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 were used during the implant procedure. Resheathing was used in 24 patients (23%) and was successful in all instances. Average implant depth was 6.1mm. TAVI resulted in a significant decrease in mean gradient from 45±14 mmHg at baseline to 9±4 mmHg at 30 days and an increase in aortic valve area from 0.6±0.2 cm^2 at baseline to 1.7±0.4 cm^2 at 30 days, respectively in the absence of significant postprocedural aortic regurgitation. This was associated with a significant improvement in the functional status as determined by a decline in the New York Heart Association class. Rate of all cause of death was 2.9 and 11.8%, 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

Amol Raizada,[1] Tom P. Stys,[2] Adam Stys,[2] Jamal Dodin,[1] Terezia Petraskova,[1] Maria Molga[1]
[1]University of South Dakota, Sioux Falls, SD; [2]Sanford 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 (1.9% 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.

Table 1

In-hospital outcome	Sanford (n=52)	National Registry (n=7710)	p-value
Death (Any cause)	0 (0%)	427 (5.5%)	0.0512
Stroke	1 (1.9%)	156 (2.0%)	0.3722
Cardiac arrest	0 (0 %)	447 (5.8%)	0.0443
TIA	0 (0 %)	28 (0.4%)	0.8271
Myocardial infarction	0 (0 %)	56 (0.7%)	0.6836
New onset atrial fibrillation	6 (11.5%)	460 (6.0%)	0.0540
Renal failure needing dialysis	0 (0%)	145 (1.9%)	0.3714
Creatinine>3	0 (0%)	276 (3.8%)	0.1493
VARC major bleeding	2 (3.8%)	267 (3.5%)	0.2740
New permanent pacemaker	4 (7.69%)	509 (6.6%)	0.1945
Major vascular injury	2 (3.8%)	493 (6.4%)	0.1992
Device success	50 (96%)	7069 (92%)	0.1191
Transapical site access complications	0 (0%)	61 (0.8%)	0.6607
Median stay of length (days)	4	6	
Live hospital discharges	52 (100%)	7286 (94.5%)	

CATEGORIES OTHER: Political, International and Societal Issues

KEYWORDS TAVR

TCT-695

The Incidence of Paravalvular Leak in Transthoracic Echocardiography-guided deployment of Transcatheter Aortic Valve is Comparable to that of Transesophageal Echocardiography-guided Deployment: An Update of the Emory Experience

Salim S. Hayek,[1] Jose F. Condado,[1] Nikolaos Spilias,[1] Shuang Lin,[1] James P. Macnamara,[1] Shuai Zheng,[1] Patricia Keegan,[2] Vasilis Babaliaros,[3] Vinod Thourani,[1] Stamatios Lerakis[1]
[1]Emory University, Atlanta, GA; [2]Emory Healthcare, Atlanta, GA; [3]Emory University, Atlanta, USA

BACKGROUND Transcatheter aortic valve replacement (TAVR) is increasingly being performed in cardiac catheterization laboratories using transthoracic echocardiography (TTE) to guide valve deployment. This minimalist 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, 86% 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 minimalist 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]), male gender (OR 3.0, 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 minimalist TAVR approach was not associated with increased PVL. TTE-guided TAVR is likely safe and cost-effective. Multicenter studies with larger sample sizes are required to confirm these findings.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Paravalvular leak, Transcatheter aortic valve replacement