CONCLUSIONS No significant association between BSA and mortality after TAVR was detected. While there was a trend towards increased mortality in patients with lower BSA, larger studies are needed to provide definitive answers. As with BMI, BSA might be of prognostic value for patients undergoing TAVR.

BACKGROUND Valve types for transcatheter aortic valve implantation (TAVI) have undergone rapid evolution. The new balloon-expandable Edwards Sapien-3 (S3) valve offers several novel features to prevent or reduce typical TAVI-related problems such as paravalvular leaks (PVLs) and vascular complications. The aim of this study was to investigate the potential differences in the clinical outcome compared to its predecessor Sapien XT (SXT).

RESULTS Comparison of both baseline characteristics of both groups showed a higher surgical risk score for the Sapien-3 group (mean STS score S3 4.1% vs. SXT 2.6%). Compared to SXT patients, S3 patients were available for complete retrospective analyses. The change in valve type was in 2014. All patients were available for complete retrospective analyses. The severity of paravalvular AR was evaluated with echocardiography 7d after TAVI. The outcome was analyzed according to the VARC-2 criteria. The effect of balloon predilatation in TAVI on long-term mortality

CONCLUSIONS The use of balloon-expandable Edwards Sapien-3 vs Sapien XT valve. A large-scale single-center experience

TCT-691 Comparison of the new balloon-expandable Edwards Sapien-3 vs Sapien XT valve. A large-scale single-center experience

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BACKGROUND The use of balloon-expandable Edwards Sapien-3 (S3) valve offers several novel features to prevent or reduce typical TAVI-related problems such as paravalvular leaks (PVLs) and vascular complications. The aim of this study was to investigate the potential differences in the clinical outcome compared to its predecessor Sapien XT (SXT).

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CONCLUSIONS No significant association between BSA and mortality after TAVR was detected. While there was a trend towards increased mortality in patients with lower BSA, larger studies are needed to provide definitive answers. As with BMI, BSA might be of prognostic value for patients undergoing TAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Body surface area, Predictors, Transcatheter aortic valve replacement

TCT-692 The effect of balloon predilatation in TAVI on long-term mortality

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BACKGROUND Direct transcatheter aortic valve implantation (TAVI) has shown to be safe and feasible with a similar success rate to TAVI with prior balloon aortic valvuloplasty (BAV). The aim of this study was to evaluate the effect of direct TAVI on long-term mortality with a self-expanding bioprosthesis.

METHODS Prospectively collected data before and after TAVI from two high-volume centers were retrospectively analyzed in all patients. Primary clinical end-point was all-cause mortality at 1 year. All outcomes were evaluated according to the VARC-2 criteria.

RESULTS We included 210 patients in the study (120 patients for non-direct TAVI and 90 patients for direct TAVI). Both groups had similar 1-year mortality rates (15% in non-direct versus 11% in direct, p<0.5). No major differences were observed concerning cardiovascular death (3% versus 2%, p<0.9), stroke (3% versus 5%, p<0.4) and acute myocardial infarction (2% versus 0%, p<0.2) in non-direct and direct TAVI groups respectively in the mid-term. The direct group had less moderate/severe paravalvular leakage (PVL) post TAVI compared to the non-direct group (8% vs 27%, p<0.01). At univariate analysis, predictors for mortality were: BAV before TAVI (p<0.2, OR: 1.71, 95%CI: 0.742-3.939), EuroScore (p<0.044, OR: 1.046, 95%CI: 1.001-1.093), failure to achieve device success (p<0.143, OR: 1.759, 95%CI: 0.821-3.926) and the interventricular septum thickness (p<0.048, OR: 1.249, 95%CI: 1.002-1.552). At multivariate analysis, independent predictor of mortality was logEuroscore (p<0.035, OR: 1.058, 95%CI: 1.004-1.144).

CONCLUSIONS Direct TAVI is safe and comparable outcomes are achieved with the current practice of TAVI with balloon aortic valvuloplasty. Further studies are necessary to assess the long-term mortality and effect on PVL of direct TAVI.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Balloon aortic valvuloplasty, Mortality, long-term, Transcatheter aortic valve implantation

TCT-693 Multicentre clinical study evaluating a novel resheathable self-expanding transcatheter aortic valve system

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BACKGROUND Transcatheter aortic valve implantation (TAVI) significantly improves the prognosis of inoperable patients with severe aortic stenosis and appears to be equivalent to surgery in high-risk patients. However, limitations of first-generation devices regarding repositioning and optimization of placement can result in complications and hence increase mortality. Therefore, it was the aim of this study to evaluate the performance of a resheathable and repositionable self-expanding TAVI system in high risk patients with aortic stenosis.

METHODS This prospective, single arm, multicentre study evaluated the safety and efficacy of the PorticoTM Transcatheter Aortic Valve Implantation System. Between March 2012 and April 2014 102 patients were included (97% Female; Mean Age: 84±5 years; S3 Score: 6.2±3.5, logistic EuroScore: 16.7±5.5 %) were treated at 7 sites in the UK, and Germany using the 18F Portico Delivery System with a 23 or 25mm Portico Valve. Patients were followed post procedure at 30, 90, 180 days and 1 year. Adverse events were categorized by VARC definitions and adjudicated by an independent events committee. Echocardiography was evaluated by an independent laboratory.
RESULTS The Portico TAVI system was successfully implanted in 100 patients. Total procedural time was 40±19 min, total implant time 13±12 min, and fluoroscopy time 19±7 min. An average of 192±76 ml of contrast was used during the implant procedure. Reshathing was used in 24 patients (23%) and was successful in all instances. Average implant depth was 6.0±2.9 mm at baseline to 9±4 mm at 30 days and an increase in aortic valve area from 0.6±0.2 cm² at baseline to 1.7±0.4 cm² at 30 days, respectively, in the absence of significant postprocedural aortic regurgitation. This was associated with a significant increase in functional status as determined by a decline in the New York Heart Association class. Rate of all cause of death was 2.9% and 6.9%, of cardiovascular death 2.9% and 7.8%, acute kidney injury stage 3 2.0% and 3.9%, life-threatening or disabling bleeding 3.9% and 3.9%, disabling stroke 2.9% and 4.9%, non-disabling stroke 1% and 2%, major vascular complications 5.9% and 6.9% at 30 days and 1 year respectively. Implantation of a new pacemaker was required in 9.8% and 10.8% of the patients at 30 days and 1 year, respectively.

CONCLUSIONS The novel Portico Transcatheter Aortic Valve allows for safe repositioning and optimization of the device position. The functional and symptomatic outcomes up to the 12 months follow appear to support the efficacy and safety of the device.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-694
“Rural” United States Experience of Incorporation of a Technologically Advanced and Procedurally Complex Cardiovascular Program – The Sanford Trans-catheter Aortic Valve Replacement Experience
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1University of South Dakota, Sioux Falls, SD; 2Sanford Heart Hospital, Sioux Falls, SD

BACKGROUND The need for trans-catheter aortic valve replacement (TAVR) coverage in a large geographical region that is sparsely populated poses peculiar challenges, especially related to low volumes of operations both at institutional and operator level, coupled with the need to provide these services to patients within reasonable proximity to where they live. We compared the TAVR data at Sanford Heart Hospital in Sioux Falls, South Dakota to the national registry data with the aim of looking at differences in TAVR outcomes in a “rural” setting.

METHODS We analyzed the data of the first 52 patients that underwent TAVR at Sanford Medical Center between September 2012 and June 2014. Once severe symptomatic aortic stenosis was confirmed and the patient deemed to be either inoperable or high-risk for surgical aortic valve replacement, they were screened for TAVR eligibility. Transesophageal echocardiogram and CT-angiogram of chest, abdomen, and pelvis were used for anatomic assessment prior to the procedure. As in the national registry, our endpoint definitions were harmonized with the Valve Academic Research Consortium (VARC) and VARC-2 definitions for stroke, transient ischemic attack, aortic valve reintervention, major bleeding, and major vascular complications. Our data was compared to outcomes noted for the national TAVR registry.

RESULTS As in the national registry, majority of Sanford TAVR patient procedures were performed through femoral access (73%). In-hospital outcomes revealed fewer cases of death from any cause, cardiac arrest, myocardial infarction, renal failure. Median length of hospital stay were also better compared to the national data (Table 1). Thirty day outcomes of Sanford TAVR program compared to the registry showed lower all cause death (9.5% vs. 7.6%), stroke (1.9% vs. 2.8%) and need for aortic valve reintervention (0% vs. 0.5%). Improvement in NYHA class was seen in 84.6% cases at Sanford compared to 72.4% in the registry. Statistical analysis did not suggest a significant difference in these outcomes, except in the incidence of cardiac arrest.

CONCLUSIONS The Sanford data showed high quality outcomes for the TAVR program implemented in rural United States. Although the p-value for these outcome measures did not attain statistical significant, likely due to the small sample size of our patients, the results were definitely comparable if not better than the national data. This data rationalizes the feasibility of developing advanced health services in rural areas of the country which may lead to better access and utilization of health care resources.

CATEGORIES OTHER: Political, International and Societal Issues

KEYWORDS TAVR

TCT-695
The Incidence of Paravalvular Leak in Transluminal Echocardiography-guided deployment of Transcatheter Aortic Valve is Comparable to that of Transesophageal Echocardiography-guided Deployment: An Update of the Emory Experience
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BACKGROUND Transcatheter aortic valve replacement (TAVR) is increasingly being performed in cardiac catheterization laboratories using transluminal echocardiography (TTE) to guide valve deployment. This minimalistic approach has been shown to be less costly, and associated with procedural outcomes equivalent to the standard approach that uses transesophageal echocardiography (TEE) guidance for valve deployment. The risk of paravalvular leak (PVL) remains a concern. Whether TTE-guided valve deployment is associated with a higher incidence of paravalvular leak (PVL) is unclear.

METHODS Medical records of 474 patients (mean age 82±8, 58% male, 85% Caucasians) who underwent TAVR with Edwards SAPIEN (60%) or SAPIEN-XT (40%) at Emory University Hospital from 2007 to 2014 via the transfemoral approach were reviewed and compared. 267 patients underwent TAVR in the cardiac catheterization laboratory under TTE guidance, while 207 patients underwent TAVR using conventional, TEE-guided approach in the hybrid operating room. Clinical characteristics, procedural outcomes and echocardiograms at baseline and follow-up were compared.

RESULTS Patients who underwent TTE-guided TAVR had a lower STS score (9.2±4.4% versus 11.2±7.8%, P=0.004), higher EF (53±13% versus 48±13%, P=0.004) and were more likely to have received a SAPIEN-XT valve (47% versus 33% P=0.007) compared to those with conventional TEE-guided approach. The incidence of at least mild post-TAVR PVL was lower in the minimalistic approach compared to the conventional one (29% versus 37% respectively, P=0.069). In a binary logistic regression model including demographics, valve type and size, TAVR approach, year of procedure and STS score, only valve size (OR 0.80, 95% CI [0.68,0.94]) and gender (OR 0.5, 95% CI [1.6,5.5]) were significant predictors of post-TAVR PVL. Procedure year, reflective of experience was close to statistical significance (OR 0.83, 95% CI [0.68,1.01]). Neither valve type (P=0.482) nor TAVR approach (P=0.368) were independently associated with post-TAVR PVL.

CONCLUSIONS The minimalistic TAVR approach was not associated with increased PVL. TTE-guided TAVR is likely safe and cost-effective. Multi-center studies with larger sample sizes are required to confirm these findings.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Paravalvular leak, Transcatheter aortic valve replacement

Table 1

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Sanford (n=52)</th>
<th>National Registry (n=7710)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death (Any cause)</td>
<td>0 (0%)</td>
<td>427 (5.5%)</td>
<td>0.0312</td>
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<tr>
<td>Stroke</td>
<td>1 (1.9%)</td>
<td>156 (2.0%)</td>
<td>0.3722</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>0 (0%)</td>
<td>447 (5.8%)</td>
<td>0.0443</td>
</tr>
<tr>
<td>TIA</td>
<td>0 (0%)</td>
<td>28 (0.4%)</td>
<td>0.8271</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0 (0%)</td>
<td>56 (0.7%)</td>
<td>0.6836</td>
</tr>
<tr>
<td>New-onset atrial fibrillation</td>
<td>6 (11.3%)</td>
<td>460 (6.0%)</td>
<td>0.0540</td>
</tr>
<tr>
<td>Renal failure needing dialysis</td>
<td>0 (0%)</td>
<td>145 (1.9%)</td>
<td>0.3774</td>
</tr>
<tr>
<td>Creatinine &gt;3</td>
<td>0 (0%)</td>
<td>276 (3.8%)</td>
<td>1.0943</td>
</tr>
<tr>
<td>VARC major bleeding</td>
<td>2 (3.8%)</td>
<td>267 (3.5%)</td>
<td>0.2740</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>4 (7.6%)</td>
<td>509 (6.6%)</td>
<td>0.1945</td>
</tr>
<tr>
<td>Major vascular injury</td>
<td>2 (3.8%)</td>
<td>493 (6.4%)</td>
<td>0.1992</td>
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<tr>
<td>Device success</td>
<td>50 (96%)</td>
<td>7069 (92%)</td>
<td>0.1191</td>
</tr>
<tr>
<td>Transapical site access complications</td>
<td>0 (0%)</td>
<td>61 (0.8%)</td>
<td>0.6607</td>
</tr>
<tr>
<td>Median stay of length (days)</td>
<td>4</td>
<td>6</td>
<td></td>
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</tbody>
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