device is designed to enable recapturability and repositionability, allowing exact positioning that is crucial in failing bioprostheses. We evaluate the acute outcome of degenerated small aortic bioprostheses treatment with the 23 mm Medtronic CoreValve Evolut R™.

METHODS From a total of 560 TAVI performed at our Institute, we selected 5 consecutive symptomatic patients with degenerated small aortic bioprostheses showing stenosis, regurgitation or combined failure. Patients (80 ± 5.5 years) had Logistic EuroSCORE of 29.1 ± 15.8 and STS score of 7.64 ± 6.2. Fast-track general anesthesia with TEE monitoring was used in all patients. All TAVI were performed by percutaneous transfemoral access using the 23 mm Medtronic CoreValve Evolut R™. After pre-closure with two ProGlide closure devices (Abbott Vascular), the EnVeo R™ 14 Fr-equivalent delivery system was introduced in the common femoral artery and precisely positioned under fluoroscopic guidance without pre-dilation inside the failed prostheses. The CoreValve Evolut R™ was then deployed without rapid ventricular pacing. Valve recapturing was performed in case of unsatisfactory positioning with the aim of obtaining minimum protrusion of the CoreValve Evolut R™ frame below the bioprosthesis implantation ring.

RESULTS Degenerated stented bioprostheses were one 21-mm Sorin Mitroflow, one 21-mm Carpentier Edwards, one 21-mm Carpentier Edwards Perimount, and two 19-mm Sorin Mitroflow. At MSCT, mean internal diameter was 17.7 mm. Baseline TTE parameters were: aortic valve area 0.67 ± 0.17 cm2, peak/mean aortic gradient 69.2 ± 20.3/44.8 ± 13.4 mmHg; aortic regurgitation was severe in one patient and moderate in two. After TAVI, aortic valve area increased to 1.34 ± 0.28 cm2, peak/mean aortic gradient decreased to 42.2 ± 12.9/23.8 ± 6.09 mmHg. Paravalvular leak was mild in three patients and moderate in one. No intra-procedural/in-hospital death, myocardial infarction, coronary obstruction, stroke and major vascular complications were observed.

CONCLUSIONS Valve-in-valve treatment of degenerated small aortic bioprostheses with the CoreValve Evolut R™ is feasible and safe. Despite a significant increase in aortic area and trans-aortic gradient in all patients, the mean echocardiographic gradient remained elevated.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS CoreValve, TAVI, Valve-in-valve

TCT-636

Self-Expanding TAVR in Patients with Low-Gradient, Low Output Aortic Stenosis: 12 Month Results from the CoreValve US Expanded Use Study

Stanley J. Chetcuti,[1] G. Michael Deeb,[1] Kimberly A. Skelding,[2] Alfred Casale,[3] Ron Waksman,[4] Ammar Bafi,[5] Jae K. Oh,[6] Steven Yakubov,[7] Michael J. Reardon,[8] David Adams,[9] Jeffrey Popma[10]
[1]University of Michigan, Ann Arbor, MI; [2]Geisinger Medical Center, Danville, United States; [3]Geisinger Medical Center, Danville, PA; [4]MedStar Washington Hospital Center, Washington, DC, United States; [5]Washington Hospital Center/Georgetown Hospital, Washington, DC; [6]Mayo Clinic College of Medicine, Rochester, MN; [7]OhioHealth Heart & Vascular Physicians - Riverside Methodist Hospital, Columbus, United States; [8]Houston Methodist DeBakey Heart & Vascular Center, Houston, United States; [9]The Mount Sinai School of Medicine, New York, United States; [10]Beth Israel Deaconess Medical Center, Boston, MA

BACKGROUND Self-expanding transcatheter aortic valve replacement (TAVR) is superior to medical therapy for patients with severe native valve aortic stenosis unsuitable for surgery. Its use in patients with low-gradient, low output aortic stenosis has not been prospectively studied.

METHODS The CoreValve US Expanded Use Study was a prospective, non-randomized, single-arm study that evaluated the safety and effectiveness of TAVR in complex subsets that included extreme risk patients with low-gradient low output (LGLO) aortic stenosis. LGLO was defined as Group A: mean gradient < 40 mmHg and peak velocity < 4 M/sec and resting LVEF ≥ 50%, or Group B: mean gradient < 40 mmHg and peak velocity < 4 M/sec and resting LVEF < 50% who did not augment with dobutamine. These results were compared with patients enrolled in the Extreme Risk cohort of the US Pivotal Trial, Group C: mean gradient < 40 mmHg and peak velocity < 4 M/sec and resting LVEF < 50% by resting echo, but who augmented with dobutamine, and Group D: mean gradient ≥ 40 mmHg or peak velocity ≥ 4 M/sec. The primary endpoint was a composite of all-cause mortality or major stroke rate at 12 months.

RESULTS 189 patients with attempted implant were enrolled between December 2012 and September 2014 in the Expanded Use Study (Groups A and B). Patients were elderly (81.8 ± 8.7 years), commonly men (56.6%) and were severely symptomatic (New York Heart Association class III or IV, 89.4%). The STS PROM was 9.9 ± 5.4%. CoreValve diameters included 23 mm (0.5%) 26 mm (22.9%), 29 mm (39.4%), and 31 mm (37.2%).

	Group A	Group B	Group C	Group D
KM rate (%) or Mean ± SD	N = 136	N = 50	N = 66	N= 550
Baseline mean gradient (mmHg)[1]	29.5 ± 4.5	25.1± 5.2*	28.8 ± 5.3[₮]	51.4 ± 12.9[ǂ]
Baseline aortic valve area, (cm^2)[1]	0.8 ± 0.2	0.8 ± 0.2	0.7± 0.3	0.6 ± 0.2[ǂ]
1 Year all-cause mortality or major stroke	26.5	27.6	43.9	27.3[ǂ]
1 Year all-cause mortality	22.2	27.6	39.4	25.8[ǂ]
1 Year major stroke	6.7	0.0	11.8[₮]	4.5[ǂ]
	N=44	**N=16**	**N=30**	**N=335**
1 Year effective orifice area (cm^2)[1]	1.8 ± 0.5	1.9 ± 0.5	1.5 ± 0.4[₮]	1.7 ± 0.5

[1]Site reported data for Groups A and B. Core lab data for Groups C and D. *P<0.05 A vs. B; [₮]P<0.05 B vs. C; [ǂ]P<0.05 C vs. D

CONCLUSIONS The use of CoreValve TAV in LGLO aortic stenosis at extreme risk for surgery was associated with a low 12-month mortality rate, and a significantly improved aortic valve area that was comparable to the results seen in the Pivotal trial.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic valve stenosis, Low-Flow, Flow-Gradient Aortic Stenosis, Transcatheter aortic valve replacement

TCT-637

Transcatheter Aortic Valve Implantation in Patients with Small Aortic Annuli Using the Edwards SAPIEN XT 20mm Balloon-Expanding Heart Valve: Early Clinical Results from A Multi-Center Registry

Rishi Puri,[1] Hardy Baumbach,[2] Harindra C. Wijeysundera,[3] Asim Cheema,[4] Ralf Mueller,[5] Simon Redwood,[6] Jonathan Byrne,[7] Helene Eltchaninoff,[8] Kaj-Erik Klaaborg,[9] Marc Pelletier,[10] Christophe Dubois,[11] Marc Ruel,[12] Marko P. Virtanen,[13] Verena Veulemans,[14] Jan-Malte Sinning,[15] Alfredo Giuseppe Cerillo,[16] Francesco Meucci,[17] Caterina Gandolfo,[18] Pieter R. Stella,[19] Roberto Blanco,[20] Matthias Gotberg,[21] Douglas F. Muir,[22] Jean-Paul Herzog,[23] Martin Thoenes,[24] Philippe Pibarot,[1] Emilie Pelletier Beaumont,[1] Josep Rodes-Cabau[1]
[1]Quebec Heart & Lung Institute, Quebec City, QC, Canada; [2]Robert-Bosch Krankenhaus Stuttgart, Stuttgart, Baden-Württemberg, Germany; [3]Sunnybrook Health Sciences Centre, Toronto, ON, Canada; [4]St. Michael's Hospital, Toronto, ON, Canada; [5]HELIOS Heart Center Siegburg, Siegburg, Germany; [6]King's College London/ St Thomas' Hospital, London, United Kingdom; [7]Kings College London, London, United Kingdom; [8]CHU de Rouen, Rouen, France; [9]Aarhus University Hospital, Aarhus N, Denmark; [10]New Brunswick Heart Center, Edmundston, NB, Canada; [11]University Hospital Leuven, Leuven, Belgium; [12]Ottawa Heart Institute, University of Ottawa, Ottawa, Ontario, Canada, Ottawa, Canada; [13]Heart Hospital, Tampere University Hospital, Tampere, Finland; [14]University Hospital, Düsseldorf, Düsseldorf, Germany; [15]Heart Center Bonn, University Hospital Bonn, Bonn, Germany; [16]Fondazione Toscana, Massa, Italy; [17]Careggi hospital, Florence, Italy; [18]Arnas Ospedale Civico Palermo, Palermo, Italy; [19]University Medical Center Utrecht, Utrecht, Netherlands; [20]Hospital de Cruces, Bilbao, Spain; [21]Lund University, Lund, Skane, Sweden; [22]James Cook University Hospital, Middlesborough, United Kingdom; [23]Edwards Lifesciences, Geneva, Switzerland; [24]Edwards Lifesciences, Nyon, Switzerland

BACKGROUND The combination of severe aortic stenosis (AS) with a small aortic annulus (SAA) presents a unique challenge to effectively treat either surgically or percutaneously. The 20mm SAPIEN XT (SXT) transcatheter heart valve (THV) is currently the smallest of its kind available for transcatheter aortic valve implantation (TAVI). We report the initial clinical outcomes and performance of this small THV.

METHODS Prospective data from a multi-center registry across 22 participating centers in Europe and Canada identified 36 patients with SAA who underwent TAVI with the 20mm SXT THV. Baseline and post-procedural clinical and echocardiographic outcomes were assessed.

RESULTS Mean age was 84±6 yrs, with a strong female preponderance (94%). The median (IQR) STS score was 8.7 (5.4, 12.2) %. Baseline mean aortic gradient, median (IQR) aortic valve area and mean annular dimensions were 49.5±17.6 mmHg, 0.50 (0.40, 0.60) cm2 and 18.5±1.6 mm respectively. Fifteen patients (42%) had a pre-existing aortic bioprosthesis measuring 19 (n=6), 21 (n=8) and 23 (n=1) mm, and these patients subsequently underwent valve-in-valve TAVI. The mean aortic annular diameter, as measured with computed tomography, in patients with native AS was 19.1±1.4 mm. A transfemoral approach was undertaken in 92% of cases, with successful implantation in all but 2 patients (6%), with no reports of procedural death, annular rupture or need for a second valve. Balloon post-dilatation occurred in 11% of cases. The incidences of in-hospital stroke, major vascular complication or death were 3, 11, and 6%, respectively. Overall, post-procedural mean transprosthetic gradient and median (IQR) valve areas were 17.7±8.1 mmHg and 1.10 (0.95, 1.30) cm2, respectively [native AS: 13.2±5.0 mmHg and 1.22 (1.15, 1.55) cm2; valve-in-valve: 24.0±7.5 mmHg and 0.98 (0.77, 1.10) cm2]. Moderate paravalvular regurgitation was evident in 1 patient.

CONCLUSIONS In patients with severe AS and SAA, TAVI with the 20mm SXT THV is technically feasible, providing satisfactory early clinical and hemodynamic results, with native valve TAVI yielding lower post-procedural gradients compared with valve-in-valve TAVI. Longer-term follow-up in a larger cohort, with clinical and hemodynamic comparisons against larger THV sizes implanted in correspondingly larger aortic annuli will be necessary to truly ascertain the feasibility of TAVI in severe AS patients with SAA.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Balloon-expandable, TAVI, TAVR

TCT-638

Rhythm Changes And Pacemaker Incidence Associated With a Repositionable Self Expanding TAVI System: A Prospective Multicenter Analysis

Ganesh Manoharan,[1] Axel Linke,[2] Helge Moellmann,[3] Christian Frerker,[4] A.J. van Boven,[5] Stephen G. Worthley,[6] Simon Redwood,[7] Jan Kovac,[8] Christian Butter,[9] Lars Sondergaard,[10] Gerhard Schymik,[11] Thomas Walther[12]
[1]Royal Victoria Hospital, Belfast, Belfast, United Kingdom; [2]University of Leipzig, Heart Center, Leipzig, Germany; [3]Kerckhoff Heart Center, Bad Nauheim, Germany; [4]Asclepios Clinic St. Georg, Hamburg, Hamburg; [5]Medisch Centrum Leeuwarden, Leeuwarden, Netherlands; [6]The University of Adelaide, Adelaide, Australia; [7]King's College London/ St Thomas' Hospital, London, United Kingdom; [8]University Hospital of Leicester, Leicester, United Kingdom; [9]Herzzentrum Brandenburg, Bernau, Germany; [10]MDSc, Copenhagen, Denmark; [11]Municipal Hospital Karlsruhe, Karlsruhe, Germany; [12]Kerckhhoff Heart Center, Bad Nauheim, Germany

BACKGROUND Incidence of rhythm changes and permanent pacemaker implantation post TAVI are variable and may differ depending on the device type. This report evaluates the incidence and associated circumstances of the rhythm disturbances observed with the St Jude Medical™ Portico™ Self Expanding TAVI system.

METHODS Rhythm information was collected as part of a prospective, single arm, multicenter study. Between December 2011 and May 2015, 198 TAVI patients were enrolled and treated at 12 sites in the UK, Germany, Netherlands, Denmark and Australia using the 18F and 19F Portico system with a 23mm (50), 25mm (50), 27mm (60) or 29mm (38) valve size. Rhythm changes during the procedure were recorded at baseline and at key steps during the implant procedure. Rhythm was recorded prior to wire passage through the valve, prior to pre-dilatation, immediately post-dilatation, prior to valve crossing, post valve deployment and at the end of the procedure. Rhythm was recorded during recovery and at all follow-up intervals.

RESULTS All 198 patients were successfully treated with the Portico system. The most common rhythm disturbances at baseline were AF (20%), LBBB (4%), and RBBB (2.5%). A total of 24 patients required a permanent pacemaker (PPM) post procedure, with complete heart block as the predominant reason (96%). Depth of implant, valve resheathing or post dilatation did not appear to impact on the need for PPM. There were 23 patients (13.5%) who developed a new LBBB during the procedure, with the majority occurring before valve deployment (73.9%). An additional 18 patients (11.1%) developed LBBB before discharge.

CONCLUSIONS The Portico TAVI system demonstrated a low rate of PPM implantation and induction of new LBBB post TAVI. There does not appear to be a consistent cause intra-operatively and further analysis is necessary to understand this phenomenon.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Pace maker implantation, TAVI

TCT-639

TAVI in local anesthesia without general anesthesia or deep sedation, a single center comparison of 30-day clinical outcome between balloon-expandable and self-expandable valves

Wolfgang Bocksch,[1] Martin Steeg,[2] Patrik Htun,[3] Michael Droppa,[4] Tobias Geisler,[5] Meinrad Gawaz,[6] Suzanne Fateh-Moghadam[7]
[1]Eberhard-karls-Universität Tübingen, Tubingen, Germany; [2]University Tuebingen, Tuebingen, Germany; [3]Zentralklinikum Augsburg, Augsburg, Germany; [4]University Hospital Tübingen, Tübingen, BW; [5]University Hospital Tübingen, Dept. Cardiology, Tübingen, Germany; [6]University Hospital Tübingen, Department of Cardiology, Tübingen, BW; [7]UC Tuebingen, Tuebingen, Germany

BACKGROUND Most centers perform transcatheter aortic valve implantation TAVI under general anesthesia (GA) or deep sedation (DS). TAVI under local anesthesia (LA) might result in less periprocedural episodes of hypotension, shorter procedure time and hospital stay. The aim of this study was to compare feasibility and clinical outcome after TAVI under LA using the self-expandable 18-F-CoreValve prosthesis (MCV) versus the 14-20F-balloon expandable Edwards Sapien XT/3 prosthesis (ESV).

METHODS Between April 2010 and October 2014, 570 consecutive pts underwent successfully transfemoral TAVI in LA exclusively without GA or DS receiving either MCV (23/26/29/31mm) or the ESV (23,26,29mm). Clinical events were evaluated according to the VARC-II criteria.

RESULTS Patients: 361 pts (age 80.6±0.34 years) with severe AS (pmean 43.1±0.77 mmHg, AVA 0.68 ± 0.01 cm2) and high surgical risk (log Euroscore 22.0± 0.67 %) underwent successfully TAVI with the MCV and 209 pts (age 81.7±0.41 years, log Euroscore 18.6±0.82 %, pmean 44.2±1.12 mmHg, AVA 0.68 ± 0.02 cm2) received the ESV Procedural outcome: Device success was 357/361 (98.9%) for MCV and 208/209 (99.5%) for ESV. Conversion to GA occurred in only 4/361 MCV pts., exclusively for complication (1 coronary obstruction, 2 severe AR, 1 prosthesis embolisation with urgent surgery) and in 0 pts after ESV. Conversion to DS occurred in 16/361 (4.4%) MCV pts. and in 5/209 (2.4%) ESV pts. Use of vasopressors were needed in 19/361 (5.2%) MCV pts. and in 6/209 (2.9%) ESV pts. In-lab-death and In-lab stroke rate was 0% in both groups. 30-day clinical outcome: 30 day all-cause mortality and major/minor stroke rate did not differ significantly between valves (death: MCV vs ESV: 5.5% vs 2.4%; p=0.052;major stroke: MCV vs ESV: 0.8% vs. 2.4%; P=0.273. minor stroke: MCV vs ESV: 0.8% vs. 0.5; p=0.273.). There was no significant difference between the two valve types concerning major vascular complication (MCV vs ESV: 4.7% vs. 7.9%; p=0.082. The rate of new pacemaker implantation was significantly different (MCV vs ESV: 24.4% vs 14.4%, p<0.01).

CONCLUSIONS Transfemoral TAVI using LA only is feasible and save in an all-comer TAVI-population using either selfexpandable or balloon-expandable transcatheter heart valves.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic disease, Local anesthesia, TAVI

TCT-640

Clinically silent pseudoaneurysms after transcatheter aortic valve implantation (TAVI) using the ProStar XL system-comparison between the CoreValve, the Edwards Sapien XT and the Edwards Sapien 3 Valve

Suzanne Fateh-Moghadam,[1] Rezo Jorbenadze,[2] Antonios Kilias,[2] Michael Droppa,[3] Patrik Htun,[4] Meinrad Gawaz,[5] Wolfgang Bocksch[6]
[1]UC Tuebingen, Tuebingen, Germany; [2]University Tuebingen, Tuebingen, Germany; [3]University Hospital Tübingen, Tübingen, BW; [4]Zentralklinikum Augsburg, Augsburg, Germany; [5]University Hospital Tübingen, Department of Cardiology, Tübingen, BW; [6]Eberhard-karls-Universität Tübingen, Tubingen, Germany

BACKGROUND Transfemoral aortic valve implantation (TAVI) requires large bore catheters. Access site and vascular complications,