

CONCLUSIONS As a result of size reduction of the delivery system and changes in the 3D sizing guidelines, the new third generation SAPIEN 3 device can be implanted in the majority of TAVR patients. Thus, significant more TAVR patients can benefit from an aortic valve replacement with the new SAPIEN 3 device. Within our cohort, implantation of the new SAPIEN 3 device resulted in excellent procedural and short-term outcomes.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-680

Pre-Procedural Work-up process In Patients Undergoing Transcatheter Aortic Valve Implantation: Results From The Written (WoRlDwide TAVI ExpieNce) Survey

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BACKGROUND Transcatheter aortic valve implantation (TAVI) has been worldwide adopted, but there are still several areas where consensus and evidence are lacking. Pre-procedural work-up process is essential to determine eligibility and predict outcomes, but may vary across centers. The objectives were to determine the real life practice related to pre-procedural TAVI planning across different centers around the world.

METHODS From January to May 2015, an online survey was distributed worldwide in centers performing TAVI regardless the number of procedures and valve type. There was a responsible to distribute the survey for each country or region.

RESULTS A total of 167 centers (including 37843 TAVI procedures) responded the questionnaire from 27 different countries in Europe, North-America and South-America. Heart team meetings were regularly scheduled in most of the centers (>95%) with high participation of interventional cardiologist (95%) and cardiac surgeon (94%), but low involvement of other specialists (radiologists 16%; internists/geriatrias 14%). While one or two surgical risk scores were used in 99% and 65% of the centers, respectively; frailty (37%), quality of life (23%) or 6 minute walking (3%) assessments were rarely performed. Moderate or low risk patients represent 20% of the TAVI candidates. Cardiac-CT was the preferred imaging study for annulus measurements and valve sizing (87%). Finally, concomitant severe coronary artery disease (CAD) was treated before or during the TAVI procedure in 79% and 4% of centers, and 3% of centers did not treat systematically significant CAD in TAVI candidates.

CONCLUSIONS In the real-world practice, up to one-fifth of patients undergoing TAVI are considered at moderate or low surgical risk. While the role of the Heart Team on the clinical-decision making process is well established, the involvement of other non-cardiovascular specialists remains anecdotic. Cardiac CT scan is the "gold standard" for annulus assessment and valve sizing, and significant CAD is treated before the TAVI procedure in the majority of centers.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-681

Aggressive oversizing of balloon-expandable transcatheter aortic valve replacement: predictor of para valvular leak with severe aortic valvar complex calcification

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BACKGROUND Higher calcification of the aortic valve complex increases the risk of post-dilatation and paravalvular leak (PVL) after transcatheter aortic valve replacement (TAVR). The role of aggressive oversizing as a predictor of PVL post TAVR is not well understood. The aim of this study was to evaluate the association between degree of aortic valve complex calcification and PVL after aggressive oversized balloon-expandable TAVR.

METHODS Between January 2013 and April 2015, a total of consecutive 347 patients with severe aortic stenosis underwent TAVR (Sapien=70 or XT=270) and had suitable contrast cardiac CT. Aggressive oversizing was defined as over 20% of area oversizing. A region of interest for calcium volume included the total leaflet region - the area from the annulus to leaflet tips and left ventricular outflow tract (LVOT) region- the area from the annulus to 5 mm inferior to it. Annular device landing zone (ALZ) consisted of the area from the annulus to 3 mm superior to it and 2 mm inferior to it. Aortic valve complex was also divided by each leaflet sector. Calcium (CA) scoring was set at 850 Hounsfield Unit threshold. Post procedural PVL was evaluated by transthoracic echocardiography at 30-days.

RESULTS Of 347 patients, aggressive oversizing was performed in 133 patients (38.3%). From these patients, 31 patients (23.3%) had PVL \leq mild (25 patients) or moderate PVL \leq (6 patients). One patient had aortic annulus injury. Mean total leaflet CA, ALZ CA, and LVOT CA were 160.9 mm³, 24.2mm³, and 0.4mm³, respectively. ALZ CA, left coronary cusp (LCC)-ALZ CA, and LCC-LVOT CA were higher in PVL (41.8 \pm 49.7 mm³ vs. 18.9 \pm 30.4 mm³; p=0.02, 22.1 \pm 28.8 mm³ vs. 8.5 \pm 16.6 mm³; p=0.016, 17.3 \pm 24.3 mm³ vs. 6.0 \pm 21.7 mm³; p=0.025, respectively). In receiver operator characteristic curve analysis, LVOT CA and LCC-LVOT CA were predictor of PVL (area under the curve (AUC) =0.739; 95% confidence interval (CI) 0.638-0.840; p <0.001, AUC=0.704; 95% CI 0.592-0.816; p=0.001, respectively).

CONCLUSIONS Of aortic valvular complex calcification, LVOT volume was the strongest predictor for PVL after aggressive oversizing balloon-expandable TAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Paravalvular leak, Predictors, TAVR

TCT-682

Impact of concomitant mitral regurgitation on mortality after transcatheter aortic valve replacement for severe aortic stenosis in high risk patients - results from a prospective single center registry

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BACKGROUND Transcatheter aortic valve replacement (TAVR) enables treatment of inoperable and high risk patients with severe aortic stenosis. Impact of concomitant mitral regurgitation (MR) on outcome in patients undergoing TAVR appears to be unclear. Therefore, it was aim of this study to evaluate the impact of MR on outcome after TAVR.

METHODS Patients with severe aortic stenosis, in which TAVR was performed between 2006 and 2014 were included into the analysis. MR was measured by echocardiography at baseline, 30 days and at one year, 30-day and 1-year mortality was calculated.

RESULTS Between January 2006 and May 2014 a total of 1530 consecutive patients (Age 80.3 \pm 5.9 years, Logistic EuroScore 20 \pm 13%, STS PROM 8.5 \pm 6.2%) with severe aortic stenosis were treated with TAVR at our institution. At baseline 178 (10.3%) of these patients presented with no MR, 1173 (68.2%) with mild MR (grade 1), 171 (9.9%) with moderate MR (grade 2) and 9 (0.5%) with severe MR (grade 3). Patients with moderate to severe MR showed significantly higher

mortality rates compared to patients with no or mild MR at 30 days (12.2% vs. 6.2%, $p=0.003$) and at one year (26.1% vs. 20.1%, $p=0.046$). Mortality was lower in patients that were additionally treated with MitraClip® system for concomitant moderate to severe MR.

CONCLUSIONS Pre-existing moderate or severe mitral regurgitation is associated with an 97 % higher mortality at 30 days and 30 % higher mortality at one year as compared to patients with no or mild MR. Larger outcome studies are necessary to investigate whether additional treatment of MR in patients with concomitant moderate to severe MR will improve the prognosis in a TAVR population.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Mitraclip, Mitral regurgitation, TAVR

TCT-683

Early Stroke After Implantation of a Self-Expanding Transcatheter Aortic Valve Prosthesis: Experience From the CoreValve Clinical Trials

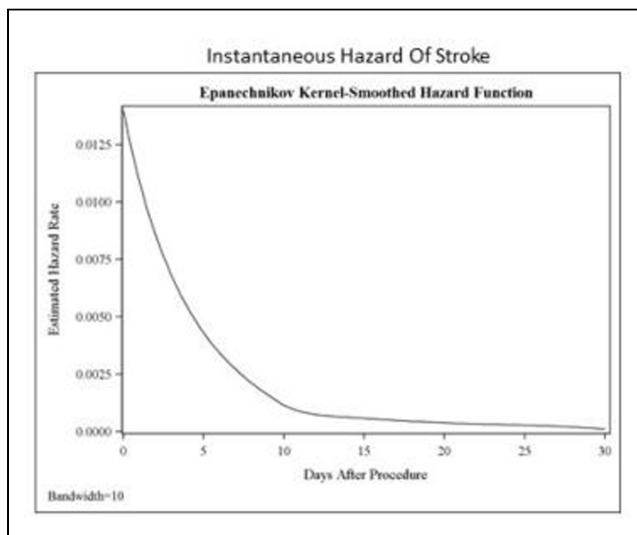
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BACKGROUND Risk of stroke after TAVR is a persistent concern; identification of stroke predictors would be of use in patient selection.

METHODS We examined the frequency and predictors of stroke among patients in the 2 CoreValve US Pivotal IDE trials and 2 Continued Access studies. Patients were followed prospectively. All patients underwent physical exam and evaluation with the NIHSS at baseline, 24 h, hospital discharge, 30 d, and 1 y postprocedure. Neurologic events lasting >24 h or with concordant imaging abnormalities were classified as strokes. Modified Rankin Scale >2 defined major stroke. All rates are K-M estimates. Instantaneous stroke hazard was modeled with the Epanechnikov kernel-smoothing function at a bandwidth = 10 points. Three predictive models were constructed using Cox Proportional Hazard functions (clinical parameters alone; clinical and imaging characteristics; clinical, imaging, and procedural characteristics).

RESULTS 3687 patients (3581 person-y) were included. Stroke occurred <30 d in 174 (4.8%) and <1 y in 270 (8.4%); major stroke occurred in 2.8% and 5.0%, respectively. All-cause mortality at 1 y was 45.1% for stroke patients and 63.2% for major stroke patients. Instantaneous hazard analysis showed an early inflection point at 10 d (Fig); 147 (4.1%) strokes occurred in this period. Clinical predictors of early stroke were total NIHSS >0 (HR=1.50), PVD (HR=1.44), prior TIA (HR=2.48), no prior CABG (HR=1.72), angina (HR=1.64), BMI<21 kg/m² (HR=2.14), and falls <6 mo (HR=1.73). Addition of imaging parameters did not change clinical predictors, but further addition of procedural parameters added predictors: rapid pacing during valvuloplasty (HR=9.9), total procedure time (HR=1.003), and total time delivery catheter in body (HR=1.011). Postimplant balloon dilation did not increase early stroke risk; non-iliofemoral access was of marginal significance (HR=0.668, $P=0.058$).



CONCLUSIONS In this first prospective examination of stroke after TAVR within a series of large trials, we observed a biphasic frequency of stroke with an early hazard occurring <10 d. Clinical predictors were largely indicators of prior atherosclerotic vascular disease and frailty indices. Readily available imaging parameters contributed little, and procedural parameters reflected the complexity of the procedure. Further refinement of imaging techniques may be of help in future prediction of early stroke.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Stroke, TAVR, Transfemoral aortic valve replacement

TCT-684

Approach and Procedural Management in Patients Undergoing Transcatheter Aortic Valve Implantation: Results From The Written (Worldwide TAVI Experience) Survey

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BACKGROUND Transcatheter aortic valve implantation (TAVI) has been worldwide adopted but there are still multiple areas where consensus and evidence are lacking. Different approaches, techniques and imaging tools are actually implemented during the procedure with several differences according to local clinical practice. The objectives were to determine the real life practice related to procedural techniques used during TAVI across different centers around the world.

METHODS From January to May 2015, an online survey was distributed worldwide in centers performing TAVI regardless the number of procedures and valve type. There was a responsible to distribute the survey for each country or region.

RESULTS A total of 167 centers (including 37843 TAVI procedures) responded the questionnaire from 27 different countries in Europe,