TCT-845
Transcatheter Aortic Valve Implantation with Edwards SAPIEN XT™ versus Medtronic CoreValve Revalving System® with AccuTrak™: The SAPERE Pilot Study
Gill Buchanan1, Alaide Chieffi2, Matteo Montorfano1, Francesco Maisano1, Azem Latib1, Micaela Cioda1, Mauro Carlino1, Filippo Foggi1, Irene Franzoni1, Alessandro Durante1, Annalessa Franci1, Remo Covello1, Chiara Gerli1, Eustachio Agneta1, Giovanni La Canna1, Pietro Spagnolo1, Orlando Alfieri1, Antonio Colombo1
1San Raffaele Scientific Institute, Milan, Italy, 2San Raffaele Scientific Institute, Milano, Italy

Background: To our knowledge no data exists comparing new generation commercially available devices for transfemoral (TF) transcatheter aortic valve implantation (TAVI).

Methods: All consecutive patients from our single-center prospective registry with AS treated with TF-TAVI with Medtronic CoreValve™ (MCV) vs. Medtronic CoreValve™ (MCV) with AccuTrak™ delivery system (MCVAT) when the devices became commercially available were included. The study endpoints were followed by the Valve Academic Research Consortium (VARC) definitions.

Results: In total, 235 patients treated in our center by TF TAVI for severe AS were included: 142 (60.4%) underwent SXT vs. 93 (39.6%) MCVAT. More females (60.6% vs. 43.0%; p = 0.008) and smaller annulus size (23.2 ± 1.9 vs. 24.3 ± 2.0; p < 0.001) were present in the SXT group. There were no differences between valves in 30-day combined safety endpoint (SXT 26.1% vs. MCVAT 29.7%; p = 0.558), all-cause mortality (3.1% vs. 6.0%; p = 0.326), moderate or severe aortic regurgitation (2.3% vs. 5.4%; p = 0.214), myocardial infarction (1.4% vs. 2.2%; p = 0.683) or stroke (0.7% vs. 1.1%; p = 0.774). Additionally, no differences were observed in life-threatening bleeding (12.4% vs. 20.4%; p = 0.100) or major vascular complications (12.0% vs. 9.7%; p = 0.583). Conversely, with SXT there was a lower occurrence of conduction disturbances/arrhythmia (16.5% vs. 37.0%; p = 0.001) and pacemaker implantation (5.8% vs. 33.3%; p < 0.001) was observed with SXT. At median follow-up of 328 (IQR 83–401) days, there was no difference in combined efficacy endpoint (4.8% vs. 9.8%; p = 0.265) or mortality (8.0% vs. 6.5%; p = 0.654).

Conclusions: In our single center experience, there was a lower incidence of arrhythmia and pacemaker, with higher device success with SXT. Differences in the characteristics of the patients treated with each valve may explain some of these findings.

TCT-844
Clinical Outcome Of Patients With Low-Flow, Low-Gradient Aortic Stenosis After Transcatheter Aortic Valve Implantation
Jury Schewel1, Dmitry Schewel2, Christian Frekker3, Thomas Thielen3, Felix Meinke1, Felix Kreidel1, Karl-Heinz Kuck1, Ulrich Schäfer1
1Aeskülos Klinik St. Georg, Hamburg, Germany, 2Asclepios Clinic St. Georg, Hamburg, Hamburg

Background: Previous studies showed that patients with impaired left ventricular (LV) function and low-flow, low-gradient (LFLG) aortic stenosis (AS) are associated with high operative risk and poor long-term outcome after surgical aortic valve replacement. The aim of this study was to investigate the clinical outcome of LFLG AS after transcatheter aortic valve implantation (TAVI).

Methods: 450 consecutive patients in high operative risk underwent TAVI with the Medtronic CoreValve (MCV) prosthesis and the Edwards SAPIEN-valve (ESV) after valve-in-valve implantation (ViVi).

Results: A total of 24 pts (70.8% male, aged 72.6±6.7 years, mean logES 32.2±19.4%) underwent a transfemoral transcatheter ViVi for a failing aortic xenograft at our institution. Due to the high frequency of small surgical valves (outer diameter - OD - 21mm: n = 11; 23mm n = 8; 25mm n = 2; ≥27mm n = 3) ViVi was predominantly done with the MCV (17pts; 71%) compared to ESV (7pts: 29%; Edwards Sapien n = 2, Sapien XT n = 5).

Background: Procedural success rate was 87.5%, with 1 pt. displaying moderate aortic regurgitation (deep implanted MCV) and 2 pts. in need of a second MCV due to valve embolisation into the ascending aorta (after attempting a high implantation within small surgical xenografts, both with an OD of 21mm). Thirty-day-mortality was 0%. The average mean aortic valve gradient (ΔPmean) decreased significantly after ViVi (30.6±14.1 mmHg vs. 26.9±11.9 mmHg; ΔPmean < 0.05). The significantly higher gradient with ESV vs. MCV after ViVi into xenografts with an OD of ≤23mm was confirmed by comparison of pooled and recently published data of n = 64 ESV (Pmean 17.8±8.4 mmHg; p < 0.001).

Conclusions: The low 30d mortality suggests that percutaneous transcatheter ViVi-procedures for failing bioprosthetic aortic valves is an effective treatment option for high-risk surgical patients. The MCV should be considered as the first choice in small surgical xenografts (OD ≤23mm) due to lower remaninig transvalvular gradients. Nevertheless, the more demanding implantation with MCV indicates that a smaller MCV-prosthesis (i.e. 23mm) is urgently needed to increase the safety of ViVi.

TCT-847
Acute assessment of transcatheter aortic valve performance after implantation into degenerated aortic surgical bioprostheses
Ulrich Schäfer1, Christian Frekker1, Dmitry Schewel2, Thomas Thielen3, Felix Kreidel1, Karl-Heinz Kuck1
1Aeskülos Klinik St. Georg, Hamburg, Germany, 2Asclepios Clinic St. Georg, Hamburg, Hamburg

Background: Transcatheter aortic valve implantation into failing aortic xenografts is increasingly accepted as a new treatment option for patients in need of re-do open heart surgery. Aim of the study was to compare the acute transcatheter hemodynamics between the Medtronic Corevalve (MCV) prosthesis and the Edwards SAPIEN-valve (ESV) after valve-in-valve implantation (ViVi).

Methods: A total of 24 pts (70.8% male, aged 72.6±6.7 years, mean logES 32.2±19.4%) underwent a transfemoral transcatheter ViVi for a failing aortic xenograft at our institution. Due to the high frequency of small surgical valves (outer diameter - OD - 21mm: n = 11; 23mm n = 8; 25mm n = 2; ≥27mm n = 3) ViVi was predominantly done with the MCV (17pts; 71%) compared to ESV (7pts: 29%; Edwards Sapien n = 2, Sapien XT n = 5).

Background: Procedural success rate was 87.5%, with 1 pt. displaying moderate aortic regurgitation (deep implanted MCV) and 2 pts. in need of a second MCV due to valve embolisation into the ascending aorta (after attempting a high implantation within small surgical xenografts, both with an OD of 21mm). Thirty-day-mortality was 0%. The average mean aortic valve gradient (ΔPmean) decreased significantly after ViVi (30.6±14.1 mmHg vs. 26.9±11.9 mmHg; ΔPmean < 0.05). The significantly higher gradient with ESV vs. MCV after ViVi into xenografts with an OD of ≤23mm was confirmed by comparison of pooled and recently published data of n = 64 ESV (Pmean 17.8±8.4 mmHg; p < 0.001).

Conclusions: The low 30d mortality suggests that percutaneous transcatheter ViVi-procedures for failing bioprosthetic aortic valves is an effective treatment option for high-risk surgical patients. The MCV should be considered as the first choice in small surgical xenografts (OD ≤23mm) due to lower remaninig transvalvular gradients. Nevertheless, the more demanding implantation with MCV indicates that a smaller MCV-prosthesis (i.e. 23mm) is urgently needed to increase the safety of ViVi.
Methods: From November 2007 to December 2011, 384 patients underwent TAVI in our center [233 Edwards and 151 CoreValve]. 74 were treated with post dilatation for residual AR following valve implantation. In this study, 68 were analyzed after excluding 6 patients due to unavailable data.

Results: Mean age was 79 ± 6.2 yrs. Male gender was 42 (61.7%). Mean logistic Euroscore and STS score were 25.2 ± 17.3 and 9.1 ± 9.1, respectively. Mean grades of aortic regurgitation at baseline, before and after post dilatation were 1.3 ± 1.1, 2.3 ± 0.7 and 0.8 ± 0.6, respectively. CT scan analysis showed annular coronary diameter 26.2 ± 2.0mm, sagittal diameter 22.2 ± 3.1mm, mid-sinusual diameter 36.3 ± 4.8mm, sinustubular junction 27.7 ± 5.9mm, annular eccentricity index 0.9 ± 0.1. Mean number of calcified commissures 1.9 ± 1.1, mean number of annular calcium spots 2.3 ± 1.2. Edwards valve was used in 13 (19.1%), while CoreValve in 55 (80.8%). Mean valve size was 27.1 ± 2.2 mm. Mean balloon size was 25.6 ± 2.3mm. Postdilatation was effective in reducing AR by 1 grade in 42 patients (79%). Effective post dilatation was achieved in 100% of patients with a “post dilatation balloon diameter/coronal diameter ratio” 0.85-1.07. Outcome of post dilatation was not influenced by the annular eccentricity index. AR following postdilatation was more in patients with heavily calcified annulums. 1 patient (1.5%) had annular tear following post dilatation. 30 days echocardiographic follow up showed 1:1:0:9 AR.

Conclusions: Effectiveness of post dilatation is multifactorial and depends mainly on the proper choice of the balloon size, which in terms depends on the annular coronal diameter assessed by CT scan. Since commissural calcification and annular eccentricity index don’t influence the outcome of post dilatation, there is no need for aggressive postdilatation to reduce AR after valve implantation.

TCT-848
Clinical Impact Of Paravalvular Leaks On Biomarkers And Survival After Transcatheter Aortic Valve Implantation.

Dmitry Schewel1, Christian Freyer1, Jury Schewel1, Felix Meinke1, Thomas Thietner1, Klaus Blaschke1, Felix Kreidel1, Karl-Henz Kuck1, Ulrich Schäfer1
1Asklepios Klinik St. Georg - University of Hamburg, Hamburg, Germany

Background: There is accumulating evidence that up to 20 % of the implanted devices after TAVI are associated with a significant degree of paravalvular leaks (PVL), but the clinical impact of PVL is still insufficiently explored.

Methods: A total of 355 patients with severe aortic valvular stenosis (AVS) were treated by TAVI (Corevalve n = 222, Edwards Sapien n = 133). Survival, NT-pro-BNP and the grade of PVL were quantified up to 12 months after implantation.

Results: Technical success rate was 97 %. Thirty-day mortality was 9.6%. Post-procedural transvalvular aortic regurgitation was seen only in a minority of cases (5%), whereas PVL were frequently observed (grade 1 in 58.2%, grade 2 in 33.9%, and grade 2+ in 7.9%). There was a clear relation-ship between PVL and adverse outcome (p < 0.001). After a transient increase NT-pro-BNP showed a significant decline. Interestingly, a PVL ≥ 2+ was associated with a much higher rise in NT-pro-BNP compared to the other groups (p < 0.01), and a post-procedural increase in NT-pro-BNP by more than 1640ng/L was associated with a significant increase in rate of death (p < 0.01).

Conclusions: TAVI is an efficient treatment option for high-risk patients with severe AVS. The incidence of PVL is an unacceptable clinical problem and still insufficiently recognized. Serial measurement of NT-pro-BNP can be used for risk-stratification in patients with a significant PVL. In general, PVL grade ≥2+ is associated with a dramatically increased 6-month mortality. Therefore, any action to fight against parapro-sthetic regurgitation is highly recommended.

TCT-849
Predictive reliability of logistic EuroSCORE II in patients undergoing transcatheter aortic valve implantation: assessment and comparison to classic systems of preoperative risk stratification

Lenard Conradi1, Miriam Silaschi1, Renate Schnabel1, Moritz Seiffert1, Gerhard Schön1, Patrick Diemer1, Johannes Schirmer1, Stefan Blankenberg1, Hermann Reichenspuner2, Hendrik Treede2, Stephan Böhm2, Michael Gehrke2, Thomas Schubert1,1University Heart Center Hamburg, Hamburg, Germany, 2Department of Medical Biometry and Epidemiology, Hamburg, Germany, 3University Heart Center Hamburg, Ham, Hamburg, 4Hamburg University, Hamburg, Germany, 5University Heart Center Hamburg, Hamburg, Hamburg

Background: The logistic European System for Cardiac Operative Risk Evaluation (logEuroSCORE II) has been introduced to improve prediction of acute mortality in cardiac surgery. No specific tools exist for evaluation of patients undergoing transcatheter aortic valve implantation (TAVI). We assessed predictive ability of the logEuroSCORE II for perioperative mortality after TAVI and compared it to four other systems of preoperative risk evaluation.

Methods: 300 consecutive patients (age80±7.7years,59.5%female) undergoing TAVI using Edwards Sapien (XT) devices were entered into a prospective dedicated database. Preoperative risk stratification was performed using logEuroSCOREs I and II, Society of Thoracic Surgeons (STS), Amblé and Parsonnet Scores. Validity of scores was assessed by receiver-operator curves (ROC) and resulting area under the curve (AUC).

Results: Observed 30-day mortality in our sample was 10.7% (32/300). Calculated scores were: logEuroSCORE I mean22.8%, CI0.1-0.426, logEuroSCORE II mean 7.3%, CI0.064-0.081, STS mean 8.6%, CI0.077-0.095, Amblé mean 6.3%, CI0.057-0.070, Parsonnet mean 22.5%, CI0.209-0.241. ROC analysis revealed none of the tested systems to possess adequate predictive value for acute mortality following TAVI logEuroSCORE I AUC0.57, CI0.45-0.69, logEuroSCORE II AUC0.58, CI0.47-0.70, STS AUC0.59, CI0.47-0.71, Amblé AUC0.55, CI0.41-0.65, Parsonnet AUC0.51, CI0.38-0.64. To estimate accuracy (sum of true-positive and true-negative predictions), Youden-indices (maximum of sensitivity and specificity) were calculated and used to determine thresholds for classification of scores as false/true. Derived accuracy was low, ranging between 34.0%(Amblé) and 52.2%(logEuroSCORE II).

Conclusions: None of the tested risk stratification systems including the new logEuroSCORE II provided adequate prediction of acute mortality in our large routine TAVI cohort. Likely, scoring systems derived from classic cardiac surgery databases are inadequate for risk prediction in TAVI patients. Therefore, specific risk models are needed for high-risk patients undergoing TAVI. Until these are available, evaluation of perioperative risk has to rely on interdisciplinary clinical judgment of individual patient factors.

TCT-850
Early Clinical Outcome of Transcatheter Valve-In Valve Implantation in The Nordic Countries

Leo Ilbberg1, Alexander Wahbe2, Henrik Nissen3, Nielsen Niels-Henrik4, Andreas Ruck5, Rolf Busand6, Kai-Erik Klauborg7, Lars Soendergaard7, Jan Harnek5, Heikki Miettinen9, Markka Eskola11, Mika Laine1
1Helsinki University Hospital, Helsinki, Finland, 2St. Elisabeth, N.A., 3Odense University Hospital, Odense C, Denmark, 4Linköping University Hospital, Linköping, Sweden, 5Karolinska University Hospital, Stockholm, Sweden, 6Tromsø University Hospital, Tromso, Norway, 7Aarhus University Hospital, Aarhus N, Denmark, 8Rigshospitalet, Copenhagen, Denmark, 9Aars University Hospital, Lund, Lund, Sweden, 10Kaupio University Hospital, Kuopio, Finland, 11Tampere Heart Center, Tampere, Finland

Background: Transcatheter valve-in-valve implantation (ViV-TAVI) has emerged as a potential option in addition to reoperative surgical aortic valve replacement to treat failed biological heart valve substitutes, however with limited experience. Herein we report the comprehensive experience of ViV-TAVI in the Nordic countries from May 2008 to January 2012.

Methods: A total of 49 ViV-TAVIs (45 aortic, 2 mitral and 2 tricuspid) were performed during this time period in 11 centers. For the aortic ViVs, the mean age of patients was 80.6 (61-91) years (M 26.9 ± 19) and mean Euroscore, Euroscore II and STS scores were 35.4, 16.3 and 14.6, respectively. The type of failure was stenosis/combined in 58% (mean peak aortic valve gradients 77 and 45 mmHg) and regurgitation 42% of cases. The SapienXTR (Edwards Lifesciences, Irvine, CA) and CoreValve® (Medtronic Inc, Minneapolis, MN) system was used in 33 and 12 cases, respectively. The access routes were transapical in 25, transfemoral in 17, transaortic in 2 and subclavian in one case. The mean follow-up was 10.6 months. The periprocedural and postoperative outcome was assessed according to the VARC criteria.

Results: There was no intraoperative mortality. The technical success rate was 95.6% (one 2nd valve implantation, one conversion to open surgery). All-cause 30-day mortality was 4.4% (one cardiac-related, one aspiration pneumonia). Major complications within 30 days were seen in 2.2%, periprocedural MI in 4.4% and major vascular complication in 3.2%. At 1 month 86.7% of the patient had either no or mild paravalvular leaks compared with mean and peak valve gradients of 17(4-38) and 30(7-68) mmHg, respectively. The mean gradient was > 20 mmHg in 17% of patients; that remained unchanged at 12 months. The 1-year survival was 85.2%.