Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

The performance goals were established based upon data from randomized controlled trials of similar embolic protection devices. The secondary objective was to assess the efficacy of the device by comparing the new diffusion-weighted magnetic resonance imaging (DW-MRI) lesion volume in the brain and the rate of death or all strokes to historical data.

RESULTS Both primary safety and performance endpoints were met early in this study. The MACCE rate at 30 days was 8.6% (upper limit of the 95% confidence interval = 22.4%; 2.6% below the predefined performance goal of 25%; $P = 0.0124$) (3 MACCE events in 35 patients in the safety cohort). Performance success was achieved in 93.8% of patients (lower limit of the 95% confidence interval = 79.9%; 4.9% above the predefined performance goal of 75%; $P = 0.0072$) (30 of 32 successful procedures in the intention-to-treat cohort). The volume of new DW-MRI lesions after use of the ProtEmbo was reduced compared with historical data. There were no deaths or strokes in the per protocol cohort of the study; 1 single cerebral infarct was observed in the safety cohort in a patient in whom the device was removed prematurely, and no cerebral protection was used during final positioning and post-dilatation of the valve prosthesis.

CONCLUSION The primary safety and performance endpoints of the PROTEMBO C trial were met. The device was easy to use and fits into the workflow of TAVR procedures. Use of the ProtEmbo was associated with a reduction in the volume of new DW-MRI lesions in comparison with historical data. Final results of the study including DW-MRI results will be presented for the first time at TCT 2021.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-52

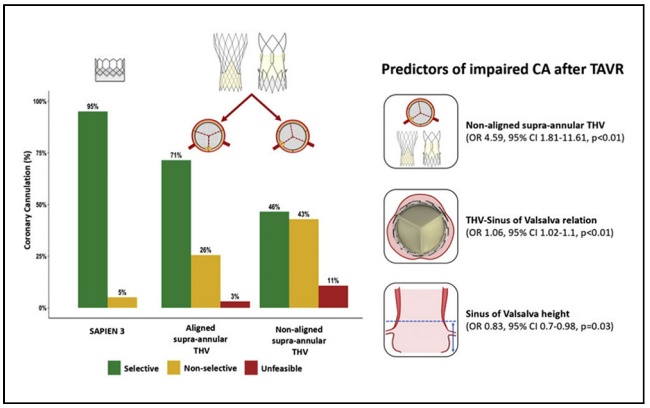
Coronary Access After TAVR With Commissure Alignment: The ALIGN-ACCESS Study

Luca Nai Fovino,[1] Andrea Scotti,[2] Mauro Massussi,[3] Francesco Cardaioli,[4] Giulio Rodinò,[5] Carolina Montonati,[6] Saverio Continisio,[7] Mauro Boiago,[1] Alice Benedetti,[8] Yuji Matsuda,[9] Luisa Cacciavillani,[8] Andrea Pavei,[10] Giulia Masiero,[11] Massimo Napodano,[12] Chiara Fraccaro,[13] Tommaso Fabris,[13] Sabino Iliceto,[14] Giuseppe Tarantini[13]
[1]University of Padua, Padua, Italy; [2]University of Padua Medical School, Padua, Italy; [3]University of Padua, Italy; [4]University of Padua, Padua, Italy; [5]Università di Padova, Catanzaro, Catanzaro, Italy; [6]University of Padua, Padua, Italy; [7]Azienda ospedaliera di Padova, Padua, Italy; [8]University of Padua, Padua, Italy; [9]Cardiology and Cardiovascular Medicine, Tokyo, Japan; [10]University of Padua, Padua, Italy; [11]University of Padua, Montegaldella, Vicenza, Italy; [12]University of Padua, Department of Cardiac, Thoracic and Vascular Sciences, Padua, Italy; [13]University of Padua, Department of Cardiac, Thoracic and Vascular Sciences, Padua, Italy; [14]University of Padua, Padua, Italy

BACKGROUND Coronary access after transcatheter aortic valve replacement (TAVR) with supra-annular transcatheter heart valves (THVs) can be challenging. Specific Evolut R/Pro (Medtronic) and Acurate Neo (Boston Scientific) THV orientations are associated with reduced neo-commissural overlap with coronary ostia. The aim of this study was to assess the impact of commissural alignment on coronary access (CA) after TAVR.

METHODS We performed coronary angiography after TAVR with intra-annular SAPIEN 3 (Edwards Lifesciences), supra-annular Evolut R/Pro and Acurate Neo THVs in 206 patients. Evolut THVs were implanted aiming for commissure alignment. Alignment of Acurate Neo was retrospectively assessed in 36 cases, intentionally attempted in 26 cases. The primary endpoint was the rate of impaired CA after TAVR.

RESULTS Thirty-eight percent of patients received SAPIEN 3, 31.1% Evolut Pro/R, 30.1% Acurate Neo THV. Final valve orientation was favorable to commissural alignment in 85.9% of Evolut and 69.4% of Acurate Neo cases (with intentional alignment successful in 88.5%). Selective CA was higher for SAPIEN 3 than for aligned and misaligned supra-annular THVs (95% vs 71% vs 46%, $P < 0.001$). Cannulation of at least 1 coronary was unfeasible with 11% misaligned supra-annular, 3% aligned supra-annular, and 0% SAPIEN 3 THVs. Independent predictors of unfeasible or nonselective CA were implantation of a misaligned supra-annular THV (odds ratio [OR]: 4.59; 95% confidence interval [CI]: 1.81-11.61; $P < 0.01$), sinus of Valsalva (SoV) height (OR: 0.83; 95% CI: 0.7-0.98; $P = 0.03$), and THV-SoV relation (OR: 1.06; 95% CI: 1.02-1.1; $P < 0.01$).



CONCLUSION Commissural alignment improves the rate of selective CA after TAVR with supra-annular THVs. Nevertheless, aligned supra-annular THVs carry higher risk of impaired CA than SAPIEN 3. Patients with a misaligned supra-annular THV, low SoV and higher THV-SoV relation are at highest risk of impaired CA after TAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-53

Same-Day Discharge Post-Transcatheter Aortic Valve Replacement Using a Standardized Clinical Pathway During the COVID-19 Pandemic: The PROTECT TAVR Study

Madeleine Barker,[1] Janarthanan Sathananthan,[2] Emily Perdoncin,[3] Patricia Keegan,[4] Chandan Devireddy,[5] Kendra Grubb,[6] Andrei Pop,[7] Jeremiah Depta,[8] Devesh Rai,[9] Mark Spence,[10] Jonathan Mailey,[11] Douglas Muir,[12] Mark Russo,[13] Alexis Okoh,[14] Meghan Smith,[15] Masud Rana,[16] Sandra Lauck,[17] John Webb,[17] David Wood[18]
[1]Centre for Heart Valve Innovation, St. Paul's and Vancouver General Hospital, Vancouver, British Columbia, Canada; [2]St. Paul's Hospital, Vancouver, British Columbia, Canada; [3]Emory University Hospital Midtown, Atlanta, Georgia, USA; [4]Emory Healthcare, Atlanta, Georgia, USA; [5]Emory University Hospital Midtown, Atlanta, Georgia, USA; [6]Emory University, Atlanta, Georgia, USA; [7]Alexian Brothers Medical Center, Elk Grove Village, Illinois, USA; [8]Rochester General Hospital, Rochester, New York, USA; [9]Sands-Constellation Heart Institute, Rochester General Hospital, Rochester, New York, USA; [10]NHS, Belfast, United Kingdom; [11]Royal Victoria Hospital, Belfast, Belfast, United Kingdom; [12]The James Cook University Hospital, Middlesbrough, United Kingdom; [13]Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey, USA; [14]Emory University School of Medicine, Atlanta, Georgia, USA; [15]Robert Woods Johnson Medical School, New Brunswick, New Jersey, USA; [16]Center for Cardiovascular Innovation, University of British Columbia, Vancouver, British Columbia, Canada; [17]St. Paul's Hospital, Vancouver, British Columbia, Canada; [18]Centre For Cardiovascular Innovation, Vancouver, British Columbia, Canada

BACKGROUND Transcatheter aortic valve replacement (TAVR) care has transitioned to early discharge home using standardized clinical pathways. The COVID-19 pandemic has placed significant stress on health care systems and highlighted the importance of appropriate and stringent resource allocation. Same-day discharge (SDD) in highly selected TAVR patients may be 1 way to provide this essential service while managing competing clinical demands. We aimed to determine the safety and efficacy of SDD post-TAVR during the COVID-19 pandemic.

METHODS Multicenter study at 7 international sites (Canada, United States, United Kingdom, and Ireland). Patient selection for SDD was at the discretion of the local multidisciplinary heart team. All sites used an abbreviated version of the 3M TAVR Clinical Pathway. The primary outcome was a composite of cardiovascular death, stroke, myocardial

infarction, all-cause readmission, major vascular complications, and new permanent pacemaker (PPM) implantation.

RESULTS From March 2020, to June 2021, 111 of 2,100 transfemoral cases (5.3%) performed at 7 sites during the COVID-19 pandemic were selected for SDD and underwent elective outpatient TAVR. Mean age was 78.8 years (standard deviation [SD]: 7.8 years), median Society of Thoracic Surgeons (STS) score was 2.2 (interquartile range [IQR]: 1.4, 4.3) and 31.5% (n = 35) had a pre-existing PPM. Overall, 96.4% received a balloon-expandable valve (n = 107). There were no major vascular complications, stroke, or death during the index admission. One patient (0.9%) required PPM implantation for complete heart block and was discharged the same day. No patients required a PPM between discharge home and 30-day follow up. The composite of cardiovascular death, stroke, myocardial infarction, all-cause readmission, major vascular complications and new PPM at 30 days occurred in 4.1% patients (n = 4 of 98). All-cause readmission rate was 4.1% (n = 4 of 98), with a cardiovascular readmission rate of 2.0% (n = 2 of 98 for transient ischemic attack [TIA] and heart failure). One patient (0.9%) contracted COVID-19 within 30 days post-TAVR.

CONCLUSION SDD post-TAVR is safe and feasible in selected patients at low risk for clinical events post-discharge. This strategy may preserve critical care resources in times of crisis such as the COVID-19 pandemic.

CATEGORIES **STRUCTURAL:** Valvular Disease: Aortic

TCT-54

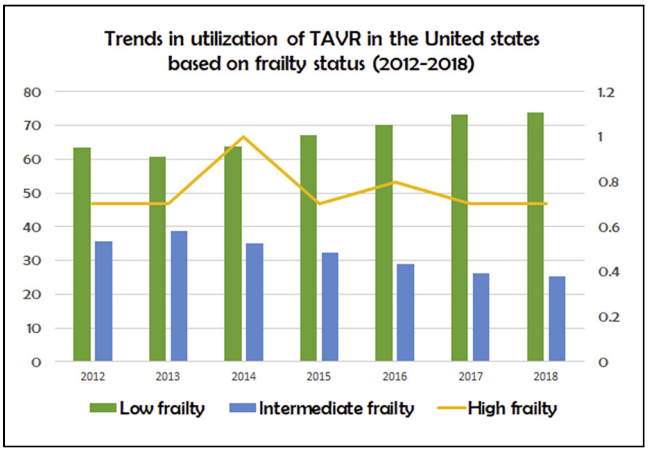
Trends in Utilization and Outcomes Associated With Use of Transcatheter Aortic Valve Replacement According to Frailty

Aaqib Malik,[1] Jayakumar Sreenivasan,[2] Syed Zaid,[3] Wilbert Aronow,[1] Alexandros Briasoulis,[4] Syed Haidry,[5] Howard Cooper,[1] Ryan Kaple,[6] Gilbert Tang,[7] Hasan Ahmad[8]
[1]Westchester Medical Center, Valhalla, New York, USA; [2]Westchester Medical Center/New York Medical College, White Plains, New York, USA; [3]Houston Methodist DeBakey Heart & Vascular Center, Houston, Texas, USA; [4]University of Iowa, Iowa City, Iowa, USA; [5]Yale University School of Medicine, New Haven, Connecticut, USA; [6]Yale School of Medicine, New Haven, Connecticut, USA; [7]Mount Sinai Health System, New York, New York, USA; [8]Westchester Medical Center/New York Medical College, Valhalla, New York, USA

BACKGROUND Aortic stenosis is a disease of the elderly and transcatheter aortic valve replacement (TAVR) is increasingly being performed in this population. In this study, we evaluated the trends in the use of TAVR according to various grades of frailty (low, intermediate, and high) and its outcomes.

METHODS In this observational study using the all-payer Nationwide Inpatient Sample in the United States from 2012 to 2018, we identified all adults (aged $\geq$ 18 years) who underwent TAVR. An administrative database validated frailty risk score was calculated using ICD-9 and ICD-10 codes. Frailty status was defined as low (risk score $<$ 5), intermediate (risk score 5-15), and high (risk score $>$ 15). Survey-specific techniques were used to perform analyses of trends in the use of TAVR.

RESULTS A total of 209,435 hospitalizations for TAVR (mean age 80.0 $\pm$ 8.6 years, 46.6% females patients) were included in this study. Over the course of the study, 70.2% of patients who underwent TAVR were of the lower-frailty status, 29.1% were intermediate, and 0.7% were with high frailty. From 2012 to 2018, the proportion of patients with low frailty who underwent TAVR significantly increased (63.4% to 73.9%), whereas there was a consistent decrease in the proportion of patients with intermediate frailty (35.8% to 25.4%) (both $P < 0.01$ for the trend). However, the proportion of high-frailty patients during the same time period of the study remained at 0.7%. The frailty status identified patients at increased risk of inpatient mortality with increasing incidence from 0.9% among the lower-frailty group, 4.8% for intermediate, and 11.6% for the high-frailty group ($P < 0.05$). Similarly, the mean length of stay was much higher with increasing frailty status from 3.8 $\pm$ 3.7 days for lower frailty, 8.6 $\pm$ 8.4 days for intermediate-, and 18.8 $\pm$ 15.8 days for high-frailty status.



CONCLUSION There is a significant rise in the use of TAVR in patients with lower-frailty status over the last 7 years in the United States, reflecting the changing practice of TAVR becoming a preferential choice for aortic valve replacement. In patients with high frailty, TAVR is associated with significantly increased mortality.

CATEGORIES **STRUCTURAL:** Valvular Disease: Aortic

TCT-55

Lifetime Management of Patients With Symptomatic Severe Aortic Stenosis: A Computed Tomography Simulation of Serial Transcatheter Aortic Valve Replacements

Giorgio Medranda,[1] Cesar Soria Jimenez,[2] Brian Case,[3] Syed Ali,[3] Corey Shea,[4] Cheng Zhang,[5] Federico Asch,[6] Gaby Weissman,[2] Christian Shults,[7] Hector Garcia-Garcia,[8] Itsik Ben-Dor,[9] Lowell Satler,[3] Ron Waksman,[10] Toby Rogers[3]
[1]Medstar Washington Hospital Center, Brooklyn, New York, USA; [2]MedStar Washington Hospital Center, Washington, DC, USA; [3]MedStar Washington Hospital Center, Washington, DC, USA; [4]MedStar Washington Hospital Center, Washington, DC, USA; [5]MedStar Cardiovascular Research Network, Washington, DC, USA; [6]MedStar Health Research Institute, Washington, DC, USA; [7]MedStar Heart and Vascular Institute, Alexandria, Virginia, USA; [8]Washington Hospital Center, Chevy Chase, Maryland, USA; [9]MedStar Washington Hospital Center, Rockville, Maryland, USA; [10]MedStar Heart Institute, Washington, DC, USA

BACKGROUND Transcatheter heart valves (THVs) will inevitably degenerate. Redo transcatheter aortic valve replacement (TAVR) is an attractive strategy but carries a risk of coronary obstruction. We sought to determine whether coronary obstruction risk could be predicted before the first TAVR using computed tomography (CT) simulation.

METHODS We analyzed paired CT scans (baseline and 30 days post-TAVR) from patients in the LRT (NCT02628899, NCT03557242) trials and EPROMPT registry (NCT03423459). We implanted virtual THVs on baseline CTs, comparing predicted valve-to-coronary (VTC) distances to 30-day CT VTCs to evaluate the accuracy of CT simulation. We then simulated implantation of a second virtual THV within the first to estimate risk of coronary obstruction and need for leaflet modification.