earlier than any prior CEPD study, showed new DWI lesions, the clinical neurologic event rate was 0%. Short deployment times, with multiple operators, point to the advantages of an integrated solution for CEPD. Captured particle amounts were higher than previously reported for any CEPD indicating improved filter design and function with EmStop compared to other CEPD.

700.05

An Economic Analysis of a Nurse-Led Sedation Protocol for Transcatheter Aortic Valve Replacement

Rahul Annabathula,[1] Haytham Allaham,[1] Hegang Chen,[1] Mark Sonbol,[1] Jacob Bernknopf,[1] Sergey Gnilopyat,[1] Macy Zincon,[2] Anuj Gupta,[1] Diljon Chahal[1]
[1]University of Maryland School of Medicine, Baltimore, MD; [2]University of Maryland Medical Center, Baltimore, MD

BACKGROUND Nurse-led sedation (NLS) protocols for transcatheter aortic valve replacement (TAVR) have comparable outcomes to monitored anesthesia care (MAC). The economic impact of NLS has not been thoroughly analyzed. This study was a cost/benefit analysis of NLS for TAVR compared to a MAC protocol in the operating room (OR) and the Cath lab.

METHODS Patients who underwent transfemoral TAVR for severe aortic stenosis at our institution from July 2018 to June 2024, excluding 2020 due to the COVID-19 pandemic, were included. Patients were divided into groups based on the type of anesthesia that they received: OR MAC, Cath lab MAC, or Cath lab NLS. The primary outcomes included in-hospital mortality, total procedural costs, and total hospital costs.

RESULTS A total of 979 patients (mean age: 78 years, female: 47%) were identified. The OR and Cath lab MAC patients were compared via 1:1 propensity matching. The Cath lab MAC and NLS patients were compared via a separate 2:1 propensity matching. There was no difference in in-hospital mortality between the OR and Cath lab MAC groups (0.63% vs. 0.63%, p=1). The total procedural costs ($46,337 +/- $11,853 vs. $55,164 +/- $10,516, p<0.0001) and total hospitals costs ($69,504 +/- $54,623 vs. $72,823 +/- $30,710, p<0.0001) were significantly lower in the Cath lab MAC group. There was no difference in in-hospital mortality between the Cath lab MAC and NLS groups (0.9% vs. 3.6%, p=0.26). The total procedural costs ($43,139 +/- $3,689 vs. $46,853 +/- $14,569, p=0.03) were significantly lower and there was a trend in total hospitals costs ($59,941 +/- $19,622 vs. $78,391 +/- $70,764, p=0.16) that favored the Cath lab NLS group (Table 1).

CONCLUSION Our study shows that the transitioning from MAC in the OR to NLS in the Cath lab has resulted in comparable safety outcomes with an absolute reduction in overall costs for TAVR patients.

Table 1: Matched Primary Outcomes (OR MAC vs. Cath Lab MAC and Cath Lab MAC vs. Cath Lab NLS)

	MAC/OR (n= 317)	MAC/CATH (n= 317)	P-Value
In-hospital Mortality (n, %)	2 (0.63)	2 (0.63)	1
Total Procedural Cost ($) (mean, SD)	55164.80 (10516.20)	46337.30 (11853.00)	<0.0001
Total Hospital Cost ($) (mean, SD)	72823.30 (30710.30)	69504.40 (54623.30)	<0.0001

	MAC/CATH (n= 111)	NLS/CATH (n= 56)	P-Value
In-hospital Mortality (n, %)	1 (0.90)	2 (3.57)	0.26
Total Procedural Cost ($) (mean, SD)	46853.10 (14569)	43139 (3689)	0.03
Total Hospital Cost ($) (mean, SD)	78391.30 (70764.30)	59941.70 (19621.90)	0.16

700.06

"Smart" Analysis of the Landmark Trial - Early Outcomes With Latest Generation Tavi Valves in Patients With a Small Aortic Annulus

Patrick W. Serruys,[1] Akihiro Tobe,[1] Niels van Royen,[2] Ignacio J. Amat-Santos,[3] Martin Hudec,[4] Matjaz Bunc,[5] Alexander Ijsselmuiden,[6] Peep Laanmets,[7] Daniel Unic,[8] Bela Merkely,[9] Renicus S. Hermanides,[10] Vlasis Ninios,[11] Marcin Protasiewicz,[12] Benno J.W. M. Rensing,[13] Pedro L. Martin,[14] Fausto Feres,[15] Manuel De Sousa Almeida,[16] Eric van Belle,[17] Axel Linke,[18] Ashokkumar Thakkar,[19] Udita Chandra,[19] Marie-Claude Morice,[20] Osama Soliman,[1] Yoshinobu Onuma,[1] Andreas Baumbach[21]
[1]University of Galway, Galway, Ireland; [2]Radboud University Hospital, Nijmegen, Netherlands; [3]Centro de Investigación Biomédica en red - Enfermedades Cardiovasculares (CIBERCV), Madrid, Spain; [4]Middle-Slovak Institute of Cardiovascular Diseases, Banska Bystrica, Slovakia; [5]University Medical Centre Ljubljana, Ljubljana, Slovenia; [6]Amphia Hospital, Breda, Netherlands; [7]North Estonia Medical Centre, Tallinn, Estonia; [8]University Hospital Dubrava, Zagreb, Croatia; [9]Semmelweis University Heart and Vascular Centre, Budapest, Hungary; [10]Isala Hospita, Zwolle, Netherlands; [11]European Interbalkan Medical Center, Thessaloniki, Greece; [12]Wrocław Medical University, Wrocław, Poland; [13]St Antonius Hospital, Nieuwegein, Netherlands; [14]University Hospital of Gran Canaria Dr Negrín, Las Palma, Spain; [15]Instituto Dante Pazzanese, Sao Paulo, Brazil; [16]NOVA University Lisbon, Lisbon, Portugal; [17]Lille University, Lille, France; [18]University of Technology Dresden, Dresden, Germany; [19]Meril Life Sciences Pvt. Ltd., Vapi, India; [20]Cardiovascular European Research Center, Paris, France; [21]Queen Mary University of London and Barts Heart Centre, London, United Kingdom

BACKGROUND Among patients with severe aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI), nearly one third have a small aortic annulus. These patients are at higher risk of prosthetic valve dysfunction. Recently, the SMART trial reported that the self-expanding Evolut series was superior to balloon-expandable Sapien series with respect to echocardiographic hemodynamic outcomes at one year. The Myval series is a novel balloon-expandable transcatheter heart valve (THV) whose clinical non-inferiority at 30 days compared to the Evolut and Sapien series was recently demonstrated in the LANDMARK trial. However, the performance of Myval series in patients with a small aortic annulus is unknown.

METHODS The LANDMARK trial is a randomized, non-inferiority trial conducted in 16 countries, which compares the safety and effectiveness between Myval THV series and contemporary THV series (Sapien and Evolut) in accordance with the third Valve Academic Research Consortium recommendations. The primary endpoint was a composite of all-cause death, all stroke, bleeding (type 3 or 4), acute kidney injury stage 2-4, major vascular complication, moderate or severe prosthetic valve regurgitation (PVR), and permanent pacemaker implantation at 30 days. This sub-study compared the clinical and echocardiographic outcomes at 30 days in patients with a small aortic annulus (aortic valve annulus area ≦430 mm^2).

RESULTS Out of 768 patients randomized in the trial, 245 (32%) patients had a small aortic annulus (125 patients in Myval, 64 in Sapien and 56 in Evolut). The proportions of female in patients with a small annulus were 86%, 81% and 88% in Myval, Sapien and Evolut, respectively. At 30 days, the primary composite endpoint occurred in 24 (20%), 13 (21%) and 18 (33%) patients in Myval, Sapien and Evolut, respectively (Myval vs Sapien: p=1.00, Myval vs Evolut: p=0.08). Myval had a lower aortic valve mean pressure gradient (MPG, Myval: 9.3mmHg; Sapien: 11.8mmHg, p<0.01) and a higher effective orifice area (EOA) compared to Sapien (1.75cm^2, 1.53cm^2, p<0.01), while having a higher MPG (Evolut: 5.8mmHg, p<0.01) and lower EOA than Evolut (2.27cm^2, p<0.01).

CONCLUSIONS At 30 days, Myval THV series had a lower aortic valve mean pressure gradient and a higher effective orifice area than Sapien. TAVI with the Myval THV series in small annulus patients with severe aortic stenosis is comparable to both the Sapien and Evolut series in terms of primary composite endpoint at 30 days.