

## TCT-649

**Safety and Efficacy of Overlapping Second Generation Drug-Eluting Stents Based Upon 2-year Clinical Outcomes. Results from the Pooled Analysis of Five Trials from the International Global RESOLUTE Program.**

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**Background:** Overlapping first generation drug eluting stents (DES) have been demonstrated in preclinical models to show evidence of a persistent inflammatory response, fibrin deposition and delayed endothelialisation. The SIRTAX (Sirolimus-Eluting Versus Paclitaxel-Eluting Stents for Coronary Revascularization) Trial (n=1012) associated the implantation of overlapping first generation DES with impaired angiographic and adverse 3-year clinical outcomes, including death or myocardial infarction (MI).

**Methods:** Patient level data from 5 controlled studies of the RESOLUTE Global Clinical Program evaluating the RESOLUTE zotarolimus-eluting stent (R-ZES) were pooled (n=5130). Enrolment criteria encompassed more complex patients, including acute MI, long lesions, unprotected left main, bifurcations, total occlusions, bypass grafts & visible thrombus. The position of the R-ZES in relation to the previous implanted stents during the index or staged procedures were reported by the study site as either 'separate,' 'abutting' or 'overlapping.' Comparisons of clinical outcomes – using propensity score adjustment of baseline anatomical and clinical characteristics – were undertaken between patients implanted with at least one overlapping DES against patients with no overlapping DES (Kaplan Meier analyses).

**Results:** 644 of 5130 study patients (12.6%) underwent overlapping DES implantation. Baseline characteristics indicated that the implantation of overlapping DES compared to non-overlapping DES (n=4486) were performed more frequently in the RCA and in more complex coronary lesions. Thirty day, 1 & 2 year clinical outcomes indicated comparable all-cause death (2 year overlap vs. non overlap: 5.1% vs. 3.5%, p=0.13), cardiac death (3.0% vs. 2.1%, p=0.36), MACE (13.3% vs. 10.7%, p=0.19), target lesion (10.9% vs. 9.0%, p=0.41) & target vessel (12.8% vs. 10.6%, p=0.25) failure, and stent thrombosis (ARC definite/probable 1.4% vs. 0.9%, p=0.16).

**Conclusions:** The adverse clinical outcomes associated with 1st generation DES were not apparent with 2nd generation DES. Overlapping second generation DES (compared to the non overlap) is safe & effective with comparable 2 year clinical outcomes, including repeat revascularisation.

## TCT-650

**Impact of the New BioMime™ Sirolimus-Eluting Stent in Complex Patients of Daily Practice – Preliminary Results of the MerIT-2 Study**

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**Background:** The new drug-eluting stent BioMime™ (Meril Life Sciences Pvt. Ltd., Gujarat, India) is composed of an ultra-thin platform (strut thickness 0.0026”), a biodegradable polymer and sirolimus. Its clinical efficacy and safety had already been demonstrated. However, the impact of the BioMime™ SES on populations from daily practice with complex lesions is not fully determined.

**Methods:** The MerIT-2 was a prospective, non-randomized, multicenter study, with minimally selected patients and evaluated clinical and safety performance of the

BioMime™ SES in the treatment of complex patients from daily practice. Native coronary lesions ranging from 2.5-3.5 mm in diameter and with  $\leq 37$  mm in length, and chronic total occlusions were included. Lesions located at the left main coronary or in saphenous vein grafts, or patients with acute myocardial infarction (MI) or left ventricular ejection fraction  $< 30\%$  were excluded. Clinical follow-up (FU) was performed in 1, 8 and 12 months; angiographic FU at 8 months. The primary outcomes were major adverse cardiac events (MACE: death, MI and target-lesion revascularization –TLR) in 1 month, and late lumen loss (LLL) in 8 months.

**Results:** A total of 242 patients were included. Mean age was 56.7 years, 37% diabetics, 32% had previous MI, most with type B2/C lesions, 40% with multiarterial disease and 52% presenting in acute coronary syndrome. Medians of lesion length, reference diameter and % stenosis were: 15.8mm [13.47-21.42], 2.79mm [2.42-2.99], and 89.8 [83.2-93.2], respectively. A total of 363 stents were implanted. There were no MACE after 30 days and the LLL in 8 months (n=132) was 0.15 mm [0.09-0.33]. Cumulative rates of MACE in 12 months were 5.7% (0.5% cardiac death; 4.7% TLR). There were 3 cases of stent thrombosis (ST) - 1 acute, 1 sub-acute and 1 late.

**Conclusions:** In this multicenter evaluation of complex “real-world” patients, the new BioMime™ SES has shown excellent efficacy and safety, with low rates of MACE and ST in 1 year, as well as low values of LLL.

## TCT-651

**Feasibility and clinical outcomes of  $\geq 38$  mm long drug eluting stent treatment for diffuse coronary artery disease in Egyptian population**

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**Background:** Diffuse long lesions are commonly encountered in routine clinical practice and often lead to use long or overlapping stents. Limited data are available on the long-term efficacy and safety of long drug-eluting stents (DES) in this complex lesion subset. We investigated the long-term efficacy and safety of  $\geq 38$ mm-long DES in patients undergoing stent implantation for de novo diffuse long lesions.

**Methods:** 129 consecutive patients who underwent coronary artery stenting with  $\geq 38$ mm-long DES in real world practice were included. Study endpoints were major adverse cardiac events including cardiac death, myocardial infarction, repeat revascularization and stent thrombosis.

**Results:** 129 pts with 153 lesions were enrolled, 85.2% were male, mean age  $58.2 \pm 10$  yrs. Lesions were treated with at least one 38mm second generation DES, all post-dilated at high atmosphere ( $> 20$  atm) with NC balloons. Mean stent size was  $3.0 \pm 0.2$  mm, mean stent length was 54.5 mm. Two-year clinical outcomes were compared between diabetic (DM) (n=40) and non-DM patients (n=89). Baseline characteristics were similar in the two groups as were mean stent length ( $50.2 \pm 13.1$  mm in DM and  $54.5 \pm 15.7$  in non-DM, p = 0.12). Mean follow-up duration was  $433 \pm 275$  days, and 2-yr cumulative major adverse cardiac events were significantly lower in the non-DM than in DM group (5.6% in non-DM vs 10% in DM, p = 0.03). Clinically driven TLR was 5.4% and no cardiac death was reported. There was 1 case defined as late stent thrombosis. The independent predictors of repeat revascularization were insulin treated type 2 diabetes mellitus, reference vessel diameter (RVD)  $< 2.75$  mm and the use of overlapping DES longer than 60 mm.

**Conclusions:** The use of  $\geq 38$ mm DES for treatment of complex diffuse disease is safe and effective with an acceptably low 2-year MACE rate. The need for repeat revascularization was increased with overlapping long DES, small RVD, and insulin treated DM patients.

## TCT-652

**A Comparison of Drug Eluting Stents in a Bench Artery Dissection Model**

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**Background:** Dissections during stenting are rare but can lead to clinical complications and necessitate use of a secondary stent thus increasing direct cost of the procedure. This study examined four popular DES products (Resolute Integrity-Medtronic; Xience Prime and Xience V-Abbott; and Promus Element-Boston Scientific) using a bench model developed to explore factors that contribute to dissections.

**Methods:** Devices (n=5) were inserted into mock vessels designed to match the compliance of a native artery and inflated from nominal to 20-atm pressure. Inner diameters and outward pressures against the vessel wall were ascertained at 500- $\mu$ m increments at each inflation pressure. Desired forces within stent body were compared to undesired forces associated with balloon transition and overhang.

**Results:** Resolute Integrity and Promus Element exerted consistent pressures within the device body and decreasing forces in the distal balloon overhang regions. Xience devices flared as they approached the distal transition, and highest vessel stretch was observed in the balloon overhang. This flaring or “trumpeting” phenomenon was not observed in other DES.