results in increased 30-day mortality. Cerebral protection devices may reduce the stroke rate.

METHODS 133 patients underwent TAVR procedures using the Claret Cerebral Protection System (CPS; Claret Medical, Inc., Santa Rosa, CA) to guard against peri-procedural strokes. Various TAVR prostheses were used (55 Sapien 3, 36 Sapien/Sapient XT, 28 Corevalve/Evolut R, 8 Portico, 4 JenaValves, 1 Centera, 1 Direct Flow) as well as different access routes (transfemoral 119, transapical 8, transaxillary 6). In 21 cases, valve-in-valve procedures were performed in degenerated surgical aortic bioprostheses; 9 patients had a left atrial appendix (LAA) thrombus. Mean patient age was 80 ± 8 years; mean logistic EuroSCORE of 27 ± 18%. Clinical follow-up was obtained at 3 days after the intervention and at discharge (mean 10 days). Histological analyses were performed in 52 patients by the CVPath Institute in Gaithersburg, MD (42 additional analyses are still in progress).

RESULTS Stroke rate after TAVR was 2.3% (3/133) at 3 days post TAVR; all were major strokes. Sapien 3 (n=2) and Evolut R (n=1) prostheses had been used in these patients. In 2 patients the cerebral protection device was not positioned as intended (one malpositioning, one positioning not possible due to kinking of the truncus brachiocephalicus) and in 1 patient the device dislocated during peri-procedural resuscitation and additional defibrillation in the presence of LAA thrombus. Histological investigations showed debris in the filters in 96% of cases. Debris was more common in the distal (87%) than in the proximal filter (73%). Acute thrombus was the most common type of debris found in 56% of filters. In 30% of all cases, valve and arterial wall tissue and calcification was found. Organized thrombus was found in 12%, while foreign material was found in 7% of all cases. The percentages of different types of debris were similar in proximal and distal filters. Foreign material was captured in 13% and 17% (proximal/distal) of filters but was not present when using the Sapien 3 prosthesis.

CONCLUSIONS Feasibility and safety of the Claret CPS was documented in these 133 patients. Histopathological analyses showed high overall debris capture and retrieval rates, with prevalence of thrombus over valve and arterial wall tissue, calcification and foreign material. Sapien 3 implantations showed no foreign material in the filters. Procedural stroke rate was low at 2.3%, occurring only when the cerebral protection device was not properly placed. Stroke rate for optimally positioned devices was 0% in this registry, which included also patients with LAA thrombus and cardiogenic shocks. Further experience and investigation is needed to ensure optimal positioning, to quantify any reduction in new cerebral lesions using protection, and to define which patients are at the higher risk for cerebral embolization.

CATEGORIES ENDOVASCULAR: Stroke and Stroke Prevention

KEYWORDS Cerebral emboli, Histological analysis, TAVR

TCT-102

SAPIEN 3 implantation in failed surgical aortic bioprostheses: Matched comparison and Insights from the Valve-in-Valve International Data (VIVID) Registry

Moritz Seiffert,[1] Hendrik Treede,[1] Dominique Himbert,[2] Susheel Kodali,[3] David Jochheim,[4] Julinda Mehilli,[4] Matheus Simonato dos Santos,[5] Axel Linke,[6] Felix Woitek,[6] Giora Weisz,[7] Vinayak Bapat,[8] Zhan Yun Lim,[9] Didier Tchetche,[10] Sabine Bleiziffer,[11] Thomas Walther,[12] Marco Barbanti,[5] Helene Eltchaninoff,[13] Eric Durand,[13] Semih Buz,[14] Christian Frerker,[15] Stephan Windecker,[16] Mohamed Abdel-Wahab,[17] Konstantinos Spargias,[18] Arend de Weger,[19] Gudrun Feuchtner,[20] Webb John,[5] Danny Dvir[5]

[1]University Heart Center Hamburg, Hamburg, Germany; [2]Bichat Hospital, University of Paris, Paris, France; [3]Columbia, New York, United States; [4]University of Munich, Munich, Germany; [5]St. Paul's Hospital - University of British Columbia, Vancouver, British Columbia; [6]University of Leipzig, Heart Center, Leipzig, Germany; [7]Shaare Zedek Medical Center, Jerusalem, Israel; [8]St Thomas Hospital, London, United Kingdom; [9]London Chest Hospital, London, UK; [10]Clinique Pasteur, Toulouse, France; [11]German Heart Center Munich, Munich, Germany; [12]Kerckhhoff Heart Center, Bad Nauheim, Germany; [13]University Hospital of Rouen, Rouen, France; [14]German Heart Center Berlin, Berlin, Germany; [15]Asclepios Clinic St. Georg, Hamburg, Hamburg; [16]Bern University Hospital, Bern, Switzerland; [17]Heart Center, Segeberger Kliniken, Bad Segeberg, Germany; [18]Hygeia Hospital, Athens, Greece, Athens, Greece; [19]Leids Universitair Medisch Centrum, Leiden, Netherlands; [20]Innsbruck Medical University, Innsbruck, Austria

BACKGROUND Transcatheter aortic valve-in-valve (ViV) implantation into degenerated bioprostheses has become an alternative to reoperative aortic valve replacement. Remaining challenges relate to residual stenosis after implantation. We report on the first comprehensive analysis of clinical outcomes of SAPIEN 3 (S3) used for ViV and compare to early generation SAPIEN XT (SXT) balloon-expandable device.

METHODS A total of 404 ViV procedures using SXT or S3 balloon expandable devices from the Valve-in-Valve International Data (VIVID) registry were included. Groups were matched for baseline characteristics and surgical bioprosthesis size and type. Subsequently, a group of 48 patients that underwent S3 implantation was compared to a 2:1 matched group of 96 patients that underwent SXT implantation. Procedural and clinical outcomes were defined by Valve Academic Research Consortium II (VARC-II).

RESULTS Patients included in the matched groups had an average age of 75.6±11.1yrs and 56.9% were male. Failure mode was stenosis, regurgitation and the combination of both in 35.4%, 33.3% and 29.3%, respectively. Mean STS PROM was 9±7.4%. Average bioprostheses label size was similar between the groups: 23.7±1.8 mm (S3) vs. 24±2.1 mm (SXT), p=0.44. Small surgical valves (label size≤21mm) were apparent in 18.8% of S3 vs. 19.2% of SXT cases (p=0.88). Procedures were performed using transfemoral access in 87.5% (S3) vs. 80.2% of (SXT, p=0.28). Implanted transcatheter valve sizes were 23.6±1.3 mm (S3) vs. 24.6±1.9 mm (SXT, p=0.001). There was a trend towards lower 30-day mortality in the S3 group (0% vs. SXT 7%, p = 0.08). Rates of adverse events were low: coronary obstruction in 0% (S3) vs. 1.1% (SXT, p = 0.48), major stroke in 0% (S3) vs. 1.1% (SXT, p = 0.48). In patients without a permanent pacemaker at baseline, a trend towards higher rates of pacemaker implantation was observed after S3 ViV (8.3% vs. SXT 2.1%, p=0.08). Residual aortic regurgitation of more than mild degree was noticed in 2.1% (S3) vs. 9.5% (SXT, p=0.1) of patients. Mean gradients after implantation were similar: 18.1±8.4 mm (S3) vs. 17.6±9.2 mm (SXT, p=0.76), as was the rate of elevated post procedural gradients: ≥20mmHg 38.3% (S3) vs. 34.8% (SXT, p=0.69), ≥40mmHg 4.3% (S3) vs. 6.7% (SXT, p=0.56). The incidence of severe patient-prosthesis mismatch (32.4% [S3] vs. 28.1% [SXT], p=0.67) was similar but a trend towards greater effective orifice areas was observed after SXT implantation (1.4±0.4 mm [S3] vs. 1.5±0.5 mm [SXT], p=0.1).

CONCLUSIONS In this multicenter experience, excellent clinical outcomes with low complication rates were achieved after aortic ViV implantation with the S3 transcatheter heart valve. However, post-procedural gradients remained elevated with this second generation device and similar to early generation device, underlining the need for careful patient selection in order to avoid severe patient-prosthesis mismatch after ViV implantation.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI, TAVR, Valve-in-valve

TCT-103

National variation in post-TAVR antithrombotic therapy utilization and associated outcomes: Insights from the STS/ACC TVT Registry®

Matthew W. Sherwood,[1] Amit N. Vora,[2] Sreekanth Vemulapalli,[2] David Dai,[3] Sharif Halim,[2] Todd Kiefer,[2] G.C. Hughes,[1] J. Kevin Harrison[2]

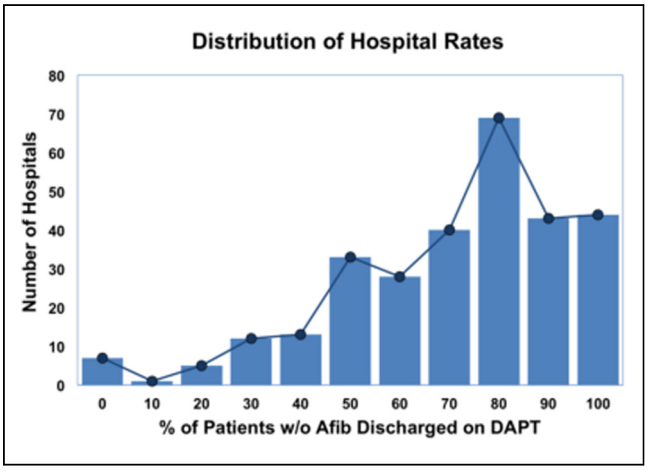
[1]Duke University, Durham, NC; [2]Duke University Medical Center, Durham, NC; [3]Duke Clinical Research Institute, Durham, NC

BACKGROUND Oral antiplatelet medications are routinely administered to patients following TAVR, however, there are limited data on the ideal antithrombotic treatment strategy or the patterns of medication use and outcomes in the U.S.

METHODS Using the STS/ACC TVT Registry we evaluated patients without pre-operative atrial fibrillation undergoing TAVR from 2011 to 2014. Clinical outcomes included death, bleeding, and stroke at 1 year of follow up.

RESULTS Overall, 5,974 patients treated at 298 hospitals were analyzed. Of these, 69% (n=4,132) were discharged on combined aspirin and a clopidogrel (DAPT), 28% (n=1,344) on aspirin alone, 5%(n=294) on clopidogrel alone, and 3% (n= 204) on no antiplatelet therapy. Antiplatelet prescribing patterns varied significantly at the hospital level (Figure). Patients discharged on DAPT were similar with respect to age (84 vs 84 years), gender (51.6% vs. 53.1% female), and most comorbid illnesses, but had higher rates of CAD (67.1% vs. 55.7%), and lower STS PROM risk scores (6.1 vs. 6.4). Regarding clinical outcomes, unadjusted 1 year death (13.3% vs. 16.5%; p<0.001) and bleeding rates (15.4% vs. 19.6%; p=0.001) were lower in patients prescribed DAPT after TAVR, while stroke rates were not

significantly different (3.4% vs. 4.3%; p=0.07) compared with those not prescribed DAPT.



CONCLUSIONS While the majority of TAVR patients in the U.S. receive DAPT therapy at hospital discharge, antiplatelet prescribing patterns varied significantly among US TAVR hospitals. Outcomes for DAPT treated patients were generally better than those not treated with DAPT, but further studies are needed to define the best antithrombotic medical treatment following TAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Antithrombotic therapy, Aortic stenosis, TAVR

TCT-104

Clinical Outcomes of Transcatheter Aortic Valve Replacement for Bicuspid Aortic Valve Stenosis

Sung-Han Yoon,[1] Thierry Lefevre,[2] Danny Dvir,[3] Jung-Min Ahn,[1] Takahide Arai,[4] Young-Hak Kim,[1] Yusuke Watanabe,[5] Paul Hsien-Li Kao,[6] Gerald Yong,[7] Wei-Hsian Yin,[8] Michael Kang-Yin Lee,[9] Edgar L. Tay,[10] Hyo-Soo Kim,[11] Bernard Chevalier,[2] Marie-Claude Morice,[12] Webb John,[13] Seung-Jung Park[1]

[1]Asan Medical Center, Seoul, Korea, Republic of; [2]ICPS, Massy, France; [3]St Paul's Hospital, Vancouver, Canada, Vancouver, Canada; [4]Institut cardiovasculaire paris sud, Massy, Paris; [5]Teikyo university school of medicine, Tokyo, Japan; [6]National Taiwan University Medical School, Taipai, Taiwan, Taiwan, Republic of China; [7]Royal Perth Hospital, Perth, Western Australia; [8]National Yang Ming University, Taipei, Taiwan, Republic of China; [9]Queen Elizabeth Hospital, Kowloon, China; [10]National University Heart Centre, Singapore, Singapore; [11]Seoul National University College of Medicine, Seoul, Korea, Republic of; [12]Institut Cardiovasculaire Paris Sud, Générale de Santé, Massy, France; [13]St Pauls Hospital, Vancouver, British Columbia

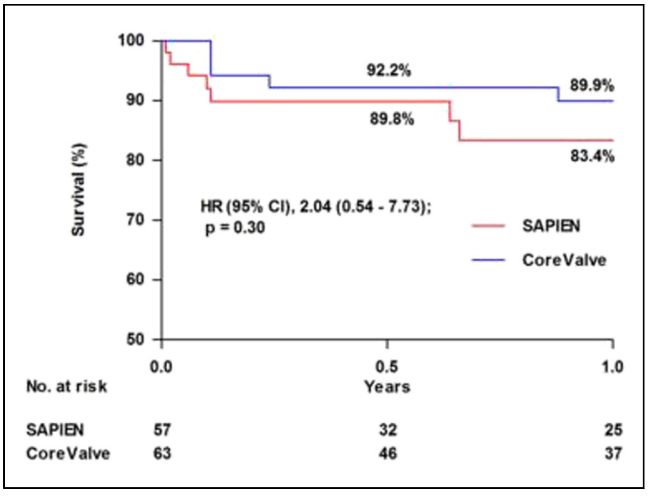
BACKGROUND Transcatheter aortic valve replacement (TAVR) has been established as alternative treatment for inoperable or high-risk patients with symptomatic severe aortic stenosis. However, TAVR for bicuspid aortic valve stenosis has been still relatively contraindicated and the clinical data of TAVR for bicuspid aortic valve has been limited. We sought to evaluate the clinical outcomes of TAVR for bicuspid aortic valve.

METHODS The Bicuspid TAVR registry was conducted in 9 centers from 7 countries in Asia, Europe and North America between March 2006 and February 2015. Baseline demographics, procedural and echocardiographic data were prospectively collected from each center and a joint database was created.

RESULTS One hundred and thirty-one patients were included. Mean age was 77.2 ± 9.4 years and 33.6% were female. Medtronic CoreValve, Edwards SAPIEN/XT and SAPIEN 3 were used in 48.9%, 43.5% and 5.3% of patients, respectively. Approaches were either transarterial (transfemoral, 78.6%; subclavian, 1.5%; direct aortic, 13.0%) or transapical (6.1%). Mean logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) and Society of Thoracic Surgeons (STS) score were 16.2 ± 12.5 and 5.3 ± 5.1, respectively. At 30 days, the incidence of all stroke, major vascular complications, life-threatening bleeding, and acute kidney injury (stage 2 or 3) were 1.6%, 4.6%, 4.6% and 3.8%, respectively. Paravalvular regurgitation moderate or greater occurred 6.3% in overall, 8.6% in CoreValve, 4.3% in SAPIEN/XT and 0.0% in SAPIEN 3. Rates of death at 30 days and 1 year were 4.1% and 12.7% for overall, 7.0% and 16.6% for SAPIEN/XT, and 1.6% and 10.1% for CoreValve, respectively. In multivariate analysis, age (hazard ratio, 1.17; 95% confidence interval: 1.01 - 1.35; p = 0.038) and creatinine (hazard ratio, 1.74; 95% confidence interval: 1.05 - 2.89; p = 0.03) were independent predictors of all-cause death.

Clinical Outcomes of TAVR for Bicuspid Aortic Valve Stenosis

	Overall (N = 121)	SAPIEN/XT (N = 57)	CoreValve (N = 64)	p value
Mortality at 30 days	5 (4.1%)	4 (7.0%)	1 (1.6%)	0.19
Mortality at 1 year	14 (12.7%)	8 (16.6%)	6 (10.1%)	0.31
All stroke	2 (1.7%)	1 (1.8%)	1 (1.6%)	0.99
Life-threatening bleeding	6 (5.0%)	2 (3.5%)	4 (6.3%)	0.68
Acute kidney injury stage 2 to 3	5 (4.1%)	4 (7.0%)	1 (1.6%)	0.19
Major vascular complication	5 (4.1%)	5 (8.8%)	0 (0.0%)	0.02
Aortic regurgitation moderate or greater	7 (6.7%)	2 (4.3%)	5 (8.6%)	0.08
Device success	111 (91.7%)	53 (93.0%)	58 (90.6%)	0.75
Safety endpoint at 30 days	98 (81.0%)	42 (73.7%)	56 (87.5%)	0.065



CONCLUSIONS This registry reflects the real-life experience of TAVR for bicuspid aortic valve stenosis.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Bicuspid aortic valve, TAVR

TCT-105

Transcatheter aortic valve implantation using a new second-generation TAVI system: J-ValveTM for high-risk patients with pure aortic regurgitation

Yingqiang Guo,[1] Da Zhu[1]

[1]West China Hospital, Chengdu, China

BACKGROUND Experience with transcatheter aortic valve implantation (TAVI) for severe aortic regurgitation is limited due to the risk of insufficient anchoring of the valve stent within the non-calcified aortic annulus. The aim of this study is to report the initial experience