patients who underwent MitraClip procedure.

Methods and results: We investigate how OMT impacts the long-term outcome among patients who underwent a MitraClip procedure for MR. This study is based on a single-centre, prospective, observational registry of patients who underwent MitraClip implantation for the treatment of symptomatic, moderate-to-severe MR. The definition of OMT was adapted from the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial definition, and defined as the use of either angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, beta-blocker and, in patients with New York Heart Association-class (NYHA) III and IV, aldosterone-inhibitors on discharge. A total of 212 patients treated for functional MR were included, with complete information on discharge medication and two-year follow-up. Among the 129 patients without OMT, 50 (39%) deaths from all causes occurred. Among the 83 patients with OMT 23 (28%) deaths occurred. The risk of death among patient without OMT was 2.1 times higher (hazard ratio, 95% confidence interval 1.1–4.1, p=0.022) compared to patients with OMT, when adjusting for age, hypertension, diabetes, ejection fraction, symptoms of heart failure according to NYHA-class, atrial fibrillation and pre-procedure measurement of creatinine and NT-pro b-type natriuretic peptide.

Conclusions: After accounting for potential confounders, patients with OMT after MitraClip procedure are at a lower risk of death compared to patients without OMT. These findings emphasize the importance of optimizing medical therapy among patients with MR after MitraClip procedure.

TAVI - Vascular access and bleeding

Is it time for gender-specific interventional cardiology? Comparison of complication and success rates of ProGlide vascular closure device in patients undergoing TAVI

D'ASCOLI Giulio [1,2], DASCOLI Giulio [1,2], DATO Enrichetta [1], BIONDI Giorgia [1], RUMIZ GONZALEZ Eva [2]

(1) Università degli Studi di Roma Tor Vergata, Facoltà di Medicina e Chirurgia, Metropolitan City of Rome, Italy; (2) Consorci Hospital General Universitari de València, Valencia, Spain

Aims: During TAVI procedure the common femoral artery is the most frequently used peripheral artery access, and the vascular closure device is a necessary instrument that is used to achieve haemostasis in transfemoral TAVI. The complication and success rates of closure devices as Perclose ProGlide are a fundamental argument, especially in the population with high haemorrhagic risk and vascular complications such as female sex. In light of this, the aim of our study was to compare the complication and success rates of the Perclose ProGlide closure device in the two different genders undergoing TAVI.

Methods and results: Patients who received the Perclose ProGlide closure device during TAVI procedures between 2018 and april 2019 at our centre were retrospectively examined. Those who had excessive tortuosity in the iliac arteries, who demonstrated atherosclerotic stenosis greater than 50% or a femoral artery with a diameter of less than 6 mm, or who had prosthetic arterial graft material in the intervention area were not included in the study. The puncture site of all patients was evaluated by computed tomographic angiography prior to the procedure. Each closure device was implemented by the same trained and experienced operator. Under profound sedation, prior to the placement of the closure device, femoral angiography was performed to check the punture site, observe calcification and amount of tortuosity. Arterial access was obteined percutaneously. A small skin opening was made to permit Perclose ProGlide advancement and the closure device was advanced over a 0.035 inch guidewire and deployed. Two sutures were placed in each arteriotomy by use of 6 Fr devices sequentially deployed with opposite rotation in a crosshair configuration. Device related vascular complications are defined as access site bleeding and the occlusion, stenosis, and dissection of the artery used for access. The Bleeding Academic Research Consortium recomendations were used as the bleeding classification measure in this study. Failure to suture, suture rupture and/or breakage and inability to tighten the knot were defined as device failure. A total of 59 patients undergoing TAVI, 29 women and 30 men, were analysed in our study. The mean age of the patients was 80.6 years ± 7.4 years. Demographic data and current comorbidities who received Perclose ProGlide closure devices are for women group diabetes (27%), smoking (6%), hypertension (68%), dyslipidaemia (41%); for men group diabetes (20%), smoking (10%), hypertension (70%) and dyslipidaemia (46%). Of the TAVI patients who received the closure devices we had a total of 9 (15%) complications/device failures and in the two subgroups analysed complication frequency and device failure were statistically significant higher in the women's group (p 0,012; IC 1,2-95) versus in the men's group, respectivetly 7 device failures (24%) and 1 complication (3%) in women versus only 1 device failure (3%) in men.

Conclusions: TAVI is a valid therapeutic option in symptomatic severe aortic stenosis and vascular access site closure significantly affects the mortality and morbidity associated with these procedures. In the future it could be important not only recognizing female sex as a specific and independent risk factor, but also employing strategies to minimise this risk. Therefore, macroscopic anatomy, the comorbidities and the gender can be an important guide in the evolution of closure devices such as the Perclose ProGlide to make procedures safer.

TAVI - Vascular access and bleeding

Impact of diabetes mellitus on female patients undergoing TAVI: insights from the WIN-TAVI registry

GOEL Ridhima [1], GOEL Ridhima [1], CHANDIRAMANI Rishi [1], CAO Davide [1], SARTORI Samantha [1], CLAESSEN Bimmer [1], NICOLAS Johny [1], ROUMELIOTIS Anastasios [1], BABER Usman [1], DANGAS George [1], MEHRAN Roxana [1]

(1) Icahn School of Medicine at Mount Sinai, NY, USA

Aims: Patients with aortic stenosis are being increasingly referred for transcatheter aortic valve implantation (TAVI) in light of its proven efficacy and safety over surgical aortic valve replacement. Although females constitute about half of all TAVI candidates, the association between important comorbidities such as diabetes mellitus (DM) and clinical outcomes after TAVI has yet to be clearly established in this subgroup. Therefore, in this study, we aimed to evaluate the impact of DM on 30-day and one-year clinical outcomes in female patients undergoing TAVI.

Methods and results: Women's International Transcatheter Aortic Valve Implantation (WIN-TAVI) is a real-world registry that exclusively enrolled female subjects with severe aortic stenosis undergoing TAVI at 19 tertiary care centres across North America and Europe between January 2013 and December 2015. All patients were followed up to 1 year after the index procedure. DM status was established based on patient clinical history as entered at the time of the procedure. The primary endpoints for this analysis were Valve Academic Research Consortium (VARC)-2 life-threatening bleeding and VARC-2 efficacy defined as a composite of all-cause death, stroke, myocardial infarction, hospitalisation for valve-related symptoms or worsening congestive heart failure, or valve-related dysfunction (clinical presentation with valve thrombosis or endocarditis). Of the 1,012 subjects included in this study, 26.1% (264) had DM at baseline. High BMI, hypertension, hypercholesterolaemia, history of carotid stenosis, myocardial infarction, stroke, and peripheral arterial disease, as well as prior coronary revascularisation, were more common in DM patients compared to non-DM patients. These subjects were also more likely to have a history of pregnancy-induced complications such as gestational diabetes or hypertension. In addition, DM patients underwent TAVI more often due to high surgical risk, age >80 years, and presentation with pulmonary hypertension, renal failure or LVEF<50%. There were no significant differences in procedural characteristics or periprocedural complications between the two groups. At 30-day follow-up, DM patients had lower rates of both VARC-2 life-threatening bleeding events (1.5% versus 5.5%, p=0.007) and VARC-2 efficacy events (3.0% versus 6.4%, p=0.04) compared to non-DM patients. At 1 year, DM patients continued to have lower rates of life-threatening bleeding (1.5% versus 5.6%, p=0.006), however differences in VARC-2 efficacy endpoint (16.4% versus 16.7%, p=0.89) were attenuated. There were no differences in all-cause mortality at both 30-day and 1-year follow-up among patients with and without DM.

Conclusions: In our study of female patients undergoing TAVI, more than one-fourth of the subjects presented with DM at baseline. These patients had a greater prevalence of both cardiovascular risk factors and a history of prior cerebrovascular events at baseline as compared to their non-DM counterparts. While DM was not associated with increased risk of mortality at any follow-up, these patients had lower rates of VARC-2 efficacy events up to 30 days and lower rates of life-threatening bleeding events up to 1 year after TAVI.

TAVI - Vascular access and bleeding

Percutaneous management of vascular complications following interventional cardiology procedures with peripheral vascular stent grafts

JAFFE Ronen [1], JAFFE Ronen [1], EITAN Amnon [1], SHIRAN Avinoam [1], ZAFRIR Barak [1], ZISMAN Keren [1], FLUGELMAN Moshe [1]

(1) Carmel Medical Center, Haifa, Israel

Aims: Interventional procedures involving large-bore devices carry increased risk for vascular access site complications. We have adopted a strategy of implanting peripheral vascular stent grafts for percutaneous management of access site bleeding following transcatheter aortic valve replacement (TAVI). We subsequently expanded the indications for stent graft implantation to other situations in our interventional cardiology practice. We review our accumulated experience implanting stent-grafts for treating vascular complications.

Methods and results: We reviewed a prospective cardiac catheterisation laboratory registry. All cases of stent graft implantation were recorded. Indications for stent-graft implantation included:1) Failure of vascular closure devices (VCD) following transfemoral TAVR: of 662 transfemoral TAVR procedures, VCD failure occurred in 134 (20%) cases. Implantation of self-expanding stent grafts (Fluency, Bard and VIABAHN, Gore) at the access site achieved haemostasis in all cases, without any major complications. A single patient developed mild leg ischaemia due to occlusion of the superficial femoral artery, which was treated conservatively. 2) Subclavian artery occlusion following TAVR: A patient sustained post-procedural subclavian occlusion. The vessel was recanalised with stent graft implantation. 3) Iliac artery rupture during TAVR: valve delivery via tortuous vasculature resulted in transection of the proximal iliac artery and haemorrhagic shock. Immediate implantation of 6 overlapping stent grafts, from the ostial iliac artery to the common femoral artery, achieved haemostasis and permitted successful valve implantation. 4) Femoral artery pseudoaneurysms: two inoperable patients developed large pseudoaneurysms following coronary angioplasty, which were unresponsive to local compression and thrombin injection. Stent graft implantation was followed by resolution of flow into the pseudoaneurysms and resorption of the haematomas. 5) Ruptured aneurysm in a degenerated saphenous vein coronary bypass graft (SVG): A patient sustained cardiogenic shock following rupture of a SVG aneurysm, which resulted in cardiac tamponade. Immediate delivery of a stent graft sealed the aneurysm.

Conclusions: Peripheral vascular stent grafts may play an important role in percutaneous management of various vascular emergencies in the cardiac catherisation laboratory.

TAVI - Echocardiography

Myocardial mechanics after SAVR and TAVR using non-invasive myocardial work curves: a pilot echocardiographic study

DONURU Srinath [(1)], DONURU Srinath [(1)], ZAYAT Rachad [(1)], LOTFI Shahram [(1)], HATAM Nima [(1)], AALJALLOUD Ali [(1)], AUTSCHBACH Rüdiger [(1)]

(1) Uniklinik RWTH Aachen, Aachen, Germany

Aims: Myocardial damage may occur after surgical aortic valve replacement (SAVR) as well as after transcather aortic valve replacement (TAVR). The novel non-invasive method for regional LV pressure - strain curves corresponds well with invasively measured myocardial work (MW) and is independent of afterload compared to ejection fraction and global longitudinal strain (GLS). In this pilot study, we aimed to compare changes of LV-MW index (MWI) between SAVR and TAVR in the early postoperative period.

Methods and results: 25 TAVR (CoreValve & Symetis) and 25 SAVR (PERIMOUNT) patients, scheduled for elective procedures received transthoracic echocardiography studies pre- and 7 days postoperatively. Besides routine measurements the following parameters were analysed: MWI, global MW efficiency (MWE), global wasted myocardial work (GWMW), GLS and global strain rate (GSR). Results n the TAVR group, 17 patients received transfermoral, 8 patients transapical TAVR. As expected, EuroSCORE II was significantly higher in the TAVR group (p=0.015). GLS was significantly lower (better) in the SAVR group compared to the TAVR group preoperatively (-13.4+4.9 vs-16.7±4.2, p=0.027). Postoperative GLS increased (worsened) in the SAVR group, though no significant difference was detected between the groups (-12.7±5.1% vs -10.4±3.4%, p=0.215) postoperatively. MWI was significantly lower in the TAVR group preoperatively (p=0.033). Within the TAVR group MWI did not decrease significantly postoperatively (1,242 mmHg% vs 1,108 mmHg%, p=0.476). However, postoperative MWI decreased significantly in the SAVR group (1,632 mmHg% vs 1,267mmHg%, p=0.043). MWE and GWMW did not differ between the groups or within the groups comparing pre- and postoperative values.

Conclusions: Despite better GLS values in SAVR patients preoperatively, we could detect a better preservation of GMWI in TAVR patients postoperatively. To evaluate the clinical impact of MWI, further studies with larger cohorts, involving biomarkers of myocardial injury are required.

Mitral valve replacement and repair - CT / MRI imaging

Evaluating the effects of TMVR on local left ventricle function with dynamic four-dimensional computed tomography

COLVERT Gabrielle [1], COLVERT Gabrielle [1], GLYNN Jeremy [2], MCVEIGH Elliot [1]

(1) University of California San Diego, La Jolla, CA, USA; (2) Tendyne (Abbott Laboratories), St. Paul, MN, USA

Aims: X-ray computed tomography (CT) is a promising tool for evaluating local left ventricular (LV) function in patients with abnormal LV geometry and regional dysfunction because of its high 3D spatial resolution and full heart volume coverage. The aim of this work was to evaluate the feasibility of measuring changes in 4DCT-derived regional myocardial strain in patients receiving transcatheter mitral valve replacement (TMVR), a population where local areas of hypokinesis and LV dysfunction are frequent, using pre-procedure and 1-month post procedure CT imaging.

Methods and results: All patients included in the analysis were treated with TMVR (Tendyne) due to significant mitral regurgitation (grade 3 or 4) and deemed not candidates for conventional mitral valve surgery. LV endocardial regional strain (CT SQUEEZ) was measured in 10 patients from retrospective 4DCT exams prior to and 1-month after TMVR. LV strain was evaluated in 90 segments (5 longitudinal x 18 circumferential) to capture the heterogenous local function with high spatial resolution. LV end-diastolic (ED) and end-systolic (ES) volumes and LV ejection fraction (EF) were also measured. Volume vs time curves were constructed across the R-R cycle, and ES was defined as the minimum point on the curve. LV strains for all 90 segments were evaluated at ES to compare before and after TMVR. As the specific anchoring system of the Tendyne TMVR device uses a tether and apical pad, local deformation of the LV is expected in this region. However, the resulting change in LV function at this specific location has not yet been characterised. Therefore, the location of the apical pad was identified on the CT images to compare strain in that segment between baseline and 1-month. Spatial patterns of LV strain showed significant changes in the majority of patients (7/10) after the valve was replaced. The maps of LV strain vs position demonstrate that the complex LV functional state of TMVR patients cannot be fully described by changes, or lack thereof, in ED and ES volumes, nor EF.

Conclusions: Changes in regional LV strain following TMVR have not been well characterised. 4DCT-derived regional strain estimates can be measured in these patients despite highly abnormal regional LV function and LV shapes. Significant changes in LV regional strain were observed following TMVR in most patients. While a reduction in strain on the endocardial surface is seen at the apical pad, this does not explain the total change in local LV strain in many patients. Further analysis of LV strain in a large group of patients could lead to a more precise understanding of the effect of the device on LV function and remodelling.

TAVI - Adjunctive pharmacotherapy

Predictive value of the Mehran score for contrast-induced nephropathy after TAVI

IACOVELLI Fortunato [1], IACOVELLI Fortunato [1], CAFARO Alessandro [2], SPIONE Francesco [1], COLUCCI Natalia [1], PIGNATELLI Antonio [3], TARSELLA Serena [1], DE CILLIS Emanuela [1], TESORIO Tullio [4], CONTEGIACOMO Gaetano [5], BORTONE Alessandro Santo [1]

(1) Policlinico University Hospital, Metropolitan City of Bari, Italy; (2) Regional General Hospital "F. Miulli", Acquaviva delle Fonti, Italy; (3) "Mater Dei" Hospital, Metropolitan City of Bari, Italy; (4) "Montevergine" Clinic, Mercogliano, Italy; (5) "Anthea" Clinic, Metropolitan City of Bari, Italy

Aims: Causes of acute kidney injury (AKI) are numerous and contrast mean (CM) administration along interventional procedures is one of them. Contrast-induced AKI (CI-AKI) is defined as an AKI that occurs within 2-3 days after CM administration which cannot be attributable to any other identifiable cause. The Mehran risk score (MS) was adopted to predict the development of CI-AKI after coronary procedures, and includes clinical and procedural variables. Aim of the present study was to investigate the value of MS in the prediction of CI-AKI development after TAVI.

Methods and results: From 2011 to 2019, 697 patients not in dialysis treatment (327 males, mean age 81.01±5.75, mean STS predicted risk of mortality 5.26±3.81%), admitted to three southern Italy heart centres to undergo TAVI were enrolled. Patients were categorised into four risk groups based on MS: low (≤ 5), moderate (6–10), high (11–15) and very high (≥ 16). Serum creatinine level was measured at baseline (1 day before the procedure), on the procedure day (after an overnight hydration), and then daily until the discharge. If there was >1 measurement post-TAVI available, the greater serum creatinine value within 48 hours was included in the analysis. Estimated glomerular filtration rate (eGFR) was calculated using the Modification of Diet in Renal Disease formula. AKI was defined as stage 1, 2, or 3 according to Valve Academic Research Consortium-2. Preoperatively, 278 (39.88%) patients suffered from chronic kidney disease (eGFR <60 ml/min), 244/609 (40.07%) in AKI- vs 34/88 (38.64%) in AKI+ group (p=0.889). AKI was recorded in 88 patients after TAVI (12.62%). The amount of CM was not significantly higher in the AKI+ group (p=0.434), and early safety was higher in the AKI- group than in the AKI+ group (23.9 vs 5.4%, respectively; p<0.001). In our population we did not find a significant difference in post-procedural incidence of CI-AKI in very high vs high vs intermediate vs low MS group (13.13 vs 12.65 vs 12.23 vs 11.11%, respectively; p=0.985), thus showing no predictive power on CI-AKI of MS. In univariate analysis, any bleeding and any transfusion were found to be significant risk factors for AKI (p<0.001 for both).

Conclusions: MS is not a predictor of CI-AKI development after TAVI, so probably AKI in such setting of patients is more due to other causes than CM administration. Thus according to the fact that AKI impact negatively on periprocedural mortality after TAVI, all available strategies to prevent it have to be applied anyway.

Other valvular and structural interventions - Other

Predicting early discharge after TAVI; cost-utility analysis

VOSKUIL Michiel [1], KOOISTRA Nynke [1], VAN LIESHOUT Chris [2], SCHUIT Ewoud [2], LEENDERS Geert [1], KRAAIJEVELD Adriaan [1], DOEVENDANS Pieter [1], FREDERIX Geert [2], STELLA Pieter [1], VOSKUIL Michiel [1]

(1) UMC Utrecht, Utrecht, the Netherlands; (2) Julius Center for Health Sciences and Primary Care, Utrecht, the Netherlands

Aims: Little is known about all up-coming costs including costs of complications during admission for TAVI and the economic benefit in case of early discharge, nor about the prognostic factors of early discharge, and whether early discharge can be predicted reliably.

Methods and results: We reviewed all TAVI patients who underwent a transfemoral TAVI procedure at our centre between January 2012 and June 2018. Baseline, procedural, and outcome characteristics were collected, as well as data regarding used resources and associated costs for the period of one day prior to procedure to thirty days post procedure. Early discharge was defined as ≤2 days after the TAVI procedure. We identified 490 patients suitable for cost analyses. Majority of costs (74%, median: €12,147) were related to the TAVI procedure itself (excluding the valve) followed by costs incurred for the admission (20%, median: €3,285) in patients without complications. Early discharge reduced costs by €1.971. Balloon-expandable valves and self-expanding valves incur comparable cost. Patients without complications incurred lowest costs (€16,474), whereas patients receiving a pacemaker incurred the highest costs (€28,799). Preprocedural characteristics predicting early discharge included smoking, increased baseline haemoglobin, and the balloon-expandable valve, and risk factors for delayed discharge included increased GFR, frailty and NYHA class (III/IV). Addition of intervention time to these preprocedural characteristics resulted in substantial improvement of the prediction model.

Conclusions: Profit of early discharge in terms of costs is limited. Reducing costs of the procedure (70% of total costs) might be most effective for cost savings.

TAVI - Tools, devices and techniques, Other valvular and structural interventions - Other

Contemporary use of balloon aortic valvuloplasty and evaluation of its success in different haemodynamic entities of severe aortic valve stenosis

PIAYDA Kerstin [1], PIAYDA Kerstin [1], WIMMER Anna [1], SIEVERT Horst [2], HELLHAMMER Katharina [1], AFZAL Shazia [1], VEULEMANS Verena [1], JUNG Christian [1], KELM Malte [1], ZEUS Tobias [1]

(1) University Hospital of Düsseldorf, Düsseldorf, Germany; (2) CardioVasculäres Centrum Frankfurt, Frankfurt, Germany

Aims: Success of percutaneous balloon aortic valvuloplasty (BAV) is commonly defined as a significant mean pressure gradient reduction after the procedure. Outcome assessment of BAV has not been evaluated in the context of different flow and gradient patterns of severe aortic stenosis (AS). We therfore aimed to investigate the relation of the mean pressure gradient reduction in association with the increase in the aortic valve area after BAV in patients with normal-flow high-gradient (NFHG) AS, low-flow low-gradient (LFLG) AS and paradoxical low-flow low-gradient (pLFLG) AS.

Methods and results: Consecutive patients from January 2010 to March 2018 undergoing BAV were divided into NFHG, LFLG and pLFLG AS after current guideline definitions. Baseline characteristics, haemodynamic and clinical information were collected and compared. The decision-making process by the local Heart Team when BAV was considered as the first treatment option of choice is as follows: 1) BAV as bridge-to-decision option in urgent situations: if patients were in cardiogenic shock or refractory heart failure due to severe AS and could not undergo a comprehensive TAVR/SAVR work-up. 2) elective situations: if patients presented with other severe comorbidities not allowing an explicit symptom allocation to severe AS, BAV was used as a “probatory” procedure to test if the increase in the aortic valve area actually led to a significant clinical improvement. 3) BAV as a single procedure: in compliance with current guideline recommendations patients with a life expectancy <12 months underwent BAV to alleviate symptoms. Other options were if the patient had other limitations preventing a treatment with TAVR/SAVR *a priori*, decided not to undergo further cardiac interventions or did not clinically improve after BAV. One-hundred-fifty-six patients were grouped into NFHG (n=68, 43.5%), LFLG (n=68, 43.5%) and pLFLG (n=20, 12.8%) AS. Mean age of the study population was 81 years. Spearman correlation revealed that the mean pressure gradient reduction had a moderate correlation with the increase in the aortic valve area (AVA) in patients with NFHG AS (r:0.529, p<0.001) but showed no association in patients with LFLG (r:0.145, p=0.239) and pLFLG (r:0.030, p=0.889) AS. Underlying reasons for patients to undergo BAV and not TAVR/SAVR *a priori* varied between groups, however cardiogenic shock or refractory heart failure (overall 46.8%) were the most common ones. After the procedure patients showed a functional improvement, represented by substantially lower NYHA class levels (p<0.001), lower NT-pro BNP levels (p=0.003) and a numerical but non-significant improvement in other echocardiographic parameters like the left ventricular ejection fraction (p=0.163) and tricuspid annular plane systolic excursion (p=0.066). An unplanned cardiac re-admission due to heart failure was necessary in 23.7%. Less than half of the patients (44.2%) received BAV as a bridge TAVR/SAVR with a median of 64 days (26-142). Survival was significantly increased in patients having BAV as a staged procedure (log-rank p<0.001).

Conclusions: The mean pressure gradient reduction might be an adequate surrogate parameter for BAV success in patients with NFHG AS, but is not suitable for patients with other haemodynamic entities. BAV as a staged procedure in selected clinical scenarios increases survival and is a considerable option in all flow states of severe AS.

Other valvular and structural interventions - Other

Mixed aortic valve disease: impact on outcome after TAVI

STATHOGIANNIS Konstantinos [1], STATHOGIANNIS Konstantinos [1], TOUTOUZAS Konstantinos [1], DRAKOPOULOU Maria [1], SOULAIDOPOULOS Stergios [1], TOSKAS Pantelis [1], XANTHOPOULOU Maria [1], OIKONOMOU George [1], LATSIOS George [1], SYNETOS Andreas [1], TOUSOULIS Dimitrios [1]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: The introduction of transcatheter valve implantation (TAVI) into clinical practice has provided new treatment options for patients with severe aortic valve stenosis. Mixed aortic valve disease with concomitant aortic regurgitation is common amongst these patients. Whether mixed aortic valve disease has an impact on the long-term outcome of patients scheduled for TAVI remains uncertain. We sought to investigate in symptomatic patients with severe aortic stenosis the impact of concomitant aortic valve regurgitation on clinical outcomes after TAVI with a self-expanding valve.

Methods and results: Consecutive patients with severe symptomatic aortic stenosis scheduled for TAVI in our tertiary centre were included in the study. Prospectively collected data before and after TAVI were retrospectively analysed in all patients. Patients with no aortic regurgitation were considered as 'isolated aortic stenosis' patients whereas patients with at least mild aortic regurgitation were considered as 'mixed aortic valve disease' (MAVD) patients. All outcomes were evaluated according to the VARC-2 criteria. Primary clinical endpoint was considered 4-year all-cause mortality. We included 200 patients (age: 81±2 years; logistic EuroSCORE 23±8%; 57% females; NYHA III 81%) in the study. Fifty-eight (24%) had isolated aortic stenosis and 152 patients (76%) had mixed aortic valve disease. The primary clinical end point occurred in 8 patients with isolated aortic stenosis and in 34 patients with mixed aortic valve disease (16% versus 22%, p=0.54). No major differences were observed in cardiovascular death (12.5% versus 11.8%, p=0.9), stroke (6% versus 3%, p=0.36) and acute kidney injury (7% versus 5%, p=0.2) between the two groups. At univariate analysis, predictors for mortality were: severe aortic regurgitation before TAVI (p=0.002, OR: 9.9, 95% CI: 2.3-41) and mean gradient (p=0.27, OR: 1.014, 95% CI: 0.98-1.04). At multivariate analysis, severe aortic regurgitation before TAVI (p=0.001, OR: 10, 95% CI: 2.41-41) was an independent predictor of long-term mortality.

Conclusions: Mixed aortic valve disease with severe aortic regurgitation before TAVI is associated with increased long-term mortality and further studies are needed in order to explore possible implications in patient selection. Several factors should be considered, including the severity of aortic regurgitation.

TAVI - Tools, devices and techniques

The impact of persistent pulmonary hypertension in women undergoing TAVR with a self-expanding valve

STATHOGIANNIS Konstantinos [1], STATHOGIANNIS Konstantinos [1], TOUTOUZAS Konstantinos [1], DRAKOPOULOU Maria [1], TOSKAS Pantelis [1], OIKONOMOU George [1], XANTHOPOULOU Maria [1], SOULAIDOPOULOS Stergios [1], LATSIOS George [1], SYNETOS Andreas [1], TOUSOULIS Dimitrios [1]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: Women have a higher prevalence of pulmonary hypertension (PH). The aim of this study was to determine the prevalence, factors and clinical outcomes associated with persistent PH in women with aortic valve stenosis undergoing transcatheter aortic valve replacement (TAVR) with a second-generation self-expanding valve.

Methods and results: Female patients with symptomatic severe aortic valve stenosis who underwent TAVR were evaluated and consecutively enrolled. PH was defined as systolic pulmonary arterial pressure (sPAP) > 40mmHg as assessed by transthoracic echocardiography. Persistent PH post TAVR was considered an sPAP above 40mmHg. Patients with an sPAP decrease after TAVR to below 40mmHg were compared to patients with persistent PH following TAVR. All outcomes were evaluated according to the VARC-2 criteria. The primary clinical endpoint was 1-year all-cause mortality. In total 139 women were included (mean age 81.05± 6.32 years old, logEuroSCORE 25.13± 9.88%, NYHA III Class 95%). Of the 139 patients, 72 (52%) had sPAP less than 40mmHg and 67 (48%) had sPAP above 40mmHg at baseline. After TAVR, 79 (57%) patients had sPAP less than 40mmHg and 60 (43%) had sPAP above 40mmHg. All patients experienced a decrease in sPAP post TAVR (44.98± 11.87mmHg to 42.44± 11.34mmHg, p=0.01). Patients with PH at baseline experienced a significant decrease in sPAP after TAVR (54.43± 10.63mmHg to 47.67± 13.40mmHg, p<0.01). Multivariable analysis identified pre-TAVR ejection fraction below 40% to be the most powerful predictor for persistent PH after TAVR (odds ratio 3.7, 95% confidence interval 1.10-12.71, p=0.034). Patients with persistent PH after TAVR had a trend for higher mortality rates at 1 year compared to those with sPAP less than 40mmHg (35% vs 20%, p=0.056).

Conclusions: Women with pulmonary hypertension and aortic valve stenosis tend to have a worse prognosis in the long-term after TAVR. Although these patients should not be excluded from TAVR, the Heart Team should consider this variable during risk assessment, while awaiting further trials.

TAVI - CT / MRI imaging

The effect of aorto-ventricular angulation on outcomes following TAVR with a self-expanding valve

STATHOGIANNIS Konstantinos [1], STATHOGIANNIS Konstantinos [1], TOUTOUZAS Konstantinos [1], DRAKOPOULOU Maria [1], OIKONOMOU George [1], XANTHOPOULOU Maria [1], TOSKAS Pantelis [1], SOULAIDOPOULOS Stergios [1], PAPANIKOLAOU Angelos [1], LATSIOS George [1], SYNETOS Andreas [1], TOUSOULIS Dimitrios [1]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: The degree of angulation between the aorta and the left ventricle (aorto-ventricular angulation, AA) poses difficulties during transcatheter aortic valve replacement (TAVR). Data concerning the impact of AA on device success and clinical outcomes after TAVR with a newer-generation self-expanding valve are limited.

Methods and results: Consecutive patients with severe symptomatic aortic stenosis scheduled for TAVR were studied. Prospectively collected data were retrospectively analysed in all patients. All patients who underwent TAVR had contrast computed tomography prior to TAVR. AA was defined as the angle between the horizontal plane and the basal plane of the aortic annulus in a coronal projection. Keeping with previously published literature, patients were divided retrospectively into two groups based on the mean AA; low angulation (group A) and high angulation (group B). All outcomes were evaluated according to the VARC-2 criteria. We included 195 patients (age: 79.79±7.97 years; logistic EuroSCORE 23.78±8.41%; 48% females; NYHA III 83%) in the study. Mean AA was 43.76±9.49°; therefore, group A was defined as AA<44° (n=127) and group B as AA≥44° (n= 74). Baseline characteristics in both groups were similar. Device success rate was no different between the 2 groups. Patients in group B had increased fluoroscopy time compared to group A (37.92±12.97 min vs 34.44±9.65 min, p=0.031). Patients in group B had increased rates of post TAVR valve dilation compared to group A (29% vs 14%, p=0.01). There were no cases of severe paravalvular leakage (PVL) after the procedure. However, patients in group B had higher rates of moderate PVL compared to patients in group A (15% vs 4%, p=0.025). A ROC curve analysis was performed and a mean AA >49.5° was found to be associated with higher rates of moderate PVL post TAVR (AUC 0.736, 95% CI: 0.588-0.883, p=0.002). Mid-term all-cause mortality was comparable to both groups (4% in group A vs 8% in group B, p=0.21).

Conclusions: In patients undergoing TAVR with a self-expanding valve aorto-ventricular angulation has an impact on procedural characteristics and post TAVR paravalvular leakage. Meticulous planning of the procedure is mandated for optimal results.

TAVI - Echocardiography

Early recovery of left ventricular systolic function after TAVI

STATHOGIANNIS Konstantinos [(1)], STATHOGIANNIS Konstantinos [(1)], TOUTOUZAS Konstantinos [(1)], DRAKOPOULOU Maria [(1)], XANTHOPOULOU Maria [(1)], TOSKAS Pantelis [(1)], OIKONOMOU George [(1)], SOULAIDOPOULOS Stergios [(1)], LATSIOS George [(1)], SYNETOS Andreas [(1)], TOUSOULIS Dimitrios [(1)]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: There is conflicting evidence about the impact of left ventricular ejection fraction (LVEF) in patients undergoing transcatheter aortic valve implantation (TAVI). The aim of this study was to investigate the mid-term effect of TAVI on patients with aortic stenosis and low LVEF.

Methods and results: In total, 278 consecutive patients with symptomatic severe aortic stenosis (AS) underwent TAVI with a newer-generation valve. For the purposes of the analysis, patients with baseline LVEF <50%, no more than moderate mitral valve regurgitation, successful valve implantation, and 1-month clinical and echocardiographic follow-up available were included in the study (n=101). All data were prospectively collected and retrospectively analysed. Outcomes were based on the VARC-2 criteria. All patients had severe symptomatic AS (mean transaortic pressure gradients: 48.39±14.00 mmHg, peak transaortic pressure gradients: 78.01±20.99 mmHg and mean aortic valve area: 0.64±0.21 cm^2). Mean baseline LVEF was 44.26±7.46%. Significant haemodynamic improvement was observed after TAVI with a mean transvalvular aortic gradient decreasing significantly compared to the baseline levels (10.40±6.18, p<0.001). A statistically significant improvement in LVEF compared to baseline was observed in the 1st month of follow-up (44.26±7.46% vs 47.69±9.10%, p<0.001). Overall, 48.5% of patients had no change in LVEF, 44.6% of patients showed an increase in LVEF and only 6.9% had a decrease in LVEF. Mid-term mortality did not differ among the 3 groups based on the LVEF change (p=0.77).

Conclusions: Patients with depressed systolic function show an early LVEF recovery after TAVI, without a mortality effect. Longer term studies are necessary in order to fully elucidate the improvement of LVEF in this population.

Mitral valve replacement and repair - Tools, devices and techniques

Prognostic role of disproportionate secondary mitral regurgitation in patients undergoing MitraClip: results from a multicentre cohort

ADAMO Marianna [1], ADAMO Marianna [1], CANI Dario [1], GAVAZZONI Mara [2], TARAMASSO Maurizio [2], FIORELLI Francesca [3], GIANNINI Cristina [3], CURELLO Salvatore [1], PETRONIO ANNA Sonia [3], MAISANO Francesco [2], METRA Marco [1]

(1) Civil Hospitals of Brescia, Brescia, Italy; (2) Universitätsspital Zürich, Zürich, Switzerland; (3) University Hospital of Pisa, Pisa, Italy

Aims: To evaluate the prognostic role of echocardiographic parameters assessing secondary mitral regurgitation (SMR) severity and left ventricular dimension, including proportionate versus disproportionate SMR, in a real-world population undergoing MitraClip.

Methods and results: We analysed 137 patients undergoing MitraClip for SMR at 3 centres. SMR was classified as proportionate or disproportionate based on the median value of the ratio between effective regurgitant orifice area (EROA) and left ventricular end-diastolic volume (LVEDV). The primary endpoint was a composite of cardiovascular mortality and heart failure hospitalisation at 2-year follow-up. Mean age was 70±10 years, 80% were males, and median EuroSCORE II was 5.7%. No differences were observed in disproportionate compared to proportionate group except for a more severe NYHA class and their expected higher EROA and lower LVEDV. Number of clips deployed, and device and procedural success, defined according to MVARC recommendations, were similar between the two groups. Residual mitral regurgitation (MR)>1+ at 30-day was more common among patients EROA>0.42 cm^2 compared to those with EROA<0.42 cm^2 (81.3% vs 58%; p=0.004). Cumulative incidence of 2-year composite endpoint was 46.1% with a numerically higher rate among patients with EROA>0.42 cm^2 compared to those with EROA ≤ 0.42 cm^2 (53.4% vs 41%; Log rank p=0.064). No significant differences were observed between patients with LVEDV> or ≤190 ml (48.4% vs 43.3%; p=0.900) and between patients with proportionate or disproportionate SMR (41.5% vs 50.3%; Log rank p=0.100). The relative risk of primary endpoint was independent from any echocardiographic parameter, including the presence of disproportionate SMR. The only independent predictors of clinical events were EuroSCORE II>8%, NYHA class and residual MR>1+ at 30-day.

Conclusions: Echocardiographic parameters, including the detection of disproportionate SMR, do not predict outcomes in a real-world setting of patients undergoing MitraClip. High surgical risk, advanced symptoms and non-optimal MR reduction increase the relative risk of 2-year clinical events.

TAVI - Tools, devices and techniques

Impact of frailty and nutritional status on mortality in patients with severe aortic valve stenosis undergoing percutaneous TAVI

AL-KASSOU Baravan [(1)], AL-KASSOU Baravan [(1)], SHAMEKHI Jasmin [(1)], FELDMANN Katharina [(1)], GERMEROTH Jana [(1)], GILLRATH Jana [(1)], WEBER Marcel [(1)], SEDAGHAT Alexander [(1)], GRUBE Eberhard [(1)], TREEDE Hendrik [(1)], WERNER Nikos [(1)], NICKENIG Georg [(1)], SINNING Jan-Malte [(1)]

(1) UKB Universitätsklinikum Bonn, Bonn, Germany

Aims: TAVI is an established treatment option for elderly patients with severe aortic valve stenosis, not suitable for open heart surgery. The current ESC guidelines recommend the STS and EuroSCORE II as tools for risk stratification. However, these surgical risk scores have major limitations, as they do not consider important risk factors such as frailty, functional, cognitive and nutritional status of the patients. The aim of this study was to assess the impact of frailty status on mortality and to evaluate the prognostic value of different frailty assessment tools on outcome in TAVI patients.

Methods and results: Our study cohort consisted of 360 consecutive patients (mean age 81±6.1 years, median STS-score 4.4 and median EuroSCORE II 4.9) who underwent TAVI between February and September 2018. The frailty status in these patients was assessed using the Katz Index of Independence in Activities of Daily Living, Fried Frailty Phenotype (FFP) and the Essential Frailty Toolset (EFT Score). The Mini Nutritional Assessment - Long Form (MNA) and the Controlling Nutritional Status (CONUT) score were used for the assessment of the nutritional status of the cohort. According to the FFP score, 163 (45.3%) cases were considered frail, 172 (47.8%) cases as prefrail, and only 25 (7.0%) patients as robust. Regarding the MNA, 186 (51.7%) patients were at normal nutritional status, whereas 150 (41.7%) patients were at risk for malnutrition, and 24 (6.7%) patients were already malnourished. The frailty tests as well as the nutrition scores showed a significant correlation with one-year all-cause mortality (FFP robust: 8.0% vs prefrail: 7.0% vs frail patients: 15.3%, p=0.04), (EFT Score <3: 7.1% vs EFT Score ≥3: 16.2%; p<0.001), (CONUT - Normal nutrition: 6.6% vs CONUT - Undernutrition: 17.9%; p=0.001), (MNA – normal nutrition: 6.4% vs malnutrition: 33.3%, p=0.001). In ROC curve analysis, comparing the predictive value of the different frailty and nutritional scales for one-year all-cause mortality, the FFP (AUC 0.7 [95% CI: 0.53 – 0.80], p=0.01) and MNA Score (AUC 0.7 [95% CI: 0.55 – 0.80], p=0.01) showed the strongest association with mortality. However, in multivariate analysis, only the nutritional tools CONUT and MNA remained independent predictors of the mortality (CONUT: HR 2.5, 95% Cl: 1.3-4.8; p=0.006; MNA: HR 1.9, 95% Cl: 1.1 to 3.2; p=0.01).

Conclusions: A comprehensive assessment of the clinical patient condition including frailty status is thought to be crucial for risk stratification and the decision-making process for which treatment option a specific patient should undergo. In this study we show that frailty and malnutrition are associated with increased mortality in patients with severe aortic valve stenosis. The CONUT and MNA score were independent predictors of one-year all-cause mortality. A combination of FFP and MNA seems to be the most suitable frailty assessment tool to predict mortality in these patients.

Mitral valve replacement and repair - Echocardiography, Other valvular and structural interventions - Other

Prevention of cardiac maternal mortality in the developing world: screening pregnant women in Hyderabad, India, for structural heart disease

PATEL Amisha [1], PATEL Amisha [1], NICOLE Aranoff [3], RANARD Lauren [1], KUMAR A. Srinivas [2], KODALI Susheel [1], LEON Martin [1]

(1) Columbia University, NY, USA; (2) Apollo Hospital Jublihills, Telangana, India; (3) Yeshiva University, NY, USA

Aims: Rheumatic heart disease (RHD) remains an important preventable cause of pregnancy-related cardiovascular morbidity and mortality, and the burden of RHD is higher in India than anywhere else in the world. We aim to: 1) define the epidemiology and demographics of valvular heart disease in at-risk pregnant women at two high-volume centres in Hyderabad, India through the use of screening echocardiograms, 2) identify the associated clinical characteristics and complications seen in this population, and 3) explore the social determinants of health that contribute to the persistence of this disease.

Methods and results: Screening echocardiograms were performed on 12,329 pregnant women at two high-volume government hospitals in Hyderabad, India between May 2017 and September 2019. Uninsured women were originally seen in a prenatal clinic and then referred, without exception, for a screening echocardiogram. Of the 12,329 pregnant women screened, 313 had a structural heart abnormality (2.5%). The average age of women who screened positive was ¬¬24.3 years. The majority of these women had no formal education or had attended primary school only. None of the 12,329 women screened had health insurance or worked outside the home. The most commonly seen abnormalities in those who screened positive were mitral stenosis (n=83, 26.5%), and atrial septal defect (n=46, 14.7%). Other structural abnormalities noted were ventricular septal defect (n=6), bicuspid aortic valve (n=9) and patent ductus arteriosis (n=7). Forty-seven women had dilated cardiomyopathy. Those with mitral stenosis had a mean Wilkins score of 6.3, a mean mitral gradient of 7.5±5.3 mmHg, and mean pulmonary artery systolic pressure of 37±16 mmHg. Thirteen women were eligible for and underwent balloon mitral valvuloplasty. All had subsequent uncomplicated deliveries.

Conclusions: The prevalence of structural heart disease in pregnant women from two high-volume medical centres in Hyderabad, India was 2.5%, predominantly due to RHD and congenital abnormalities. Larger-scale efforts may better elucidate the epidemiology and cost-effectiveness of screening for structural heart disease in this dually at-risk population and identify candidates for intervention. A better understanding of these patterns may help address the social determinants of health (eg overcrowding, sanitation, and literacy) that contribute to this preventable cause of maternal mortality.

TAVI - Vascular access and bleeding

Comparison of clinical outcomes after transcarotid and trans-subclavian vs transfemoral TAVI: a propensity-matched analysis

VILLECOURT Aurélien [1], VILLECOURT Aurélien [1], FAROUX Laurent [1], MUNEAUX Alexandre [1], TASSAN-MANGINA Sophie [1], HEROGUELLE Virginie [1], PONCET Anne [1], NAZEYROLLAS Pierre [1], RUGGIERI Vito Giovanni [1], METZ Damien [1]

(1) HOPITAL ROBERT DEBRE CHU REIMS, REIMS, France

Aims: Transcarotid and trans-subclavian accesses are increasingly used as alternative approaches for transcatheter aortic valve implantation (TAVI) when the transfemoral access is not suitable. However, concerns remain about the risk of periprocedural stroke and long-term outcomes following transcarotid or trans-subclavian TAVI. The present study sought to compare early- and long-term outcomes of transcarotid or trans-subclavian versus transfemoral TAVI after propensity-score matching.

Methods and results: The 260 patients who underwent TAVI through a transfemoral (n=220), transcarotid (n=32) or trans-subclavian (n=8) approach at our institution during a 4 years period were identified. A 1:1 matching based on the propensity-score was performed and lead to a study population of 80 patients (40 transfemoral and 40 transcarotid or trans-subclavian patients). Primary endpoints were early complications whereas secondary endpoints were long-term outcomes. There was no difference in the baseline characteristics of the 2 groups. At 30-day post-TAVI, there was no significant difference in mortality and stroke rates between transfemoral and transcarotid or trans-subclavian TAVI (5% vs 5% mortality, p=1.000 and 2 vs 1 stroke, p=1.000, respectively). After a median follow-up of 21 months, the risk of death (p=0.950), stroke (p=0.817) and myocardial infarction (p=0.155) did not differ between the 2 groups.

Conclusions: After propensity-score matching, no significant difference in early and long-term outcomes was observed between transfemoral and transcarotid or trans-subclavian TAVI. These findings should encourage Heart Teams to consider a transcarotid or trans-subclavian approach when transfemoral access is not available.

TAVI - CT / MRI imaging

CT is the main component of the global exposure to ionising radiation for patients benefitting from a transfemoral TAVI

VILLECOURT Aurélien [1], VILLECOURT Aurélien [1], FAROUX Laurent [1], BLANPAIN Thierry [1], KINNEL Marine [1], MORA Caroline [1], TASSAN-MANGINA Sophie [1], HEROGUELLE Virginie [1], NAZEYROLLAS Pierre [1], METZ Damien [1]

(1) HOPITAL ROBERT DEBRE CHU REIMS, REIMS, France

Aims: X-rays are widely used for TAVI realisation, for pre-TAVI assessment (coronary angiography ± PCI and CT scan), and sometimes in the aftermath of the intervention (electrophysiology study, pacemaker implantation). TAVI has become an alternative to surgical valve replacement for patients at intermediate-to-low risk, a population that is likely to experience an increase in radiation-induced cancer risk following TAVI. The main objective of our study was therefore to evaluate the overall exposure to ionising radiation for patients benefitting from a transfemoral TAVI.

Methods and results: All patients who underwent transfemoral TAVI for a symptomatic aortic stenosis in our centre over a 26 months period were included. Dosimetric indicators (i.e. dose area product or dose length product) of preprocedural coronary angiography and computed tomography, TAVI procedure, and any post-procedural interventions (electrophysiology study and/or pacemaker implantation) were collected and converted into an effective dose. The primary endpoint was the cumulative effective dose, calculated by summing effective doses received during the TAVI procedure and during pre- and post-procedural irradiating exams. 119 transfemoral TAVI procedures were included, and the mean cumulative effective dose was 37.3 mSv. When only three procedures were necessary (71% of the population), 75% of the overall effective dose was from the computed tomography, while only 11% of this dose came from the TAVI procedure itself and 14% came from the coronary angiogram.

Conclusions: Overall exposure to ionising radiation for patients benefitting from a transfemoral TAVI seemed acceptable, and the majority of the overall effective dose was from the computed tomography.

TAVI - Tools, devices and techniques

Long-term outcome with new-generation prostheses in patients undergoing TAVI

TAMM Alexander [(1)], TAMM Alexander [(1)], GEYER Martin [(1)], OMAR Hahad [(1)], ANDRES Beiras [(1)], MÜNZEL Thomas [(1)], VON BARDELEBEN Stephan [(1)]

(1) Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Mainz, Germany

Aims: Transcatheter aortic valve implantation (TAVI) is today the first option for older patients with aortic valve stenosis (AS) at intermediate or high risk for surgery. Constant development of bioprosthetic valves and delivery systems has reduced complications and improved outcomes over the years. The third-generation Edwards SAPIEN 3 Valve (S3) and the second-generation Medtronic Evolut R Valve (ER) are currently the most frequently used worldwide. There is a paucity of published data regarding long-term outcomes in these new-generation TAVI patients.

Methods and results: In our retrospective, single-centre analysis we included patients with severe aortic stenosis who underwent transfemoral TAVI with a new-generation prosthesis between 2014 and 2016. Peri- and post-procedural outcomes of these patients were analysed according to the VARC-2 criteria. The study population consisted of 359 patients (mean patient age 82±7 years, 47% male, mean EuroSCORE II 8.0±8). The S3 group included 215 patients, the ER group 144 patients. Median follow-up period was 3.8 years (IQR 3.3 to 4.4 years, maximum follow-up in living patients 5.1 years). Device success rates were equal in both groups (93.0% vs 92.4%, p=0.812). We report a 30-day mortality of 2.8% in the S3 group, 2.1% in the ER group, respectively (p=0.674). There was no difference in stroke rate, conversion to open heart surgery, major vascular complications, life-threatening or disabling bleeding or myocardial infarction. Implantation of a new permanent pacemaker was lower in the S3 group (S3: 27.4% vs ER: 44.5%, p=0.002). While prosthesis mean gradients were higher in the S3 group (12.0 mmHg vs 8.2 mmHg, p<0.001), there was a tendency to fewer paravalvular leaks (PVL ≥ 2: 1% vs 3.6%, p=0.088). All-cause mortality up to 5 years did not show a difference between patient groups (mean survival S3 3.5 years, ER 3.3 years, p=0.895). Independent predictors of death were impaired left ventricular function (HR 1.61, p=0.007), chronic kidney injury (HR 1.55, p=0.032), peripheral artery disease (HR 2.10, p=0.003), malignant tumor (HR 2.40, p<0.001) and periprocedural stroke (HR 3.95, p=0.007).

Conclusions: We present a comparison of the new-generation aortic valve prostheses Edwards SAPIEN 3 and Medtronic Evolut R concerning long-term as well as periprocedural outcomes. The analysed cohort consisted of patients at intermediate to high surgical risk. Yet, 30-day mortality was very low both in S3 and ER patients. Device success and periprocedural outcomes in both groups were comparable and are in line with previous studies using VARC-2 definitions. New-generation TAVI valves offer an excellent implant and outcome success rate compared to early transcatheter aortic valve replacement. Long-term survival was independent of prosthesis choice and was mainly attributed to pre- and intraprocedural comorbidities and complications.

Other valvular and structural interventions - Other

Survival and quality of life after TAVI relative to the general population

ZELIS Jo [(1)], ZELIS Jo [(1)], VAN 'T VEER Marcel [(1)], HOUTERMAN Saskia [(1,2)], PIJLS Nico [(1)], TONINO Pim [(1)]

(1) Catharina Ziekenhuis Eindhoven, Eindhoven, the Netherlands; (2) Netherlands Heart Registration, Utrecht, the Netherlands

Aims: Little is known about survival and quality of life (QoL) of patients treated by transcatheter aortic valve implantation (TAVI) compared to the age- and sex-matched general population. In this study we compared subgroups of the National Heart Registration TAVI cohort to the Dutch age- and sex-matched population at the level of survival and QoL.

Methods and results: Th were extracted from the Netherlands Heart Registration (NHR) the TAVI cohort (time period 2013-2017) and compared to the national Dutch population data collected from the national statistics office, Statistics Netherlands (CBS). Subgroups were defined according to sex and age (<65, 65-80 and >80). For QoL analyses the age subgroups <65, 65-75 and >75 were used. Long term survival was significantly higher in the general population compared to the TAVI population. Elderly TAVI patients (>80 years) had the same survival as the age-matched general population. Survival in women was better than in men in both the general population and the TAVI cohort. Patients treated by TAVI, aged 65 years and older had a comparable QoL to that of the general population.

Conclusions: This study shows that TAVI patients aged 80 years and older have a similar long-term survival as the age-matched general population. However, because of lower survival in under 80 TAVI patients, the overall long term survival of all TAVI patients is worse than that of the general population in the Netherlands. This study also suggests that QoL after TAVI treatment is comparable to QoL in the general population.

TAVI - CT / MRI imaging

Defining optimal fluoroscopic projection for TAVI with self-expanding device: concordance between the "double-S curve" and "cusp-overlap" methods

BEN-SHOSHAN Jeremy [1,2], ALOSAIMI Hind [1], PIGHI Michele [1,3], THÉRIAULT LAUZIER PASCAL [1], PAVEL Overtchook [1], MARTUCCI Giuseppe [1], SPAZIANO Marco [1], FINKELSTEIN Ariel [2], GADA Hemal [4], PIAZZA Nicolo [1]

(1) McGill University Health Centre, QC, Canada; (2) Ichilov, Tel Aviv-Yafo, Israel; (3) University of Verona, Verona, Italy; (4) PinnacleHealth Cardiovascular Institute, Wormleysburg, Pennsylvania, Wormleysburg, USA

Aims: Optimal fluoroscopic views for transcatheter aortic valve implantation (TAVI) with self-expanding devices require co-perpendicular projection of the annulus and delivery catheter. The "double-S curve" method defines the intersection of the optimal projection curves of the annulus and delivery catheter as implantation view. Recently, the "cusp-overlap" approach, consisting of overlapping projection of the left and right coronary cusps, was suggested to determine TAVI optimal view. Herein, we assess the concordance between optimal views generated by the double-S curve and cusp-overlap methods.

Methods and results: We included 100 consecutive patients with severe native aortic valve stenosis undergoing TAVI with self-expanding devices planned by preprocedural multidetector computerised tomography (MDCT). Optimal projection for TAVI was determined by the double S-curve model as a view in which both the aortic valve annulus and the delivery catheter appear perpendicular on fluoroscopy. Optimal projection according to the cusp-overlap technique was also assessed by MDCT by overlapping the left and right coronary cusps, and concordance between methods was evaluated in vertical (cranial/caudal [CRA/CAU]) and horizontal (left/right anterior oblique [LAO/RAO]) axes. TAVI using the double-S curve model was associated with high procedural success rate (98%), low complication rate and absence of moderate or severe paravalvular leak. The double-S curve and cusp-overlap techniques provided views located in the RAO/CAU quadrant in 82% and 87% of patients, respectively, with no significant difference in mean coordinates [RAO 14.7±15.2 vs 12.9±12.5, p=0.36 and CAU 27.0±9.4 vs 26.9±10.4, p=0.9 respectively). The two methods correlated significantly in both horizontal and vertical axes (Pearson's correlation coefficient r =0.54 and 0.58, respectively, p<0.001). Discrepancy between implantation views generated by the two methods occurred mostly on the horizontal rather than vertical axis (10.6±8.3 and 7.0±5.9, respectively, p<0.001).

Conclusions: The double S-curve is a reliable model for definition of optimal projection for TAVI with self-expanding devices and is associated with satisfying outcomes. The cusp-overlap technique provides projections comparable to the double-S curve model and its application might preclude intraprocedural fluoroscpic image processing or substantial C-arm adjustments.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Thirty-day outcomes with the novel PASCAL transcatheter valve repair system in patients with tricuspid regurgitation from the multicentre, prospective CLASP TR early feasibility study

KODALI Susheel [1], KIPPERMAN Robert [2], ELEID Mackram [3], SMITH Robert [4], GRAY William [5], LIM Scott [6], GREENBAUM Adam [7], ZAHR Firas [8], HAHN Rebecca [1,9], DAHOU Abdellaziz [9], DAVIDSON Charles [10]

(1) Columbia University, NY, USA; (2) Morristown Medical Center, NJ, USA; (3) Mayo Clinic, MN, USA; (4) The Heart Hospital Baylor Scott & White, TX, USA; (5) Lankenau Medical Center, PA, USA; (6) University of Virginia Health System University Hospital, VA, USA; (7) Emory University Hospital Midtown, GA, USA; (8) Oregon Health & Science University, OR, USA; (9) Cardiovascular Research Foundation, NY, USA; (10) Northwestern University Feinberg School of Medicine, IL, USA

Aims: Tricuspid regurgitation (TR) is prevalent and associated with high morbidity and mortality with limited treatment options. This is the first report of 30-day outcomes from the ongoing prospective, multicentre, single-arm CLASP TR early feasibility study (EFS) of the PASCAL transcatheter valve repair system (Edwards Lifesciences, Irvine, CA) in the treatment of patients with TR.

Methods and results: 34 patients with symptomatic TR reviewed by the local Heart Team and central screening committee were treated with the PASCAL repair system. Data were collected at baseline, discharge, and 30-day follow-up and reviewed by an independent clinical events committee and echocardiographic core lab. Feasibility endpoints included safety (composite major adverse event (MAE) rate), procedural efficacy, and echocardiographic, clinical and functional endpoints. Mean age was 76 years, 53% female, and 88% atrial fibrillation/flutter. At baseline, 81% of patients had ≥severe TR with 16% severe, 16% massive, and 48% torrential, 79% were in New York Heart Association (NYHA) class III-IV, 70% had oedema, and mean LVEF was 58%. At 30 days, one non-cardiovascular mortality was reported. The MAE rate was 5.9% with no cardiovascular mortality, stroke, MI, renal complications or reintervention. At 30 days, 83% of patients achieved TR severity reduction by at least 1 grade (on a five-grade scale) with 57% ≤moderate TR ($p<0.001$) in paired analysis. Echocardiography showed significant reduction in PISA EROA and mean vena contracta width by 36% (0.75 cm^2 vs 0.48 cm^2, $p=0.023$) and 46% (1.36 cm vs 0.73 cm, $p<0.001$), respectively. 91% of patients were in NYHA class I-II ($p<0.001$), and six-minute walk distance and Kansas City Cardiomyopathy Questionnaire score significantly improved by 54 m ($p<0.001$) and 14 points ($p=0.002$), respectively.

Conclusions: In this early experience, the PASCAL transcatheter valve repair system showed a favourable safety profile and performed as intended in patients with symptomatic TR. At 30 days, the PASCAL repair system resulted in statistically significant TR reduction with significant improvements in functional status, exercise capacity, and quality of life. The study is ongoing.

TAVI - Tools, devices and techniques

TAVI uptake in a large-volume institution: pattern of use and clinical outcomes from 12 years experience with 1,590 patients

DENISE Todaro [(1)], TODARO Denise [(1)], BARBANTI Marco [(1)], COSTA Giuliano [(1)], LA SPINA Ketty [(1)], PICCI Andrea [(1)], SGROI Carmelo [(1)], TAMBURINO Corrado [(1)]

(1) C.A.S.T. - Azienda Ospedaliera "Policlinico Vittorio Emanuele", Catania, Catania, Italy

Aims: The adoption, penetration, and clinical use trends of transcatheter aortic valve implantation have been quite variable at national and local levels and have evolved over time. The study aims to assess in-hospital and long-term (10-year) outcomes of the entire cohort of consecutive patients undergoing TAVI in a single institution and to analyse the TAVI trends throughout the 12-year period.

Methods and results: Based on local TAVI registry, the study collected all consecutive TAVI performed in a single centre between June 2007 and August 2019. Clinical and procedural outcomes were defined according to the Valve Academic Research Consortium–2 consensus. Trends in patient characteristics and outcome over time were estimated by the Mann-Kendall trend test. A total of 1,590 procedures were performed and the number of procedures linearly increased (trendline $y = 20.98 x – 16.85$; $R^2 = .,93$). The mean STS score was 4.5±3.2 and the mean age was 80.9±5.5 years. The approach was mainly transfemoral (96.5%) and under local anesthesia (97.5%), with a prevalence of self-expanding devices (n=1.182, 74.4%). Device success was 90.3% and more-than-mild residual aortic regurgitation was reported in 5.5% of patients. In-hospital mortality rate was 3.8%. During hospitalisation incidence of disabling stroke, life-threatening bleeding and need of permanent pacemaker were 1.1%, 4.6% and 11.9%, respectively. At 1 year the rates of all-cause mortality, cardiovascular mortality and stroke were 14.9%, 9.2% and 3.4%, respectively. 10-year survival rate was 21.3%. Trend analysis showed a marked decrease in patient risk profile (mean Society of Thoracic Surgeons mortality risk score 5.2%±3.3% in 2007 vs 3.6%±2.1% in 2019; $p<0.001$), although age remained unchanged all along the study period. Over the years there was a significant improvement in device success (p for trend <0.001), mainly due to the reduction of post-procedural moderate or severe residual regurgitation (20% in 2007; 0.6% in 2019, p for trends < 0.001). In-hospital outcomes showed a trend in reduction of in-hospital mortality and significant reduction of cardiovascular mortality, and the rate of permanent pace-maker implantation decreased from 22.2% in 2007 to 10.2% in 2019 ($p<0.001$). Likewise, time of post-procedural hospitalisation decreased from 5.9±2.9 days in 2007 to 3.4±2.6 days in 2019, (p for trends <0.001). Also 30-day and 1-year all-cause mortality decreased significantly between the years 2008 and 2018 from 14.2% to 6% and from 26.1% to 18.3%, respectively.

Conclusions: This all-comers TAVI experience, in line with major randomised trials, confirms the excellent results gained by the procedure over the years with a positive trend in terms of clinical and procedural outcomes

Tricuspid / Pulmonary valve - Tools, devices and techniques

Early clinical experience with a simple tricuspid valve repair system

REARDON Michael [(1)], REARDON Michael [(1)]

(1) Houston Methodist Hospital, TX, USA

Aims: Tricuspid regurgitation is a prevalent disease associated with high morbidity and mortality, with an unmet clinical need for a percutaneous treatment option for high surgical risk patients. The aim of the 4TECH TriCinch study is to evaluate the safety and effectiveness of the TriCinch Transcatheter Repair System in symptomatic patients suffering from moderate or greater functional tricuspid regurgitation (FTR).

Methods and results: The study is a multicentre, prospective, single-arm, non-randomised trial evaluating up to 90 patients in 20 centres worldwide. Study cohort includes patients with moderate or greater FTR with tricuspid annular dilatation of ≥40 mm, New York Heart Association Class II or higher, left ventricular ejection fraction ≥30%, and whom the Heart Team deems suitable for TriCinch implantation. Patient exclusion is primarily due to systolic pulmonary artery pressure of >60 mmHg, previous tricuspid valve procedure, tethering distance >10 mm, or presence of trans-tricuspid lead that may interfere with the procedure. Primary endpoint is all-cause mortality at 30 days post-procedure. Secondary endpoints include technical success defined per MVARC, number of induvial adverse events, functional improvement parameters, and quantitative improvement in TR grade evaluated on transthoracic echo. All echo parameters are adjudicated by an independent core lab including, TV annular diameter, TV area, vena contracta, PISA EROA, quantitative EROA, TV regurgitant volume, TAPSE, as well as the five-class TR grading system (mild, moderate, severe, massive, and torrential). Twenty-four patients have been treated with the TriCinch device to date. The study is currently enrolling and is registered with ClinicalTrials.gov, numbers NCT03294200 and NCT03632967. Early experience includes a frail 86 y.o. female with baseline characteristics of moderate-severe FTR, a clinical history of atrial fibrillation, arterial hypertension, sPAP of 45 mmHg, ejection fraction 55%, and mitral regurgitation 1+. The TriCinch procedure was successfully performed in under one hour with significant reduction in TR. Final clinical and echo assessment confirmed reduction of TR to mild with a vena contracta of 2mm (baseline 7mm) and a septo-lateral diameter of 27mm (baseline 40mm). Patient was discharged post-procedure in good clinical and haemodynamic condition. Another reported experience includes an 83 y.o. female with baseline characteristics of severe FTR, arterial hypertension, sPAP of 50 mmHg, ejection fraction of 55%, mitral regurgitation of 2+. The TriCinch procedure was performed under one hour with improved outcomes in TR reduction with a vena contracta of 5mm (baseline 11mm), septo-lateral diameter of 36mm (baseline 50mm). Patient was discharged post-procedure in good clinical and haemodynamic condition. At the one-month follow-up, patient reported an improvement in QOL and has returned to normal physical activity.

Conclusions: Early experience with the TriCinch device has demonstrated feasibility and efficacy in high risk patients suffering from FTR with an encouraging reduction in TR grade and meaningful improvements in QOL. Further data and evaluation will confirm the observations of the early results.

TAVI - Echocardiography

The two-year follow-up of SAPIEN 3 20mm transcatheter heart valve implantation in small body size Asian patients

MEGURO Kentaro [(1)], MEGURO Kentaro [(1)], MURAMATSU Yusuke [(1)], HASHIMOTO Takuya [(1)], AKO Junya [(1)]

(1) Kitasato University School of Medicine, Kanagawa, Japan

Aims: Transcatheter aortic valve implantation (TAVI) is effective in treating severe aortic stenosis. It was reported that small transcatheter heart valve (THV) implantation was associated with the prosthetic-patient mismatch (PPM), however, little is known about the mid-term outcomes after SAPIEN 3 20 mm THV implantation in small body size. The purpose of this study was to clarify the mid-term outcomes of SAPIEN 3 20 mm THV implantation in Japanese patients with a small body size.

Methods and results: We retrospectively collected the hospital records of consecutive patients who underwent TAVI using the SAPIEN 3 20 mm THV between October 2016 and April 2019. Clinical and echocardiographic data before, one month, one year and two years after TAVI were collected. Ten Japanese patients (all female, mean age 87±5 years, body surface area 1.28±0.13 m^2, STS score, 8.1±2.1) received a SAPIEN 3 20 mm THV in our institution. All the procedures were successful, and the 30-day, one-year and two-year mortality rates were 0%. The functional class and the echocardiographic findings significantly improved (aortic valve area (AVA), 0.5±0.2 cm^2 to 0.9±0.2cm^2; mean pressure gradient (mPG), 60.2±21.3 mmHg to 20.6±4.8 mmHg; $p<0.001$, $p<0.001$, respectively). Only mild paravalvular leakage was observed in 3 patients (30%). However, the values of the indexed effective orifice area in 7 patients (70%) after SAPIEN 3 20 mm THV implantation were less than 0.85 cm^2/m^2, suggesting patient-prosthesis mismatch (PPM). One and two years after TAVI, the AVA (1.0±0.3 cm^2, 0.9±0.2 cm^2, ns, compared to 1 month after TAVI), mPG (21.1±6.9 mmHg vs 22.4±8.2, ns, compared to 1 month after TAVI) was maintained during the follow-up period (Median 26 months, IQR 12-30 months). At two years, 4 patients (57%) were diagnosed with moderate haemodynamic structural valve deterioration (SVD, mPG ≥ 20 mmHg or peak velocity ≥ 3 m/s), however, no patient showed severe SVD (mPG ≥ 40 mmHg or peak velocity ≥ 4 m/s).

Conclusions: The implantation of a SAPIEN 3 20 mm THV was safe and effective in high surgical risk elderly Japanese patients with a small body size. PPM after SAPIEN 3 20mm THV may be prevalent among Japanese patients, however, the AVA and mean pressure gradient was maintained for two years after TAVI. A longer careful follow-up period might be necessary to clarify the consequences of the small THV implantation in small body size.

Other valvular and structural interventions - Other

Balloon valvuloplasty with non-occlusive balloon as destination therapy in elderly with severe aortic stenosis: a pilot study

SCALONE Giancarla [1], SCALONE Giancarla [1], AIMI Alessandro [1], MARIANI Luca [1], DI VITO Luca [1], D'ANTONIO Antonella [1], SILENZI Simona [1], GROSSI Pierfrancesco [1]

(1) Ospedale C e G "Mazzoni", Province of Ascoli Piceno, Italy

Aims: Balloon aortic valvuloplasty (BAV), may be the only option in elderly patients with comorbidities and high-risk scores that make transcatheter aortic valve replacement (TAVR) a futile procedure or in inoperable patients with anatomy that precludes TAVR. Among risks inherent in BAV is low cardiac output due to rapid ventricular pacing (RVP), especially in patients with severely impaired left ventricular function. We herein report our experience utilising a non-occlusive balloon for BAV, which does not require RVP.

Methods and results: From 2017 to 2018, 11 high-risk elderly patients were treated with BAV as destination therapy for symptomatic severe aortic stenosis (AS) and were all prospectively included in the study. Their haemodynamic parameters were invasively evaluated during catheterisation, pre- and post-BAV at the same session. We performed two balloon inflations, of 30 seconds each one. All procedures were completed without RVP. All post-BAV patients were regularly followed-up by outpatient visit and echocardiogram. The mean age of the patients was 87.36±4.65 years (82% females) and the mean of Society of Thoracic Surgeons risk score (STS) was 9.27%±3.3. The ejection fraction prior to the procedure was 46.7%±13.3. Eight patients (72.7%) were admitted with diagnosis of acute heart failure; 5 patients (45.4%) were classified as NYHA Class III and 3 patients (27.3%) as NYHA IV. The mean pressure gradient between the left ventricle and the aorta before and after inflation was 38.8±20.8mmHg, and 19.33±10.26 mmHg, respectively (p=0.012). The peak-to-peak gradient before and after inflation was 71.33±17.72 mmHg, and 26.50±12.6 mmHg, respectively (p=0.003). There were no reports of device-related safety events (i.e., death, stroke, annulus rupture, coronary occlusions, or ventricular perforation) during the procedure. At a mean of 14.09±4.2 months follow-up, 3 patients (27.3%) died from extra-cardiac causes (mean time of events 11±1.0 months). The mean transaortic pressure gradient assessed by echocardiogram was 27.9±12.5 mmHg (p=0.05, compared to mean pressure gradient before BAV) and all patients were classified as NHYA II.

Conclusions: Our preliminary data showed that BAV as destination therapy for severe AS offered immediate and long-term significant haemodynamic improvement in high-risk elderly patients.

Other valvular and structural interventions - Other

Long-term outcome following valve-in-valve TAVI for failing stentless surgical aortic bioprosthetic valves

DUNCAN Alison [1], DUNCAN Alison [1], QUARTO Cesare [1], YADAV Rashmi [1], DAVIES Simon [1]

(1) The Royal Brompton & Harefield NHS Trust, London, United Kingdom

Aims: Valve-in-valve transcatheter aortic implantation (ViV-TAVI) is an alternative to redo-surgery for patients with failing aortic valve replacement (AVR), but the procedure may be technically challenging due to lack of anatomic fluoroscopic markers. We aim to report outcome at 1-, 3-, and 5-years after ViV-TAVI for failing stentless AVR.

Methods and results: We report all patients undergoing ViV-TAVI for failing stentless AVR between 2009 and 2019 at our centre. Forty patients (70±15years, range 25-88years) are reported. Stentless AVRs were homografts (n=27), Freestyle valves (n=7) and Toronto valves (n=6). All patients had severe aortic regurgitation and all were in New York Heart Association Class III or IV. Pulmonary hypertension (>60 mmHg) was present in 74% of patients, 32% had previous coronary bypass grafts, 31% had chronic kidney disease (estimated glomerular filtration rate<60 ml/min/1.73m^2), 14% had severe pulmonary disease (carbon monoxide transfer factor <35%), and 13% had previous stroke. European System for Cardiac Operative Risk Evaluation (EuroSCORE II) was 21±14%; Society of Thoracic Surgeons risk score 15±9%. Malpositioning occurred in 3 patients, device embolisation in 2; there were no cases of coronary obstruction. Post-procedural paravalvular leak was absent/trivial/mild in 35 patients. 1-, 3-, and 5-year actuarial mortality rates were 15.9%, 24.5%, and 32.5% respectively. At 5 years, all surviving patients were in New York Heart Association Class I or II and brain natriuretic peptide levels had decreased from 635±947ng/L to 204±152ng/L. There were no cases of late valve migration, structural valve dysfunction, or increase in severity of paravalvular leak. Though left ventricular ejection fraction did not change, there were significant reductions in mitral regurgitation severity, left ventricular filling pressure (E/E' decreased 18±8 to 13±7, p=0.029), and pulmonary arterial pressure (48±15 mmHg to 35±13 mmHg, p=0.007).

Conclusions: The five-year outcome in a high-risk population after ViV-TAVI for failing stentless aortic bioprosthesis is encouraging, with symptomatic improvement, stable device function, and improvement in left ventricular haemodynamics.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Two-year outcomes with the Cardioband tricuspid system from the multicentre, prospective TRI-REPAIR study

NICKENIG Georg [1], VON BARDELEBEN Ralph Stephan [2], SCHAEFER Ulrich [3], ALESSANDRINI Hannes [4], JULIARD Jean-Michel [5], URENA-ALCAZAR Marina [5], LATIB Azeem [6], MONTORFANO Matteo [6], BALDUS Stephan [7], MAISANO Francesco [8], HAUSLEITER Jeorg [9]

(1) University Hospital Bonn, Bonn, Germany; (2) University Medical Center, Mainz, Germany; (3) University Heart Center, Hamburg, Germany; (4) St. George Hospital, Hamburg, Germany; (5) Bichat Hosptial, Paris, France; (6) San Raffaele Institute, Milan, Italy; (7) University Hospital Cologne, Cologne, Germany; (8) University Hospital Zurich, Zurich, Switzerland; (9) Luwig-Maximilians University Hospital, Munich, Germany

Aims: Severe or greater tricuspid regurgitation (TR) is associated with high morbidity and mortality rates with limited treatment options. We report the two-year outcomes of the Cardioband Tricuspid Valve Reconstruction System (Edwards Lifesciences, Irvine, CA, USA) in the treatment of moderate-to-severe functional TR in 30 patients enrolled in the single-arm, multicentre, prospective TRI-REPAIR study.

Methods and results: Eligible patients had moderate-to-severe, symptomatic TR in the absence of untreated left-heart disease and were deemed inoperable due to unacceptable risk for open-heart surgery by the local Heart Team. Clinical, functional, and echocardiographic data were prospectively collected before and up to two years post procedure. An independent core lab assessed all echocardiographic data and an independent clinical event committee adjudicated the safety events. Mean patient age was 75 years, 73% were females, 23% had ischaemic heart disease, and 93% had atrial fibrillation. At baseline, 83% were in NYHA Class III-IV, 63% had oedema, and LVEF was 58%. Technical success was 100%. At two years, survival rate was 72%. Two patients underwent late device-related secondary interventions. Of the 29 patients who entered 2 year follow-up, between baseline and two years (paired analyses), echocardiography showed average reductions of annular septolateral diameter of 22% (44mm vs 34mm, $p<0.001$), PISA EROA of 67% (0.85cm^2 vs 0.28cm^2, $p=0.009$), and mean vena contracta of 45% (1.2cm vs 0.7cm, $p=0.007$). Clinical assessment showed that at two years 81% of patients were in NYHA Class I-II ($p=0.003$). Six-minute walk distance improved by 71m ($p=0.092$). Kansas City Cardiomyopathy Questionnaire score improved by 12 points ($p=0.075$). Oedema was absent in 88% ($p=0.125$) of the patients.

Conclusions: These results show that the Cardioband Tricuspid System performs as intended and appears to be safe in patients with symptomatic and moderate-to-severe functional TR. At two years significant reduction of TR through a sustained decrease of annular dimensions, improvements in heart failure symptoms, quality of life, and exercise capacity were observed.

Tricuspid / Pulmonary valve - Tools, devices and techniques

Thirty-day outcomes with the Cardioband tricuspid system in the U.S. early feasibility study

GRAY William [1], LIM Scott [2], SMITH Robert [3], KODALI Susheel [4], KIPPERMAN Robert [9], ELEID Mackram [5], REISMAN Mark [6], WHISENANT Brian [10], DAHOU Abdellaziz [7], DAVIDSON Charles [8]

(1) Lankenau Medical Center, PA, USA; (2) University of Virginia Health System University Hospital, VA, USA; (3) The Heart Hospital Baylor, Plano, TX, USA; (4) Columbia University Medical Center, NY, USA; (5) Mayo Clinic, MN, USA; (6) University of Washington, WA, USA; (7) Cardiovascular Research Foundation, NY, USA; (8) Northwestern University Feinberg School of Medicine, IL, USA; (9) Morristown Medical Center, NJ, USA; (10) Intermountain Medical Center, UT, USA

Aims: Increasing grades of tricuspid regurgitation (TR) are associated with progressively greater morbidity and mortality however treatment options for isolated significant disease are limited. We report the 30-day outcomes of the Cardioband Tricuspid Valve Reconstruction System (Edwards Lifesciences, Irvine, CA, USA) in the treatment of symptomatic chronic moderate or greater functional TR despite medical therapy.

Methods and results: In this single-arm, multicentre, prospective early feasibility study (EFS), eligible patients had moderate or greater symptomatic functional TR and were deemed candidates for transcatheter tricuspid repair by the local Heart Team and screening committee. In the 22 patients with 30-day data currently available, clinical, functional, and echocardiographic data were prospectively collected at baseline, discharge, and 30-day follow-up. An independent core lab assessed all echocardiographic data and an independent clinical event committee adjudicated the safety events. Mean patient age was 78 years, 77% were female, 96% had atrial fibrillation, and 68% had pulmonary hypertension. At baseline, 27% had severe TR, 23% massive TR, and 50% torrential TR. 73% were in NYHA Class III-IV, 59% had oedema, and mean LVEF was 59%. Technical success was 96%, and all patients were alive at 30 days. Between baseline and 30 days, echocardiography showed 83% of patients achieved TR severity reduction by at least 1 grade (on a five-grade scale) with 44% patients ≤moderate TR ($p<0.001$) and average reductions of 38% in PISA EROA (0.77cm^2 vs 0.48cm^2; $p=0.003$), 35% in mean vena contracta (1.4cm vs 0.9cm; $p<0.001$) and 15% in septolateral annular diameter (45mm vs 38mm; $p<0.001$). At 30 days, 71% of patients were in NYHA Class I-II ($p<0.001$). Kansas City Cardiomyopathy Questionnaire score improved by 13 points (54 points vs 66 points; $p=0.003$).

Conclusions: The Cardioband Tricuspid System is a favourable treatment option for patients with clinically significant functional TR. Results from this study demonstrate high procedural success and no 30-day mortality. There is significant reduction of functional TR through annular reduction along with clinically significant improvements in functional status and quality of life.

TAVI - Adjunctive pharmacotherapy

Bleeding complications drive early mortality of patients with atrial fibrillation after TAVR

STACHON PEter [1], STACHON Peter [1], KAIER Klaus [1], ZEHENDER Manfred [1], LOTHER Achim [1], BODE Christoph [1], VON ZUR MÜHLEN Constantin [1]

(1) Universitäts-Herzzentrum Bad Krozingen, Freiburg, Germany

Aims: Atrial fibrillation is a risk factor for poor post-operative outcome after transfemoral transcatheter aortic valve replacement (TF-TAVR). The present study analyses the outcomes after TF-TAVR in patients with or without atrial fibrillation (AF) and identifies independent predictors for in-hospital mortality in clinical practice.

Methods and results: All 57,050 isolated TF-TAVR performed between 2008 and 2016 in Germany were identified. 44.2% of patients had AF. Patients with AF were at higher risk for unfavourable outcome after TAVR. Including all baseline characteristics for a risk-adjusted comparison, AF was an independent risk factor for in-hospital mortality after TAVR. Among patients with AF (n=25,309), EuroSCORE, NYHA class or renal disease had only moderate effects on mortality, while the occurrence of post-procedural stroke substantially increased in-hospital mortality (OR 3.55, $p<0.001$). However, the strongest independent predictor for in-hospital mortality among patients with AF was bleeding (OR 11.04, $p<0.001$). Bleeding also was by far the strongest predictor for prolonged mechanical ventilation (OR 25.36, $p<0.001$).

Conclusions: The present study demonstrates that the incidence of bleeding defines the early outcome of patients with AF after TF-TAVR. Thus, the periprocedural phase demands particular care in anti-thrombotic regimen.

TAVI - Adjunctive pharmacotherapy, Other valvular and structural interventions - Other

Outcomes of TAVI in high- or low-volume centres in Germany

STACHON Peter [1], STACHON Peter [1], OETTINGER Vera [1], KAIER Klaus [1], ZEHENDER Manfred [1], BODE Manfred [1], VON ZUR MÜHLEN Constantin [1]

(1) Universitäts-Herzzentrum Bad Krozingen, Bad Krozingen, Germany

Aims: Transcatheter aortic valve implantation (TAVI) is the most common aortic valve replacement in Germany. Since 2015 the German Society of Cardiology certifies those hospitals that meet minimum requirements (50 interventions per centre and 25 per interventionalist and year) in order to ensure a high quality. The current study analyses the impact of these requirements on case number and in-hospital outcomes.

Methods and results: All isolated TAVI procedures and in-hospital outcomes between 2008 and 2016 were identified by ICD and OPS codes. 73,467 isolated transfemoral and transapical TAVI procedures were performed in Germany between 2008 and 2016. During that period, the number of TAVI procedures per year rose steeply whereas the overall rates of hospital mortality and complications declined. In 2008, the majority of procedures were performed in hospitals with fewer than 50 cases per year (54.63 %). Until 2014, the share of patients treated in low-volume centres constantly decreased to 5.35 %. After the revision of recommendations, the share further declined to 1.99 %. In the two years after the introduction of minimum requirements on case numbers, patients were at decreased risk for in-hospital mortality when treated in a high-volume centre (risk adjusted odds ratio 0.62, p=0.012). The risk for other in-hospital outcomes (stroke, permanent pacemaker implantation and bleeding events) did not differ after risk-adjustment (p=0.346, p=0.142, and p=0.633, respectively).

Conclusions: A minimum volume of 50 procedures per centre and per year appears suitable to allow for sufficient routine and thus better in-hospital outcomes, while ensuring nationwide coverage with the TAVI procedure.

TAVI - Tools, devices and techniques

Real-world use of cerebral protection in patients undergoing transfemoral TAVR

STACHON Peter [1], STACHON Peter [1], KAIER Klaus [1], ZEHENDER Manfred [1], BODE Christoph [1], VON ZUR MÜHLEN Constantin [1]

(1) Universitäts-Herzzentrum Bad Krozingen, Freiburg, Germany

Aims: Preventing strokes is an important aim in TAVR (transcatheter aortic valve replacement) procedures. Embolic protection devices may protect from cardiac embolisms during TAVR, but use and outcomes in clinical practice remain controversial.

Methods and results: Isolated transfemoral TAVR procedures performed in Germany with or without cerebral protection devices were extracted from a comprehensive nationwide billing dataset. In the most recent years available, 2015 and 2016, 25,560 TAVR procedures were analysed. The overall share of procedures employing cerebral protection devices was 2.8%. In order to compare outcomes, which may be related to the use of a cerebral protection device, a risk-adjusted comparison was performed. While the risk of in-hospital mortality did not differ (OR 0.71, 95% CI: 0.43-1.23, p=0.223), the risk for stroke was significantly higher in patients receiving a cerebral protection device (OR 1.73, 95% CI: 1.15-2.52, p=0.009). Risk for delirium was lower in patients with cerebral protection device (OR 0.72, 95% CI: 0.53-0.99, p=0.04).

Conclusions: Based on our findings and previous studies the routine use of cerebral protection devices should be performed with caution until further data from randomised controlled trials show a reliable reduction of strokes or cerebral failure such as delirium or long-term cognitive decline.

2020 PCR e-Course Peripheral interventions

Euro20A-OP049
Abstract | Oral presentation

Below the knee - Stents, devices and techniques

Oriented CD34 antibody immobilisation on endovascular devices for enhanced endothelialisation – in vitro characterisation and in vivo testing

KUTRYK Michael [1,2], KUTRYK Michael [1,2], ZHANG Qiuwang [1,2], DUNCAN Sebastian [1,2], DE MESTRAL Charles [1]

(1) St. Michael's Hospital, ON, Canada; (2) Li Ka Shing Knowledge Institute, ON, Canada

Aims: The longterm patency of small diameter expanded polytetrafluoroethylene (ePTFE) grafts, commonly used for peripheral arterial bypass, is limited by thrombotic occlusion of these devices, and the formation of thrombi on bioprosthetic heart valves can lead to devastating consequences. We developed a novel method to affix a base matrix that allows for oriented antibody attachment to endovascular devices and medically relevant biomaterials. The coating provides a biocompatible surface that can capture CD34+ mononuclear cells and promote the formation of an endothelial cell monolayer.

Methods and results: Dopamine, through self-polymerisation, was deposited on the surface of cobalt-chromium, ePTFE, polyurethane, and bovine pericardium. Subsequently, the poly-dopamine coating was allowed to react with amino-PEG8-t-Boc-hydrazide followed by incubation with CD34 antibody that had undergone oxidation of the oligosaccharides in the Fc region to yield reactive aldehyde group. The coated surface was characterised by scanning electron microscopy (SEM), transmission electron microscopy and X-ray photoelectron spectroscopy. An *in vitro* cell binding assay was used to examine the ability of immobilized antibody to bind CD34+ cells, and a porcine carotid interposition model was used to test CD34 antibody-coated grafts for enhanced endothelialisation. The coating was smooth and had a thickness of approximately 300 nm. The main chemical elements on the coated surface included carbon, oxygen, fluorine, nitrogen and silicon. Immobilised CD34 antibody was able to bind CD34+ cells but not CD34- cells. The intermediate coating without CD34 antibody and non-coated materials failed to bind CD34+ cells. We demonstrated robust binding of CD34+ cells *in vitro* on the surface of cobalt chromium, bovine pericardium, ePTFE, and polyurethane. *In vivo* assessment in a pig carotid interposition model showed a confluent monolayer of endothelial cells on the luminal surface of CD34 antibody coated grafts while only very sparse cells were seen in non-coated grafts and grafts with intermediate coating only, as assessed by SEM.

Conclusions: Our data suggests that our unique biocompatible coating with oriented anti-CD34 antibodies can effectively capture CD34+ cells and can be adopted to improve the performance of endovascular devices through enhancement of surface endothelialisation.

Euro20A-OP100
Abstract | Oral presentation

Other peripheral interventions - Other

Sirolimus-coated angioplasty balloons in the salvage of thrombosed arteriovenous grafts

TAN Chieh Suai [1], TAN Chieh-Suai [1], TANG Tjun Yip [1], TAN Ru Yu [1], PANG Suh Chien [1], GOGNA Apoorva [1], CHONG Tze Tec [1], TAN Chee Wooi [1]

(1) Singapore General Hospital, Singapore General Hospital, Singapore

Aims: Sirolimus-coated balloons (SCB) have been found to prevent restenosis in coronary artery disease but have not been studied in arteriovenous access circuits. Previous studies demonstrated that thrombosed arteriovenous grafts (AVG) have poor post-intervention primary patency. This study therefore aims to determine the patency outcomes of thrombosed arteriovenous graft (AVG) following treatment with SCB.

Methods and results: This is a single-centre, prospective pilot study (ClinicalTrials.gov Identifier: NCT03666208) to investigate the use of sirolimus-coated angioplasty balloons in the salvage of thrombosed AVG. Patients who presented with thrombosed AVG were offered enrolment and are treated with SCB at the graft vein junction after successful percutaneous thrombolysis and angioplasty to salvage their AVG. These patients were followed-up for 6 months. The primary endpoint is the patency rate at 3 months, while the secondary endpoints include patency rates and the number of interventions needed to maintain patency at 6 months. A total of 20 patients (mean age: 68±9.7 years old, female:65%) with thrombosed AVG (brachioaxillary AVG: n=15, bachiobasilic AVG: n=2, forearm AVG: n=2) were recruited. Sixty-five percent (n=13) of thrombolysis was performed with recombinant tissue plasminogen activator and the remaining with urokinase. The sizes of the high-pressure plain angioplasty balloons used to treat the graft vein junction were between 6-8mm in diameter. Cutting balloons were required in four patients for adequate vessel preparation. The majority of the patients (n=13, 65%) were treated with 7mm SCB balloon while the rest (n=7, 35%) were treated with 8mm SCB. No residual stenosis or clots were seen in any interventions. The primary patency rate at 3 months post-intervention was 70%. Five patients have yet to complete their 6-month follow-up. Using the Kaplan-Meier technique, the estimated mean primary patency and assisted patency post-intervention were 263.6±40.8 days. and 301.9±38.3 days, respectively. Four patients had recurrent thrombosis post-intervention and their AVG were eventually abandoned. One patient died from intracranial haemorrhage and one patient had explant of the AVG due to infection. Both were unrelated to the procedure and their grafts were still patent at the time of the event.

Conclusions: The results from this pilot study suggest that SCB may be useful in improving patency rates of thrombosed AVG after successful salvage therapy. Larger randomised controlled studies are needed to verify the findings.

Below the knee - Stents, devices and techniques

12-month clinical outcomes of sirolimus-eluting bioresorbable peripheral scaffold system following percutaneous transluminal angioplasty of below-the-knee arteries in patients with critical limb ischaemia: the CREDENCE BtK-1 study

SOMESHWAR Vimal [1], SOMESHWAR Vimal [1], BANODE Pankaj [2], KAMERKAR Dhanesh [3], WARAWDEKAR Gireesh [4], KHANNA Narendra [5], KUMAR Viveka [6], UKIRDE Vivek [6], DANI Sameer [7], DESAI Sanjay [8], CHANANA Bharat [9]

(1) Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Maharashtra, India; (2) Datta Meghe Institute of Medical Sciences, Maharashtra, India; (3) Ruby Hall Clinic, Maharashtra, India; (4) Holy Family Hospital & Medical Research Center, Maharashtra, India; (5) Indraprastha Apollo Hospital, Delhi, India; (6) Max Super Speciality Hospital, Delhi, India; (7) Lokmanya Tilak Municipal General Hospital And Medical College, Maharashtra, India; (8) Life Care Institute of Medical Science & Research, Gujarat, India; (9) M.S.Ramaiah Hospital, Karnataka, India; (10) Maharaja Agrasen Hospital, Delhi, India

Aims: The aim of this study was planned to evaluate the safety and performance of the sirolimus-eluting bioresorbable peripheral scaffold system in patients with critical limb ischaemia following percutaneous transluminal angioplasty of below-the-knee arteries.

Methods and results: The CREDENCE BtK-1 is a first-in-man prospective, multicentre and open-label study conducted at 12 different clinical centres across India. The safety endpoint included the absence of clinical complications at one month. Performance endpoints were primary patency, limb salvage rates, target lesion revascularisation, improvement of Rutherford-Becker classification and ankle-brachial index at 12-month follow-up. The angiographic endpoint was late lumen loss at 6-month follow-up. Quantitative vessel analysis was performed on all target lesions to evaluate the percentage stenosis, minimal lumen diameter and reference vessel diameter. A total of 32 scaffolds were deployed in 30 patients to treat 32 lesions. The mean lesion length was 27.69±7.66mm. The in-segment post-procedural minimal lumen diameter and in-scaffold percentage diameter stenosis were found to be 2.56±0.56mm and 22.56±14.74%, respectively. The primary patency was 88.9% as evaluated by colour-flow Doppler ultrasound at 12 months. The mean ankle-brachial and Rutherford-Becker classification indexes improved significantly ($p<0.001$) from baseline to 12-month follow-up. Moreover, the limb salvage rate was 92.60% and no target lesion revascularisation was observed through 6-month follow-up.

Conclusions: Clinical outcomes demonstrated that implantation of sirolimus-eluting bioresorbable peripheral scaffold system has favourable safety and performance in the treatment of critical limb ischaemia with no target lesion revascularisation and scaffold thrombosis up to 12-month follow-up following percutaneous transluminal angioplasty of below the knee arteries.

Iliac / Femoral / Popliteal - Stents, devices and techniques

Transradial intervention of TASC D femoropopliteal lesions using dedicated radial-to-peripheral devices: a single-centre experience

TAN GuangMing [(1)], TAN GuangMing [(1)], YAN Bryan [(1)]

(1) Faculty of Medicine, The Chinese University of Hong Kong, Ma Liu Shui, Hong Kong

Aims: Transradial (TR) intervention is associated with fewer bleeding complications, earlier ambulation and improved patient comfort but is rarely used for complex peripheral vascular interventions (PVI). We describe our initial experience using dedicated TR-PVI devices in complex PVI.

Methods and results: We retrospectively analysed 13 TR-PVI procedures performed between January 2018 and December 2019 on 11 consecutive patients (35% critical limb ischaemia and 65% claudicants) with 15 TASC II D femoropopliteal lesions using longer-length radial devices designed for PVI that include a 119cm or 149cm length 6Fr guiding sheath with full hydrophilic coating, a 0.035" 400cm hydrophilic wire, rapid-exchange balloon catheter and self-expanding nitinol stents with working length of 200cm, and a radial compression device. 2 patients underwent bilateral TR-PVI in a single session. Primary endpoint was procedural success and safety endpoints were access site complications such as radial artery haematoma >2cm, spasm or occlusion. Mean patient age was 62.7 (IQR 58-67), height 1.70m (IQR 1.65-1.75) and BMI 28.1 (IQR 22-31.5). Mean occlusion length was 210mm (IQR 150-300) and PACSS calcium grade 4 in all lesions. Concomitant iliac and/or below-the-knee lesions were treated in 6 (47%) cases. The tibial-peroneal trunk was the most distal lesion treated using TR-PVI. Additional access was required in 5 (38%) cases with the commonest reason being additional angioplasty procedure such as atherectomy. Procedural success was 100% with stent implantation in 84% of lesions. Mean procedural time was 122 minutes (IQR 90-120) and fluoroscopy time 43 minutes. Radial artery haematoma occurred in 4 (30%) and radial artery occlusion occurred 2 (9%) of patients. All patients were ambulatory immediately post procedure.

Conclusions: We demonstrated TR-PVI for complex TASC D femoropopliteal lesions is feasible and safe using dedicated radial-to-peripheral devices. Early patient ambulation and freedom from vascular access site complications are major advantages of TR-PVI.

Iliac / Femoral / Popliteal - Stents, devices and techniques, Other peripheral interventions - Other

Impact of infrapopliteal run-off on clinical outcomes following endovascular intervention in patients with iliac and superficial femoral arterial disease

KIM Woohyeun [(1)], KIM Woohyeun [(1)], RHA Seung-Woon [(1)], CHOI Byoung Geol [(1)]

(1) Korea University Guro Hospital, Seoul, Republic of Korea

Aims: Peripheral arterial disease is a challenging clinical entity due to complicated anatomy and medical comorbidity. The aim of this study was to evaluate the prognostic role of distal vascular bed patency in patients with iliac and superficial femoral artery (SFA) disease undergoing endovascular therapy (EVT).

Methods and results: A total of 581 patients (652 limbs, 1,017 lesions) who underwent EVT for iliac and SFA disease from 2004 to 2016 were analysed. Patients were divided into two groups according to the presence of a below-the-knee (BTK) artery disease; non-BTK group (260 patients, 367 limbs) and BTK group (258 patients, 285 limbs). We compared major clinical outcomes between the two groups up to 5 years. During the follow-up period (median 2,323.2 days), BTK group showed a trend toward higher incidence of target lesion revascularisation (TLR; 22.5% vs 11.7%; p<0.001), target extremity revascularisation (TER; 22.8% vs 14.2%; p=0.005), and major adverse limb events (MALEs; 44.2% vs 19.1%; p<0.001) than non-BTK group. After adjusting for baseline characteristics, presence of a BTK disease remained a significant predictor of MALEs (HR 1.75 [1.18-2.58], p=0.005). In patients undergoing SFA EVT, the presence of BTK disease was a significant predictor of MALEs (HR 1.75 [1.16-2.63]; p=0.007). Further, the presence of SFA disease was more important in iliac artery EVT than in the presence of BTK disease (HR 3.82 [1.78-8.21]; p=0.001).

Conclusions: Patency of distal vascular beds of the diseased vessel is an important prognostic factor in patients undergoing EVT for iliac and SFA disease. A proper evaluation and management of the distal vascular beds (BTK arteries for SFA, and SFA for iliac disease) may be important for achieving better outcomes.

Iliac / Femoral / Popliteal - Stents, devices and techniques

REFLOW study, investigating the LEGFLOW paclitaxel-coated balloon in real-world long and complex femoropopliteal lesions

BOSIERS Marc [1], WAUTERS Jeroen [1]

(1) az Sint-Blasius, Dendermonde, Belgium

Aims: To investigate the efficacy of the paclitaxel-eluting LEGFLOW balloon catheter in the treatment of real-world long and complex femoropopliteal lesions.

Methods and results: The REFLOW study was a prospective, multi-national, non-randomised, single arm study evaluating the safety and efficacy of the LEGFLOW paclitaxel-eluting balloon dilatation catheter in the treatment of stenotic or occlusive lesions >150 mm long in the femoropopliteal arteries of symptomatic patients (Rutherford 2-5). A total of 120 study subjects were enrolled in a period of 30 months, between October 2015 and May 2018. The mean age was 71.06 years and 79 patients were men (65.8%). Mean lesion length was 216.08 mm. 45% of the lesions were occluded, whereas 55% were stenotic. Primary endpoint was primary patency at 12 months, defined as absence of a haemodynamically significant stenosis on duplex ultrasound (systolic velocity ratio no greater than 2.4) at the target lesion and without TLR within 12 months. Technical and procedural success (<30% residual angiographic stenosis without major complications) was achieved in all 120 cases (100%). Primary patency was 84.60% at 6 months and 71.10% at 1 year. Freedom from TLR was 79.90% at 1 year.

Conclusions: If longer term follow-up confirms no safety concern on these paclitaxel devices, the excellent results of the newer drug-eluting devices, and the LEGFLOW paclitaxel-eluting balloon in particular, demonstrate a valid and effective alternative to treat long and complex real-world femoropopliteal lesions.

Below the knee - Stents, devices and techniques

First-in-man experience with the MOTIV BRS in below-the-knee arteries

BOSIERS Marc [1], WAUTERS Jeroen [2]

(1) St. Franziskus-Hospital, Münster, Germany; (2) AZ Sint-Blasius, Dendermonde, Belgium

Aims: To evaluate the safety and efficacy of the MOTIV Bioresorbable Scaffold (Reva Medical) in below-the-knee arteries, for the treatment of patients with rest pain or minor tissue loss (CLI) due to presence of lesions of max 40mm in length.

Methods and results: A prospective, single-centre, single-arm pivotal study in 15 patients. There is a primary efficacy endpoint; primary patency rate at 12 months, defined as no evidence of at least 50% restenosis or reocclusion within the originally treated lesion, and there is a primary safety endpoint, defined as the proportion of subjects who experience serious device-related adverse events within 30 days post procedure.

Conclusions: Study phase is recruiting, with 6 out of 15 patients enrolled.

Iliac / Femoral / Popliteal - Stents, devices and techniques

Endovascular extra-anatomic femoropopliteal bypass for limb salvage in chronic critical limb ischaemia

DI PRIMIO Massimiliano [1,2], DI PRIMIO Massimiliano [1,2], ANGELOPOULOS Georgios [1,2], PRIOLLET PASCAL [2], LAZARETH Isabelle [2], EMMERICH Joseph [2], YANNUTSOS Alexandra [2]

(1) Hôpital Privé de Parly II, Le Chesnay, France; (2) GH Paris Site Saint Joseph, Paris, France

Aims: To report the initial clinical experience with fully endovascular extra-anatomic femoro-popliteal bypass (FPB) for limb salvage in patients with critical limb ischaemia (CLI) and no traditional endovascular or surgical revascularisation options.

Methods and results: Between June 2013 and May 2018, endovascular procedure was proposed for limb salvage during a multidisciplinary team meeting on fifteen hospitalised patients (median age 67 years; 73% men) with CLI and a high risk of major amputation. Primary outcome was amputation-free survival at 1 year. Secondary outcomes included mortality, cardiovascular (CV) events and major limb amputation at 1 year, primary/secondary bypass patency and wound healing at the last follow-up visit. Procedure-related complications (deaths, CV events, haemorrhages) were recorded through 30 days. Technical procedure success rate was 100%. Major periprocedural outcomes occurred in two patients (13%): One patient died secondary to cardiogenic shock; one patient suffered acute coronary syndrome associated with iliopsoas bleeding. No major amputation occurred through 30 days. Median follow-up period was 21.5 (18.25-45.5) months (last follow-up visits in April 2019). Amputation-free survival at 1-year and at the last follow-up visit was 80% and 53%, respectively. Cumulative mortality at 1-year and at the last follow-up visit was 13% and 33%, respectively. Primary and secondary bypass patency was 27% and 60%, respectively. Complete wound healing was achieved in 11 patients (73%).

Conclusions: Endovascular extra-anatomic FPB represents an innovative approach for limb salvage in CLI with no traditional endovascular or surgical revascularisation options. Our clinical experience highlights that this technique remains challenging because of frequent comorbidities and the fragility of this patient population.

Iliac / Femoral / Popliteal - Adjunctive pharmacotherapy

The use of ultrasound accelerated thrombolysis versus catheter-guided thrombolysis for the treatment of deep vein thrombosis of lower extremities

GARCIA Daniel [1], ANSARI Mohammad [2], GARCIA Daniel [1]

(1) Ochsner Medical Center, LA, USA; (2) Texas Tech University Health Sciences Center, TX, USA

Aims: Ultrasound-facilitated thrombolysis (UAT) can benefit the treatment of deep vein thrombosis (DVT). Currently systemic anticoagulation with combination of catheter direct thrombolysis (CDT) has been used as the standard treatment. This therapy provides additional benefit of preventing post-thrombotic syndrome. We aimed to do a meta-analysis comparing the clinical outcomes between UAT and CDT.

Methods and results: Pub Med, Cochrane and Embase were systematically searched for all the clinical data that directly compared CDT and UAT for acute DVT of lower veins. Primary outcomes included ≥50 % thrombus reduction and repeat target vessel thrombolysis. Secondary outcomes included major and minor bleedings, additional angioplasty (PTA+ stent) and mean days of hospital stay. We used fixed or random effect analysis using the Cochrane Handbook of Systematic Reviews and RevMan 5.2 for statistical analysis. A total of 5 clinical studies were included in the analysis and provided a total of 342; 157 in the CDT group and 185 in the UAT. There were significantly higher rates of ≥50 % thrombus reduction in the UAT group compared to CDT (87% vs 79%; p=0.02) and significantly less thrombosis recurrence in the UAT group compared to the CDT (16% vs 17%, p<0.01). Secondary outcome analysis showed less, but not significant, stent use (42% vs 60%) in the UAT group. There was no difference between groups in terms of length of hospital stay, minor and major bleeding events.

Conclusions: Newer thrombolysis techniques can improve outcomes of acute lower extremity DVT treatment. UAT might be associated with better restenosis rates given better thrombus burden reduction. This might imply in less angioplasty and stent use. Complication rates were similar between both groups. In-depth analysis and further randomised trials should be pursued to determine these benefits.

Other peripheral interventions - Other

Endovascular intervention and open surgical repair for chronic mesenteric ischaemia

GARCIA Daniel [1], GARCIA Daniel [1], ANSARI Mohammad [2]

(1) Ochsner Medical Center, LA, USA; (2) Texas Tech University Health Sciences Center, TX, USA

Aims: Chronic mesenteric ischaemia can be managed by open surgical repair (OS) or alternatively, by endovascular repair. Clinical outcomes may vary between these two modalities. We evaluated the clinical and procedural outcomes between the two treatment modalities through a meta-analysis of current clinical studies.

Methods and results: Systematic review of Pub Med, Chocrane and Embase database was performed for all clinical studies that directly compared OS and endovascular therapy for chronic mesenteric ischaemia. Primary outcomes were post-procedure mortality. Secondary outcomes included long-term survival, restenosis and secondary lesion patency. We used random effect analysis according to the Cochrane Handbook of Systematic Reviews and RevMan 5.2 for statistical analysis. A total of 19 studies (18 retrospective and one prospective) provided a total of 9,279 patients (3,830 in the endovascular group and 5,449 in the OS). Majority of patients were men older than 65 years. There was a trend towards less the post-procedural death in the endovascular group (1.3% vs 5.6%, p=0.1). There was no difference in long-term survival between endovascular and OS group (80% vs 78%, p=1). Restenosis rate was significantly better in the OS group (20% vs 32, p<0.01). Vascular complications were significantly less in the endovascular group (18% vs 38%, p<0.01).

Conclusions: Our analysis suggested that endovascular therapy has good mortality and complication rates, although OS is associated to superior patency over the time. Endovascular therapy might be indicated for the patients who are not good surgical candidates. Newer-generation stents can help to improve lesion patency. Further randomised studies are warranted.

Other peripheral interventions - Other

Radiofrequency catheter ablation – the old good friend of the great saphenous vein

BAKRACHESKI Nikola [1], BAKRACHESKI Nikola [1], ZIMBOVA Marija [1], MOJSOVSKA Violeta [1], KOVACESKA-BASHUROSKA Elena [1]

(1) Cardiology Center St. Stephen, Sveti Stefan, The former Yugoslav Republic of Macedonia

Aims: To confirm the efficacy and safety of ambulatory performed endovenous radiofrequency ablation in patients with chronic vein insufficiency.

Methods and results: We observed 241 patients submitted to the endothermal closure of the great saphenous vein with second-generation ClosureFast catheter as an ambulatory procedure. Out of them 154 patients (64%) were female and 87 patients (36%) male, with mean age 53.5 (±9.5 years). The CEAP score was as follows: 173 patients (72%) had C2S, 58 patients (24%) with C4S and 10 patients (4%) with C5S disease. The ultrasound guided procedure included: skin marking of the great saphenous vein and side branches, vein puncture and 7F introducer sheath insertion, delivering the ClosureFast catheter up to 2 cm from the saphenofemoral junction, infiltration of tumescent anesthesia, final tip position verification, application of radiofrequency energy at 120ºC along the great saphenous vein, and confirmation of the vein closure at the end of the procedure. After putting on elastic stockings patients were advised a 30-minute walk. The patients were followed-up on clinical outcomes, and colour duplex ultrasound was performed on day 3 and day 10, 6 weeks and 1 year after the procedure. The results showed that 100% (N=241) of the patients were able to leave the hospital within an hour of the procedure. At day 3, all the patients (100%) were able to return to their working activities. Colour duplex-ultrasound assessment on day 3 demonstrated that 98.76% (N= 239) of the patients had completely occluded great saphenous vein and no remaining reflux. The result was consistent at day 10, and 6 weeks after the procedure. Three patients (1.24%) presented with aseptic phlebitis of side-branches of the great saphenous vein with complete restitution after 6 weeks. Fourteen patients (5.81%) had residual paraesthesia at day 3, only 5 of them (2.07%) after 10 days, and there was no residual paraesthesia 6 weeks after the procedure. Seven patients (2.90%) had recanalised great saphenous vein after 1 year.

Conclusions: Radiofrequency catheter ablation of the great saphenous vein performed in an ambulatory setting is a feasible and safe procedure with high success rate and low complication rate, allowing patients to return to working activities in less than 72 hours.

Iliac / Femoral / Popliteal - Stents, devices and techniques, Other peripheral interventions - Other

One hundred and eighty-day safety evaluation of the Chocolate Touch DEB catheter in the swine peripheral artery model

TZAFRIRI Rami [(1)], TZAFRIRI Rami [(1)], SPOGNARDI Anna Maria [(1)], BAILEY Lynn [(1)], KEATING John [(1)], MARKHAM Peter [(1)], BINYAMIN Gary [(2)], PIZARRO Maria [(2)], KONSTANTINO Eitan [(2)], EDELMAN Elazer R. [(3,4)]

(1) CBSET, Inc, MA, USA; (2) TriReme Medical, Inc., CA, USA; (3) M.I.T, MA, USA; (4) Brigham and Women's Hospital, MA, USA

Aims: We evaluated the preclinical safety of a novel paclitaxel-coated balloon catheter (PCB) with a nitinol constraining structure positioned over it, designed to improve acute treatment of stenotic and occluded arteries.

Methods and results: Animal experiments were performed at an AAALAC-accredited, GLP-adherent laboratory (CBSET Inc., Lexington, MA). PCBs (TriReme Medical, Singapore) with 5.53 mg paclitaxel and (3 µg/mm^2, 6×80 mm) and a proprietary excipient were advanced under angiography and inflated for 120 sec in peripheral arteries of 34 Yorkshire swine (target balloon-to-artery ratio between 1.06:1-1.08:1). Treated arteries (n=48) received a single PCB inflation (clinical dose) or a 3 sequential PCB inflations at the same angiographic site. Thrombogenicity of the device by visual inspection post-deployment. Control arteries (n=20) received a single inflation of a POBA (Pacific Plus™, Medtronic). Animals were euthanized at 7d for scanning electron microscopy (SEM) evaluation of acute surface injury, endothelialisation, leukoctye adherence, and adherent thrombi, and at 30-180d (n=6-8/time point) for target site histopathologic assessment. Tissues distal to the target site were assessed grossly and histologically for evidence of embolisation-associated ischaemia and potential downstream toxicity. All treatments with PCB and POBA were successful in peripheral vessels, with minimal or no adherent thrombus on removed catheters and survival of all animals to scheduled time points. Histologically, PCB treatments were associated with favourable tissue responses at both doses, consistent with device biocompatibility comparable to that observed with POBA. Arterial injury was rare and negligible, while inflammation was overall negligible to minimal. PCB treatments resulted in vascular changes which were interpreted to predominately reflect concomitant tissue responses related to both balloon deployment and presence of paclitaxel, with no distinct excipient-related effects and no evidence of downstream or systemic adverse effects. Endothelialisation was mostly complete in all groups, and neointima minimal. Macroscopic, histologic and SEM findings indicated arterial patency and lack of thrombogenicity in both groups.

Conclusions: Overall, treatment in peripheral arteries with the TriReme paclitaxel-coated balloon catheter at 1x clinical dose or 3x safety margin dose, resulted in acceptable acute device performance, and no adverse safety events, and similar to POBA.

Below the knee - Vascular access and bleeding

Use of ultrasound to guide anterograde femoral artery puncture, closure and early repuncture in critical limb ischaemia

RUGGIERO Rossella [1,2], RUGGIERO Rossella [1,2], KHOKHAR Arif [2], PONTICELLI Francesco [2], STICCHI Alessandro [2], MANGIERI Antonio [2], LARICCHIA Alessandra [2], GIANNINI Francesco [2], COLOMBO Antonio [2], DALLA PAOLA Luca [2], PALENA Luis Mariano [2]

(1) Ospedale Sant'Anna, Province of Ferrara, Italy; (2) Maria Cecilia Hospital, Province of Ravenna, Italy

Aims: Diabetic patients with critical limb ischaemia often require multiple interventions and repeated puncture, closure and re-access of the same vessel. Ultrasound-guided arterial access is a safe and effective technique that can reduce complications. We report our preliminary experience in using ultrasound to guide initial puncture, deployment of vascular closure devices and subsequent re-puncture in diabetic patients with critical limb ischaemia undergoing endovascular therapy.

Methods and results: This is a single-centre prospective registry that enrolled all patients referred to our tertiary diabetic foot clinic for endovascular treatment of critical limb ischaemia. All patients underwent ultrasound-guided anterograde femoral arterial puncture. Before the puncture, vessel anatomy, site of femoral bifurcation, presence of calcification and pulse wave velocity evaluation was undertaken using a vascular ultrasound probe (Samsung, Seoul, South Korea). Following the completion of the procedure, ultrasound was again used to guide Angio-Seal™ (Terumo, Somerset, New Jersey) closure device deployment. Particularly, we assessed the correct position of the anchor of the device into the vessel, the complete adherence of the anchor to the vessel wall and the absence of subsequent bleeding by using colour-Doppler ultrasound. Pulse wave velocity was used to detect the presence of residual arterial stenosis (defined as the absence of distal value >100 m/sec) and it was evaluated in before and after the implanted device. In patients with the recent deployment of an Angio-Seal, if repeat ipsilateral arterial access was required, even within 90 days, ultrasound was utilised to re-puncture and reseal the same artery with a second Angio-Seal. The primary endpoint was the achievement of successful haemostasis with no access site complications at the time of discharge. 32 patients underwent endovascular therapy for critical limb ischaemia between November 2019 and January 2020. The primary endpoint was achieved in 30 patients (94%). In the remaining two cases, the presence of blood loss was immediately identified by vascular ultrasound, and further manual compression achieved successful haemostasis. 4 patients (12%), had a prior Angio-Seal deployment of the ipsilateral artery within 90 days. Repeat ultrasound-guided access and deployment of a second Angio-Seal was successfully performed with no subsequent complications. No cases of vascular occlusion or severe stenosis of the femoral artery were detected in our patients.

Conclusions: Ultrasound-guided anterograde femoral access is a safe and effective technique in patients undergoing endovascular therapy for critical limb ischaemia. Ultrasound allows direct visualisation during insertion and deployment of an Angio-Seal closure device. This facilitates repeat arterial access and Angio-Seal deployment in patients with a recent Angio-Seal device. Combined treatment of Angio-Seal closure and the routine ultrasound-guidance access showed high efficacy and safety outcomes in patients who underwent endovascular treatment.

Below the knee - Adjunctive pharmacotherapy

Clinical impacts of oral anticoagulant therapy in patients with ischaemic wounds

ITO Nobuhiro [(1)], ITO Nobuhiro [(1)], HIRAMORI Seiichi [(1)], TOMOI Yusuke [(1)], SOGA Yoshimitsu [(1)], ANDO Kenji [(1)]

(1) Kokura Memorial Hospital, Fukuoka, Japan

Aims: Recent studies suggested the main cause of below-the-knee (BTK) artery lesions is thrombus. Although anticoagulant therapy is one of important options for thrombotic lesions, the impact of oral anticoagulant therapy on BTK lesions remains unclear.

Methods and results: A retrospective analysis was performed in patients undergoing endovascular treatment (EVT) for *de novo* BTK lesions at our hospital from October 2004 to March 2018. The subjects consisted of 247 below-the-knee lesions with ischaemic wounds. Outcome measures were wound healing and target lesion revascularisation (TLR), at 3, 6, and 12 months after EVT. In the baseline characteristics of this study, median age was 73 (±9.6) years old, and men were 72%. Oral anticoagulant therapy users were 22.2%. 81.3% were classified into Rutherford class 5. At 3-months after procedure, wound healing rate of anticoagulant therapy group was significantly higher than no anticoagulant therapy group (23.6% vs 11.9%, p=0.03). At 6 months and 12 months after the procedure the wound healing rate of anticoagulant therapy group had a tendency to be higher than non-anticoagulant therapy group, although it was not statistically significant (30.9% vs 20.3%, p=0.09, 34.5% vs 25.5%, p=0.18). There was no significant difference between anticoagulant therapy group and no anticoagulant therapy group in TLR at 3, 6, and 12 months after procedure (10.9% vs 8.85%, p=0.64, 18.1% vs 15.6%, p=0.65, 25.5% vs 21.9%, p=0.57).

Conclusions: This study suggested a possible beneficial effect of oral anticoagulant therapy after EVT for BTK lesions. A further large scale study is needed to clarify the efficacy of oral anticoagulant therapy.

Other peripheral interventions - Other

The predictors of clinical outcome in patients undergoing endovascular intervention for lower extremity peripheral arterial disease

KIM Byung Ok [(1)], KIM Byung-Ok [(1)], SEO Jongkwon [(1)], KIM Gwang-Sil [(1)], LEE Hye Young [(1)], BYUN Young Sup [(1)], KIM Byung Gyu [(1)]

(1) Inje University Sanggye Paik Hospital, Seoul, Republic of Korea

Aims: Patients with peripheral arterial disease (PAD) have a higher mortality rate than age-matched patients without PAD. Also more than half of patients with symptomatic PAD have polyvascuar disorder including coronary artery disease (CAD). This study aimed to identify the predictors of mortality outcomes in patients with peripheral artery disease undergoing lower extremity endovascular interventions.

Methods and results: We studied 300 consecutive patients admitted for symptomatic lower extremity arterial disease. A total of 196 patients without angina and prior coronary revascularisation (72±10 years, 156 men) who underwent lower extremity endovascular intervention (claudication, n=74; critical limb ischaemia, n=122) were retrospectively analysed. All patients underwent coronary angiography but not simultaneous coronary revascularisation. CAD was defined as angiographically significant (≥50%) stenosis of coronary arteries and severity was classified as none, 1-, 2-, or 3-vessel disease (VD). All-cause mortality and major adverse cardiac and cerebrovascular event (MACCE) rates were compared between the patients with CAD and those without CAD. MACCE included any of the following adverse events: cardiac death, cerebrovascular death, acute myocardial infarction, stroke, and congestive heart failure. During follow-up, all-cause mortality and MACCE at 3 year were 16.3% and 19.8%, respectively. The independent risk factors for all-cause mortality were old age (HR=1.05, p=0.043), lower body mass index (HR=0.83, p=0.016), critical limb ischaemia (HR=3.74, p=0.033) and the presence of CAD (HR=2.85, p=0.027). This variable surpassed all classical risk factors (including smoking and history of hypertension or diabetes mellitus). Of the 196 patients, 101 patients (52%) had asymptomatic CAD; 1-VD (n=35, 18%); 2-VD (n=32, 16%); 3-VD (n=28, 14%). At 3 year follow-up, patients with CAD had significantly higher all-cause mortality (19% vs 11%, p=0.018) and higher MACCE rate (26% vs 8%, p=0.001) compared to those without CAD. Furthermore, the severity of CAD had graded associations with the all-cause mortality and MACCE rate (Figure). Independent predictors of CAD were critical limb ischaemia (CLI) (OR = 2.43, p=0.018) and presence of the below-the-knee lesions (OR = 2.04, p=0.019). In addition, CAD was more prevalent in the patients with lower BMI (61% vs 41%, p=0.007).

Conclusions: Asymptomatic coronary artery disease (CAD) was found in half of the patients undergoing endovascular intervention for lower extremity arterial disease and was associated with higher mortality and MACCE rate. Therefore, detection of CAD might be important for risk stratification for these patients, especially those with lower body mass index or critical limb ischaemia.

Iliac / Femoral / Popliteal - Adjunctive pharmacotherapy

Impact of cilostazol on clinical outcomes of endovascular therapy for small femoropopliteal lesions

HIRAMORI Seiichi [1], HIRAMORI Seiichi [1], SOGA Yoshimitsu [1], TOMOI Yusuke [1], ITO Nobuhiro [1], ANDO Kenji [1]

(1) Kokura Memorial Hospital, Fukuoka, Japan

Aims: It has been reported that small vessels are one of the independent predictors of endovascular therapy (EVT) in femoropopliteal (FP) lesions. Several studies have shown that cilostazol improves outcomes of EVT for FP lesions. However, there is a paucity of data about the efficacy of cilostazol in small FP lesions.

Methods and results: This study was an observational study examining consecutive patients performing EVT for *de novo* FP lesions from January 2004 to March 2018. "Small vessel" was defined as vessel diameter less than 4mm. Study subjects consisted of 449 limbs with (n=124) or without cilostazol (n=325). Outcome measures were restenosis, target lesion revascularisation (TLR) and mortality at 1 year. The incidence of restenosis at 1 year was significantly lower in cilostazol group than non-cilostazol group (27.2% versus 40.0%, p=.04). However, there were no significant differences in TLR (19.5% versus 24.3%, p=.22) and mortality (5.9% versus 11.5%, p=.66). After adjustment for confounders, cilostazol was an independent predictor of restenosis (hazard ratio (HR): 0.69, 95% CI: 0.50 to 0.93, p=.02).

Conclusions: Our study suggests cilostazol is expected to improve EVT outcomes even in small FP lesions.

Other peripheral interventions - Other

Long-term clinical outcome of a multicentre experience on percutaneous interventional treatment of high-risk and intermediate-to-high risk acute pulmonary embolism

RUSSO Filippo [1], RUSSO Filippo [1], CHIEFFO Alaide [1], GALLI Mario [2], MAFFEO Diego [4], FERRI Luca [1], ANCONA Marco [1], BELLINI Barbara [1], ZIVIELLO Francesca [1], CIANFANELLI Lorenzo [1], MONTORFANO Matteo [1]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy; (2) Sant'Anna Hospital, Como, Italy; (3) Spedali Civili Di Brescia, Province of Brescia, Italy; (4) Poliambulanza, Province of Brescia, Italy

Aims: Acute pulmonary embolism (PE) is associated with high morbidity and mortality; treatment strategies vary widely among patients, according to their clinical presentation and haemodynamic status. Percutaneous interventional procedures seem to be attractive considering the high prevalence of contraindications to systemic fibrinolysis (SF) in high or intermediate-to-high risk PE patients. We sought to retrospectively evaluate patients' clinical outcome who submitted percutaneous interventional treatment because of high or intermediate-to-high risk PE in 6 Italian centres.

Methods and results: Between 2011 and 2019, in six centres, 130 patients affected by high or intermediate-to-high risk PE were subject to urgent percutaneous interventional treatments by means of rheolytic thrombectomy (RT) or ultrasound–assisted thrombolysis (USAT). At the time of abstract submission, complete patient data and analysis were available for only 82 patients. Patients' median age was 71 years old (IQR 59-80), 35 (42%) were females and most of them had at least one risk factor for PE. Of note 30% had high-risk PE with obstructive shock at presentation. A total of 37 (45%) of patients had absolute contraindication to SF and the remaining had comorbidities resulting in a potentially high risk of major bleeding in case of SF. A loco-regional fibrinolytic was administered in 76 (93%) of the patients at maximum dosage of 50 ml by means of tissue-type plasminogen activator; infusion duration in patients treated with USAT was up to physician's decision but up to 12 hours maximum. In RT treated patients, after pulmonary angiography, 8F JR4 or MP guide catheters were used to reach pulmonary arteries and thrombectomy catheters were advanced under fluoroscopy guide to the segmental pulmonary branches in which several thrombectomy runs were performed; in 90% of USAT treated patients, pulmonary angiography was not performed and catheters were positioned under fluoroscopy guide in culprit major vessels according to CT performed at admission. Primary objectives were considered as efficacy, in terms of technical and procedural success, and safety, in terms of low rates of major bleeding. Technical and procedural success, defined as the ability to deliver catheters in pulmonary arteries and to significantly reduce thrombus burden improving patients' haemodynamic conditions was obtained in 76 (93.8%) of cases. In-hospital mortality rate was 10% due to refractory cardiogenic shock, all in high-risk PE and treated by means of RT in the majority of cases; only 5 major bleedings according to BARC classification occurred, due to access site complication in 4 cases and intracranial haemorrhage in one case. In 96% of survivors, early improvement in right ventricle function by echocardiographic post-procedural evaluation was documented, regardless of patients' risk status at presentation and interventional strategy adopted; younger age, male gender and presence of deep vein thrombosis seem predictors of good clinical outcome. At 42 months median follow-up, 8 patients died because of cancer. All survivors were free of symptoms without any residual right ventricle dysfunction or residual pulmonary hypertension.

Conclusions: Our eight year multi-centre experience confirms efficacy and safety of percutaneous interventional treatment in PE, especially when complicated by severe haemodynamic compromise or when SF is contraindicated, even at long term follow-up.

AAA - Prosthesis, devices and techniques

Short-term follow-up for stenting coarctation of aorta in an adult

YAHYA Ali [(1)], YAHYA Ali [(1)], AMBER Khalid [(1)]

(1) al najaf cardic centre, al najaf, Iraq

Aims: Mortality and morbidity rate among patients where uncovered stents were used in treating adult coarctation of aorta and short-term outcomes.

Methods and results: 75 patients with coarctation of aorta were involved in this study. Data collection included age, sex, blood pressure, laboratory findings of glucose, renal function and lipid profile. Echocardiography was performed for all patients and after diagnosis of coarctation of aorta, chest CT was performed to confirm the diagnosis with stenosis of aorta in more than 50%. All patients underwent catheterisation of aorta with 2 sheaths, one femoral and other radial, to measure invasive pressure gradient across the stenosis. If the gradient was more than 20 mmHg then intervention was indicated. Radial contrast injection with fluoroscopy localised stent position followed by stenting with Palmaz uncovered stent, with pre- and post-dilation if needed then pressure gradient measurement across the stent. Procedural success is defined as pressure gradient across coarctation 0 mmHg. For all patients invasive blood pressure measurement before and after stenting, during catheterisation proximal and distal to stenosis, with follow-up by upper limb blood pressure measurement by sphygmomanometer on both arms on day 1, first month, 6 months and 1 year. Chest CT follow-up was performed for all patients at 6 months and 1 year for any aortic wall injury or aneurysm development. Over the 12-month period of the study, 75 patients with coarctation of aorta were assessed including 45(60%) women and 30 (40%) men. The age range was 16 years to 41 years with the mean age 25.7 years (SD ±6.6). After diagnosis of coarctation all patients enrolled in this research had invasive blood pressure measurement in the descending and ascending aorta before and after intervention, performed by pressure gradient across the stenosis to determine indication and success of intervention. There were no deaths or complications during intervention. After stent implantation sudden elevation of blood pressure was seen in 5 patients (15%), almost all patients experienced an immediate reduction in mean systolic blood pressure pre-coarctation (from 159.80±20.5 to 120.87±31 mm Hg) (95% confidence interval of this difference from 30.5 to 47.4) (p-value >0.0001). At 6-month follow up we found 88.4% improved blood pressure control (no need for antihypertensive medication with normal blood pressure reading on measurement by sphygmomanometer on both arms) with a similar improvement at 1-year check-up visit at which 84.9% blood pressure control (no need for antihypertensive medication with normal blood pressure reading on measurement by sphygmomanometer on both arm). 69 patients (92% of those who had a stent implanted) returned for the 6-month follow-up evaluation, 53 patients (70% of those who had a stent implanted) returned for the 1-year follow-up evaluation. CT angiography follow-up in 39/69 patients (52% of those who had a stent implanted) at 6 months and in 18/45 patients (24% of those who had a stent implanted) at 1 year showed no aortic wall injury or aneurysm development, and at 1-year follow-up no mortality occurred.

Conclusions: Uncovered stents appear to be safe in treating coarctation of aorta. Treating coarctation with stents significantly reduces the need for drugs in treating hypertension.

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Posters

Iliac / Femoral / Popliteal - Vascular access and bleeding

TRIACCESS study: randomised comparison between radial, femoral and transpedal access for percutaneous superficial femoral artery angioplasty

ZOLTÁN Ruzsa [1,4], RUZSA Zoltán [1,4], CSAVAJDA Ádám [1], MÓNIKA Deák [1], VÉGH Eszter [1], BÉLA Merkely [4], KWAN Tak [3], OLIVIER F Bertrand [2], BALÁZS Nemes [4]

(1) Bács-Kiskun County Hospital, Teaching Hospital of the Szent-Györgyi Albert Medical University, Kecskemét, Hungary; (2) Université Laval, QC, Canada; (3) Mount Sinai Beth Israel, NY, USA; (4) Semmelweis University, Cardiac and Vascular Center, Budapest, Hungary

Aims: Traditional access for the treatment of femoral artery lesions is the femoral artery (FA) approach, but radial (RA) and pedal access (PA) are alternative access sites. The aim of the study was to compare the success rate and complication rate of different access sites for the treatment of superficial artery stenosis in a randomised study.

Methods and results: 180 consecutive patients were randomised in a prospective study to treat symptomatic superficial femoral stenosis, via RA, FA and PA. Primary endpoint: technical success, rate of major and minor access site complications. Secondary endpoints: major adverse events (MAE), procedural factors, cross-over rate, and duration of hospitalisation. Technical success was achieved in 96.6 %, 100 % and 100 % patients in RA, FA and PA group (p=ns), respectively. Secondary access site was used in 30 %, 3.3 % and 30 % in the RA, FA and PA access group (p<0.01). Stent implantation was done in the femoral artery in 26.6%, 58.3% and 71.6% cases in RA, FA and PA group (p<0.01). CTO recanalisation was performed in 34/36 (100%), 30/30 (100%) and 45/45 (100%) cases successfully in RA, FA and PA group (p=ns). Contrast consumption, fluoroscopy and procedure times were not statistically different, but the X-ray dose was significantly lower in PA than in the RA and FA access group (63.1 vs 162 vs 153 Dyn). The cumulative rate of access site complications in the RA, FA and PA group was 3.3% (0 % major and 3.3% minor), 15% (3.3% major and 11.6% minor) and 3.3% (0% major and 3.3% minor) (p<0.01), respectively. The cumulative incidence of MAE's at 6 months in the RA, FA and PA group was 25 % vs 21.6% and 5% (p<0.01).

Conclusions: Femoral artery intervention can be safely and effectively performed using radial, femoral and pedal access, but radial and pedal access is associated with lower access site complication rates. Pedal access is associated with lower X-ray dose and major adverse events than radial and femoral access.

Other peripheral interventions - Other

Diagnostic and prognostic impact of copeptin in acute pulmonary embolism

OZMEN caglar [(1)], OZMEN Caglar [(1)], DEVECI Onur Sinan [(1)], KARAASLAN Muhammet Bugra [(2)], BAYDAR Oya [(1)], AKRAY Anil [(1)], DENIZ Ali [(1)], KANADASI Mehmet [(1)], DEMIR Mesut [(1)], HANTA Ismail [(1)], USAL Ayhan [(1)]

(1) Çukurova Üniversitesi Tıp Fakültesi, Adana, Turkey; (2) Osmancık Devlet Hastanesi, Çorum, Turkey

Aims: Pulmonary embolism is a common disease that is associated with significant morbidity and mortality rates up to 17.4 %. Early diagnosis and risk classification may provide better prognosis. Copeptin has emerged as a valuable diagnostic biomarker in several clinical conditions. We aimed to determine the diagnostic and prognositic value of copeptin in pulmonary embolism.

Methods and results: Thirty-two patients and 40 healthy individuals were included in the study. Copeptin concentrations and right ventricular dysfunction were analysed. After these first measurements, pulmonary embolism patients were evaluated for pulmonary embolism-related mortality on 1-year follow-up. Copeptin level was higher in pulmonary embolism patients that in the controls (8.3 ng/mL vs 3.8 ng/mL, p<0.001). Copeptin was found to be significantly higher in the patients with mortality and right ventricular dysfunction (10.2 vs 7.5 ng/ml, p: 0.001; 10.5 vs 7.5 ng/ml, p<0.001, respectively). Copeptin reflected pulmonary embolism severity: in low risk patients copeptin was 6.1 ng/mL, in intermediate-low risk patients was 8.3 ng/mL and in intermediate/high risk patients was 10.5 ng/mL (p<0.001 for each). When cut off value of copeptin is taken as ≥5.85, its sensitivity and specificity were 71.9% and 85.0%, respectively for predicting pulmonary embolism (AUC=0.762, %95 CI: 0.635-0.889, p<0.0001).

Conclusions: Copeptin measurement had moderate sensitivity and specificity in the diagnosis of pulmonary embolism and copeptin was significantly higher in the patients with mortality at 1-year follow-up. Copeptin may be a useful new biomarker that reflects a new pathophysiological axis in the diagnosis, risk classification, and prognosis of pulmonary embolism.

Other peripheral interventions - Other

Catheter-directed thrombolysis in a spectrum of venous disorders using cost-effective locally fashioned hardware: experience from the Indian subcontinent

GOEL AMIT [1], GOEL Amit [1], BHALLA NEERAJ [1]

(1) BLK Super Speciality Hospital, Delhi, India

Aims: Catheter-based endovascular techniques have revolutionised therapeutic options for treatment of vascular occlusions. The technology has recently received much attention in the treatment of thrombosis of venous system. A single-centre retrospective observational study was undertaken in a tertiary care hospital in the Indian subcontinent to evaluate the efficacy and safety of catheter directed thrombolysis (CDT) in patients with recent onset of venous thrombosis in various clinical scenarios and its follow-up during the period from January 2019 to October 2019.

Methods and results: Single-centre retrospective observational study was undertaken in a tertiary care hospital in the Indian subcontinent to evaluate the efficacy and safety of catheter directed thrombolysis (CDT) in patients with recent onset of venous thrombosis in various clinical scenarios and its follow-up during the period from January 2019 to October 2019. Thrombosis of the venous system was documented by Doppler and confirmed by venography. Pulse spray pharmaco-mechanical CDT was performed with either alteplase or reteplase through a locally fashioned multi-side-hole catheter within the thrombus. Adjunctive therapies like plain balloon angioplasty/stenting for residual stenosis or thrombus aspiration/mechanical thrombectomy for residual thrombus were carried out. The technical success, clinical success, and frequency of complications for the entire population were analysed. A total of 11 patients underwent this novel therapy. Male to female ratio was 1.2:1 and mean age was found to be 50.81 years. The indications observed were DVT of lower limb, DVT of upper limbs, thrombosis of AVF in patients undergoing haemodialysis and pulmonary embolism. CT evaluation as a part of preprocedural planning was done in 36.3% of the cases. Alteplase was given in 81.8% of the patients and reteplase was given in the remaining cases. Complete and partial technical success was achieved in 72.7% and 27.2%, respectively. Clinical success, which was assessed by resolution of symptoms, was attained in 100% of the patients. Adjunctive therapies were performed in 45.4% of the patients. No mortality was recorded during thrombolysis and the follow-up period. No major bleeding or allergic reaction was observed. All patients following CDT were managed with NOAC/VKAs.

Conclusions: Catheter directed thrombolysis is a highly efficacious, rapid, and safe method for recanalisation of venous thrombosis. Adjunctive therapies further improve the technical and clinical success.

Other peripheral interventions - Other

Utility of controlling nutritional status score for long-term clinical outcome of patients with critical limb ischaemia: insights from the I-PAD registry

SUNOHARA Daisuke [1], SUNOHARA Daisuke [1], MIURA Takashi [1], KATOH Tamon [2], KANZAKI Yusuke [3], ABE Naoyuki [4], YOKOTA Daisuke [5], YANAGISAWA Takashi [6], SENDA Keisuke [7], OKINA Yoshiteru [8], WAKABAYASHI Tadamasa [9], OYAMA Yushi [10], KARUBE Kenichi [11], ITAGAKI Tadashi [12], MOCHIDOME Tomoaki [1], KOBAYASHI Takahiro [1], KASAI Toshio [1], IKEDA Uichi [1]

(1) Nagano Municipal Hospital, Nagano, Japan; (2) Shinshu University, Nagano, Japan; (3) Shinonoi General Hospital, Nagano, Japan; (4) Red Cross Hospital in Nagano, Nagano, Japan; (5) Iida Hospital, Nagano, Japan; (6) Saku General Hospital Saku Medical Center, Nagano, Japan; (7) Aizawa Hospital, Nagano, Japan; (8) Joetsu General Hospital, Niigata, Japan; (9) Suwa Genaral Hospital, Nagano, Japan; (10) Suwa Red Cross Hospital, Nagano, Japan; (11) Okaya Citizen's Hospital, Nagano, Japan; (12) Ina Center Hospital, Nagano, Japan

Aims: Critical limb ischaemia (CLI) is the most advanced stage of peripheral artery disease. General malnutrition usually occurs in CLI patients because of lack of appetite, therefore clinicians need to accurately assess the nutritional status of CLI patients. The Controlling Nutritional Status (CONUT) score is a simple score for nutritional assessment. However, little is known about the precise ability of the CONUT score for predicting the clinical outcome of CLI. Thus, the aim of this study was to investigate of the association of the CONUT score with 3-year clinical outcome in CLI patients.

Methods and results: From August 2015 to July 2016, a total of 335 consecutive patients (427 limbs) who underwent endovascular treatment (EVT) were enrolled in the I-PAD prospective, observational, cohort study from 7 institutes in Nagano prefecture, Japan. We extracted a total of 91 consecutive CLI (Rutherford scale 4 or higher) patients (93 limbs) from the I-PAD registry. There were 33 patients in Rutherford scale 4, 49 patients in scale 5 and 9 patients in scale 6. The follow-up period was 3 years and the mean follow-up period was 924.0±432.6 days. The CONUT score was calculated from serum albumin, total cholesterol concentration, and total lymphocyte count. The CONUT score states that the higher the CONUT score, the worse the nutritional status. The primary endpoint was major adverse cardiac or cerebrovascular events (MACCE; a composite of death, non-fatal myocardial infarction, and stroke) and the secondary endpoint was major or minor amputation. The patients were a mean age of 75.0±10.8 years old, 67.0 % of men (n=61) and the mean CONUT score was 2.0±0.9. The respective C-statistics for the CONUT score for 3-year MACCE was superior to Geriatric Nutritional Risk Index (GNRI) (0.67 vs 0.41, p=0.01). The subjects were divided into two groups according to the CONUT score based on receiver operating characteristic curve findings. There were 56 CONUT-high (≥3) patients and 35 CONUT-low (<3) patients. Kaplan-Meier analysis revealed that CONUT-high patients had a significantly higher frequency of MACCE rate (57.1% vs 22.9%, p=0.001). Multivariate testing to evaluate the association between the CONUT score and MACCE showed CONUT-high to be a significant predictor of MACCE (HR 1.25, 95% CI: 1.06-1.46, p=0.006). According to Kaplan-Meier analysis, the frequency of major or minor amputation was significantly greater for CONUT-high limbs (30.5% vs 8.8%, p=0.006).

Conclusions: CLI patients with poor nutrition had a poor prognosis. The CONUT score is well-known as a nutrition assessment tool and it may be useful to predict the long-term clinical outcome of CLI patients who undergo EVT. Clinicians should pay close attention to CLI patients with the CONUT score of ≥3 and need to actively intervene in CLI patients with poor nutrition.

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Posters

Iliac / Femoral / Popliteal - Stents, devices and techniques

Clinical outcomes after balloon angioplasty with Crosser device for heavily calcified common femoral and popliteal artery disease

KATSUMATA Haruka [(1)], NAKAO Masashi [(1)], INAGAKI Yusuke [(1)], EBIHARA Suguru [(1)], TANAKA Kazuki [(1)], OTSUKI Hisao [(1)], YAMAGUCHI Junichi [(1)], HAGIWARA Nobuhisa [(1)]

(1) Tokyo Women's Medical University Hospital, Tokyo, Japan

Aims: There was no data about clinical outcomes after endovascular treatment (EVT) using a Crosser catheter (C. R. Bard, Inc.) as a crossing or flossing device for a heavily calcified lesion in the non-stenting zones such as CFA or PA. We investigated the efficacy and safety of EVT using a Crosser catheter for isolated and heavily calcified CFA and PA disease.

Methods and results: We analysed consecutive 64 patients (72 lesions; CFA 30, PA 42), who received endovascular procedure for heavily calcified CFA or PA lesions with Crosser catheters between April 2015 and April 2019, retrospectively. The primary endpoint was clinically-driven target vessel revascularisation (TLR). The secondary endpoints were primary patency, overall survival, freedom from major adverse cardiovascular events (MACE; all-cause death, myocardial infarction, and stroke), and major adverse limb events (MALE; major amputation and revascularisation for target limb). The median follow-up was 18.5 months. As a whole study population, the mean age was 70±9.5 years old, with a male prevalence of 73.6%. The mean proposed peripheral arterial calcium scoring system (PACSS) grade was 2.9±0.9. Procedural success defined as <50% residual stenosis without suboptimal result was 94.4 %. We did not experience any bail-out stentings and target lesion related complications in all cases. The 1- and 2-year clinically-driven TLR-free rate for CFA lesions after EVT were 87.4 % and 82.2 %, and those for PA lesions were 76.8% and 62.8%, respectively. The 1-year primary patency rate for CFA lesions after EVT was 82.8% and that for PA lesions was 71.4%. The 1-year MACE-free rate for CFA lesions after EVT was 93.2%, and that for PA lesions was 82.9%. The 1-year MALE-free rate for CFA lesions after EVT was 74.4%, and that for PA lesions was 74.7%. Several studies had reported that primary patency at 1-year in CFA and PA were both around 70%. In the present study, we included only the lesion with heavy calcification. Then, the adverse event rates seemed to be satisfactory for this high-risk subsets in comparison with previous reports.

Conclusions: EVT with a Crosser device for heavily calcified CFA and PA lesions, so called non-stenting zone, seems to be safe and feasible. The further large-scale, randomised-control study would be warranted to clarify the advantage of this fascinating device in contemporary practice.

Iliac / Femoral / Popliteal - Vascular access and bleeding

Treatment of iliac artery disease with distal radial artery access

TANIGUCHI Norimasa [(1)], TAKAHASHI Akihiko [(1)], MIZUGUCHI Yukio [(1)], YAMADA Takeshi [(1)], HASHIMOTO Sho [(1)], NAKAJIMA Shunsuke [(1)], HATA Tetsuya [(1)], WASHIMI Souichirou [(1)]

(1) Sakurakai Takahashi Hospital, Kobe, Japan

Aims: The distal radial approach (dRA) was introduced as the alternative access site in the conventional radial approach for percutaneous coronary intervention (PCI). As conventional radial access now has been used for peripheral vascular disease, dRA is considered to be similarly feasible for the treatment of peripheral vascular disease. However, there have been no reports regarding percutaneous vascular intervention for an iliac lesion using dRA. We describe our first experiences with performing stenting for iliac artery stenosis with the distal radial approach in three patients.

Methods and results: Case 1: A 71-year-old man with a height of 167 cm and a history of cerebral infarction, renal insufficiency, and hypertension presented with chest pain. Since the emergency coronary angiogram with right distal radial access revealed total occlusion of the left circumflex coronary artery, PCI was performed and successfully completed. Two weeks later, the patient developed critical limb ischaemia in the left foot. A 4.5-Fr sheath introducer with a length of 108 cm was inserted from the left distal radial artery. The tip of the catheter reached just above the iliac bifurcation when the catheter was fully advanced. The subsequent angiogram revealed severe stenosis in the left external iliac artery. A floppy guide wire with a length of 300 cm was advanced through the lesion. Direct stenting was conducted with the EverFlex (6.0×100 mm). The patient was discharged 2 weeks later without sequela. Case 2: A 74-year-old man with a height of 155 cm and a history of myocardial infarction, hypertension, and prostatic cancer was admitted to the hospital with intermittent claudication. Selective angiography with dRA revealed severe stenosis in the left iliac artery. A 5.5-Fr catheter was introduced into the end of the descending aorta. Then a Treasure Floppy Guide Wire was introduced into the lesion, and a Zilver PTX stent (10.0×80 mm) was deployed. Further, a Protégé GPS stent (12.0×40 mm) was also implanted, on the proximal side of the stent. The final angiogram showed good dilatation. Case 3: A 74-year-old man (height, 160 cm) was admitted to our hospital. Case 3:A 74 year-old man with a height of 160 cm had a history of hypertension, atrial fibrillation, and peripheral arterial disease. A 4.5-Fr parent sheath introducer with a length of 108 cm was inserted with dRA. The subsequent angiogram of the descending aorta revealed severe stenosis in the left external iliac artery. A floppy guide wire with a length of 300 cm was advanced through the lesion. Direct stenting was conducted with the EverFlex stent (6.0×60 mm). Subsequently, post-dilatation was conducted with a 7.0×40-mm balloon catheter, and the stent was well dilated. The patient discharged next day without sequela.

Conclusions: Distal radial access for iliac stenosis is feasible in selective patients using the currently available devices, which may contribute to reducing radial occlusions and haemorrhagic complications. Further development of devices for distal radial access, including guiding catheters, balloons, and stent catheters, is warranted.

Other peripheral interventions - Other

IVUS and OCT may be appropriate in carotid revascularisation

CHERNYAVSKIY Mikhail [1], ZHERDEV Nikolai [1], CHERNYAVSKIY Mikhail [1], CHERNOVA Darya [1], CHERNOV Artemii [1], KUDAEV Yurii [1], KOMAKHA Boris [1]

(1) National Medical Research Center. VA Almazov, Saint Petersburg, Russian Federation

Aims: The use of additional methods of intravascular imaging is a promising direction in endovascular surgery of the carotid arteries. In our opinion, this topic is poorly studied and requires the study of its clinical and scientific significance.

Methods and results: 30 procedures using IVUS and 28 procedures with the use of OCT were performed during the stenting of the ICA. Visualisation procedures were carried out before and after stent implantation and its post-dilatation to determine the reference diameter of the stent, detecting the protrusion of plaque. In 100 % of cases in both groups a distal embolism protection device was used. There was no statistically significant relationship between the plaque structure and the occurrence of protrusion through stent cells. Protrusion of plaque was detected in 5 patients in the IVUS group, 4 of which were implanted with a stent with an open cell design. In the OCT group residual stenosis was detected in 6 patients with severe calcification of plaques. In both groups there were no complications at the site of vascular access, 30-day mortality was 0 %. In 1 (3.33 %) patient in the IVUS group there was stent thrombosis intra-operatively with ischaemic stroke (NIHSS 13 points, mRs 5 points). There was stroke in 30 days with no significant neurological signs (mRs 0-1 points) in 2 (7.14 %) patients in the OCT group.

Conclusions: The use of intravascular visualisation methods in stenting of the ICA makes it possible to obtain additional information in particular patients. There are some limitations in using OCT.

Other peripheral interventions - Other

Clinical implication of coronary artery disease on long-term outcome in patients with chronic limb ischaemia

KIM Woohyeun [(1)], KIM Woohyeun [(1)], RHA Seung-Woon [(1)], CHOI Byoung Geol [(1)]

(1) Korea University Guro Hospital, Seoul, Republic of Korea

Aims: Patients with atherosclerotic disease in more than one vascular territory have worse long-term outcome. The aim of this study was to assess the presence of coronary artery disease (CAD) and evaluate the prognostic implication of CAD in patients with chronic limb ischaemia (CLI).

Methods and results: A total of 515 patients with CLI who underwent percutaneous transluminal angioplasty (PTA) were analysed. Patients were divided into two groups (CAD group with angiographic stenosis≥ 70% [268 patients] vs non-CAD group [247 patients]). Furthermore, the efficacy of concurrent percutaneous coronary intervention (PCI) was evaluated by comparing subgroups (CAD group with concurrent PCI vs without concurrent PCI). We compared major clinical long-term outcomes between the two groups using Cox regression. CAD was identified in 52.0% of patients undergoing PTA for CLI. During the 5-year follow-up, CAD group showed a trend toward higher incidence of major adverse cardiac events (MACE, 8.5% vs 13.1%; p=0.10), cardiac death (CD, 1.2% vs 3.7%; p=0.07), myocardial infarction (MI, 1.6% vs 3.7%; p=0.14) and coronary revascularisation (2.0% vs 7.5%; p<0.01). After adjusting for potential confounders, presence of CAD was a significant predictor of MACE (HR 2.22, p=0.01), CD (HR 3.65, p=0.05), MI (HR 3.56, p=0.04) and coronary revascularisation (HR 4.09, p=0.01). However, there was no difference in long-term outcome between the concurrent PCI and non-concurrent PCI groups.

Conclusions: Patients with CLI had high prevalence of CAD and CLI patients with CAD also had poor prognosis. Our results suggest that identifying and managing CAD through routine CAG is a reasonable strategy to improve the prognosis of CLI patients.

Other peripheral interventions - Other

Endovascular treatment with covered CP stent of adult patients with coarctation of the aorta

MÖBIUS-WINKLER Sven [1], MOEBIUS-WINKLER Sven [1], DÄHNERT Ingo [2], KLEIN Friederike [1], SCHULZE Christian [1], KRETZSCHMAR Daniel [1]

(1) Jena University Hospital - Hospital Lobeda, Jena, Germany; (2) Heart Center Leipzig- University Leipzig, Leipzig, Germany

Aims: Aortic coarctation (CoA) of adults is a rare congenital heart disease that results in a narrowing of the aorta most commonly at the level of ligamentum arteriosum. Adult patients often present with symptoms like claudication and dyspnoea beside hypertension. CoA is often accompanied with other congenital heart defects. Despite doubling the survival rate due to surgical repair, endovascular management of adult patients with CoA emerged as the preferred strategy over surgery. We report on a single centre experience of 5 consecutive cases treated endovascular within our hospital.

Methods and results: Patients diagnosed and treated between 2017 and 2019, were predominantly male (4/5), mean age was 35 years (18-66). Initial diagnosis was made due to claudication (3 of 5) and dyspnoea (3 of 5). Mean ankle-brachial index (ABI) was 0.7 at rest and 0.6 after exercise. All patients were treated endovascularly with a covered stent graft (CP Stent), dilated with BIB- balloon of 16-22 mm. There was no complication during or post endovascular treatment of CoA, and the pressure gradient was reduced from mean 35 mmHg to 0 mmHg in all cases. ABI increased to 0.9 at rest. Patients were discharged 2 days after the procedure.

Conclusions: Coarctation in adults is a rare entity and often accompanied with claudication and objective reduction of ABI of both legs. Endovascular therapy is safe and feasible without relevant complication rates.

Other peripheral interventions - Other

Pelvic congestion syndrome: diagnostic, treatment and results

SHUGUSHEV Zaurbek [(1)], MAXIMKIN Daniil [(1)], SHUGUSHEV Zaurbek [(1)], AKULOVA Anastasia [(1)], FAIBUSHEVICH Aleksandr [(1)], BARANOVICH Vladislav [(1)]

(1) Peoples' Friendship University of Russia, Moscow, Russian Federation

Aims: Pelvic congestion syndrome (PCS) is described as dilation of the ovarian veins (OV) and refluxing incompetent pelvic veins. Pelvic vein embolisation (PVE) is known to be a safe and effective treatment for the abolition of pelvic venous reflux. The aim of our study: to present experience of pelvic vein embolisation in patients with PCS.

Methods and results: The study was conducted at the Central Clinical Hospital N°2 named after N.A. Semashko Russian Raiways at the centre of Cardiovascular Pathology. The study included 32 women aged between 18 and 55 years with clinical signs of pelvic vein incompetence: chronic, dull, lower abdominal pain – 11 (34%), dyspareunia-17 (53%), bladder irritability and urgency - 4 (13%), dysmenorrhea -9(28%), vulvar swelling – 2 (6%) and lower extremities varicose – 30 (94%), rectal discomfort- 13 (41%), umbosacral neuropathy – 13 (41%).Refluxing dilated ovarian veins have been detected in 24 (75%) patients. PVE was conducted under local anaesthesia using femoral approach. Embolisation interlock coils were used (Boston Scientific, USA). The average age of patients was just over 41 years, and their average visual analog scale (VAS) score for pelvic pain before treatment was about 8.3. The average diameter of the veins was 9.1±1.8 mm. Successful embolisation was performed in 24 patients (75%) of them: embolisation of the right OV in 6 patients (25%), 3 patients underwent PVE on both sides (12.5%), on the left OV - 15 patients (62.5%). In 8 patients, contrast venography was performed, embolisation was not carried out since the contrast filling did not last more than 20 seconds, the valves with an expanded diameter of OV were consistent. The postoperative period was uneventful. On the first day after surgery, 12 patients (50%) had a temperature increase to 37°C, 1 patient (4%) had a haematoma along the medial surface of the right thigh, and 3 (12.5%) had a menstrual rhythm disturbance (the cycle shifted), 8 patients (33.3%) had discomfort in the pelvic area for up to 1 month. Patients underwent check-ups after 7 days, one, three and six months. On the follow-up Doppler sonography, decrease of diameter of all pelvic veins as well as decrease of blood flow in them was observed. Left and right ovarian veins could not be detected because of coil occlusion. The average visual analog scale (VAS) score for pelvic pain after treatment was about 0.5. No patient showed any coil displacement.

Conclusions: contrast venography of the pelvic veins is a highly informative method for diagnosing PCS. Pelvic vein embolisation in PCS is an effective and low-trauma procedure that ensures the elimination of reflux in the dilated OV.

Iliac / Femoral / Popliteal - Stents, devices and techniques

DEB vs percutaneous transluminal angioplasty in femoropopliteal artery lesions up to 10 cm in length

TOMOI Yusuke [1], TOMOI Yusuke [1], SOGA Yoshimitsu [1], HIRAMORI Seiichi [1], ITO Nobuhiro [1], KATSUKI Tomonori [1], IMADA Kazuaki [1], ANDO Kenji [1]

(1) Kokura Memorial Hospital, Fukuoka, Japan

Aims: We sought to compare the clinical outcomes between drug-coated balloon (DCB) and conventional percutaneous transluminal angioplasty (PTA) in femoro-popliteal (FP) artery lesions to up 10 cm length in real-world clinical settings.

Methods and results: This is a single-centre, retrospective study examined from a clinical database of 788 patients (972 limbs) who had undergone successful FP (from the superficial femoral artery ostium to the proximal popliteal artery) endovascular therapy (EVT) for symptomatic peripheral artery disease (PAD) (Rutherford 2-4) from January 2010 to December 2018. Of these, 228 patients (250 limbs) had undergone EVT using DCB or conventional PTA. Outcome measures were primary patency and clinically-driven target revascularisation (CD-TLR). Restenosis was defined as a peak systolic velocity ratio >2.4 on a duplex scan or >50% stenosis on angiography. The mean follow-up period was 49.4±29.2 months. Baseline characteristics were well balanced except for haemodialysis, current smoking, and preprocedural ABI. Lesion length, reference of vessel diameter, and presence of chronic total occlusion was significantly longer and larger, and higher in DCB compared with conventional PTA. Conversely, the severe calcification lesion was significantly included in conventional PTA. At 1 year, primary patency and freedom from CD-TLR was similar between DCB and conventional PTA (90.6% vs 77.7%; p=0.13, 96.8% vs 87.0%; p=0.13). Furthermore, all-cause mortality at 1 year was not significantly difference between the two groups. (95.8% vs 96.8%; p=0.93).

Conclusions: Conventional PTA might be sufficient for short (up to 10cm length) FP artery lesions in real-world clinical settings.

Iliac / Femoral / Popliteal - Stents, devices and techniques

Combination therapy of heparin-bonded covered stent with bare-nitinol stent and predictors of restenosis after heparin-bonded covered stent implantation assessed by IVUS

KATSUKI Tomonori [(1)], KATSUKI Tomonori [(1)], TOMOI Yusuke [(1)], SOGA Yoshimitsu [(1)], HIRAMORI Seiichi [(1)], ANDO Kenji [(1)]

(1) Kokura Memorial Hospital, Fukuoka, Japan

Aims: To examine clinical outcome for combination therapy of heparin-bonded covered stent (VIABAHN [VIA]) and bare-nitinol stent (BNS), and to determine independent predictors of restenosis after VIA implantation assessed by intravascular ultrasound (IVUS).

Methods and results: A retrospective analysis was conducted of VIA use in the femoropopliteal artery of 69 patients (79 lesions) treated between June 2012 and November 2018. We divided the treated lesions into two groups depending on whether BNS was added at the proximal site of VIA, or not: combination of VIA and BNS group (COM) (n=19) vs VIA group (n=60). Cumulative incidence of restenosis in the two groups was estimated using Kaplan-Meier curves, while logistic regression analysis was performed to identify IVUS predictors of restenosis within 12 months after VIA implantation. The median follow-up duration was 21.6 months (interquartile range, 13.2-28.8 months). During the clinical follow up, restenosis rate in the COM group was 14% (2 lesions) at 1 year and 36% (4 lesions) at 2 years, while that in VIA group was 26% (14 lesions) at 1 year and 38% (17 lesions) at 2 years, with no significant difference between the two groups (log-rank, p=0.75). In COM group, 63.9±7.2% of plaque burden remained at the proximal reference segment before BNS implantation, while a greater proportion of proximal lumen cross-sectional area (CSA) (COM; 32.0±9.1 vs VIA; 24.6±10.8mm^2, p=0.01) and less proximal plaque burden (COM; 31.1±7.2 vs VIA; 40.8±10.0%, p<0.001) were obtained after BNS implantation. In VIA group, 14 lesions developed restenosis within 12 months. Multivariate logistic regression analysis of the VIA group revealed proximal plaque burden was an independent predictor of restenosis within 12 months after VIA implantation (odds ratio [OR] 1.15, 95% confidence interval [CI] 1.01-1.30, p=0.01), with the optimal cutoff value of 43% (area under the receiver operating characteristic curve 0.79, sensitivity 91%, specificity 69%).

Conclusions: Patency at 2 years in combination of VIA and BNS was comparable with only VIA. Plaque burden at proximal reference segment was an independent predictor of restenosis after VIA implantation.

Iliac / Femoral / Popliteal - Stents, devices and techniques, Other peripheral interventions - Other

Retrograde pedal access for revascularisation of superficial femoral artery complex lesion

PAPOYAN Simon [1,2], PAPOIAN Simon [1,2], SCHEGOLEV Alexandr [2], DANIIL Syromyatnikov [1], MELKIKYAN Agnessa [1,2]

(1) Inozemtcev Moscow Municipal Hospital, Moscow, Russian Federation; (2) Pirogov Russian National Research Medical University, Moscow, Russian Federation

Aims: Endovascular revascularisation is an established approach for limb salvage in the setting of critical limb ischaemia. However, failure rate of antegrade recanalisation in complex femoropopliteal occlusions is as high as 20%. We aimed to evaluate limb salvage after recanalisation of superficial femoral artery (SFA) using retrograde pedal access in patients with critical limb ischaemia (CLI).

Methods and results: We report a series of 26 patients who underwent retrograde pedal access and recanalisation of superficial femoral artery chronic total occlusions after failed antegrade attempts. This is a retrospective review of prospectively maintained data for all patients who underwent ultrasound-guided percutaneous pedal access for retrograde endovascular treatment of SFA occlusion between 2017 and 2019. All patients had undergone prior unsuccessful attempts at antegrade revascularisation or it was impossible due the anatomical characteristics (flush SFA occlusion, tortuosity of iliac artery). Pedal vessel access was followed by angioplasty with selective stenting and completion angiogram. Patients were followed-up with duplex ultrasound to evaluate for patency. Time-dependent outcomes were determined by Kaplan-Meier survival analyses. Median follow-up was 12 months. A total of 26 patients (22 men, 4 women, mean age 68) underwent retrograde SFA recanalisation. All patients had critical ischaemia. Before procedure the mean value of ABI was 0.28. According to the TASC-II classification, 8 patients had TASC type C, and 16 patients had TASC D. Retrograde pedal access was successful in 96.1% of the patients (dorsalis pedis 4, posterior tibial 22). Retrograde revascularisation was achieved in 21 patients (84%) using balloon angioplasty and additional stent placement in 4 patients (16%). Revascularisation failed in 1 patient (3.84%). There were no pedal access site complications. All patients experienced improvement or resolution of their symptoms. The mean ABI increased from 0.28 to 0.83 after successful treatment. The 30-day major adverse cardiac events (MACE), major adverse limb events (MALE), and amputations were all 0%. At 1 year, limb salvage was 88±8% with amputation-free survival of 81±12% and freedom from MALE of 81±10%. Primary assisted and secondary patencies were both 84±10% at 1 year.

Conclusions: Early outcomes for ultrasound-guided retrograde pedal access show that it is safe, with low 30-day mortality, and a low rate of MACE. Freedom from MALE and limb salvage are both high at 1-year follow-up. This technique expands revascularisation options after failed conventional endovascular antegrade approaches for patients with critical ischaemia for limb salvage.

Other peripheral interventions - Other

Endovascular approach for TASC II type C and D aorto-iliac lesions

PAPOYAN Simon [1,2], PAPOIAN Simon [1,2], SCHEGOLEV Alexandr [2], MITICHKIN Alexandr [1], ABRAMOV Igor [2]

(1) Municipal Clinical Hospital named after F.I. Inozemtsev, Moscow, Russian Federation; (2) Pirogov Russian National Research Medical University, Moscow, Russian Federation

Aims: The aim of this study was to evaluate the technical success rates, primary patency and complication for TASC C and D aorto-iliac lesions treated by endovascular procedure.

Methods and results: Data from 101 consecutive patients with 105 chronic iliac artery stenoses and/or occlusions who were treated with endovascular treatment (EVT) in the period between 2013 and 2018 were retrospectively reviewed. The TASC II classification of the disease severity for aorto-iliac lesions was used to define the lesion category. The number of patients with TASC C and D lesion morphology was 77 (79 limbs) and 24 (25 limbs) accordingly. All patients were judged to be candidates for EVT if they reported disabling claudication, had failed with medical therapy or had rest pain or gangrene (Fontaine stage IIb, III, IV). Endovascular approach was the treatment of choice during study period in all patients. The baseline characteristics of both groups were comparable, except for smoking and coronary artery disease. The more commonly associated comorbidity in patients with TASC D lesions was coronary artery disease (30.4%; p=0.029). A total of 105 limbs (101 patients) had been evaluated with anatomic variables, access site, and time of procedure. Most of the patients were treated for claudication (61.9%). Occlusion was higher in TASC D lesions than in TASC C lesions, but statistical significance was not achieved (60% vs 85.1%, p=0.086). Bilateral iliac artery occlusions were observed in 4 patients, 4 of which were in TASC D lesions. The procedure time was longer for TASC D lesions than for TASC C lesions (163 82 min vs 105 34 min; p=0.002), where there was more common use of the brachial and femoral approach simultaneously. There were two perioperative deaths in the TASC D lesion group, with the causes being 1 iliac artery rupture and 1 myocardial infarction. The total perioperative complication rate was higher in the TASC D lesion group than in the TASC C lesion group 6.6% vs 2.2% (p=0.073). These complications included 2 distal embolisations, 2 iliac artery ruptures, 1 post-punctional haematoma and 1 brachial artery thrombosis. Four patients with type D arterial lesions, who failed technically, were treated with bifemoral bypass. The corresponding 2-year primary patency rates were 94.9% for TASC C lesions and 88.4% for TASC D lesions; however, there was no statistically significant difference between the groups considering the primary patency.

Conclusions: This study demonstrated that the outcomes of EVT for TASC C and D aorto-iliac lesions were acceptable, with better technical success in TASC C lesions than in TASC D lesions. Furthermore, the 2-year patency rate for both TASC C and TASC D lesions was acceptable, and brachial access was useful for complex anatomy although with a high failure rate.

Other peripheral interventions - Other

Recanalisation of radial artery occlusion

KALEDIN Alexandr [(1)], KALEDIN Alexandr [(1)], KOCHANOV Igor [(1)], PODMETIN Petr [(1)], SELETSKIY Sergey [(1)]

(1) North-West State Medical University named after I.I. Mechnikov, Saint-Petersburg, Russian Federation

Aims: Identify the predictors of radial artery occlusion (RAO) and evaluate the possibility and feasibility of recanalisation of RAO.

Methods and results: The factors that cause the occlusion of the radial artery (RA) are analysed. The factors include: 1) small diameter of the RA (d ≤2.0 mm) or inconsistency of the size of the device and RA; 2) high RA bifurcation; 3) spasm RA; 4) tortuosity of the RA; 5) mediacalcinosis; 6) injury to the wall of the RA and the long-term location of the catheter (introducer) in the RA; 7) incorrect haemostasis; 8) anticoagulation; 9) Distal RA (dRA). Recanalisation of occlusions was performed retrogradely (accessed through the dRA on the hand) and antegradely (accessed through the ipsilateral ulnar artery) with the hand dynamic strength assessment by the wrist exerciser prior to and after the recanalisation. Patency of the recanalised artery was estimated 1-2 months after the recanalisation via ultrasound or angiography. Predictors of RAO based on the interim results of the TENDERA RCT. RA access (n=240). RAO n=15 (6.3%). Diameter RA (mm) RA non-occlusion (RAno): Δ 2.6 (2.3–2.9); RAO-Δ 2.4 (2.1–2.5). Device size 5 Fr: RAno-89%, RAO-11%. 6 Fr: RAno-96%, RAO-4%. Operation time (min): RAno-Δ 25.2, RAO-Δ 36.1. High RA bifurcation: RAno-87%; RAO-13%. Spasm RA: RAno-84%; RAO-16%. Loop RA: RAno-92%; RAO-8%. Mediacalcinosis:RAno-100%. Injury RA: RAno-85%; RAO-15%. Heparin 40-60 IU/Kg: RAno-93%; RAO-7%. Heparin 90-110 IU/Kg: RAno-95%; RAO-5%. In the register of our clinic, the rate of RA access with control of patency of the RA n=2809. Predictors of RAO in our register. RAO n=153 (5.4%). Diameter RA (mm) RA non occlusion (RAno): Δ 2.7 (2.2–3.1); RAO-Δ 2.3 (2.1–2.5). Device size 5 Fr: RAno-100%. 6 Fr - RAno-95%, RAO-5%. High RA bifurcation: RAno-80%; RAO-20%. Spasm RA: RAno-81%; RAO-19%. Loop RA: RAno-97%; RAO-3%. Mediacalcinosis:RAno-78%; RAO-22%. Injury RA: RAno-77%; RAO-23%. Heparin 40-60 IU/Kg: RAno-94%; RAO-6%. Heparin 90-110 IU/Kg: RAno-95%; RAO-5%. The influence of each factor individually on the occurrence of RAO was indicated. When analysing such factors as spasm, loop RA and injury RA (n=52), any of these combinations was accompanied by RAO in more than 73%. Comparison of dRAl and pRA access to RAO showed that with dRA, occlusion occurs less frequently. TENDERA RCT. RAO: dRA-3%; proximal RA access (pRA)-6,3%. The results of our clinic. RAO: dRA-1,4%; proximal RA access (pRA)-5,4%. Recanalisation RAO was performed in 104 patients. Total successful recanalisation was performed in 85 (82%) patients. Success with retrograde approach noted in 99% of patients, with antegrade approach in 83%. Reocclusion after the retrograde method was detected in 37% and only in 19% after the antegrade method. Dynamic strength analysis demonstrated that after the PCOFRA recanalisation an insignificantly increased number of the wrist exerciser grips was observed: before recanalization, 40.1; after recanalization, 43.7. But patients did not feel these changes.

Conclusions: It is difficult to determine the only underlying cause of RAO; RAO is a low-symptom or asymptomatic complication, but its recanalisation makes it possible to reuse RA during endovascular procedures. The success of retrograde recanalisation is higher than that of antegrade recanalisation, but long-term results (reocclusion) are worse. Both methods have a risk of embolic complications. After RAO recanalisation, the dynamic strength of the hand increases, but patients do not feel it.

Below the knee - Imaging, Iliac / Femoral / Popliteal - Echography and other imaging

The impact of angioscopic yellow plaque in femoropopliteal artery associated with below-the-knee runoff

YAMAGUCHI Tomohiro [(1)], YAMAZAKI Takanori [(1)], YAHIRO Ryousuke [(1)], OKAI Tsukasa [(1)], MIZUTANI Kazuki [(1)], EHARA Shoichi [(1)], IZUMIYA Yasuhiro [(1)], YOSHIYAMA Minoru [(1)]

(1) Osaka City University, Osaka, Japan

Aims: Poor runoff of crural vessels has the clinical impact of poor prognosis of PAD patients undergoing endovascular therapy (EVT) for femoropopliteal artery (FPA). Pathological findings suggests that the below-the-knee (BTK) lesions are commonly comprised of thrombi, possibly derived from up-stream atherosclerotic lesions. In coronary arteries, yellow plaque (YP) is already known to be associated with acute coronary syndrome. The aim of this study is to validate a hypothesis that YP is associated with poor BTK runoff through micro-thrombosis.

Methods and results: We enrolled 25 consecutive patients (with 27 lesions) who underwent EVT for FPA or BTK lesions. The median age was 75 years (quartile 70.5-77.5), and 17 (63.0%) were male. The median Rutherford class was 3 (quartile 2-3), and 2 (7.4%) patients had critical limb ischaemia. We performed angioscopy for the FPA before the EVT procedure, and assessed the morphologies of the plaques in FPA. Plaques was graded as white (grade 0); light yellow (grade 1); yellow (grade 2); and bright yellow (grade 3). Median maximum YP colour grade (maxYP) in FPA was 2 (quartile 1-3). Simultaneously, we calculated BTK runoff score with the selective angiogram according to the revised version of the scoring system proposed by Rutherford et al, and the median runoff score was 3 (quartile 1-6.5). Mann Whitney U-test showed that maxYP of grade 3 had a significant relation to the poor BTK runoff (higher BTK runoff score, p=0.0151). Conversely, survival classification and regression tree analysis revealed that cut-off value of BTK runoff score to estimate the presence of grade 3 YP in FPA is 3.0 (p=0.032).

Conclusions: There is a clear correlation between angioscopic grade 3 YP in FPA and BTK runoff score. This study suggests femoropopliteal YP has a relation to the lesion formation of BTK probably through the thrombus formation, which may lead to the indication of optimal antithrombotic therapy in patients with high BTK runoff score.

Other peripheral interventions - Other

Comparison of arteriovenous haemodialysis fistulas treatment with percutaneous transluminal angioplasty with plain balloon vs DEB

HUYUT Mustafa [1], HUYUT Mustafa [1]

(1) New Century University Hospital Gaziosmanpasa, Istanbul, Turkey

Aims: Treatment of arteriovenous fistulas with percutaneous plain balloon angioplasty (PTA) and drug-coated balloon angioplasty (DCB) are safe and effective at short-term follow-up. The current study aims to investigate the comparison of the clinical outcomes in hospital and 12 months after the treatment of arteriovenous haemodialysis fistulas with percutaneous plain balloon angioplasty vs drug-coated balloon angioplasty.

Methods and results: Forty-six patients who had haemodialysis fistula flow insufficiency, were divided into two groups randomly. In this study, twenty-three patients (10 men; mean age 63.51±6.43 years), who underwent successful recanalisation of brachial arteriovenous fistulae stenosis, were recruited for plain PTA group (15 brachiocephalic, 8 ulno-basilic distal AVF) and twenty-three patients (12 men; mean age 65.51±9.21 years), who underwent successful recanalisation of brachial arteriovenous fistulae stenosis with DCB angioplasty were recruited (18 brachio-cephalic, 5 ulno-basilic distal AVF) for DCB group from July 2016 to January 2018. For the PTA interventions, after achieving haemodynamic success (<30% residual stenosis) procedure was stopped. The follow-up intervals were in-hospital, 3, 6 and 12 months. Clinical endpoints analysed included the composite of all-cause death, haemodialysis insufficiency due to restenosis and acute thrombosis of fistula. Five consecutive patients died (all-cause) (21.73 %) in the plain PTA group and four consecutive patients died (all-cause) (17.39%) in DCB group (p>0.05). Fistula dysfunction recurred in three patients (13.04 %) in PTA group and in two patients (8.69 %) in DCB group (p>0.05). PTA was repeated in five patients (21,73 %) in plain PTA group, and in two patients (8.69 %) in DCB group (p=0.01) during the follow-up period. And one patient referred to redo surgery (4.76 %) at a median FU time of 340 days (p=0.01) in plain PTA group. No thrombosis was observed in either group. One-year primary patency rates were 85.72% ± 3.24 in plain PTA group and 87.62±3.12 in DCB group (p>0,05). No access-induced distal ischaemia occurred during follow-up.

Conclusions: Treatment of arteriovenous fistulas with PTA was safe and effective in both plain balloon and DCB groups in the treatment of haemodialysis fistulae with acceptable restenosis rates at mid-term follow-up results. But in plain PTA group, repeat PTA necessity will be significantly higher.

Carotid stenting - Stents, devices and techniques

Long-term outcomes of the MicroNET-covered stent system routine use for symptomatic and increased-stroke-risk in clinically asymptomatic carotid revascularisation: five-year evidence from the PARADIGM-EXTEND prospective academic study

MAZUREK Adam [1], MAZUREK Adam [1], BORRATYNSKA Anna [2], TOMASZEWSKI Tomasz [2], LESNIAK-SOBELGA Agata [1], URBANCZYK Malgorzata [3], WILKOLEK Piotr [1], TRYSTULA Mariusz [4], DRAZKIEWICZ Tomasz [4], PODOLEC Piotr [1], MUSIALEK Piotr [1]

(1) Jagiellonian University, Department of Cardiac and Vascular Diseases, John Paul II Hospital, Kraków, Poland; (2) John Paul II Hospital, Department of Neurology and Outpatient Neurology Clinic, Kraków, Poland; (3) John Paul II Hospital, Deptartment of Radiology, Kraków, Poland; (4) John Paul II Hospital, Deptartment of Vascular Surgery, Kraków, Poland

Aims: Diffusion-weighted magnetic resonance imaging indicates that MicroNET-covered embolic prevention stent system effectively minimises periprocedural embolisation and prevents lesion-related post-procedural cerebral embolisation in carotid artery stenting but long-term clinical data are scanty. The aim of this study is to provide long-term clinical and duplex ultrasound evaluation of safety and efficacy of the MicroNET-covered embolic prevention stent system routinely used in unselected, consecutive carotid revascularisation.

Methods and results: PARADIGM-EXTEND is in all-comer, all-referrals-tracked, consecutive carotid revascularisation patient study with no exclusion criteria other than lack of NeuroVascular Team-determined indication to carotid revascularisation. In clinically asymptomatic patients revascularisation is mandated only with ipsilateral lesion- or brain-level increased-stroke-risk criteria or in case of contralateral carotid stenosis-related stroke/asymptomatic occlusion. Adverse events are adjudicated by an independent clinical event committee. Currently 451 patients (48-87 years, 59% symptomatic, 127 women, any atrial fibrillation 8.9%) with 490 arteries crossed the first follow-up window of 30 days. There has been 100% MicroNET-covered embolic prevention stent system use (i.e., not a single other stent type has been used throughout study duration). Proximal/distal intra-procedural neuroprotection use was 38.3%/61.7%. Large balloon/high-pressure stent optimisation was routinely performed, leading to a single-digit (6.9%) mean post-procedural residual angiographic stenosis. Independent neurologist and duplex evaluation are performed before and after (48 hours and 30 days, then yearly) carotid revascularisation. Periprocedural death or major ischaemic stroke rate was 0%. One event (asymptomatic extension of a prior infarct scar in a patient with prolonged hypotension) was adjudicated as a minor ischaemic stroke (0.22%), one as NSTEMI (type 2 infarct in a patient with 2-vessel non-revascularisable CTO; 0.22%). By 30 days there were no further ischaemic strokes (0%) but there was 1 haemorrhagic transformation (preprocedural large recurrent incremental ischaemic stroke requiring treatment due to aggravating symptoms) that led to death (0.22%) and 1 bleeding-related death (0.22%). Thus at 30 days total death/stroke rate was 0.66%, and total death/stroke/MI rate was 0.88%. By 60 months there was 1 ipsilateral (device-unrelated), 3 contralateral and 2 posterior circulation ischaemic strokes. Baseline velocities were 3.72±1.25 and 0.63±0.69 m/s (peak-systolic and end-diastolic). Post-procedural in-stent velocities were normal and remained normal throughout the 60-month follow-up period: 0.78±040 and 0.21±0.10 (1y); 0.75±0.36 0.19±0.09 (2y); 0.75±0,35 and 0.21±0.09 (3y); 0.72±0.27 and 0.20±0.07 (4y); 0.79±0.58 and 0.21±0.11m/s (5y). There were 2 in-stent restenoses by 1y (including 1 with *de novo* post-procedural neck radiotherapy) and 1 other by 2y (total 2y in-stent restenosis of 1.1%) but no further ones occurred (0% in-stent restenosis at 2-5y).

Conclusions: PARADIGM-EXTEND long-term clinical and duplex ultrasound evidence is consistent with normal healing and sustained safety and stroke prevention efficacy of the MicroNET-covered embolic prevention stent system used routinely (on top of optimised medical therapy) for stroke prevention in symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis.

Carotid stenting - Vascular access and bleeding

Introduction of transradial approach for carotid artery stenting in everyday clinical practice

VÉGH Eszter Mária [1], VEGH Eszter Maria [1], NEMES Balázs [2], CSOBAY-NOVAK Csaba [2], HÜTTL Artur [2], ÖRDÖG Szabolcs [1], MERKELY Bela [2], RUZSA Zoltán [1,2]

(1) Bács-Kiskun Megyei Kórház, Nyíri Way, Hungary; (2) Semmelweis Egyetem Városmajori Szív- és Érgyógyászati Klinika, Városmajor Street, Hungary

Aims: Carotid artery stenting (CAS) is a well-established therapeutic option for preventing stroke. Transfemoral approach is the widely-used access to perform the procedure, however it involves prolonged patient immobilisation. Two high-volume centres in Hungary have introduced transradial approach (TR) to clinical practice.

Methods and results: Between 2009 and 2019, 2,386 CAS procedures were performed in these centres. Clinical characteristics, radiation doses, volume of contrast material, screening and procedure times of consecutive patients were recorded prospectively in a register and restrospectively analysed. Transradial approach was applied in 1,096 patients. Their mean age was 68±6 years, 66% of them were male. The ratio of TR has shown an increase from 30% to 77% in CAS cases during the ten years. While the duration of the procedure (41 min vs 23 min, $p<0.05$) has shown a significant decrease and ascended as more complex cases were performed via radial access, the fluoroscopy time (12.8 min vs 7.7 min, $p<0.001$) and the applied contrast material (159 ml vs 85 ml, $p<0.001$) decreased after five years and did not change significantly after that. Medians of procedure durations, X-ray durations and doses, and the applied contrast material did not show differences between transradial and transfemoral access. Conversion to TF was needed in 8% and did not differ significantly during the examined period. No difference was observed between the two approaches regarding the incidence of major cardiovascular events, minor or major vascular events and hospitalisation days.

Conclusions: During the introduction into clinical practice of the novel transradial approach for CAS, an initial learning curve was observed in the first 5 years regarding the parameters of the procedure. The occurrence of adverse events was concordant between the two access approaches. Transradial procedure is an effective and safe alternative of the traditional transfemoral approach. In high volume centres, a major shift between two procedures can be performed in five years.

Ischaemic stroke - Tools, devices and techniques, Other stroke interventions - Other

Annual procedure volumes of PFO closure after cryptogenic stroke vary between large European countries

SONDERGAARD Lars [8], PIETZSCH Jan [1], GEISLER Benjamin [1,10], DANIELS Matthew [2,3,4,5], BUSCA Rachele [6], TARANTINI Giuseppe [7], KASNER Scott [9], SONDERGAARD Lars [8]

(1) Wing Tech Inc., Menlo Park CA, USA; (2) The University of Manchester, Manchester, United Kingdom; (3) Oxford University, Oxford, United Kingdom; (4) Southampton University NHS Foundation Trust, Southampton, United Kingdom; (5) Osaka University, Osaka, Japan; (6) W. L. Gore & Associates, Milan, Italy; (7) University of Padua, Province of Padua, Italy; (8) Rigshospitalet, Copenhagen, Denmark; (9) University of Pennsylvania, Philadelphia PA, USA; (10) Massachusetts General Hospital/Harvard Medical School, Boston MA, USA

Aims: Patent foramen ovale (PFO) closure plus antiplatelet therapy reduces recurrence of cryptogenic ischaemic stroke when compared to antiplatelet therapy only. However, there are limited data on the utilisation of transcatheter PFO closure (PFOc). Our goal was to determine procedure volumes and PFOc utilisation as the proportion of candidates in large European countries.

Methods and results: National statistics were obtained for Germany, England, France, and Italy for the last five years (2014-18). Eligibility was defined similarly to the REDUCE trial: ischaemic stroke or transient ischaemic attack (TIA), age ≤60 years, and presence of a PFO. Stroke and TIA incidence was obtained from stroke registry data. The eligible candidate pool for analysis purposes included current year candidates, plus patients of the prior two years not treated with PFOc. The number of PFOc was compared to the number of candidates. For Germany, where only combined volumes for PFO and atrial septal defect closure are available, a lower age cut-off of 20 years was used to exclude many atrial septum repair cases. Numbers needed to treat (NNT) assumed the hazard rate for ischaemic stroke recurrence from a recent meta-analysis, and limited analysis to a two-year horizon. In 2018, PFOc was performed in 6,172; 295; 1,962; and 3,192 cases in Germany, England, France, and Italy, respectively. This corresponded to procedure incidence rates of 7.51; 0.53; 2.94; and 5.26; per 100,000 population. These latest volumes reflect a total five-year increase in procedure volumes of 128% in Germany, 462% in France, 36% in Italy, and a decline of 37% in England. The largest absolute increases in Germany, France, and Italy were observed between the 2017 and 2018 data years (+2,829; +1,335; +520 procedures, respectively) following randomised trial publication. In all analysed countries except England there was a statistically significant trend to higher procedure volumes over time ($p<0.05$). Annual ischaemic stroke incidence, based on country-specific registry data, varied between 85 (France) and 123 (Germany) per 100,000 general population. The TIA incidence rate was 29 per 100,000. Together, this yielded an annual PFOc candidate pool <60 years of age of 2,823; 1,854; 1,741; and 1,942 for Germany, England, France, and Italy. The resulting eligible patient population was 6,415; 5,668; 6,238; and 3,650, respectively. Proportions of treated patients vs candidate pool were 96%; 5%; 31%; and 87% for Germany, England, France, and Italy respectively, suggesting a >19-fold difference in uptake across Europe. The proportion of treated patients 60 years and older (candidates outside existing trial evidence) was 33% in Germany, 14% in England, and 26% in France. If all annual PFOc candidates were treated, the annual absolute reduction of recurrent ischaemic strokes, compared to antiplatelet therapy, would be between 299 and 427 for all countries, leading to NNTs between 15 and 21. Among the limitations of our analysis is the use of different data sources for procedure counts and candidate calculation, some uncertainty about German volumes, and our assumption that reported procedures were limited to stroke and TIA indications.

Conclusions: PFO closure volumes differ across large European countries. Procedure volumes increased dramatically after the 2017 announcement of trial results. Many PFO patients at risk for a recurrent stroke remain untreated in several of the studied countries, particularly England and France.

Carotid stenting - Stents, devices and techniques, Ischaemic stroke - Tools, devices and techniques

Cardiology cathlab-based management of thrombotic carotid stenoses in acute ischaemic stroke: tools, techniques, local stroke unit collaboration, challenges and patient outcomes

MUSIALEK Piotr [1], MUSIALEK Piotr [1], MAZUREK Adam [1], TOMASZEWSKI Tomasz [2], URBANCZYK Malgorzata [3], BANYS R. Pawel [3], DRABIK Leszek [1], KLECHA Artur [4], KOWALCZYK S.Tomasz [4], PODOLEC Piotr [1], GRUNWALD Iris Q. [5]

(1) Jagiellonian University Dept. of Cardiac and Vascular Diseases, John Paul II Hospital, Krakow, Poland; (2) Dept. of Neurology, John Paul II Hospital, Krakow, Poland; (3) Dept. of Radiology, John Paul II Hospital, Krakow, Poland; (4) Dept. of Cardiology, Podhalanski Mulitipeciality Hospital, Nowy Targ, Poland; (5) Neuroscience and Vascular Simulation, Anglia Ruskin University and Southend University Hospital NHS Foundation Trust, Chelmsfors and Westcliff-on-Sea, United Kingdom

Aims: Shortage of endovascular operators able to deliver thrombectomy in acute ischaemic stroke on a 24/7/365 basis is a fundamental challenge in many healthcare settings around the world, including a number of Europaen countries. Another key barrier is getting multispeciality teams to work collaboratively with each other in the acute ischaemic stroke setting - as is already done (albeit on an elective rather than acute basis) in managing stroke mechanistic pathologies such as atrial fibrillation (pharmacology/ablation) or PFO/left atrial appendage (diagnostic workup and closure).

Methods and results: Within the Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ MicroNET-covered embolic prevention stent system (symptomatic and increased-stroke-risk asymptomatic carotid stenosis) unselected consecutive patient study we have treated, on an emergent basis, 17 patients (13 men, age 58-75 years, median 67 years) with acute ischaemic stroke caused by severe/thrombus-containing carotid artery stenoses. All cases were performed as part of our pathway towards a 24/7 thrombectomy stroke service. All lesions (100%) were thrombotic (mobile thrombus - 29%). Proximal neuroprotection by flow reversal was used in 15/17 patients (88%); in 2 patients (12%) filter protection was applied as proximal system use was unfeasible. All cases were done under activated clotting time control and using, consistent with the study protocol, the MicroNET-covered embolic prevention stent system that was optimised with large balloons/high pressures. There were no procedure- or device-related complications. Thrombolysis in Cerebral Infarction scale 3 flow was achieved in all cases in absence of distal embolisation. Vascular access closure device use was 76%. A favourable 30-day clinical outcome (modified Rankin scale of 0-2) rate was 94%. One patient had a haemorrhagic stroke transformation that finally led to death. By 30 days no new stroke, stent thrombosis, myocardial infarction or other serious adverse event(s) occurred.

Conclusions: Cardiologists skilled in carotid interventions are naturally positioned to deliver acute ischaemic stroke treatment. 24/7 interventional services and networks for acute myocardial infarction have long been established and, as demonstrated in our centre, the services and skills can be translated - in collaboration with a local stroke unit/neurology - to acute ischaemic stroke. Breaking away from traditionally-perceived ”territories” towards working as a multispeciality acute ischaemic stroke team is a logical concept that provides an effective healthcare solution for large numbers of stroke patients currently needing -and not receving- thrombectomy. Working hand-in-hand with neurology and radiology in managing acute carotid syndromes is thus part of a natural evolution towards cardiologist-performed full interventional stroke services including thrombectomy to address unmet societal and healthcare systems needs.

Ischaemic stroke - Tools, devices and techniques

Suture-mediated PFO closure: efficacy at three-month transoesophageal follow-up

ANCONA Marco [1], ANCONA Marco [1], BENEDUCE Alessandro [1], MORONI Francesco [1], FALASCONI Giulio [1], BELLINI Barbara [1], FERRI Luca [1], RUSSO Filippo [1], CHIEFFO Alaide [1], AGRICOLA Eustachio [1], MONTORFANO Matteo [1]

(1) San Raffaele Hospital, Metropolitan City of Milan, Italy

Aims: Suture-mediated PFO closure has already been shown to be safe and effective. Nevertheless, post-procedural PFO patency at follow up has been assessed only by trans-thoracic echocardiography (TTE) with microbubble test, with limited sensitivity. The aim of this single centre study is to evaluate the efficacy of suture-mediated PFO closure at three-month follow-up by transesophageal echocardiography (TEE), which has higher sensitivity than TTE.

Methods and results: A total of 65 patients underwent suture-mediated PFO closure at IRCCS San Raffaele Scientific Institute between March 2017 and June 2019. All patients underwent preprocedural TEE to confirm PFO diagnosis and assess anatomical feasibility of suture-mediated PFO closure. PFO anatomies were deemed suitable for suture-mediated closure if: i) there was no interatrial septum aneurism; ii) there was no cribriform PFO; iii) there was no left-right shunt at colour Doppler. Baseline right-to-left shunt evaluation was performed with microbubble test at rest and during Valsalva manoeuvre. It was classified as absent, mild (grade 1), moderate (grade 2) and severe (grade 3). Right-to-left shunt evaluation at three-month TEE follow up was performed in the same way. At baseline evaluation, all patients had a positive microbubble test, with 31% having a grade 1 shunt, 52% having a grade 2 shunt and 17% having a grade 3 shunt. Procedural success was achieved in 100% of patients. Mean procedural time was 92±31 minutes. Intraprocedural TEE guidance was performed only in the first three patients (4.6%) of the series. There were 5 (8%) vascular access related complications, all managed conservatively. Among 65 patients who underwent suture-mediated PFO closure, 42 patients have already performed three-month TEE follow up and were included in the present study. There were no recurrences of of cerebrovascular accidents. Mean TEE follow-up was 101±38 days. There were no device detachments, while one small iatrogenic atrial septal defect was documented; furthermore, 1 case of device thrombosis (2%) was documented. At micrububble test during Valsalva manoeuvre, right-to-left shunt was absent in 71% of patients, grade 1 in 12%, grade 2 in 14% and grade 3 in 2% of patients. A total of 83% of patients had a residual right-left shunt ≤1.

Conclusions: Although this is a small single-centre study, this is the first report of TEE evaluation at follow up of suture-mediated PFO closure. Residual right-left shunt was absent or mild in 83% of patients and moderate in 14%. Suture-mediated PFO closure efficacy evaluated with TEE appears consistent with the previously reported efficacy evaluated with TTE.

Other stroke interventions - Other

Comparison between traditional devices and new technology for the percutaneous closure of PFO: a single-centre experience

CORCIU ANCA Irina [1], DE MARCO Federico [1], TUSA Maurizio [1], BRAMBILLA Nedy [1], TESTA Luca [1], BEDOGNI Francesco [1]

(1) IRCCS Policlinico San Donato, Metropolitan City of Milan, Italy

Aims: Percutaneous closure of patent foramen ovale (PFO) is a valid treatment for selected patients with paradoxical embolism, with a major complication rate of 0.2% and 1.5%. Most of these complications could be avoided by the use of a suture-mediated "deviceless" closure (NobleStitch™ EL System), which was proven to be feasible and effective in the majority of septal anatomies. The aim of our study was to compare the feasibility, safety and efficacy of percutaneous PFO closure using two different techniques, the NobleStitch system and traditional devices as a single centre experience.

Methods and results: 147 consecutive patients (mean age 48±12 yrs, 70 females) with clinical indication for PFO closure with favourable anatomy were randomly chosen to undergo the procedure using the NobleStitch EL (63 patients, 48±11 yrs- Group A), and other devices (Amplatzer, and GORE) (84 pts, Group B, 49± 12 yrs) respectively. The patients with unfavourable interatrial septal anatomies (large aneurysm, multiple defects, baseline Doppler left to right shunt) were excluded. All patients underwent: 1) preprocedural evaluation (clinical, imaging); 2) percutaneous procedure in general anaesthesia under transesophageal echocardiographic guidance; 3) follow up evaluation at 1 month, 6 months and 1 year after the procedure (clinical and microbubble ultrasound: transthoracic echocardiography and transcranial Doppler). The main indications for the PFO closure were represented by transient ischaemic attack in 84 patients (57.1%), cryptogenic stroke in 33 patients (22.5%), decompression sickness from professional diving in 10 patients (6.8%), and disabling migraine with aura in 20 patients (13.6%). Successful device deployment with no significant end-procedural shunt was obtained in all patients from Group B and almost in all from the Group A (1 patient underwent device implantation for NobleStitch failure). No major intraprocedural complications were observed. In Group A 1 stroke in the first post-operative day was registered, in a patient with unknown cerebral vascular malformation. There was no significant difference between the two groups (Group A vs Group B) in terms of mean days of follow-up (191±131 vs 189± 141), and no significant residual right-to-left shunt (RLS grade ≤1): 60 patients (96.7%) in Group A, 84 patients (100%) in Group B, respectively; 2 significant RLS were registered in Group A, and none in Group B. There were no device-related complications in Group A, while a symptomatic thrombosis of the device at 60 days in Group B was found.

Conclusions: Our single-centre experience demonstrates that the percutaneous PFO closure with NobleStitch EL in favourable atrial septal anatomies provides an effective closure, with excellent safety profile at medium-term follow-up when compared to traditional devices.

Ischaemic stroke - Tools, devices and techniques

Real-world experience and outcomes after device-led PFO closure

KHAN Usman Azhar [1], KHAN Usman Azhar [1], BRENNAN Paul [1], LOCKHART Christopher [1], OWENS Colum [1], SPENCE Mark [1]

(1) Royal Victoria Hospital, Belfast, United Kingdom

Aims: A patent foramen ovale (PFO) is a common defect that affects up to 34% of the population. Recent evidence has emerged supporting PFO closure in the event of cryptogenic ischaemic stroke, transient ischaemic attack (TIA), systemic embolism and migraine. We aimed to report real-world experience and outcomes for all consecutive patients that had PFO closure in our hospital between March 2009 and October 2019.

Methods and results: We retrospectively analysed baseline clinical characteristics, indications for PFO closure, procedural characteristics and long-term clinical follow-up using our dedicated hospital database and Northern Ireland Electronic Care Record. PFO closure was performed in 133 patients between March 2009 and October 2019. 59 (44%) of cases were performed between 2009 and 2016 with 74 (56%) cases performed between 2017 and 2019, coinciding with the publication of supporting randomised control trials. The mean patient age was 43±15 years and 69 (52%) patients were female. 16 (12.1%) of patients had a history of systemic hypertension, 4 (3%) diabetes mellitus and 35 (26%) had a smoking history. Only one patient had a thrombophilia diagnosis. Cerebrovascular events including ischaemic stroke and TIA's were the leading indication for PFO closure in 123 (92.5%) cases. Systemic embolism, platypnea-orthodeoxia syndrome and decompressive illness were the indications in 4 (3%), 2 (1.5%) and 1(0.75%) case(s), respectively. "Other" indications made up the remaining 3 patients. The majority of procedures were performed under general anaesthetic (GA) in 129 (97%) cases. All cases were performed using trans-oesophageal echocardiography guidance. The mean procedure time was 38±23minutes and the mean size of percutaneous device used was 25mm. GORE (52%) and Amplatzer (35%) septal occluders were the most commonly used devices. There were no procedural deaths. Cardiac tamponade, major vascular injury, pulmonary embolism and/or device embolism did not occur in any patient. Only one patient had a new arrhythmia (atrial fibrillation (AF)) during the periprocedural period. The median length of stay was 1 day. Antithrombotic data at discharge was available for 129 (97%) patients. The main antithrombotic strategy adopted was dual antiplatelets in 112 (87%) cases, single antiplatelet in 10 (8%) cases and oral anticoagulation ± a single antiplatelet made up the remainder of cases, respectively. No patients were readmitted to hospital for bleeding events on interrogation of NIECR. The median follow-up duration after PFO closure was 31 months (range 2-1,439months). 3 patients suffered a recurrent neurological event during follow-up, giving an event rate of 0.6/100 patient-years (PY). Infective endocarditis was not observed for any patients. 5 (3.8%) patients had a diagnosis of new AF or atrial flutter during follow-up, all of which occurred within three months of the procedure. 3 patients (2.3%) died during follow-up (median age 56 years [20-75years]) but all of these deaths were non-cardiac in nature.

Conclusions: PFO closure was performed safely in our hospital with a very low rate of procedural complications. New arrhythmias and cerebrovascular events occurred in a low proportion of the population. Our real-world outcomes in combination with the previously published major randomised control trials support the continued application of device-led PFO closure in patients with cryptogenic ischaemic stroke, TIA and/or systemic embolism.

LAA closure - Tools, devices and techniques

Early results with the new-generation WATCHMAN FLX LAA occlusion device

CRUZ-GONZÁLEZ Ignacio [1], KORSHOLM Kasper [2], TREJO-VELASCO Blanca [1], THAMBO Jean Benoit [5], MAZZONE Patrizio [7], RIOUFOL Gilles [6], GRYGIER Marek [3], MÖBIUS-WINKLER Sven [4], BETTS Timothy [8], NIELSEN-KUDSK Jens Erik [2]

(1) Hospital Clínico Universitario de Salamanca, Salamanca, Spain; (2) Aarhus Universitetshospital, Skejby, Aarhus Municipality, Denmark; (3) Poznan University of Medical Sciences, Poznań, Poland; (4) Friedrich Schiller University Jena, Jena, Germany; (5) Centre Hospitalier Universitaire de Bordeaux, Bordeaux, France; (6) Claude Bernard University Lyon 1, Villeurbanne, France; (7) San Raffaele Hospital, Metropolitan City of Milan, Italy; (8) Oxford University Hospitals NHS Trust, Oxford, United Kingdom

Aims: The new-generation WATCHMANTM FLX device (Boston Scientific, Marlborough, USA) features a reduced height, a closed distal end, more anchors, more fabric and it can be fully recaptured and repositioned. We report early experience with this device from centres taking part in a European limited market release programme.

Methods and results: A total of 165 patients undergoing LAAO with the WATCHMAN FLX device were enrolled in a prospective, multicentre observational post-authorisation registry. Mean age was 75.4±8.9 years, CHA2DS2-VASc score 4.4±1.4 and HASBLED score 3.5±1.2. Prior bleeding was the primary indication in 140 (84.8%) patients. Preprocedural LAA sizing was assessed either by transesophageal echocardiography (TEE) (61.8%) or by cardiac computed tomography (CT) (38.2%). LAA morphology was classified as chicken-wing in 32.1%, windsock in 20%, cauliflower in 16.4% and cactus-shaped in 4.2% patients. Technical success was achieved in all patients with the first device implanted in 159 (96.4%). Devices were successfully implanted at first attempt in 129 (78.2%) or recaptured only 1–2 times in 34 (20.6%). Procedure-related complications occurred in 4 (2.4%) patients, including 1 (0.6%) pericardial effusion treated by percutaneous drainage and 3 (1.8%) access-related complications. No strokes, deaths or device embolisations occurred. After 54 days (IQ range: 21.75) follow-up imaging was performed in 127 (76.9%) patients, with TEE in 67(40.6%) and cardiac CT in 40 (24.2%). Device-related thrombus was detected in 7 (4.2%) patients. Significant peri-device leak (>5 mm) was only present in 1 (0.6%) patient, and minor leaks (3-5mm) in 8 (4.8%) patients. No device displacement or late embolisation took place. During a median follow-up of 55 days (IQ range: 103.75), 1 (0.6%) patient died, 1 (0.6%) suffered an ischaemic stroke, 2 (1.2%) were hospitalised for decompensated heart failure and 6 (3.6%) had a haemorrhagic complication, with 4 (2.4%) major bleeds and 2 (1.2%) minor bleeds.

Conclusions: LAAO with the WATCHMAN FLX was safe and effective in a wide range of LAA morphologies, with a low procedural complication rate, high degree of LAA sealing and favourable short-term efficacy outcome.

LAA closure - Tools, devices and techniques

LAA closure with the Ultraseal device

PAGNOTTA Paolo Antonio [1], PAGNOTTA Paolo Antonio [1], MAURO Chiarito [1], SANZ-SANCHEZ Jorge [1], REGAZZOLI Damiano [1], PELLONI Elisa [2], PISANO Francesco [2], FERRANTE Giuseppe [1], STEFANINI Giulio Giuseppe [1], REIMERS Bernhard [1]

(1) Humanitas Research Hospital, Metropolitan City of Milan, Italy; (2) Ospedale Regionale Umberto Parini, Aosta Valley, Italy

Aims: Left atrial appendage (LAA) closure is considered an effective option in patients with non-valvular atrial fibrillation (NVAF) and contraindications to long-term oral anticoagulant (OAC) therapy. However, there are some concerns about safety of currently available devices. Our aim is to provide an assessment on feasibility and safety of the Ultraseal LAA closure device in patients with NVAF and contraindications to long-term OAC therapy, stratifying our results according to the use of the first- or second-generation of this device.

Methods and results: Forty-four consecutive patients with NVAF undergoing Ultraseal device implantation between July 2016 and December 2019 at two institutions were included. Transesophageal echocardiography and computed tomography angiography was performed on all patients prior to LAA closure. Of these, 10 patients were treated with the new-generation Ultraseal II device. Procedural success was achieved in all patients except two who experienced incorrect device deployment with incomplete LAA closure. Procedure duration halved during the first 18 months of the enrolment. The only periprocedural adverse events observed were a myocardial infarction and an in-hospital death due pneumonia. At mean follow-up (305± 150 days), all other patients, except one who died after 6 months from acute heart failure, were alive and free from major bleedings and ischaemic strokes. No device thromboses were noted at 45- to 60-day transesophageal echocardiography.

Conclusions: Our results suggest that the Ultraseal device is a feasible option for LAA occlusion. Notably, the learning curve in this registry was fast, paralleled by extremely low complication rates. No differences were observed at discharge and at mid-term follow-up between the two generations of the device. These results should be considered hypothesis generating and larger studies are mandatory.

LAA closure - Tools, devices and techniques

Intracardiac echocardiography for guiding transcatheter LAA occlusion with the novel WATCHMAN FLX device

NIELSEN-KUDSK Jens Erik [1], NIELSEN-KUDSK Jens [1], KORSHOLM Kasper [1], SAMARAS Athanasios [1], ANDERSEN Asger [1], JENSEN Jesper Møller [1]

(1) Aarhus Universitetshospital, Skejby, Aarhus Municipality, Denmark

Aims: The present study aimed at investigating the efficacy and safety of intracardiac echocardiography (ICE) from the left atrium to guide left atrial appendage occlusion (LAAO) with the novel WATCHMAN FLX device (Boston Scientific).

Methods and results: Single-centre, prospective cohort study of consecutive patients undergoing LAAO with the WATCHMAN FLX device between March 2019 and October 2019 (n=50). All patients underwent preprocedural cardiac CT for procedural planning. The procedure was performed under local anesthesia with ICE from the left atrium (single transseptal puncture, ViewFlex Xtra, Abbott). Clinical follow-up was conducted 8 weeks after the procedure and included cardiac CT and transesophageal echocardiographic (TEE). Efficacy outcomes were technical success, procedure time and LAA sealing at 8-week follow-up. Periprocedural complications within 7 days of implantation, and major adverse events during short-term follow-up were collected. Mean age was 73.5±7.6 years, CHA2DS2-VASc 4.1±1.4 and HASBLED 2.4±0.9 with 30 patients (60%) having a prior major bleeding. The cohort showed a wide range of different LAA morphologies including shallow anatomies.

Conclusions: This initial experience, suggests that an effective and safe LAAO can be achieved with the novel WATCHMAN FLX device using ICE guidance from the left atrium. The LAA sealing rate with this device was remarkably high at follow-up.

Ischaemic stroke - Tools, devices and techniques

Incidence of atrial fibrillation on Holter monitoring after percutaneous PFO closure: a prospective observational study

ODORICO Xavier [1], ODORICO Xavier [1], MACIA Jean Christophe [1], ARQUIZAN Caroline [1], AKODAD Myriam [1], AGULLO Audrey [1], DELSENY Delphine [1], ROBERT Pierre [1], LATTUCA Benoit [2], CAYLA Guillaume [2], LECLERCQ Florence [1]

(1) CHU MONTPELLIER, MONTPELLIER, France; (2) CHU Nimes Caremeau, Nimes, France

Aims: An increased risk of atrial fibrillation (AF) after patent foramen ovale (PFO) closure was observed in randomised trials but systematic screening of AF was not performed in these studies. The objective of this study was to evaluate incidence of AF in patients who underwent percutaneous PFO closure with serial 24-hour ambulatory ECG monitoring during 6-month follow-up.

Methods and results: All consecutive patients undergoing PFO closure for cryptogenic stroke or decompression sickness were prospectively included in 2 centres. A 24-hour ambulatory ECG was performed after the procedure (day 0), at 1- and 6-month follow-up in all patients. Primary endpoint was incidence of AF defined as an irregular rhythm without discernible P waves lasting at least 30 seconds on ECG monitoring. Secondary endpoints were clinical outcomes (hospitalisation from cardiovascular causes, new stroke or bleeding) up to 6-month follow-up. Between February 2018 and March 2019, a total of 62 patients underwent PFO closure: 59 (95.2%) for cryptogenic stroke and 3 (4.8%) for decompression sickness. In the overall population, 40 were male (64.5%) and the mean age was 48±9.5 years. An atrial septal aneurysm was present in 37 patients (64.9%), 57 patients (91.9%) received an Amplatzer PFO Occluder device (Abbott Vascular) and 5 (8.1%) an Occlutech PFO device (Occlutech) with a mean size of 26±5.0 mm. After a mean follow-up of 33.3±12.2 weeks, new onset AF occurred in 3 patients (4.84%), all within the first 45 days after closure. All AF were paroxysmal (including one periprocedural) and all were asymptomatic. Two patients (3.2%) requiring oral anticoagulant therapy according to a high stroke risk based on the CHA2DS2-VASc score. There were no adverse events for any patient. Age (RR 1.26 [0.98;1.61] p=0.276), sex (p=0.55) and device (p=1.0) were not statistically associated with occurrence of AF but all patients with AF were men and received an Amplatzer device.

Conclusions: Incidence of AF, evaluated with systematic 24-hour ambulatory ECG monitoring at 6-month follow-up after PFO closure, was relatively low (<5%). Always paroxysmal, AF occurred within the first 45 days after the procedure and was not associated with adverse outcomes.

LAA closure - Tools, devices and techniques

Conscious sedation vs general anaesthesia for WATCHMAN LAA closure

ALLAKKIS Wasim [2], KLEINECKE Caroline [1], ALLAKKIS Wasim [2], BUFFLE Eric [3], LIU Xiao-Xia [4], BRACHMANN Johannes [2], GLOEKLER Steffen [3], SCHNUPP Steffen [2], JIANGTAO Yu [5]

(1) REGIOMED Klinikum Lichtenfels, Lichtenfels, Germany; (2) REGIOMED Klinikum Coburg, Coburg, Germany; (3) University hospital, Bern, Switzerland; (4) Beijing, Beijing, China; (5) Katholisches Klinikum Koblenz Montabaur / Marienhof Koblenz, Koblenz, Germany

Aims: Limited evidence exists on the impact of conscious sedation (CS) or general anesthesia (GA) on periprocedural outcomes after left atrial appendage closure (LAAC). The aim of the present study was to compare safety and efficacy of CS versus GA for LAAC with WATCHMAN devices.

Methods and results: 303 consecutive patients underwent LAAC with WATCHMAN devices under GA at the REGIOMED hospital Lichtenfels, Germany, between 2012 and 2017. Respectively, 218 patients received LAAC under CS at the REGIOMED hospital Coburg, Germany, between 2016 and 2018. After a 1:1 propensity score matching, 196 (CS) vs 115 (GA) patients were compared. The safety endpoint was a composite of major periprocedural complications (death, stroke, pericardial tamponade, major bleeding, major access vessel complication, need for bail-out surgery, device embolisation, severe kidney injury, cardiogenic shock, need for cardio-pulmonary resuscitation) and postoperative pneumonia. The efficacy endpoint consisted of device success and duration of postoperative monitoring in the intermediate care or intensive care unit. The prevalence of female gender (49.0% [CS] vs 36.5% [GA], p=0.03) was higher in the CS group. All other baseline characteristics were similar: age (78.0+7.3 [CS] vs 77.0+6.8, p=0.23), CHA2DS2-VASC (4.8+1.4 vs 4.6+1.7, p=0.40) and HAS-BLED (3.4+0.8 vs 3.4+0.9, p=0.63) score, coronary artery (57.7% vs 52.2%, p=0.53) and lung disease (7.1% vs 9.1%, p=0.52), as well as renal function (glomerular filtration rate: 55.3+26.0 vs 56.2+22.8, p=0.75). In five cases (2.6%) CS were converted to GA (in one due to LAA perforation with cardiogenic shock, in one due to epistaxis with aspiration, and in three due to respiratory failure). The primary safety endpoint (3.5% [CS] vs 7.0% [GA], p=0.18) did not differ significantly, although a numerically higher rate of events was observed in GA. This was driven by a numerically slightly higher rate of postoperative pneumonia (2.6% vs 4.3%, p=0.51). The rate of major periprocedural complications (2.5% vs 3.5%, p=0.73) and its components were comparable between the groups: death (0.5% vs 0.0%, p=>0.99), stroke (0.5% vs 0.0%, p=>0.99), pericardial tamponade (1.0% vs 3.5%, p=0.20), major bleeding (1.5% vs 3.5%, p=0.43), major access vessel complication (0.5% vs 0.9% p=>0.99), need for bail-out surgery (0.0% vs 0.0%, p=1.0), device embolisation (0.0% vs 0.0%, p=1.0), severe kidney injury (0.5% vs 0.0%, p=>0.99), cardiogenic shock (1.0% vs 0.0%, p=0.53) and need for cardio-pulmonary resuscitation (1.0% vs 0.0%, p=0.53). With regard to efficacy, device success was comparable between the groups (96.9% vs 93.9%, p=0.24). However, postoperative monitoring was significantly shorter in the CS group (median, hours: 4.0±59.9 vs 24.0±10.8 p=0.03).

Conclusions: In patients undergoing left atrial appendage closure with the WATCHMAN device, conscious sedation compared to general anesthesia showed comparable safety and efficacy. Therefore, the type of anesthesia for LAAC may be tailored to patient comorbidities, operators` experience and hospital logistics.

Ischaemic stroke - Imaging, Other stroke interventions - Other

Hierarchal application of PFO closure trial criteria to patients referred for TEE as part of workup of embolic stroke of undetermined source/transient ischaemic attack

COUGHLAN Jj [(1)], COUGHLAN Jj [(1)], WATERS Max [(1)], SZIRT Richard [(1)]

(1) Tallaght University Hospital, Dublin 24, Ireland

Aims: In this study, we analysed all patients referred for transoesophageal echo as part of the work up of embolic stroke of undetermined source/transient ischaemic attack. Our aim was to determine the proportion of patients referred for TOE who would meet the criteria for PFO closure based on hierarchal application of the inclusion and exclusion criteria in the recent positive PFO closure trials (REDUCE, CLOSE).

Methods and results: Consecutive patients were identified from our case ledger. The case ledger is a comprehensive record of all TOEs performed in our centre. All cases were reviewed and patients undergoing TOE for work up of stroke/TIA of uncertain aetiology were identified. Baseline, demographic, clinical, laboratory and technical data was collected for all patients using our IT system and a database was formed. 169 patients in total were identified with a mean age of 60.7 years (range: 23-84 years). There was a roughly 50:50 split between diffusion weighted imaging (DWI)-positive lesions identified on MRI Brain for the cohort as a whole (DWI + on MRI: 49.8%, DWI - on MRI: 50.2%). An additional 8% of patients had evidence of old infarcts or microvascular ischaemia on MRI Brain. Of the patients with DWI positive lesions, 73.8% were in the carotid territory, 19% in the vertebrobasilar territory and the remaining 7.2% were mixed. Left atrial appendage thrombus was identified on one study (0.59%). PFO was identified in 13% cases (22/169). Only 10 of these cases demonstrated DWI positive MRI lesions and only 50% of these cases were aged 18-60 years, the inclusion age range for the recent positive PFO closure trials. Only 13.6% of PFOs identified (3/22) were eligible for PFO closure based on hierarchal application of the REDUCE and CLOSE trial criteria.

Conclusions: PFOs were identified in a smaller than expected number of patients in our cohort (13%). Only 13.6% of PFOs identified met the criteria for PFO closure as per the hierarchal application of the REDUCE and CLOSE criteria. Care must be taken when interpreting the significance of a PFO in patients, particularly in those who do not meet the criteria for PFO closure based on their clinical presentation or cerebral imaging.

Other stroke interventions - Other

Parameters of allergic reaction after implantation of different PFO occluders – prospective randomised pilot study

DVORAKOVA Aneta [1], DVORAKOVA Aneta [1], MATES Martin [1], KOPRIVA Karel [1], KMONICEK Petr [1], SEDLACKOVA Lenka [1], JIRKOVSKA Olga [1], HOLY Frantisek [1], PALLOVA Kvetoslava [1], NEUZIL Petr [1]

(1) Na Homolce Hospital, Prague 5, Czech Republic

Aims: To evaluate parameters of allergic response after transcatheter closure of patent foramen ovale (PFO) using three different types of PFO occluders in a pilot randomised study.

Methods and results: The study included 39 patients aged 29-72 years, 18 men and 21 women, who met institutional criteria for transcatheter PFO closure. Three types of PFO occluders were randomly implanted into 3 groups: 1. the Amplatzer® device (St. Jude Medical) made from nitinol with wire treatment to reduce nickel leaching, and polyester fabric; 2. the Figulla® device (Occlutech) made from nitinol covered with titanium oxide, and PET-patch; 3. the Ultrasept device (Cardia) that consists of nitinol covered with polyvinyl alcohol. Plasma levels of CRP, full blood count including eosinophils, IgE, eosinophil cationic protein (ECP), fibrinogen and cytokine panel were measured at baseline (24 hours before procedure) and 6 hours, 24 hours, 7 days, 1 month and 6 months after occluder implantation. For final analysis only patients with normal baseline levels of IgE, eosinophils, ECP and CRP were included (Group 1 n=7, Group 2 n=9, Group 3 n=6). Procedural success was 100 % and there were no major complications. Between 3 groups of patients there were no significant changes detected in plasma levels of ECP, IgE, eosinophils. No measurable elevation of interleukins 1 a 6 was detected.

Conclusions: Despite the claimed different manufacturing process of nitinol PFO occluders there were no significant differences in selected markers of allergic response after implantation in 6 months follow-up. Supported by IG NNH 170502.

LAA closure - Tools, devices and techniques

Twelve-month follow-up of LAA closure using the LAmbre device in patients with non-valvular atrial fibrillation

LLAGOSTERA MARTIN Marc [(1)], LLAGOSTERA MARTÍN Marc [(1)], MAS STACHURSKA Aleksandra [(1)], NEGRETE Alejandro [(1)], SALVATELLA GIRALT Neus [(1)], TIZÓN-MARCOS Helena [(1)], MILLÁN SEGOVIA Raul [(1)], SANCHEZ CARPINTERO Andrea [(1)], MOLINA FERRAGUT Lluis [(1)], RIBAS BARQUET Nuria [(1)], VAQUERIZO MONTILLA Beatriz [(1)]

(1) Hospital del Mar, Barcelona, Spain

Aims: Although left atrial appendage closure (LAAC) is becoming a newly-emerging procedure worldwide for stroke prevention in atrial fibrillation patients, there are still some anatomic features of left atrial appendage which significantly limits its use. LAmbreTM (Lifetech Scientific, Shenzen, China) is a new, self-expanding left atrial appendage occluder, and it is highly adaptable to different morphologies. First registries showed a high rate of implant success in complex anatomies and good short-term clinical results. However, available mid-term results regarding this device are still limited.

Methods and results: From March 2017 to July 2019, 46 consecutive patients with atrial fibrillation and contraindication to oral anticoagulation who underwent LAAC with the LAmbre device were included in this prospective, single-centre observational registry. Clinical, lab test and procedure-related data were recorded during enrolment and follow-up. A transoesophageal echocardiogram (TEE) was performed before, during the procedure and at 1-month follow-up. Patients were discharged on the day after 2D-echo to exclude device dislocation, embolisation, and pericardial effusion. All the patients were prescribed only aspirin 100mg daily for 3 months after the procedure. After 3 months, patients with successful sealing were then left without antiplatelet therapy unless ischaemic cardiomyopathy or other medical condition required it. Patients were followed in the outpatient clinic at 1, 3, and 12 months after the procedure. Device success was defined as proper and stable implant in the LAA without peri-device leakage (unsuccessful sealing). Procedure success included device success with absence of device-related complications and absence of procedure-related complications. Sealing was considered successful when there was either no flow (complete) or the presence of a minimal residual flow of < 3 mm. According to Bleeding Academic Research Consortium (BARC), a major bleeding event was defined as type 3a to 5. The mean age of the patients was 75±9 years (46% female). Patients presented complex clinical profile with high cardiovascular risk (96% hypertension, 52% diabetes mellitus type 2 83% chronic kidney disease) and both high thrombotic and haemorrhagic risks (CHA2DS2-VASc and HAS-BLED scores were 4.5±1.6 and 4.1±1 respectively). 18 patients (39%) presented a previous transient ischaemic attack/stroke and 29 patients (63%) had previous history of major bleeding event. Procedure success was achieved in 45 patients (98%) and device success in 100% of the patients. 2 patients (4%) presented major bleeding event and 1 patient (2%) died during procedure due to transeptal puncture complication (non-device related dead). 40 patients (89%) had 1-month follow-up TEE. No thrombus or significant leak ≥3mm were found in any patient. At a mean 21±6 months (36 patients (80%) with completed 12-month follow-up); cumulative clinical events were as follow: 0% overall death, 1 patient (2%) stroke, 5 patients (11%) major bleeding event (4 patients BARC 3a and 1 patient BARC 3c, respectively).

Conclusions: In this high thrombotic and haemorrhagic population, the LAmbre device seems to be a safe and effective option for LAAC, showing remarkable device success in any left atrial appendage anatomy and promising mid-term performance regarding prevention of stroke and bleeding with single antiplatelet therapy.

LAA closure - Atrial fibrillation

Percutaneous LAA closure versus direct oral anticoagulants in elderly patients (>80) with atrial fibrillation: results from a propensity-matched analysis in real-life patients

CANEIRO-QUEIJA Berenice [1], CANEIRO-QUEIJA Berenice [1], RAPOSEIRAS-ROUBIN Sergio [1], ESTÉVEZ-LOUREIRO Rodrigo [1], ABU-ASSI Emad [1], GONZÁLEZ-FERREIRO Rocío [2], BASTOS-FERNÁNDEZ Guillermo [1], BAZ-ALONSO Jose Antonio [1], CRUZ-GONZÁLEZ Ignacio [2], RODÉS-CABAU Josep [3], IÑIGUEZ-ROMO Andrés [1]

(1) Hospital Álvaro Cunqueiro, Vigo, Spain; (2) Hospital Universitario de Salamanca, Salamanca, Spain; (3) University Institute of Cardiology and Respirology of Quebec, QC, Canada

Aims: Information comparing left atrial appendage closure (LAAC) to direct oral anticoagulation therapy (DOAC) is scarce. Our aim is to compare the clinical outcomes between LAAC and DOACs of an elderly population (over 80 years old).

Methods and results: We retrospectively collected data from 1,144 patients over 80 years old with atrial fibrillation from three different tertiary hospitals. 970 patients received DOACs and 174 patients underwent LAAC. We performed a propensity score matching analysis (PSM), with a caliper of 0.2. After propensity score with matching analysis, 58 patients receiving DOACs alone and 58 patients treated with LAAC with similar baseline risk factors, comorbidities and risk scores were selected. Outcomes of DOACs and LAAC were assessed by Cox regression. Both groups had similar cardiovascular risk factors with a greater proportion of diabetic and hypertensive patients among LAAC group (37.4% and 90.2% vs 20.3% and 70.3%, respectively). Patients undergoing LAAC had more frequently history of bleeding, anaemia or previous cancer. CHA2DS2VASC score was also significantly higher in these patients. During a median follow-up of 2.0 years (range 0.9-3.5) event rate for the combined endpoint of death, bleeding and embolic events was 24.9%. 81 embolic events were recorded (27 patients had transient ischaemic attacks and 52 were diagnosed with stroke, 2 patients with pulmonary embolism and 2 more with peripheral embolic events). 131 bleedings were recorded with 1.5% intracranial bleeding. After propensity score matching, no differences regarding the primary composite endpoint were found (HR 1.05, 95% CI: 0.15-7.51; p=0.955). Bleeding events were more frequent in LAAC group, especially during the first three months. Thereafter rates become similar in both groups with no statistically significant differences (HR 1.79, 95% CI: 0.73-4.41; p=0.205). We calculate the time-to-first bleeding for LAAC 0.9± 1.3 vs 1.7±1.3 on DOACs. Mortality was numerically greater in patients on DOACs (31.8%) vs LAAC (26.4%). However, this finding did not reach statistical significance (HR 0.70, 95% CI: 0.33-1.47; p=0.343).

Conclusions: LAAC has no differences in terms of embolic events, bleeding events and mortality compared to DOACS in a population of elderly patients over 80 years old. In our population, LAAC is a strategy as safe and effective as DOACs and represents an alternative to consider in real-life patients older than 80 years.

LAA closure - Tools, devices and techniques

Length of stay following percutaneous LAA occlusion: data from the prospective, multicentre AMPLATZER Amulet Observational study

PIAYDA Kerstin [1], PIAYDA Kerstin [1], AFZAL Shazia [1], NIELSEN-KUDSK Jens Erik [2], SCHMIDT Boris [3], MAZZONE Patrizio [4], BERTI Sergio [5], FISCHER Sven [6], LUND Juha [7], MONTORFANO Matteo [4], ZEUS Tobias [1]

(1) Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; (2) Aarhus Universitetshospital, Skejby, Aarhus Municipality, Denmark; (3) Agaplesion Markus Krankenhaus, Frankfurt, Germany; (4) Ospedale San Raffaele, Metropolitan City of Milan, Italy; (5) Fondazione Toscana "Gabriele Monasterio", Province of Pisa, Italy; (6) Harzklinikum Dorothea Christiane Erxleben GmbH, Quedlinburg, Germany; (7) Turku University Hospital, Turku, Finland

Aims: To evaluate factors associated with the length of stay (LoS) in subjects undergoing percutaneous left atrial appendage occlusion (LAAO) in a prospective multicentre observational study.

Methods and results: Subject characteristics, procedural data and the occurrence of serious adverse events (SAE) were analysed from the AMPLATZERTM AmuletTM Observational Study (funded by Abbott). SAEs were adjudicated by an independent clinical events committee for relatedness to the LAAO procedure or device. The study enrolled 1,088 subjects undergoing Amulet device implant attempt at high-risk for stroke (CHA2DS2-VASc score 4.2±1.6) and major bleeding (HAS-BLED score 3.3±1.1; 72% with prior major bleeding) often contraindicated to anticoagulation (83%). Subjects were enrolled from 17 countries, with the top-three enrolling countries being Germany (n=378, mean LoS 2.7days), Italy (n=178, mean LoS 3days) and Spain (n=105, mean LoS 3days). Subjects were divided into three groups: early (E, 0-1day, n=588, 54.7%), regular (R, 2-3days, n=338, 31.4%) and late (L, ≥4days, n=150, 13.9%) discharge. Twelve subjects were not categorised by LoS: 8 with unsuccessful implant attempts, three who died prior to discharge, and one withdrawn after device embolisation and surgical LAA ligation. Procedure- and device-related SAE during the in-hospital stay (E:1.4% vs R: 3% vs L: 22%, p<0.0001) were major triggers for a prolonged in-hospital stay. Of the 35 subjects in the late discharge group with an SAE prior to discharge, cardiac or bleeding complications were the most common underlying conditions, occurring in 24 subjects. Multivariate regression analysis identified gender as the only characteristic independently associated with LoS (male gender: -0.8, 95% CI: [-1.33 to -0.28], p=0.003), adjusted for HAS-BLED and CHA2DS2-VASc scores. At baseline, female patients were older (76.1±8years vs 74.6±9years, p=0.004) and had a higher CHA2DS2-VASc score (4.7±1.5 vs 3.9±1.6, p<0.0001). With regard to SAEs prior to discharge, there was no sex-based difference (male: 4.6% vs female: 6.0%, p=0.316). At 30 days, the overall mortality did not differ between groups (E: 0.3% vs R: 0% vs L: 0.7%, p=0.398).

Conclusions: Over half of the subjects receiving an Amulet device were discharged within 1 day of the implant procedure. SAEs were a major trigger for a late discharge after LAAO. Female gender was the only independent characteristic associated with a prolonged in-hospital stay. The 30-day mortality did not differ between subjects discharged at an early, regular, or late timeframe.

Other stroke interventions - Other

Six months or continued antiplatelet therapy after transcatheter closure of PFO for cryptogenic stroke prevention? Impact on stroke risk and clinical outcome of patients at nine-year follow-up

MOUTHUY François-Pierre [(1)], MOUTHUY François-Pierre [(1)], SLUYSMANS Thierry [(1)], PASQUET Agnes [(1)], PEETERS Andre [(1)], KEFER Joelle [(1)]

(1) Cliniques universitaires Saint-Luc UCLouvain, Woluwe-Saint-Lambert, Belgium

Aims: Transcatheter patent foramen ovale (PFO) closure is a valuable therapy to prevent recurrent cryptogenic stroke. Duration of antiplatelet therapy after the procedure is still under debate. The aim of our study was to compare the clinical outcome of patients treated with a short (6 months) versus prolonged (> 6 months) period of antiplatelet therapy.

Methods and results: On 314 consecutive patients undergoing a PFO closure in our institution between 1999 and 2018, 265 (130 males, 43±10 years) had a prior cryptogenic stroke. The PFO closure device (109 Amplatzer, 99 Cardia, 13 STARFlex, 6 GORE HELEX, 13 Premiere, 23 Occlutech, 2 PFM occluders) was successfully implanted in all cases, and residual shunt was observed in 1.5 % of patients at echocardiographic follow-up. There were no significant differences in baseline characteristics between patients receiving a short (group 1; N=59) versus a long (group 2; N=206) duration of antiplatelet therapy (median 181 vs 644 days of treatment, p<0.001). Thrombophilia (8.4 vs 8.2%), prior atrial fibrillation (0 vs 0.4%) and atrial septal aneurysm (47 vs 62%), were observed at a similar rate (p=NS for comparison between group 1 and 2, respectively). At follow-up (median 9.3 in group 1 and 9.4 years in group 2, p=0.45), Kaplan-Meier analysis showed that overall survival was similar in both groups (100 vs 98.5±1%; p=0.30). There were no differences between group 1 and 2 in the observed stroke rates (0.8 vs 0.4 per 100 patient-years, p=0.27) nor bleeding rates (1.3 vs 1 per 100 patient-years, p=0.45). Univariate analysis showed that short antiplatelet therapy was not associated with an increased risk of recurrent stroke (HR: 0.426 (95% IC 0.125-1.455), p=0.173). The observed rate of atrial fibrillation was 0.7 per 100 patient-years at follow-up after procedure.

Conclusions: The present study suggests that, in selected patients undergoing a transcatheter PFO closure after cryptogenic stroke, a short duration of antiplatelet agents did not impair the clinical outcome and was not associated with an increased stroke risk at 9 years of follow-up, as compared with a continued antiplatelet therapy beyond 6 months after the procedure.

LAA closure - Tools, devices and techniques

General anaesthesia versus conscious sedation in patients undergoing TEE-guided LAA occlusion: insights from the prospective, multicentre Amplatzer Amulet observational study

PIAYDA Kerstin [1], PIAYDA Kerstin [1], NIELSEN-KUDSK Jens Erik [2], SCHMIDT Boris [3], MAZZONE Patrizio [4], BERTI Sergio [5], FISCHER Sven [6], LUND Juha [7], MONTORFANO Matteo [4], DELLA BELLA Paolo [4], ZEUS Tobias [1]

(1) Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany; (2) Aarhus Universitetshospital, Skejby, Aarhus Municipality, Denmark; (3) Agaplesion Markus Krankenhaus, Frankfurt, Germany; (4) Ospedale San Raffaele, Metropolitan City of Milan, Italy; (5) Fondazione Toscana "Gabriele Monasterio", Province of Pisa, Italy; (6) Harzklinikum Dorothea Christiane Erxleben GmbH, Quedlinburg, Germany; (7) Turku University Hospital, Turku, Finland

Aims: Many percutaneous structural heart disease interventions are safely and efficiently performed using conscious sedation (CS) instead of general anesthesia (GA). This concept has not been evaluated in a representative number of patients undergoing percutaneous left atrial appendage occlusion (LAAO). Therefore, we aimed to evaluate the safety and efficacy of LAAO using CS.

Methods and results: Patients from the prospective, global AMPLATZERTM AmuletTM Observational Study (funded by Abbott) were divided into two groups depending on the anesthetic method (GA vs CS). Patients undergoing LAAO with intra-cardiac echocardiographic (ICE) guidance were excluded as ICE procedures were most commonly performed using only local anesthesia. Baseline information, peri- and post-procedural efficacy and complications through seven days were compared. Serious adverse events were adjudicated by an independent clinical events committee. Of 1,088 subjects undergoing an implant attempt in the Amulet observational study, 130 were excluded because of ICE guidance and nine did not have an anesthesia type reported and were also excluded. Remaining patients were categorised by GA (n=607, 64%) or CS (n=342, 36%) usage. Mean age was 75 years in both groups. GA and CS groups were similar at baseline, besides greater history of previous major bleeding (GA: 75% vs CS: 65%, p=0.001) and previous stroke (GA: 28% vs CS: 21%, p=0.016) in the GA group. LAAO technical success was achieved in 99% of both groups. The procedure duration (GA: 35±22 min vs CS: 27±19 min, p<0.001), total amount of contrast medium (GA: 105±81 mL vs CS: 86±66 mL, p<0.001) and fluoroscopic time (GA: 13±9 min vs 12±13 min, p<0.001) were less in CS cases. Procedure- or device-related serious adverse events during the first seven days were numerically higher in the CS group but did not reach statistical significance (GA: 4.9% vs CS: 7.6%, p=0.114). The total length of stay was shorter in the GA group (GA: 2.3±3.9 days vs CS: 2.7±4.3, p<0.001). Peri-device residual flow was absent or ≤ 5mm (assessed by an independent core laboratory) one to three months after the procedure in 99.7% of the GA and in 100% of the CS group (p=1.000) using transesophageal assessment.

Conclusions: In this prospective, multicentre observational study, LAAO with the AMPLATZER Amulet occluder is safe and feasible using CS during TEE-guided procedures. Procedures tend to be more efficient with a shorter duration and less contrast and fluoroscopic time when CS is used. Implant success and LAA sealing were >99% in both GA and CS methods. Procedure- or device-related serious adverse events occurred numerically more often in the CS group but did not reach statistical significance.

Other stroke interventions - Other

First endovascular treatment results of acute ischaemic stroke at regional stroke referral centre

MONOSOV Dmitrii [1], MONOSOV Dmitrii [1], SAVELLO Aleksandr [1], YANISHEVSKIY Stanislav [1], SIMAKOV Kaym [1], KUZMIN Alexey [1], ZUBAREV Dmitrii [1]

(1) National Medical Research Center. VA Almazov, Saint Petersburg, Russian Federation

Aims: We aimed to assess the first endovascular treatment results of AIS at our centre.

Methods and results: We performed a retrospective analysis of AIS patients treated with endovascular approach at our centre between January 2018 and September 2019, based on a registry with prospective and consecutive patient collection. Thirty-five endovascular interventions were performed in patients with AIS (67±10.5 years old; male – 19 [54.2%]). From stroke onset to hospital arrival time was 147.8±88 minutes. The site of occlusion on CT angiogram were large carotid vessels n=31 (89%), right-side lesions were revealed in 21 patients, left side in 13 patients, bilateral thrombosis of internal carotid arteries was detected in one patient. Four patients (11.4%) received intravenous tissue plasminogen activator prior to endovascular procedure. We used aspiration (n=23) and stent retriever technique (n=12). Overall mean time to final recanalisation from femoral access to final revascularisation was 50±36 minutes over all cases. An overall final revascularisation result of (mTICI 3) was achieved in 18 (51%) cases, mTICI 2b was achieved in 7 (20%) cases. Partial mTICI 2a and mTICI I revascularisation rate was 6% (n=2), mTICI 0 rate was 23% (n=8). Modified Rankin Scale (mRS) scores at discharge were as follows: mRS 0 - 5.8%, mRS 2 - 8.5%, mRS 3 - 20%, mRS 4 - 20%, mRS 5 - 5.7%, mRS 6 - 40%. It should be noted that in the mRS 6 scores group the angiographic result of mTICI III was achieved in 28.5% of cases, mTICI 2b in 14.2% of cases.

Conclusions: Currently endovascular treatment (EVT) is the standard of care for large vessel occlusion (LVO) in AIS. In response, stroke system of care was adapted by forming regional stroke referral centres, operating around the clock to facilitate timely patient access to this therapy.

LAA closure - Vascular access and bleeding

Acute and mid-term outcomes of left atrial appendage closure in octogenarians versus non-octogenarians: a 1,502 patient-years study

MOHREZ Yamen [1], MOHREZ Yamen [1], GLOEKLER Steffen [3], SCHNUPP Steffen [1], MAHNKOPF christian [1], BRACHMANN Johannes [1], CHEIKH-IBRAHIM Mohammad [1], ALLAKKIS Wasim [1], FABIAN Nietlispach [2], WINDECKER Stephan [3], STREIT Samuel [3], DOBLIES Janosch [3], TAKWA Cherni [3], MATE Fankhauser [3], MEIER Bernhard [3], KLEINECKE Caroline [4]

(1) Klinikum Coburg GmbH II. Medizinische Klinik (Kardiologie, Angiologie, Pneumologie), Coburg, Germany; (2) University Hospital of Zürich, Zürich, Switzerland; (3) University hospital, Bern, Switzerland; (4) klinikum, Lichtenfels, Germany

Aims: In patients with atrial fibrillation, left atrial appendage closure (LAAC) offers equivalent stroke protection to oral anticoagulation, obviating an increased risk of bleeding. The subgroup of octogenarians is at highest risk for both thromboembolic and bleeding events. Whether LAAC in this growing patient subset may be similarly beneficial with regard to net clinical benefit was the purpose of the present study.

Methods and results: Three real-world registries (Bern, Coburg, Zurich), enrolling a total of 744 consecutive patients (mean age 76.3±8.0 years) undergoing LAAC with AMPLATZER and WATCHMAN devices from July 2009 to April 2018, were retrospectively analysed. Device success, major periprocedural complications, stroke and bleeding rates at follow-up, as well as mortality, were assessed for octogenarians and non-octogenarians. The primary efficacy endpoint was a composite of all-cause stroke, systemic embolism, and cardiovascular/unexplained death. The primary safety endpoint consisted of major periprocedural complications and major bleeding events at follow-up. The combined hazard endpoint (i.e. the net clinical benefit) was a composite of all the above-mentioned hazards. Furthermore, the risk reduction for stroke and major bleeding events was calculated for both groups comparing the observed event rates to the predicted rate by the CHA2DS2-VASc and HAS-BLED score. 261 octogenarians (84.0±3.0 years) and 483 non-octogenarians (70.4±7.8 years) with a mean follow-up of 1.7±1.3 and 2.3±1.6 years, and a total of 1,502 patient-years were included. Events are reported per 100 patient-years. Octogenarians showed a higher stroke- (CHA2DS2-VASc score 5.2±1.2 [octogenarians] vs 4.3±1.7 [non-octogenarians], p=<0.0001), and bleeding risk (HAS-BLED score 3.3±0.8 vs 3.1±1.1, p=0.0008). Device success (96.2% vs 97.7%, p=0.34) and major periprocedural complications (3.4% vs 4.8%, p=0.40) were similar between the groups. As expected, major bleeding events (4.7% vs 2.5%, p=0.024), all-cause stroke and TIA (4.3% vs 2.1%, p=0.01), as well as cardiovascular death (13.0% vs 6.6%, p=<0.0001) occurred more often in octogenarians. The rate of non-cardiovascular and unexplained death (5.6% vs 2.9%, p=0.12) did not differ. The primary safety endpoint was comparable (30/446, 6.7% vs 47/1056, 4.4%; HR, 1.2; 95% CI: 0.73-1.98; p=0.48) between the groups. The primary efficacy endpoint occurred more often in octogenarians (61/446, 13.7% vs 80/1056, 7.6%; HR, 7.0; 95% CI: 4.53-10.93; p=<0.0001). Altogether, octogenarians had a lower net clinical benefit from LAAC (82/446, 18.4% vs 116/1056, 11.0%; HR, 4.6; 95% CI: 3.11-7.0; p=<0.0001). Compared to the anticipated stroke rate, the observed rate decreased by 41.1% in octogenarians and 56.3% in non-octogenarians. The observed bleeding rate was reduced by 10.0% octogenarians and 40.8% non-octogenarians.

Conclusions: LAAC can be performed with similar procedural success and safety in octogenarians. In the mid-term, it both reduces stroke and bleeding events, although to a lesser extent than in non-octogenarians. From which level of comorbidities, stroke- and bleeding risk and age, LAAC will be of no benefit or harm, remains to be determined by further studies.

Ischaemic stroke - Imaging

On-table catheter-based neuro-salvage performed by cardiologists for embolic complication during endovascular procedure

LI-WEI Liu [1], LIN Mao-Shin [1]

(1) National Taiwan University Hospital, Taipei City, Taiwan

Aims: Iatrogenic emboli may be released during endovascular procedures, causing permanent neurological complications and catastrophic outcomes. This study sought to report clinical results of neuro-salvage techniques, performed by interventional cardiologists without moving the patient, to manage thromboembolic complications.

Methods and results: Between July 2013 and December 2017, a total of 8 patients suffered from embolic complications during endovascular procedures (2 radiofrequency catheter ablations, 5 coronary angiogram/angioplasties and 1 subclavian artery angioplasty). Catheter-based neuro-salvage was attempted by experienced interventional cardiologist colleagues promptly in the same catheterisation room. Access to the supra-aortic vessels was achieved. Local intra-arterial thrombolysis was given in 5 patients (63%) and balloon angioplasty in 3 (38%). Intra-arterial thrombectomy with a stent retriever was attempted in 3 patients, but failed in 1. A combination of different techniques was used in 3 patients (38%). Final thrombolysis in cerebral infarction (TICI) grade 3 flow was achieved in 7 patients (88%). Favorable clinical outcome at discharge (modified Rankin Scale of 0~2) was observed in 7 patients (88%), without 30-day mortality.

Conclusions: Our experience demonstrated that acute embolic complications during endovascular procedures can be salvaged by interventional cardiologists with acceptable angiographic and clinical results.

Chronic heart failure - Tools, assist devices and techniques

Alcohol septal ablation in patients with hypertrophic obstructive cardiomyopathy: experience at a reference centre in Chile

CATALDO Pabla [1], CATALDO Pabla [1], VERDUGO Fernando [1], SANDOVAL Jorge [1], DAUVERGNE Christian [1], MENDEZ Manuel [1], PINEDA Fernando [1], URIARTE Polientzi [1], MONSALVE Rodrigo [1]

(1) hospital del torax, Colina, Chile

Aims: Depending on the severity of septal hypertrophy and mitral valve derangements, patients with hypertrophic cardiomyopathy may develop left ventricular outflow tract (LVOT) obstruction and mitral regurgitation, which have major impact on symptoms and prognosis. Surgical myomectomy has been considered standard treatment in patients with hypertrophic obstructive cardiomyopathy (HOCM) who remain symptomatic despite medical therapy. Alcohol septal ablation (ASA), is a minimally invasive therapy for HOCM.

Methods and results: Our aim was to assess short- and long-term outcomes and complications of ASA performed on symptomatic HOCM patients in our centre. We performed a retrospective observational study of patients undergoing ASA for HOCM between January 2002 and September 2018. According to local protocol, clinical evaluation and echocardiography were performed at baseline and 6 months after ASA. Local databases were reviewed, along with direct patient contact when required. ASA was performed in 73 patients with HOCM. Mean age was 57.5±12.8 years; 63% were male; 83.5% were on III-IV NYHA class, 32.9% had syncope; 12.3% had family history of sudden cardiac death, 93.6% received beta blockers, 6.8% had implantable cardioverter defibrillator. Mean alcohol injection per procedure was 2.45±1.03 cc. Invasive resting gradients were acutely reduced from 61.2±36.3 mmHg to 23.4±27.5 mmHg ($p<0.001$), and dynamic gradients from 106.5±37.3 mmHg to 31.0±28.0 mmHg ($p<0.001$). Haemodynamic success (reduction in resting gradient to <30 mmHg or dynamic gradient >50%) was achieved in 82.2% patients. We observed improvements in mitral regurgitation at ventriculography ($p<0.001$), a decline of ≥1 severity degree was noticed in 53 patients (72.6%). Maximal creatine kinase after ASA was 2,055±851 U/l. Average length of hospitalisation was 4.4±5.0 days. Reablation was performed on 12 patients, 7 were planned staged procedures and 5 due to unsuccessful ASA. We observed no in-hospital mortality. Permanent pacemakers were implanted in 9 patients. Vascular access complications occurred in 3 patients. Coronary dissection and cardiac tamponade each occurred in 1 patient respectively. Complications were more frequent after reablation (50% vs 17%, $p<0.01$). At 6 months, we observed improvements in NYHA class ($p<0.001$), a decline of ≥1 NYHA class was found in 68 patients (93.2%). Echocardiographic assessment exposed reductions in septal thickness (25.0±5.5 vs 17.1±5.3 mm, $p<0.001$), LVOT gradients (86.7±27.3 vs 38.4±15.1 mmHg, $p<0.001$) and systolic anterior motion of the mitral valve prevalence (61.6% vs 27.4%, $p=0.002$). At 12 months, we detected only 1 death due to COPD. No cardiovascular deaths were noted in patients achieving 5 years of follow-up (n=49).

Conclusions: ASA was a safe and effective procedure in treatment of symptomatic HOCM, resulting in reductions of septal thickness, LVOT gradients and mitral regurgitation severity, as well as an improvement in NYHA class.

Chronic heart failure - Tools, assist devices and techniques

Home monitoring and direct data transmission via iPhone to patient's hospital file – modern outpatient management

STREIT ROSENBERG Tine [1], STREIT ROSENBERG Tine [1], BJERG Bodil [1], BOIE Virginia [1], BRØNDUM Pernille [1], GREEN Allan [1], CARLSEN Jørn [1]

(1) Rigshospitalet, Copenhagen Municipality, Denmark

Aims: Continuous monitoring of clinical data including blood pressure, weight and pulse along with clinical assessment is of major importance in the follow-up of patients with pulmonary arterial hypertension (PAH). In this study home monitoring and virtual outpatient visits were evaluated in comparison with standard follow-up with physical attendance in the outpatient unit.

Methods and results: A pilot study with 16 patients with PAH so far have been included in this preliminary study, 8 men and 8 women with mean age 57 years [16-75]. Patients were recruited from the Outpatient Unit in the Heart Center at our hospital. A blood pressure monitor and a scale with Bluetooth technology were provided and an iPhone set up for direct data transmission to MyChart, Epic's patient portal. Data and yes/no answers to five clinical questions were submitted by the patient every week. In this study the technology of transmission of home monitored data directly to MyChart in EPIC has proven to be feasible for all included patients. Patients have incorporated the measurements in their daily life-routines and found the availability of consecutively registered data as a natural part of being actively involved in own disease monitoring. The availability of data in EPIC has provided an enforced foundation for clinical decision making both by subsequent virtual and physical consultations. The project was started in November 2019 and will be evaluated after 12 weeks. After adjustments, a cohort of 200 patients will be included.

Conclusions: Home monitoring with data transmission directly to MyChart in Epic has proven to be a feasible technology effectively providing increased amounts of data for subsequent outpatient consultations. Also, patients may not need physical consultations but can benefit from virtual consultations based on these data. Home monitored patient data are increasingly used in follow-up programs. The introduction of direct transmission of data to MyChart in Epic allows for a personalised follow-up guided by symptom progression. With increased availability of transmissible data, a more complete patient assessment will be possible. Furthermore, prognostic patterns hopefully will be available in the large amount of data collected.

Chronic heart failure - Tools, assist devices and techniques

The enhancement of haemodynamic forces (intraventricular pressure gradients) measured using cardiovascular magnetic resonance images for patients with anterior infarctions treated with the Revivent TC system compared to patients treated by optimal medical therapy

KELLE Sebastian [1,2,4], JUREVICE Justina [1,5], GÖTZE Collin [1,2], PEDRIZZETTI Gianni [3], LAPINSKAS Tomas [1,5], ZAMANI Mahsa [1], KLEIN Patrick [6], ANKER Stefan [2,4]

(1) German Heart Institute Berlin, Berlin, Germany; (2) Charité – Universitätsmedizin Berlin, Berlin, Germany; (3) Universität Triest, UTI Giuliana, Italy; (4) Deutsches Zentrum für Herz- Kreislauf-Forschung (DZHK) e.V., Berlin, Germany; (5) Lithuanian University of Health Sciences, Kaunas, Lithuania; (6) St. Antonius Ziekenhuis, Nieuwegein, the Netherlands

Aims: Surgical ventricular reconstruction proved to be an effective therapy in patients with heart failure with reduced ejection fraction following a myocardial infarction, despite being highly risky surgical procedure. The aim of our study was to detect the change in haemodynamic forces (an equivalent for intraventricular pressure gradients) - for patients treated with the BioVentrix Revivent TC™ system, offering less invasive ventricular reconstruction for patients with heart failure, compared to patients treated with optimal medical therapy (OMT) and healthy controls.

Methods and results: Data from 22 aged-matched heart failure (HF) patients treated with the Revivent TC System, 12 patients treated with OMT and 19 healthy subjects were analysed. The evaluation and comparison of haemodynamic force parameters (as an equivalent to intraventricular pressure gradients) derived from cine cardiac magnetic resonance (CMR) images at baseline and 12-month period follow-up was performed and compared at both time points. BioVentrix treatment group demonstrated significant increase in left ventricular ejection fraction (LV-EF) in 12-month follow-up period (24±9 vs 34±11%, $p<0.0001$), compared to OMT group (28±6 vs 33±10%, $p=0.037$). Regarding the haemodynamic forces parameters, BioVentrix treatment group demonstrated significantly better development of entire heartbeat haemodynamic force FRMSx acting from lateral to septal wall (0.0067±0.0027 vs 0.0091±0.0038, $p=0.004$), as equal to 50% increase compared to significant decrease by 22% in OMT group (0.0092±0.0041 vs 0.0074±0.0029, $p=0.018$). Diastolic deceleration FRMSx also increased significantly by 119% in BioVentrix treatment group (0.0044±0.0018 vs 0.0084±0.004, $p=0.001$), when compared to significant decrease by 19% in OMT group patients (0.0084±0.0045 vs 0.0065±0.0041, $p=0.046$).

Conclusions: HF patients treated with the Revivent TC System demonstrate significant improvement in LV-EF and haemodynamic forces, especially in those forces acting from the lateral to septal wall. The most significant improvement was demonstrated in diastolic deceleration.

Acute heart failure - Tools, assist devices and techniques, Chronic heart failure - Tools, assist devices and techniques

Early procedural and clinical outcomes with a novel percutaneous left ventricular support device in high-risk PCI: an update from the lead-in cohort of the SHIELD II clinical trial

KAPUR Navin [1], KAPUR Navin [1], KANDZARI David [2], JORDE Ulrich [3]

(1) Tufts Medical Center, MA, USA; (2) Piedmont Atlanta Hospital, GA, USA; (3) Montefiore Medical Center Moses Division, NY, USA

Aims: The HeartMate Percutaneous Heart Pump (PHP) is a percutaneous circulatory support catheter capable of delivering a self-expanding 24-French impeller when deployed across the aortic valve. The SHIELD II trial is a multicentre, randomised trial comparing procedural and clinical outcomes among patients undergoing percutaneous coronary intervention (PCI) requiring haemodynamic support with the PHP or Impella systems. The SHIELD II study was halted in 2017 due to unexpected device malfunctions. We now report initial clinical experience with the first 75 roll-in patients from the SHIELD II trial.

Methods and results: Principal enrolment criteria included patients undergoing elective/urgent high-risk PCI with left ventricular ejection fraction (LVEF) ≤35% and a last patent coronary conduit, unprotected left main disease or ≥50% stenosis in all three major coronary arteries. Patients included in the lead-in phase of the randomised trial were evaluated for procedural, haemodynamic and 90-day clinical outcomes. The primary endpoint is the composite of cardiovascular death, myocardial infarction, stroke, repeat revascularisation, major bleeding (BARC 3 and 5), aortic regurgitation >2 degrees above baseline and severe hypotension requiring pharmacologic therapy. Among 75 patients undergoing high-risk PCI with the PHP system, the prevalence of diabetes was 61.3%; prior MI 65.3%; and LVEF (mean±standard deviation) 25±8%. Procedural characteristics included: 2.5±1.4 lesions treated and device support duration 101±53 minutes. In a paired analysis, treatment with the PHP system was associated with a significant increase in cardiac power and mean arterial pressure. In the roll-in phase of the SHIELD II trial, five device malfunction events were observed in a total of five patients. In two cases, the PHP motor stopped abruptly during the procedure due to fluid ingress. Of the remaining three device malfunction cases, two required replacement of the console and one pump was unable to be resheathed through the catheter but was removed via 14 Fr vascular access sheath without complication.

Conclusions: The HeartMate PHP device is a novel percutaneously-delivered (non-surgical) trans-valvular axial flow pump. Early experience with the PHP device among the roll-in cohort of the SHIELD II trial demonstrated successful device insertion, completion of high-risk and complex PCI, and device removal. The PHP device provided a broad range of blood flow up to 6.2 litres per minute and with the greatest increase in cardiac output observed among patients with baseline cardiac index <2.0. Manufacturing improvement was implemented and re-launch of the SHIELD II trial in 2020 is now cleared by the FDA. Collectively, these findings support that the PHP device is a first-in-class self-expanding trans-valvular axial flow pump with strong potential for clinical utility among patients with heart failure requiring PCI. Completion of the SHIELD II Study is required to confirm the safety, efficacy, and utility of the PHP device.

Chronic heart failure - Tools, assist devices and techniques

The impact of the coronary sinus Reducer upon left ventricular function; multicentre registry – the REDUCE-LV study

TZANIS Georgios [1,2], TZANIS Giorgos [1,2], LEENDERS Geert [3], PALMISANO Anna [1], STELLA P.R. [3], DEKKER M. [3], PONTICELLI Francesco [2], GALLONE G. [1], SILVIS M.J.M. [3], BALDETTI Luca [1], MANGIERI Antonio [2], LARICCHIA Alessandra [2], ESPOSITO Antonio [1], COLOMBO Antonio [2], GIANNINI Francesco [2]

(1) Ospedale San Raffaele, Metropolitan City of Milan, Italy; (2) Maria Cecilia Hospital, Province of Ravenna, Italy; (3) Universitair Medisch Centrum Utrecht, Utrecht, the Netherlands

Aims: Coronary sinus (CS) Reducer is a balloon-expandable mesh, implanted percutaneously in the CS to create a narrowing of the CS lumen and to establish a pressure gradient across it, which in turn has been shown to improve refractory angina of patients with coronary artery disease (CAD) not amenable to further revascularisation. Aim of this study multicentre registry was to investigate the effect of CS Reducer upon left ventricular performance of CAD patients with refractory angina.

Methods and results: In this ongoing multicentre registry, data from 2 centres have been collected to date. Prior to device implantation and at 4 months, all patients underwent clinical assessment with evaluation of Canadian Cardiac Society (CCS) class and evaluation of resting ventricular volumes and function by CMR. Myocardial perfusion reserve was evaluated by Stress-CMR. Thirty-one patients (26 males/5 females, 65±9 years), underwent successful Reducer implantation. Seventeen patients (55%) had history of previous coronary artery bypass grafting and 22 patients (71%) previous percutaneous coronary intervention. Twenty-two patients (71%) improved by ≥ 1 CCS class. Fourteen patients (45%) experienced 2 CCS class reduction, 5 patients (31%) 3 CCS class reduction and 8 (29%) patients did not experience any benefit in angina class. Four months after Reducer implantation, we noticed a trend for improvement in left ventricular (LV) ejection fraction (EF) (from 57±13 to 60±12 %, p=0.10) and reduction in LV end-systolic volume (from 30±15 to 21±10 ml, p=0.069). LV end-diastolic volume did not changed significantly (from 72±16 to 66±19 ml, p=0.20). Patients with reduced baseline systolic function (n=9, EF<50%) presented a greater increase of EF at follow up compared to patients with preserved EF (22±24 vs -0.4±11 %; p=0.001) and a greater decrease LVESV (28±22 vs 3±41 ml; p=0.05).

Conclusions: CS Reducer implantation improved angina symptoms, myocardial perfusion and left ventricular function in patients with refractory angina. The observed improvement was pronounced in the subgroup of patients with reduced ejection fraction encouraging further application of therapy in patients with ischaemic cardiomyopathy.

Acute heart failure - Tools, assist devices and techniques

The challenge and benefits of veno-arterial ECMO therapy

KUROIWA Nobuyuki [(1)], KUROIWA Nobuyuki [(1)], OKA Norikiyo [(1)], IWATA Yo [(1)], OKINO Shinichi [(1)], FUKUZAWA Shigeru [(1)]

(1) Funabashi Municipal Medical Center, Funabashi, Japan

Aims: Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) therapy after cardiopulmonary arrest (CPA) or collapse of haemodynamics is still challenging. Our aim is to reveal the risk factors of poor prognosis using our single-facility data.

Methods and results: We have reviewed 77 patients who underwent VA-ECMO therapy between January 2009 and December 2019. ECMO was placed immediately for patients with cardiopulmonary arrest (CPA) who had a chance to run ECMO within 60 minutes of total cardiopulmonary resuscitation (CPR) time or patient with collapsed haemodynamics. Mean age was 63.3±16.1 and male ratio was 74.0%. 48 patients were STEMI (20 LM=left main, 11 MV=multiple vessel) and 29 were "others". Overall survival rate was at 28.6% and cerebral performance categories (CPC) 1 & 2 were at 23.4%. We compared the risk factors between (a) survival (n=22) vs non-survival (n=55) group and (b) CPC 1 & 2 (n=18) vs CPC 3,4 & 5 (n=59) group. The risk factors we referred to were STEMI, LM, MV, CPA, total CPR time, haemodynamic collapse to ECMO time, collapse in or out of the hospital, complication related to ECMO, ventricular tachycardia/fibrillation, age, gender, coronary risk factors, usage of IABP or Impella®, haemodialysis requirement and blood tests. Univariate analysis shows between (a), the number of STEMI were 9 (40.9%) vs 39 (70.9%) (p=0.01), LM were 2 (9.1%) vs 18 (32.7%) (p=0.03), LM+MV were 4 (18.2%) vs 27 (49.1%) (p=0.01), age 54.4 vs 66.8 (p<0.01) and complication related to ECMO were 4 (18.2%) vs 28 (50.9%) (p=0.01). Between (b), the number of STEMI were 7 (38.9%) vs 41 (69.5%) (p=0.02), HCO3- 18.25 vs 14.54 (p=0.02], ABE -9.6 vs -14.3 (p=0.04), lactate 5.8 vs 9.5 (p=0.03) and complication related to ECMO were 3 (16.7%) vs 29 (49.2%) (p=0.01). Multivariate analysis reveals odds ratio of age 0.940 (95% CI: 0.904-0.978) (p<0.01), complication related to ECMO 0.129 (95% CI: 0.030-0.553) (p=0.01) for (a) and age 0.951 (95% CI: 0.913-0.990) (p=0.01), complication related to ECMO 0.170 (95% CI: 0.037-0.770) (p=0.02) and lactate 0.856 (95% CI: 0.741-0.990) (p=0.04) for (b) respectively.

Conclusions: The value of VA-ECMO therapy is higher for patients with younger age and without complications related to VA-ECMO in terms of survival and CPC grade. Additionally, lower initial lactate leads to a better CPC grade, which results in a better neurological outcome. However existence of CPA or CPR time, collapse in or out of the hospital and usage of IABP or Impella did not affect on the outcome of survival and CPC grade.

Acute heart failure - Adjunctive pharmacotherapy, Chronic heart failure - Tools, assist devices and techniques

Catheter-directed therapy in high-risk and intermediate-high-risk acute pulmonary embolism improves haemodynamic parameters: analysis from an urgent code registry

PORTERO-PORTAZ Juan J. [(1)], PORTERO-PORTAZ Juan J. [(1)], CORDOBA-SORIANO Juan G. [(1)], GALLARDO-LOPEZ Arsenio [(1)], GUTIERREZ-DIEZ Antonio [(1)], MELEHI-EL ASSALI Driss [(1)], JIMENEZ-MAZUECOS Jesus [(1)]

(1) Hospital General Albacete, Albacete, Spain

Aims: Catheter-directed therapy (CDT) is an increasing practice for selected patients with high-risk and intermediate-high-risk PE. Nowadays, it is not well known if performing this strategy in an urgent form improves haemodynamics without increasing the risk of bleeding.

Methods and results: Prospective registry of 65 consecutive patients (51% male, 60 years old) undergoing CDT (10.7% high-risk PE, 89.3% intermediate-high-risk, mean sPESI score 2) between April 2017 and December 2019. The cephalic or basilic veins were the access in 92% and in all cases, local thrombolytic therapy with continuous perfusion of r-TPA (1 mg/h up to 24 hours) was used (18.5% with local bolus). Additionally, thrombus fragmentation (67%) and aspiration (10%) were used in some selected cases. Angiographic improvement was documented according to Miller Score: 22.2 points vs 11.3, $p<0.001$. The efficacy endpoint (shock development or death) was observed only in 1 patient (1.5%, intracranial bleeding) and the safety endpoint (BARC bleeding 3 or 5) was observed in 2 patients (3%). The 88% of patients objectively improved at 24 hours and a significant improvement of all measured haemodynamics was targeted: systolic pulmonary pressure (57 mmHg vs 43, $p<0.001$), mean pulmonary pressure (36 mmHg vs 27, $p<0.001$), right atrial pressure (12 mmHg vs 9, $p<0.001$) and cardiac output (3.6 l/minute vs 4.9, $p<0.001$).

Conclusions: CDT for treatment of high-risk and intermediate-high-risk of PE improves haemodynamics at 24 hours, with low rate of major bleeding events.

Acute heart failure - Tools, assist devices and techniques, Chronic heart failure - Tools, assist devices and techniques

Contemporary trends in inpatient use of intra-aortic balloon counterpulsation and Impella in the US and associated survival to discharge

NATHAN Sandeep [(1)], NATHAN Sandeep [(1)], RHOTEN Stephanie [(2)], LAYTON Andrew [(2)], YU Tiffany [(2)]

(1) University of Chicago Medical Center, IL, USA; (2) Navigant Consulting, MA, USA

Aims: Conflicting data exist on contemporary trends in intra-aortic balloon counterpulsation (IABC) and Impella use and associated clinical outcomes. This retrospective, real-world claims-based study details recent use of percutaneous IABC or Impella in the United States along with patients' clinical characteristics and survival rates.

Methods and results: In-patient U.S. hospital stays spanning 2015-2017 and involving percutaneous insertion of either IABC or Impella were identified using Current Procedural Terminology (CPT) codes 33976 or 33990, respectively. Stays with other types of mechanical circulatory support (e.g., ECMO, TandemHeart) were excluded. Two large national U.S. healthcare claims databases were queried – Medicare Fee-For-Service 5% Standard Analytical Files (CMS) and Truven MarketScan Commercial Claims and Encounters (Truven) – to capture a subset of both elderly and working-age populations. Patient and case characteristics and survival at discharge were described. In total, 5,001 in-patient stays with IABC (2,024 CMS; 2,977 Truven) and 1,094 with Impella (540 CMS; 554 Truven) were identified. On average, there were 675 and 992 IABC patients and 180 and 185 Impella patients annually in the CMS and Truven databases, respectively. IABC volume decreased about 10% annually in the Truven database but remained stable in the CMS database. Impella volume increased in both the Truven and CMS databases by 25% and 38% annually on average, respectively. In the CMS dataset, IABC use was 33.6% female with mean age 71.3 (SD 9.7) and Impella 30.6% female, 72.1 (SD 10.3) years. Regional use of IABC was 38.6% in the South, 26.9% Midwest, 19.2% Northeast, and 15.1% West; while regional use of Impella was 44.1% in the South, 22.4% Midwest, 16.7% Northeast, and 16.7% West. Truven IABC cases were 25.1% female with mean age 55.3 (SD 7.7) years, and Impella cases 26.2% female with a mean age of 55.2 (SD 7.9) years. Regional utilisation of IABC in Truven was 47.6% in the South, 24.5% North Central region, 17.3% Northeast, and 10.4% West; while Impella use was 56.3% in the South, 19.0% North Central, 13.7% Northeast, and 10.8% West. Unadjusted survival at discharge for IABC and Impella cases was 73.8% and 71.7% in CMS cases and 82.7% and 70.9% in Truven cases. Cardiogenic shock was significantly associated with lower survival at discharge for both IABC and Impella cases (CMS: IABC 63.4% vs 86.4% [Odds Ratio 3.7, p<0.0001], Impella 49.4% vs 90.7% [OR 10.0, p<0.0001]; Truven: IABC 78.6% vs 84.7% [OR 1.5, p<0.0001], Impella 63.4% vs 76.5% [OR 1.9, p=0.0009]). Performance of cardiac surgery was significantly associated with higher survival at discharge for IABC cases (CMS: 86.5% vs 63.4% [OR 0.3, p<0.0001]; Truven: 89.0% vs 78.1% [OR 0.4, p<0.0001]). For Impella cases, cardiac surgery was significantly associated with lower survival at discharge among CMS cases (51.3% vs 73.4% [OR 2.6, p=0.0041]), but non-significant higher survival at discharge among Truven cases (79.0% vs 70.0% [OR 0.6, p=0.1633]).

Conclusions: IABC still remains widely used in clinical practice, though Impella use has been rising in recent years for both elderly and younger patients across the United States. Survival at discharge was significantly greater in the absence of cardiogenic shock in both IABC and Impella cases. Use in the context of cardiac surgery was significantly associated with higher survival for IABC cases, but lower survival for elderly patients using Impella.

Acute heart failure - Tools, assist devices and techniques

Central venous pressure as haemodynamic mortality predictor in cardiogenic shock

KAPUR Navin [1], THAYER Katherine [1], GARAN A. Reshad [2], HERNANDEZ-MONFORT Jaime [3], MAHR Claudius [4], WENCKER Detlef [5], SINHA Shashank [6], VOROVICH Esther [10], ABRAHAM Jacob [8], BURKHOFF Daniel [9], KAPUR Navin [1]

(1) Tufts Medical Center, MA, USA; (2) Beth Israel Deaconess Medical Center (BIDMC), MA, USA; (3) Cleveland Clinic Florida, FL, USA; (4) University of Washington Medical Center, WA, USA; (5) Baylor Scott & White Medical Center - Grapevine, TX, USA; (6) Inova Heart and Vascular Institute, VA, USA; (7) Henry Ford Hospital, MI, USA; (8) Providence Portland Medical Center, OR, USA; (9) Cardiovascular Research Institute, CA, USA; (10) Northwestern Memorial Hospital, IL, USA

Aims: Cardiogenic shock (CS) is a complex syndrome that continues to be associated with high morbidity and mortality despite treatment innovations over the last decade. One explanation could be the lack of risk stratification of these patients, causing the inability to properly tailor treatment protocols. We hypothesise that haemodynamic parameters can help assist in forming appropriate treatment protocols by identifying patients with this high risk of mortality using a simple cutoff.

Methods and results: Patients were selected for analysis from the Cardiogenic Shock Working Group (CSWG) registry, a contemporary real-world registry that includes in-patient data on baseline demographic, metabolic, and haemodynamic parameters for all-cause CS patients from 10 centres across the United States between 2014 and 2017. CS severity was determined using the maximum Society of Cardiac Angiography and Intervention (SCAI) stage of each patient defined by treatment across their in-patient stay. Patients with a maximum SCAI stage of B or C were selected for this analysis (n=273) since they did not escalate past 1 acute mechanical support device and their baseline haemodynamics are most representative of their CS progression prior to any receiving any support. Haemodynamic parameters, including those which require the placement of a pulmonary artery catheter (PAC) and those that do not, were analysed in these cohorts for their ability to predict in-hospital mortality. PAC parameters analysed included pulmonary artery (PA) systolic and diastolic pressures (PASP, PADP), pulmonary capillary wedge pressure (PCWP), PA saturation, and pulmonary artery pulsatility index (PAPI). Non-PAC parameters analysed included mean arterial pressure (MAP), cardiac power output (CPO), and central venous pressure (CVP). Baseline CVP and PA saturation were the most predictive of in-hospital mortality with areas under the ROC curve of 0.75 each. Because of the simplicity of obtaining CVP, it was further analysed for a potential mortality prediction cut-off. Based on ROC curve analysis, a cut-off of 12 suggested the closest approximation to a sensitivity of 1 and a specificity of 0. Results from univariate logistic regression showed that for every 1 mmHg increase in baseline CVP, the risk of in-hospital mortality increases by 15% in these patients (OR: 1.15, 95% CI: 1.073-1.239). Additionally, mortality is much less frequent in patients with a CVP <12 compared to in those with a CVP greater than 12 (2.5% v. 12.87%, p=0.002). After stratifying the analysis by CS aetiology, CVP remained a significant predictor of mortality in both the acute myocardial infarction (AMI) cohort (n=84) (OR 95% CI: 1.20, 1.00-1.43) and the heart failure (HF) cohort (n=189) (OR 95% CI: 1.16, 1.06-1.26). Among HF patients, mortality was significantly more frequent among those with a CVP >12 compared to those with CVP <12 (12.2% v. 2.1%, p=0.009). While this trend was also apparent in the MI cohort, due to small sample size the difference was not significant (20.0% v. 6.25%, p=0.24).

Conclusions: Based on these results, we can conclude that baseline CVP is an easily obtained haemodynamic parameter that is an accurate predictor of in-hospital mortality among early-stage CS patients, regardless of aetiology. Additionally, a CVP of 12 could serve as a simple cut-off to identify high-risk patients. Further studies are needed to confirm these findings in a larger cohort with additional time points.

Chronic heart failure - Echocardiography and other imaging

The effect of percutaneous atrial septal defect closure on the right atrial remodelling index in patients with secundum atrial septal defect

OZTURK Onder [1], OZTURK Onder [1], OZTURK Unal [1]

(1) Diyarbakir Gazi Yasargil Education and Research Hospital, Diyarbakir, Turkey

Aims: Atrial septal defect (ASD) represents a common congenital heart disease. Chronic right atrial (RA) volume overloading in ASD results in geometrical and histological changes of the RA including dilatation and even myocardial fibrosis. Percutaneous closure represents the treatment of choice for ASD. Successful device closure of ASD significantly reduces right heart volume and dimensions, leading to an improvement of symptoms. In this study, we aimed to investigate the effect of percutaneous ASD closure on the right atrial remodelling index in patients with secundum ASD.

Methods and results: We prospectively examined 43 consecutive patients (14 male, 29 female) who underwent percutaneous transcatheter closure of a secundum ASD. Echocardiography was performed on admission, prior to cardiac catheterisation and then one month after ASD closure. Peak global RA longitudinal strain was analysed by 2D-STE. 2D echocardiographic images of the right atrium were obtained in apical 4-chamber view at end-expiration. Peak systolic RA strain was evaluated using 2D speckle tracking imaging. We calculated the RA peak systolic strain obtained from the apical four-chamber view at end-expiration. RA volume was indexed to body surface area (RAVI). We defined the ratio of RA peak systolic strain and RAVI as RA remodelling index (RARI = [RA peak systolic strain/ RAVI]). Patients' mean age was 35.9±8.5 years. The mean diameter of the occlusive devices was 19.4±7.3 mm. Right ventricular (RV) end-diastolic diameters were significantly decreased after percutaneous ASD closure (44±6 vs 37±4 mm, $p<0.05$). Left atrial (LA) diameters (41±7 vs 37±5 mm, $p<0.05$) decreased significantly after the intervention, whereas left ventricular (LV) end-diastolic diameters (45±6 vs 46±4 mm, NS) remained unchanged. After closure of the defect, a significant increase was observed in longitudinal RA strain (25.7±9.4% vs 36.7±9.8%, $p<0.001$) and RARI (0.56±0.29 vs 0.97±0.42, $p<0.001$).

Conclusions: After percutaneous transcatheter closure of a secundum ASD, there was an increase in RARI. RARI appears to be helpful for the assessment of RA function and of response to correction of volume overload after percutaneous transcatheter closure of a secundum ASD.

Chronic heart failure - Echocardiography and other imaging

Accuracy of atrial septal defect sizing by 3D TEE; the role of the 'halo sign'

AGGELI Constantina [(1)], AGGELI Constantina [(1)], DIMITROGLOU Yannis [(1)], APOSTOLOU Ifigeneia [(1)], DRAKOPOULOU Maria [(1)], KASTELLANOS Stylianos [(1)], LATSIOS George [(1)], VAVURANAKIS Manolis [(1)], TOUTOUZAS Konstantinos [(1)], TSIAMIS Eleftherios [(1)], TOUSOULIS Dimitris [(1)]

(1) National and Kapodistrian University of Athens, Athens, Greece; (2) National and Kapodistrian University of Athens, Athens, Greece

Aims: In patients undergoing percutaneous closure of secundum atrial septal defect (ASD), device selection is based on defect sizing by TEE and in particular 3D measurements as well as 2D balloon-stretched derived measurements. We sought to investigate whether in patients with the presence of the 'halo sign', defined as increased tissue thickness at the edge of the ASD rims, there is an agreement between the aforementioned sizing methods with a view to avoid balloon sizing.

Methods and results: Consecutive patients referred to our department for single ASD closure without complex anatomy were included in our study. 3D datasets for ASD quantification as well as 2D data sets for measurement of balloon-stretched 2D dimensions were acquired and analysed offline. Circumference was measured from multiplanar reconstruction images and circumference derived diameter was calculated as: diameter= circumference/π. During the analysis of 3D datasets, researchers were blinded to the 2D balloon-stretched measurements. Patients were stratified according to the presence of the halo sign and the correlation between the circumference derived diameter and the balloon-derived diameter was calculated using correlation analysis and Bland-Altman plots. Forty patients (17 males, 42.5%) with mean age 46.8 (SD=12.3) years were included in our study. The halo sign was present in 17 patients (42.5%). In the whole study population, the mean maximal and mean minimal diameter measured by 3D TEE were 17.9 (5.7) mm and 15.5 (5.8) mm, respectively, while mean circumference and median area were 52.3 (17.6) mm and 202mm^2 (IQR= 125-328mm^2), respectively. Mean balloon-stretched diameter was 17.8 (5.5) mm. In patients with the halo sign mean difference between circumference derived diameter and balloon stretched diameter was 0.2 (0.6) mm and was non-significant (p=0.182). On the contrary statistically significant difference 1.6 (1.5) mm (p<0.001) was found in patients without the halo sign. The discrepancy between the aforementioned diameters was significantly lower in patients with the halo sign (p<0.001). Pearson correlation between circumference derived and balloon stretched diameters in patients with the halo sign was strong (r=0.994) and was significantly stronger than correlation in patients without the halo sign (r=0.967, p<0.001) There was a good correlation between closure device size and 3D derived ASD circumference in the whole study population (R2=0.897) which was even higher in patients with the halo sign (R2=0.981). In this subgroup, the selected size of the closure device would not have differed significantly even without balloon sizing (p=0.414).

Conclusions: The ASD sizing by 3D echocardiography is accurate in patients with the halo sign. This study justifies further investigation concerning the reliability of 3D imaging in this population for the selection of the ASD device size with a view to avoid balloon sizing, decrease procedural time and thus simplify the procedure.

Acute heart failure - Tools, assist devices and techniques, Chronic heart failure - Tools, assist devices and techniques

Invasive assessment of haemodynamic response to rapid saline loading in heart transplant recipients

KODEBOINA Monika [1], KODEBOINA Monika [1,2], DI GIOIA Giuseppe [1,2], VAN DURME Frederik [1], HEYSE Alex [1], VERSTREKEN Sofie [1], HEGGERMONT ward [1], DIERCKX Riet [1], GOETHALS marc [1], BARTUNEK jozef [1], VANDERHEYDEN Marc [1]

(1) Olv Ziekenhuis, Aalst, Belgium; (2) University of Naples Federico II, Metropolitan City of Naples, Italy

Aims: A pulmonary capillary wedge pressure (PCWP) ≥25 mm Hg following volume load or exercise has been proposed as a partition value for detection of HfpEF. However, the haemodynamic response to volume challenge in heart transplant (Tx) recipients has never been studied.

Methods and results: 24 heart Tx recipients (Age: 65± 14 years) with normal LV function (55±7 %) and without rejection and graft vasculopathy underwent right heart catheterisation to measure haemodynamic response to volume loading before and after a rapid saline infusion of 7mL/kg over 10 min. PCWP, right atrial pressure (RAP), mean pulmonary artery pressure (PA) were obtained and the PCWP and indexed (i) stroke volume (SV) data were used to construct Starling (SVindex/PCWP) curves. Patients were categorised into those with elevated filling pressures (group A, n=13 patients) defined by a PCWP ≥ 15 mm Hg at rest or ≥ 25 mm Hg following volume loading vs those without (group B, n=11 patients). No difference in age of donor and transplant, baseline haemodynamics and EF was noted between both groups. Saline infusion significantly increased PCWP and mean PA in both groups without any significant change in BP and heart rate. Interestingly saline infusion was associated with a significant rise in SV and SVi in group B not in group A patients. Moreover, in group B patients the Starling curves revealed a larger SVi at any given PCWP compared to group A patients.

Conclusions: In the transplanted heart, volume loading increases filling pressures and is able to unmask left ventricular diastolic dysfunction. Interestingly, those with HFpEF are characterised by a blunted Frank Starling response as evidenced by higher PCWP and failure to increase SV for any given PCWP. Further prospective studies are warranted to unravel the underlying mechanisms.

Chronic heart failure - Echocardiography and other imaging

Vessel FFR in heart transplant recipients with and without graft vasculopathy

NAGUMO Sakura [1], NAGUMO Sakura [1], GALLINORO Emanuele [1], VERSTREKEN Sofie [1], DIERCKX Riet [1], HEGGERMONT Ward [1], BARTUNEK Jozef [1], DE BRUYNE Bernard [1], SONCK Jeroen [1], COLLET Carlos [1], VANDERHEYDEN Marc [1]

(1) Cardiovascular Center Aalst, OLV Clinic, Aalst, Belgium

Aims: To assess the usefulness of vessel fractional flow reserve (vFFR) derived from coronary angiography to detect cardiac allograft vasculopathy (CAV) in heart transplant recipients.

Methods and results: This retrospective study was performed in patients who underwent heart transplant between January 1987 and December 2018. In heart transplant patients referred for annual check-up, undergoing surveillance coronary angiography, the extent of CAV was graded according to the criteria proposed by the International Society of Heart and Lung Transplantation (ISHLT). In those patients, three-dimensional coronary geometries were constructed from the latest coronary angiography and pressure losses were calculated using CASS vFFR. vFFR values were obtained for each major native coronary vessel. The most distal value was used for the analysis and vFFR values ≤0.80 were considered as significant disease. For the patient-level analysis, the lowest vFFR value of the 3 major epicardial vessels was selected. In 65 heart transplant patients with a mean age of 53.7±10.1 years, 8.5 years (IQR 1.90, 15.2) years post heart transplantation, a total number of 173 vessels (59 LAD, 61 LCX, 53 RCA) were analysed. Most donors (76.9%) and recipients (67.7%) were male. Mean donor and recipient age were 35.7 and 53.7 years, respectively. The most frequent indication for heart transplant was ischaemic cardiomyopathy (ICMP). Mean vFFR was 0.84±0.15, median 0.88 (IQR 0.79, 0.94). A vFFR ≤0.80 was present in 24 patients (48 vessels). Heart transplant patients with previous history of ICMP had lower vFFR as compared to those with non-ICMP (0.70±0.22 vs 0.79±0.13, p=0.06). When categorising functional vessel characteristics by CAV classification a significant lower vFFR (p=0.009) and a higher percent diameter stenosis (p<0.001) was observed in patients with higher CAV grade. Use of vFFR reclassified 31.9% of patients compared to the anatomical ISHLT criteria. Despite a CAV score of 0, a pathological vFFR ≤ 0.80 was detected in 8 patients (34.8 %).

Conclusions: The impairment of coronary flow assessed by vFFR in a subgroup of patients without CAV according to standard ISHLT criteria, suggests the presence of a diffuse vasculopathy undetectable by conventional coronary angiography. Therefore, we speculate that vFFR may be a helpful tool in risk stratification post heart transplant.

Chronic heart failure - Tools, assist devices and techniques

Prognostic role of heart failure history on clinical outcomes of patients with secondary mitral regurgitation treated by MitraClip

ADAMO Marianna [1], ADAMO Marianna [1], GAVAZZONI Mara [3], ESTEVEZ-LOURERO Rodrigo [2], CASTIELLO Assunta [1], TARAMASSO Maurizio [3], PORTOLES Antonio [2], BENITO Tomas [2], CURELLO Salvatore [1], MAISANO Francesco [3], METRA Marco [1]

(1) CIVIL HOSPITALS OF BRESCIA, BRESCIA, Italy; (2) Hospital Álvaro Cunqueiro, Vigo, Spain; (3) Universitätsspital Zürich, Zürich, Switzerland

Aims: We aim at investigating the prognostic role of heart failure (HF) history in patients with secondary mitral regurgitation (SMR) undergoing MitraClip intervention.

Methods and results: We retrospectively analysed 186 patients with severe SMR undergoing MitraClip between October 2010 and October 2018 at 3 European centres. HF history was assessed using four different definitions: i) number of HF hospitalisation during the 12-month period before the procedure; ii) number of days spent in hospital in the 12-month period before the procedure; iii) time between the last HF hospitalisation and the procedure; iv) time between the first diagnosis of severe SMR and the procedure. The primary endpoint was a composite of all-cause death and HF hospitalisations up to 3-year follow-up. Patients who have had more than one HF hospitalisation during the 12-month period before MitraClip were more likely to be male and to to have more advanced symptoms compared to those with only 1 or no HF hospitalisation (80% vs 55% and 59.5%; p=0.007 and NYHA IV: 51.4% vs 21.4% e 28.4%; p=0.009). Instead, patients who have had one prior HF hospitalisation had higher left ventricular ejection fraction and smaller ventricles compared to the others. No significant differences between groups have been observed with respect to procedural data. Cumulative incidence of primary endpoint was higher in patients who have had more than one HF hospitalisation compared to those with one or none prior HF hospitalisation (70.5% vs 48.6% and 50.2%, Log rank p=0.008), and in patients who have spent more than 10 days in hospital during the 12-month period before the procedure compared to the others (70.6% vs 51.5%, log rank p=0.015). Stratifying the population according to time from last hospitalisation and time from first diagnosis of severe SMR (tertiles), no significant differences in primary endpoint have been noted between groups. Among variables describing HF history only the number of HF hospitalisation in the 12-month period before MitraClip increased the adjusted relative risk of events (HR=1.59 [CI 95%=1.09-2.12]; p=0.015). A significant decrease in the total number of HF admission (39 vs 146; p<0.001) and days of hospitalisation (413 days vs 1,655 days; p<0.001) has been observed in the 12-months period after MitraClip compared to the 12-months period before.

Conclusions: Heart failure history has to be carefully evaluated in SMR patients suitable for MitraClip. More than one HF hospitalisation in the 12 months before the procedure increases the risk of death or HF readmission at long-term follow-up.

Chronic heart failure - Echocardiography and other imaging

Long-term durability of a newer generation self-expanding valve in patients undergoing TAVI

STATHOGIANNIS Konstantinos [1], STATHOGIANNIS Konstantinos [1], TOUTOUZAS Konstantinos [1], DRAKOPOULOU Maria [1], SOULAIDOPOULOS Stergios [1], XANTHOPOULOU Maria [1], OIKONOMOU Giorgos [1], TOSKAS Pantelis [1], SYNETOS Andreas [1], LATSIOS George [1], TOUSOULIS Dimitrios [1]

(1) "Ippokrateio" General Hospital of Athens, Athens, Greece

Aims: The long-term durability of the newer generation transcatheter heart valves (THV) is still under investigation. The aim of this study was to investigate the long-term durability of a newer-generation self-expanding THV in patients with severe aortic stenosis undergoing transcatheter aortic valve implantation (TAVI).

Methods and results: In total, 151 consecutive patients with symptomatic severe aortic stenosis (AS) underwent TAVI with a second-generation self-expanding THV. All patients underwent transthoracic echocardiography before the procedure, at discharge and at 1-year follow-up or at the closest time period to it. All data were prospectively collected and retrospectively analysed. Echocardiographic parameters were based on the latest ESC Guidelines. Clinical and procedural outcomes were based on the VARC-2 criteria. All patients had severe symptomatic AS (mean transaortic pressure gradients: 49.03±14.42 mmHg, mean aortic valve area indexed: 0.36±0.08 cm^2/m^2, NYHA Class III 89%). Mean baseline LVEF was 50.54±9.50%. Pre-TAVI none/mild mitral regurgitation (MR) rates were 76.8% (n=116) and moderate/severe MR rates were 23.2% (n= 35). At discharge, significant haemodynamic improvement was observed with lower mean transaortic pressure gradients, higher mean aortic valve area indexed and higher mean LVEF compared to the baseline values (10.64±5.94mmHg, p<0.001; 0.96±0.33 cm^2/m^2, p<0.001; 52.11±9.02%, p=0.005, respectively). The percentage of patients with moderate/severe MR was reduced to 12.6% (n=19; p<0.001). The percentage of patients with moderate/severe paravalvular leakage (PVL) was 7.9% (n= 12). At 1-year follow up, the haemodynamic parameters had been largely unchanged. The LVEF was 52.67±7.10% (p=0.628) and the mean transaortic pressure gradients was 10.09±4.82mmHg (p=0.501). The mean aortic valve area index had significantly increased (1.69±0.49 cm^2/m^2, p=0.006). The rates of moderate/severe MR remained the same (13%, p=0.65), as did the PVL rates (p=0.76). At a mean follow-up period of 335±166 days, 7 patients in total had died (4.6%), 1 patient due to cardiac causes and the rest due to non-cardiac causes.

Conclusions: The long-term durability of the self-expanding THV is strong at 1 year, with re-assuring haemodynamic parameters. Longer-term data are still needed in order to fully elucidate the durability of the THVs

Acute heart failure - Tools, assist devices and techniques, Chronic heart failure - Tools, assist devices and techniques

Cardiac autonomic nerve stimulation improves haemodynamics and clinical status in advanced heart failure patients

CUCHIARA Michael [6], DIAZ Temístocles [2], MARIN Y KALL Christian [1], BOEHMER John [3], COWIE Martin [4], MEBAZAA Alexandre [5], CUCHIARA Michael [6]

(1) University of Miami, FL, USA; (2) Pacífica Salud, Panama City, Panama; (3) Penn State Health Milton S. Hershey Medical Center, PA, USA; (4) Imperial College London, London, United Kingdom; (5) Paris Diderot University, Paris, France; (6) NeuroTronik Inc, Durham, USA

Aims: Despite heart failure therapy advances, symptomatic congestion and low cardiac output in acute heart failure is a leading cause of mortality and morbidity.The purpose of this study was to investigate transvenous cardiac autonomic nerve stimulation (CANS) effects on in-hospital haemodynamics and signs and symptoms of congestion.

Methods and results: The study was a single-centre, open label, clinical investigation of CANS. Twenty two subjects with LVEF <40% and at least two signs and symptoms of congestion were consented and enrolled. A purpose-built electrical stimulation catheter was placed in the left brachiocephalic vein via left subclavian vein access and connected to a purpose-built bedside neurostimulator used to deliver CANS therapy in-hospital for up to 96 hours. The subjects had a mean baseline NT-proBNP of 10,518 pg/mL, LVEF of 25%, pulmonary capillary wedge pressure (PCWP) of 20 mmHg and presented with symptoms. CANS therapy was provided for a mean duration of 70 hours. There were no device or study related adverse events reported. During CANS therapy mean cardiac index increased (1.8 to 2.0 L/min/m^2), mean systemic vascular resistance decreased (24 to 20 WU), and mean PCWP decreased (20 to 14 mmHg) with stable MAP and HR. At discharge, mean oedema pitting score improved 2 points, mean 6 minute hall walk distance (6MHW) increased 92 m and mean KCCQ-12 increased 12 points. At 30 day follow-up, oedema pitting score improved 3 points, 6MHW increased 102 m and mean KCCQ-12 improved 38 points from baseline. Haemodynamic and clinical improvements occurred in the presence of stable medical management. Patients received at least 80 mg/day of furosemide, had minimal change to existing heart failure medical management, received no new IV vasoactive therapies, and a majority of the patients (17/22) received no furosemide dose up-titration during CANS therapy.

Conclusions: Alongside concomitant medical therapy, CANS holds promise as a tool to improve in-hospital haemodynamics and relieve congestion.

Chronic heart failure - Echocardiography and other imaging

Determination of optimal implantation site for wireless haemodynamic implant

ZAFAR Haroon [1,2], MANAVI Tejaswini [1,2], VAZQUEZ Patricia [1,2], TUBASSAM Muhammad [1,3], SHARIF Faisal [1,2,3,4], ZAFAR Haroon [1,2]

(1) National University of Ireland Galway, Galway, Ireland; (2) Lambe Institute for Translational Research, Galway, Ireland; (3) University Hospital Galway, Galway, Ireland; (4) BioInnovate Ireland, Galway, Ireland

Aims: Central venous pressure (CVP) measurement could predict a wider range of heart failure (HF) conditions. This is the first work, to our best knowledge, where the central venous system (CVS) is being considered as a potential site of implantation of a wireless pressure sensor for HF monitoring. It is essential to analyse the anatomy of the CVS in order to make the right choice for implantation of a wireless pressure sensor. This study will show data obtained from analysis of the most relevant anatomical features of the inferior vena cava (IVC) and will discuss how the optimal site was chosen.

Methods and results: 20 CT scans from patients diagnosed with peripheral vascular disease (PVD) and aortic abdominal aneurysm (AAA) were used to take measurements in the infra-renal area of the vena cava. These CT scans were taken from the archive at the University Hospital Galway, Ireland. Of the 20 patients, four were discarded as they presented AAA. This condition does not allow proper visualisation of the IVC and therefore measurements would not be accurate. In order to find the optimal site of implantation within the CVS, several factors were taken in consideration. These are: anatomical features of the vena cava, to find an optimal geometry for good sensor anchoring; diameter of the vessel, to ensure no obstruction of blood flow and proper design of the anchor; link distance, for clear wireless readings. The study of the IVC anatomical features showed that the area between the lower renal vein and the iliac join seems an ideal candidate for implantation. It presents a very straight geometry, which may allow relatively simple design of the anchor. In addition to this, surgical access through the femoral vein is easy, and there are no major delicate structures around it. The measurements obtained show that the diameter of this area is wide enough to accept a sensor without obstruction of blood flow (2D simulations corroborated this). Finally, link distance is ideal for the use of wireless recording of the implant.

Conclusions: These findings will be used for the design of a novel anchor suitable for deployment of a wireless sensor in the chosen IVC region. This design will be validated in acute and chronical studies with animals, and compare with the standard implantation site in the pulmonary artery (PA).

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Posters

Acute heart failure - Tools, assist devices and techniques

The cathlab nurse: a pilot project of a multidisciplinary training process

MANI Stefania [(1)], CAPRIOGLIO Francesco [(1)], PERTILE Francesco [(1)]

(1) Ospedale San Bortolo di Vicenza, Province of Vicenza, Italy

Aims: The scientific, medical and technological progress of the past few years have brought the need to update, redefine and standardise the skills in the interventional cardiology sector. The teams who operate in the cath lab are composed of multidisciplinary figures, who interact and work on the use of new technologies and equipment, with the aim of ensuring the best diagnosis and caring service both in elective and emergency situations. The management of cases involving a multidisciplinary approach highlights the necessity of specific training for the cath lab nurse.

Methods and results: In order to ensure that the nurse acquires those skills, we propose a pilot project that allows the nurses to rotate inside the heart surgery and cardiology units, including their intensive care units and surgery rooms. The rotation in the operative units mentioned above, consists of coaching of the cath lab nurse by the anesthesiologist to acquire skills as anesthesiologist nurse and in the heart surgery intensive care unit and surgery room to obtain skills on how to manage appliances like Impella, ECMO and IABP. Through the examination of two clinical cases, in which a multidisciplinary approach was necessary, we want to demonstrate the necessity to apply that training process.

Conclusions: Through the implementation of this pilot each nurse will develop skills that will allow them to work safely and ensure optimal patient care collaborating with the other multidisciplinary figures.

Renal denervation - Adjunctive pharmacotherapy

Long-term follow-up of patients undergoing renal sympathetic denervation

DAEMEN Joost [(1)], DAEMEN Joost [(1)], NANAN PANDAY Rajiv [(1)], FEYZ Lida [(1)], ZEIJEN Victor [(1)], VERSMISSEN Jorie [(1)], KARDYS Isabella [(1)], VAN MIEGHEM Nicolas [(1)]

(1) Erasmus MC, Rotterdam, the Netherlands

Aims: Renal sympathetic denervation (RDN) has been studied as a new treatment option for patients with (resistant) hypertension and has been proved to significantly reduce blood pressure within several months. Thus far, there is a paucity of data on longer-term effects. Therefore, the objective of this study was to assess the long-term effects of RDN on blood pressure (BP), concomitant use of antihypertensive drugs and renal function in patients with hypertension up to five years post procedure.

Methods and results: This study was a retrospective, single-centre, single-arm study. All patients who underwent successful RDN for (therapy resistant) hypertension were included. All patients were aged 18 years or older with use of antihypertensive drug(s) prescribed for hypertension or a documented intolerance to antihypertensive medication. A total of 68 patients who underwent RDN for (resistant) hypertension were followed yearly for 5 years. Outcomes included change in both office and ambulatory BP, change in use of antihypertensive drugs, long-term safety of the procedure and change in renal function over time. Linear mixed models were used to examine the repeated measurements over time. Mean age was 67.9±9.4 years, 54% of the patients were female and average number of antihypertensive drugs was 3.4±1.2. At baseline, mean daytime 24h BP was 145.1/83.4±17.2/12.4 mmHg and mean office BP was 169.1/92±21.3/ 13.8 mmHg. At five years follow-up, there was an estimated sustained decrease in daytime ambulatory SBP of -17.0 mmHg ($p<0.001$). Consistent reductions were seen in all other ambulatory BP measurements ($p<0.001$ for all). Office SBP and DBP showed an estimated decrease of -25 mmHg and -8 mmHg, respectively ($p<0.001$ for both). Defined daily drug dose decreased with an estimated -0.6 DDD ($p=0.008$) between baseline and 36 months and remained stable thereafter. No major procedure-related adverse events occurred during follow-up.

Conclusions: RDN resulted in a significant and sustained decrease in both office and ambulatory blood pressure up to 5 years. The effect appeared to occur independently of changes in drug therapy with a significant decrease in DDD of antihypertensive drugs up to 5 years post treatment.

Renal denervation - Tools, devices and techniques

Three-year safety and efficacy in the Global Symplicity Registry: impact of antihypertensive medication burden on blood pressure reduction

MAHFOUD Felix [1], MAHFOUD Felix [1], MANCIA Giuseppe [2], SCHMIEDER Roland [3], NARKIEWICZ Krzysztof [4], RUILOPE Luis [5], SCHLAICH Markus [6], WILLIAMS Bryan [7], FAHY Martin [8], BÖHM Michael [1]

(1) Saarland University Hospital, Homburg, Germany; (2) University of Milano-Bicocca, Monza, Italy; (3) University Hospital Erlangen, Erlangen, Germany; (4) Medical University of Gdansk, Gdansk, Poland; (5) Hospital Universitario 12 de Octubre, Madrid, Spain; (6) The University of Western Australia, Perth, Australia; (7) University College London, London, United Kingdom; (8) Medtronic PLC, Santa Rosa, USA

Aims: The Global Symplicity Registry (GSR) is currently the largest international registry of renal denervation (RDN) patients with over 2,700 patients enrolled. We sought to investigate the impact of initial antihypertensive medication burden on blood pressure (BP) reduction after RDN. We hypothesised that greater medication burden at baseline would lead to less BP reduction at follow-up.

Methods and results: GSR enrols patients with uncontrolled hypertension and/or conditions associated with sympathetic nervous system activation. Patients received RDN using either the Symplicity Flex or Symplicity Spyral catheter. Patients are followed at 3, 6, 12, 24 and 36 months post-procedure to assess office and 24-hour BP and collect data on any adverse events. Adverse event rates were calculated as proportions of total patients eligible for follow-up. Patients were analysed according to their antihypertensive medication burden at baseline. Medication burden was defined as the number of prescribed medications at baseline, irrespective of prescribed dosages or medication adherence. Changes in office BP for different medication burdens were compared using a linear test of trend and adjusting for baseline BP using ANCOVA analysis. In December 2019 there were 2,652 patients enrolled at 196 centres in 45 countries. For the entire cohort, mean age was 60.9±12.0 years, 57.8% male, 38.1% with DM, 20.5% with CKD, 12.4% with AF and >99% of patients had a history of hypertension. Mean (± SD) office and 24-hour systolic BP (SBP) reductions at 3 years were -17±29 mmHg (n=1183) and -9±20 mmHg (n=500), respectively (both p<0.0001 from baseline). At 3 years, adverse event rates included 2.5% myocardial infarction, 1.0% vascular complication, and 0.6% renal artery re-intervention. Patients experienced reductions in office SBP at 3 years despite varying baseline antihypertensive medication burden. Reduction in office SBP at 3 years in patients treated with 1, 2, 3, 4 or >4 medications was -27±34 mmHg (N=12), -21±29 mmHg (N=51), -17±28 mmHg (N=170), -19±28 mmHg (N=375), and -14±29 mmHg (N=570), respectively (p=0.46).

Conclusions: Safety and durability of the RDN procedure is demonstrated with 3-year follow-up data in GSR. Clinically and statistically significant averaged reductions in office and 24-hour SBP at 3 years follow up were observed in all groups irrespective of antihypertensive medication burden.

Renal denervation - Blood pressure monitoring

A follow-up experience six months after renal denervation of patients with resistant arterial hypertension

FESCHENKO Daria [1], FESCHENKO Daria [1], RUDENKO Boris [1], SHANOYAN Artem [1], GAVRILOVA Natalya [1], CHIGIDINOVA Darya [1], HEICHIEVA Galina [1], SHUKUROV Firdavs [1], VASILIEV Dmitriy [1]

(1) National Medical Research Center for Preventive Medicine of the Ministry of Healthcare of the Russian Federation, Moscow, Russian Federation

Aims: This study sought to assess blood pressure-lowering efficacy of radiofrequency-based RDN using Symplicity Spyral™ catheter among patients with resistant arterial hypertension. The goal was to evaluate the clinical and medico-social efficacy of treatment of resistant arterial hypertension, including patients with chronic kidney disease (eGFR<60 mL/min/1.73 m^2), using bilateral radiofrequency ablation of sympathetic renal nerves.

Methods and results: 92 patients were included in this study. Inclusion criteria were office systolic BP >140 mmHg, despite prescription of three antihypertensive drugs including diuretics with stable doses for at least six weeks. 44 patients (48%) suffered from chronic kidney disease (34% - 30 ≤ eGFR< 45 mL/min/1.73 m^2; 66% - 45 ≤ eGFR< 60 mL/min/1.73 m^2). The procedure was successfully performed in all patients. An average of 51.4±12.4 ablations including an average of 32.2±12.5 branch ablations was performed using the Symplicity Spyral multielectrode catheter. The six-month follow-up showed a decrease in blood pressure in 84 patients according to daily blood pressure monitoring: the average reduction of systolic office BP was −8.1± 11.3 mmHg and systolic 24 h ambulatory blood pressure monitoring was −8.7±12.3 mmHg. 8 patients did not respond to the intervention. There were no major adverse events and complications in all cases. After 6 months renal function declined by 6.4 mL/min/1.73 m^2 in patients without chronic kidney disease (baseline eGFR 83 ± 15 mL/min/1.73 m^2) and by 3.1 mL/min/1.73 m^2 in patients with CKD (eGFR <60 mL/min/1.73 m^2; baseline eGFR 44 ± 12 mL/min/1.73 m^2).

Conclusions: According to data obtained during the 6-month study the transcatheter denervation of the renal arteries is a safe method for reducing blood pressure in patients with resistant hypertension. Efficacy and safety data of this trial confirm the important role of the sympathetic renal nerves in the pathogenesis of refractory hypertension and suggest that sympathetic renal denervation may be effective in patients of this group.

Other hypertension - Other

The protective effects of radiofrequency pulmonary artery denervation on the progression of chronic thromboembolic pulmonary hypertension

FESCHENKO Daria [1], FESCHENKO Daria [1], RUDENKO Boris [1], DRAPKINA Oksana [1], SHANOYAN Artem [1], GAVRILOVA Natalya [1], SHUKUROV Firdavs [1], VASILIEV Dmitriy [1]

(1) National Medical Research Center for Preventive Medicine of the Ministry of Healthcare of the Russian Federation, Moscow, Russian Federation

Aims: Chronic thromboembolic pulmonary hypertension is a potentially curable disease because of improved efficacy of drug and surgical treatment. In Russian Federation there are few experienced centres performing pulmonary endarterectomy and balloon pulmonary angioplasty. Until recently, specific drug therapy was not available for most patients because of its high cost. This study aimed to assess the safety and efficacy of radiofrequency pulmonary artery denervation with the Simplicity system in patients with distal chronic thromboembolic pulmonary hypertension.

Methods and results: 60 chronic thromboembolic pulmonary hypertension patients with mean pulmonary artery pressure > 25 mm Hg and absence of proximal artery lesion defined by pulmonary angiography were randomised into 2 groups. Group 1 included 30 patients who underwent pulmonary artery denervation procedure. The other 30 patients were assigned to the control group (only angio plus right heart catheterisation). The procedure of pulmonary artery denervation was performed at the lateral wall of main pulmonary artery and ostium of the left and right pulmonary arteries using the electrode from the Simplicity denervation system. The programmed ablation parameters were temperature >50°C and time=120 s. Using the coronary guiding technique, the tip of electrode was applied at each spot rotating the tip with pace of 2 mm. The success was defined by decrease of mean pulmonary artery pressure >10%, absence of complications. The primary endpoint was comparison of mean pulmonary artery pressure change from baseline to 12 months in pulmonary artery denervation group compared with change from baseline to 12 months in control group. The secondary point was change in 6-min walk distance and pulmonary vascular resistance at the 12-month follow-up. There were no complications after pulmonary artery denervation. Haemodynamic success was achieved in 93% of all cases. The mean number of radiofrequency applications to achieve success was 10.3 per patient. During the follow-up period 3 patients died in the pulmonary artery denervation group: (1 died of gastro-intestinal bleeding, 2 of right ventricular failure) and 3 patients in control group. The mean decreases in the mean pulmonary artery pressure were 8.7 mm Hg in the pulmonary artery denervation group and 3.1 mm Hg in control group ($p<0.05$). After pulmonary artery denervation significant decrease in pulmonary vascular resistance (8.3±2.8 WU vs 11.2±3.7) was observed in comparison with the control group. 6-min walk distance significantly increased by 81 m after pulmonary artery denervation and 29 m in control group ($p<0.05$). This improvement was associated with significant improvements in the WHO functional class.

Conclusions: The usage of the Simplicity denervation system in pulmonary artery denervation procedure is safe and effective. Further studies are required to determine the role of pulmonary artery denervation in the treatment of chronic thromboembolic pulmonary hypertension. The next step of pulmonary artery denervation development will be the use of this method combined with recommended treatment (medical therapy, pulmonary endarterectomy and balloon pulmonary angioplasty) as additional option, that may sufficiently improve outcomes in some patients.

Renal denervation - Echography and other imaging

Renal artery variations in patients with essential hypertension from the RADIANCE-HTN SOLO trial

SANGHVI Kintur [1], SANGHVI Kintur [1], WANG Yale [2], DAEMEN Joost [3], MATHUR Anthony [4], JAIN Ajay [5], SUHAIL Dohad [6], SAPOVAL Marc [7], AZIZI Michel [7], MAHFOUD Felix [8], KIRTANE Ajay [9]

(1) Deborah Heart and Lung Center, NJ, USA; (2) Minneapolis Heart Institute, MN, USA; (3) Erasmus MC ingang Westzeedijk, Rotterdam, the Netherlands; (4) The William Harvey Research Institute - Barts and The London, London, United Kingdom; (5) BARTS Health NHS Trust, London, United Kingdom; (6) Cedars-Sinai Medical Center, CA, USA; (7) Hôpital Européen Georges Pompidou, Paris, France; (8) Saarland University Hospital, Homburg, Germany; (9) Columbia University, NY, USA

Aims: To assess the variability of renal artery (RA) anatomy and presence of RA pathology in patients with mild-to-moderate essential hypertension enrolled in the RADIANCE-HTN SOLO trial.

Methods and results: RADIANCE-HTN SOLO was a multicentre, international, blinded, randomised, sham-controlled trial evaluating ultrasound-based endovascular renal denervation (RDN) in patients aged 18-75 years with mild-to-moderate hypertension that was either uncontrolled on 0-2 antihypertensive medications (office BP of ≥140/90 and <180/110 mmHg) or controlled on 1-2 antihypertensive medications (BP <140/90 mmHg). Consented subjects meeting other eligibility criteria had pre-randomisation renal CT or MR angiography (CTA, MRA) to confirm anatomic eligibility and to define RA ablation sites in eligible patients. Images were prospectively evaluated for RA anatomy and pathology such as fibromuscular dysplasia (FMD) and atherosclerotic RA stenosis. A total of 324 patients underwent RA imaging (282 CTA and 42 MRA). Mean age was 55±10 years, 41% were female, and 20% were non-Caucasian. 178 patients (55%) had single left and right RA of mean diameter 5.4±0.9 and 5.1±0.8 mm and mean length 40.0±12.9 and 52.0±13.1 mm, respectively. 28 patients (8.6%) had at least 1 short (<25mm) main RA. 128 patients (39.5%) had ≥1 accessory RA, with similar mean diameter of the left and right accessory RA (2.4±0.8 mm and 2.3±0.8 mm, respectively). 27 patients (8.3%) had at least one kidney with dual RA with mean diameter of 4.0±0.9 mm on the left and 3.9±0.9 mm on the right. 18 patients (5.6%) had atherosclerotic RA stenosis, 9 (2.8%) of which had ≥30% stenosis, and 10 patients (3.1%) had FMD. 2 patients (0.6%) had incidentally discovered tumours of the kidney and adrenal gland.

Conclusions: Pre-procedure CTA or MRA imaging is a valuable aid in assessing RA anatomy prior to RDN because of highly variable RA anatomy. As expected, CTA or MRA infrequently detected secondary causes of hypertension such as RA stenosis or adrenal tumour in this cohort of middle-aged patients with mild-to-moderate hypertension.

Renal denervation - Blood pressure monitoring

Long-term outcome of renal nerve denervation in Thai patients

WONGPRAPARUT Nattawut [(1)], WONGPRAPARUT Nattawut [(1)], PANCHAVINNIN Pariya [(1)], TRESUKOSOL Damras [(1)], ROUBSANTISUK Weeranuj [(1)], BURANAKITJAROEN Peera [(1)], PONGAKASIRA Rungtiwa [(1)]

(1) Siriraj Hospital, Bangkok, THAILAND

Aims: Due to ethinic difference, renal nerve denervation (RDN) has shown 1-year effective blood pressure reduction in Asian population. We aim to find the long-term outcome of RDN in Thai patients.

Methods and results: Eighteen RDN procedures were performed between 2012 and 2018 at our institution. Pre and post office systolic blood pressure (BP), diastolic BP, mean arterial BP and heart rate were observed at 3, 6, 12 months, then annually up to 7 years. Effectiveness of RDN outcome defined by either 1) the reduction of office systolic blood pressure ≥10 mmHg, or 2) the reduction of antihypertensive drugs, or both outcomes achieved. Mean follow-up period was 37.0±26.4 months. Three patients had died during follow-up period, all from non-cardiac causes. Seven patients underwent RDN using Symplicity® catheter and 11 patients using Symplicity Spyral® catheter. Median of 20 (IQR 16-24) total successful ablations were performed. RF ablation performed at the distal branch in 11 patients (61.1%). The mean (±SD) changes in office SBP were -31.9±17.3 mmHg at the discharge date, -16.8±32.3 mmHg at 1 year, -9.0±26.1 mmHg at 3 years, -5.6±39.3 at 5 years and -17.0±8.4 at 7 years. The average antihypertensive drugs received were decreased from 5.2±1.2 at baseline to 3.9±1.5 at 1 year, 4.2±1.0 at 3 years, 4.2± 0.5 at 5 years and 4.0± 0.0 at 7 years. Eighty-one percent of patients had effective RDN outcome at 1 year. In the patients who had effective RDN outcome at 1 year, the benefit of effective RDN outcome was maintained in long-term through the follow-up period, with the exception of 1 patient who had blood pressure rebound 5 years after RDN and was successfully treated with redo RDN.

Conclusions: Effective RDN outcome achieved in 81% of the patients at 1 year. The benefit of effective RDN outcome is maintained up to 7 years follow-up in the patients who respond to treatment.

Renal denervation - Tools, devices and techniques

Comprehensive assessment of human accessory renal artery peri-arterial renal sympathetic nerve distribution

SATO Yu [1], SATO Yu [1], KAWAKAMI Rika [1], JINNOUCHI Hiroyuki [1], SAKAMOTO Atsushi [1], BARMAN Neil [2], COLEMAN Leslie [2], POCOCK Ginger [2], ROMERO Maria [1], VIRMANI Renu [1], FINN Aloke [1,3]

(1) Cvpath Institute Inc, MD, USA; (2) ReCor Medical Inc., CA, USA; (3) University of Maryland, Baltimore County, MD, USA

Aims: Renal denervation (RDN) is a novel treatment for patients with hypertension. Accessory renal arteries (ARA) have been reported in nearly 30-40% of patients and those less than <3 mm in diameter have been excluded from some RDN trials. Despite the belief that ablation of the ARA peri-arterial nerves results in greater blood pressure reduction, the anatomic distribution of peri-arterial renal nerve fibers has not been well studied. Here we assessed the size of the accessory renal arteries and histologic peri-ARA nerve distribution in human autopsies.

Methods and results: Main renal and accessory renal arteries with surrounding tissues were collected from human autopsy subjects, and histological evaluation was performed. ARA was defined as an artery that arises from the aorta above or below the main renal artery or a renal artery that bifurcated within 20 mm of the take-off of the main renal artery. A dominant renal artery (DRA) was defined as an artery that perfused >50% of the kidney. The diameter of the ARA, number of nerves, distance from arterial lumen to nerves, and area of the nerves were evaluated in histological serial section from proximal to distal. Ten kidneys with accessory arteries were collected. These samples contained 14 accessory arteries. Nine kidneys had a DRA, and one kidney had no DRA but had 4 separate renal arteries. A total of 171 renal artery histologic sections (DRA; 63, ARA; 108) with 7,287 nerves were evaluated. The median diameter of the ARA by histology was smaller than the DRA (3.64 [2.72-4.42] mm vs 3.97 [3.61-5.91] mm, p=0.0346). The median number of nerves was less in the ARAs than in DRAs (24 [8-48] vs 40 [20-76], p<0.0001). The median distance from the arterial lumen to the nerves in the ARAs was shorter than for DRAs (1.55 [0.93-3.91] mm, vs 2.19 [1.03-5.67] mm, p<0.0001). In both DRAs and ARAs, there was a longer distance from lumen to nerves in the proximal versus distal sections of the renal arteries (proximal, middle and distal renal arteries: ARA; 3.00 [1.21-5.90], 1.33 [0.90-2.86], and 1.18 [0.85-2.11], respectively, p<0.0001. DRA; 3.97 [1.59-7.78], 2.03 [1.01-4.89] and 1.07 [0.83-1.60], respectively, p<0.0001) was observed. The median size of nerves in the DRAs was comparable to ARAs (DRA vs ARA; 0.006 [0.002-0.018] mm^2 vs 0.006 [0.002-0.019] mm^2, p=0.7902). Accessory arteries were divided into large (≥3 mm diameter) and small (<3 mm) based on the diameter of the artery on angiography, the group with larger diameter showed a greater number of nerves than the group with smaller arteries (32 [16-56] vs 20 [4-36], p<0.0001). Similarly, in arteries ≥3 mm in diameter by angiography, the DRAs as compared to ARAs had a greater number of nerves (40 [20-76] vs 32 [16-56], p=0.0204).

Conclusions: ARAs showed a smaller number of nerves compared to DRAs, however, this was not surprising as the diameter of the ARAs was smaller than DRAs. Nevertheless, our results suggest that ablation of ARA peri-arterial nerves, particularly for vessels ≥3.0 mm, may result in an additional advantage for blood pressure reduction.

Renal denervation - Blood pressure monitoring

Renal denervation treatment in patients with resistant hypertension: one-year follow-up

ABRAS Marcel [3], MOISEEVA Anna [1], CARAUS Alexandru [1], MOSCALU Vitalie [1], CALENICI Oleg [2], SUREV Artiom [1], CALENICI Eugen [1], GRIB Andrei [3], VASCENCO Alexandru [3], CARAUS Mihaela [4]

(1) Cardiology Institute, Chisinau, REPUBLIC OF MOLDOVA; (2) CH LILLEBONNE CHI CAUX VALLEE DE SEINE, LILLEBONNE, France; (3) State University of Medicine and Pharmacy "Nicolae Testemitanu", Chisinau, REPUBLIC OF MOLDOVA; (4) University Hospital St. Spiridon, Iasi, ROMANIA

Aims: A comparison of the influence of renal denervation versus pharmacological treatment with sympathetic nervous system blockers on blood pressure in patients with resistant hypertension.

Methods and results: 90 patients with resistant hypertension without comorbidities after a 3-week standardised treatment with losartan100 mg, amlodipine 10 mg and indapamid 1.5 mg and confirmation of their resistance, were randomly assigned into three equal groups of 30 patients, depending on medication supplemented to previously administered: IM group - selective I1-imidazoline agonist moxonidine, IIB group - cardioselective beta-blocker bisoprolol and IIID group – renal artery denervation. Patients were assessed by ambulatory blood pressure monitoring at baseline, 3-, 6- and 12-month follow-up. The compliance to drug treatment was confirmed by 8-item Morisky Medication Adherence Scale. Renal denervation was performed with a Symplicity Spyral catheter. The mean 24-hour systolic blood pressure (SBP m/24 h) at baseline was 179.0±2.02 mmHg in IM group versus 177.96±2.44 mmHg in IIB group and 176.92±1.97 mmHg in IIID group, p >0.05. Statistically significant dynamics were recorded, starting with 3 months of evaluation in all three groups, the group of patients undergoing denervation of the renal arteries demonstrating a net superior effect compared with pharmacological treatment: - 6.48±0.81 mmHg in I M group versus – 6.2±0.88 mmHg in II B group and – 23.28±1.9 mmHg in III D group, p<0.001. The beneficial effect was maintained until the end of the study, when in the observational group supplemented with moxonidine SBP m/24 h were 159.6±1.72 mmHg with a total reduction of – 19.9±0.7 mmHg from baseline, in bisoprolol group – 164.08±1.93 mmHg with a reduction of – 13.88±1.13 mmHg and 141.76±0.77 mmHg in renal denervation group with a total reduction of – 35.16±2.23 mmHg, p<0.001. The mean 24-hour diastolic blood pressure (DBP m/24 h) increased at baseline in all three groups (105.52±1.28 mmHg in IM versus 108.6±1.6 mmHg in IIB and 107.24±0.92 mmHg in IIID, p >0.05). SBP m/24 h noted a significantly reduction at 3-month follow-up: - 4.8±0.96 mmHg in IM group versus - 3.64±0.47 mmHg in IIB group and – 12.08±0.63 mmHg in IIID group, p<0.001. The maximum reduction in DBP m/24 h were registered at 12-month follow-up, a comparative analysis of dynamics between groups showing a presence of statistical difference due to superiority of renal denervation treatment in amelioration of this parameter: - 13.68±0.83 mmHg in IM group versus – 10,72±0.64 mmHg in IIB group and – 20.2±1.28 mmHg in IIID group, p<0.001.

Conclusions: The application of all three treatment regimens has been shown to be effective in reducing SBP and DBP values m/24 hours in patients with resistant hypertension, with a superior but comparable effect of moxonidine to bisoprolol and the absolute superiority of renal denervation treatment versus both pharmacological treatment regimens.

Renal denervation - Tools, devices and techniques

Easy real-time assessment of the procedural success of radiofrequency renal denervation by the impedance drop during energy delivery

PEKARSKIY Stanislav [1], PEKARSKIY Stanislav [1], BAEV Andrei [1], MORDOVIN Viktor [1], FALKOVSKAYA Alla [1], SITKOVA Ekaterina [1], LICHIKAKI Valeria [1], ZUBANOVA Irina [1], RIPP Tatiana [1]

(1) Cardiology Research Institute of the Tomsk National Research Medical Center, Tomsk, Russian Federation

Aims: We hypothesised that the procedural success of radiofrequency RDN may be accurately evaluated based on the relative impedance decrease during energy delivery.

Methods and results: We conducted a prospective clinical study of radiofrequency RDN in patients meeting criteria of true resistant hypertension. The RDN was performed as a series of point treatments along the circumference of the trunk and major branches of the renal artery. To evaluate the serial treatment, we averaged the maximal values of the impedance drop across all point treatments with a full duration. We assessed the relationships between obtained mean impedance drop and blood pressure (BP)-lowering at 6 months post-procedure using linear regression analysis and comparison of the groups with "successful" and "unsuccessful" procedures depending on whether the mean impedance drop was ≥10% or <10%, respectively. Fifty-two patients with quality recordings of the electrophysiology parameters during RDN completed 6-month follow-up. The mean 24-h systolic BP decreased significantly after RDN by -14.3 mmHg [95% CI: -8.7; -19.9]. Individually, the BP decrease was positively and significantly related to the mean impedance drop during RDN, r=0.35, p=0.013. The mean impedance drop by 10% predicted the decrease of 24-h mean systolic BP by -9.9 mmHg. The group analysis demonstrated a powerful lowering of mean 24-h systolic BP in the 38 patients in whom the mean impedance drop during RDN was ≥10%, versus the almost zero average effect in the remaining 14 patients with the mean impedance drop<10%, -18.4 vs -0.5 mmHg, respectively, p=0.003.

Conclusions: The mean impedance drop 10% or greater during the radiofrequency RDN may be an effective criterion of the procedural success of the intervention provided that the treatment has sufficient anatomical completeness. Guiding radiofrequency RDN by the impedance drop has potential to significantly improve the efficacy of the procedure.

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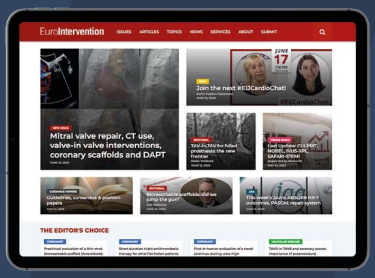

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