BACKGROUND Preliminary reports on the clinical performance of patients undergoing transcatheter aortic valve replacement (TAVR) with the novel self-expanding ACURATE neo (NEO) (Symetis SA, Eclubens, Switzerland) are promising, however information regarding one-year outcome is lacking. Therefore we aimed to assess the clinical outcome using the ACURATE neo in a single-center population according to the updated Valve Academic Research Consortium (VARC-2) criteria.

METHODS 104 consecutive patients undergoing transfemoral TAVR with the NEO for severe stenosis of the native aortic valve were enrolled and data prospectively collected.

RESULTS Mean age was 81±6 years, 51% were female with a median logistic Euroscore of 13.4% [7.8-19.0]. The distribution across the small, medium and large size was 36%, 36% and 28%, respectively. VARC-2 defined device success was achieved in 89% of patients; 7% cases developed moderate paravalvular leakage. Procedure related mortality was 1% and rates of in-hospital life-threatening bleeding, major vascular complications and all stroke were 3%, 17% and 2%, respectively. Permanent pacemaker implantation (PPI) in patients without prior PPI (n=95) was required in 8%. At one year no patient was lost to follow-up. All-cause and cardiac mortality were 4% and 2%, respectively. Symptomatic benefit was high with 90% of patients reporting a NYHA class II or less, however 10% of patients were hospitalized due to valve-related symptoms or congestive heart failure. Rates of life-threatening bleeding, major vascular complications and stroke were 7%, 17% and 4%, respectively. One patient suffered a myocardial infarction and one patient required repeated procedure. There were no cases of endocarditis or valve thrombosis. Incidence of PPI at one year was 13%.

CONCLUSION In this single-center analysis using the novel ACURATE neo, we found high procedural success and a favorable safety profile. At one year, all-cause mortality rates and need for PPI were low.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-321

Transcatheter Aortic Valve Replacement with a Self-Expanding Bioprosthesis Augmented with a Porcine Pericardial Wrap

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BACKGROUND Successful transcatheter aortic valve replacement (TAVR) includes the avoidance of paravalvular leak. Self-expanding valves naturally conform to irregularly shaped native anatomy and this report describes the initial experience with addition of a pericardial wrap designed to minimize paravalvular leak.

METHODS Patients with severe symptomatic aortic stenosis were evaluated by a heart team and deemed to be at high risk for surgical intervention and underwent TAVR using the Evolut Pro device (Medtronic, Minneapolis, MN) at a single institution between March and June of 2017. The procedural and thirty day outcomes are reported.

RESULTS The Evolut PRO Transcatheter Aortic Valve (TAV) was implanted in 45 patients during the study period. The mean age of patient population was 83.5 (6.7) years, and 31 (68.9%) were female. Mean STS-PROM was 6.1%. Forty-four patients underwent implantation for severe native aortic stenosis, 1 patient underwent implantation for bioprosthetic aortic valve stenosis. Conscious sedation was used in 41/45 cases (92%). All patients underwent successful procedures - 42 patients had transfemoral access, 2 suprasternal access, and 1 patient had direct aortic access. Valve sizes used were 23mm (3 patients), 26mm (12 patients), and 29mm (30 patients). There were no procedural complications and all patients survived to hospital discharge. Paravalvular leak was mild or less in 43/44 (98%) of the patients. Permanent pacemaker implant was required in 4 patients (8.9%). There was no mortality. Thirty day follow up ECHO showed no changes. Post procedural ECHO findings are listed in the Table.

Variables	Pre-Procedure	24 Hours Post-Procedure	p-Value
Aortic Valve Orifice Area, Mean (SD)	0.75 (0.18)	2.23 (0.69)	<0.001
Aortic Valve Orifice Area Index, Mean (SD)	0.38 (0.10)	1.17 (0.42)	<0.001
Aortic Valve Mean Gradient, Mean (SD)	39.94 (15.82)	9.20 (5.70)	<0.001
Aortic Valve Peak Velocity, Mean (SD)	4.10 (0.78)	2.05 (0.46)	<0.001
Paravalvular Leak, n (%)			
None	–	11 (24.4)	NA
Trace/Mild	–	33 (73.3)	NA
Moderate	–	1 (2.2)	NA
Severe	–	0 (0.0)	NA

CONCLUSION In the largest real world report of TAVR with Evolut Pro TAV device, implant using conscious sedation was marked by high procedural success rate, minimal paravalvular leak and infrequent need for permanent pacemaker.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-322

In Vitro Optimisation of a Transcatheter Polymeric Aortic Valve

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BACKGROUND Few polymeric valves have advanced beyond preclinical investigation despite different polymers, geometries and manufacturing techniques being adopted. Recently, styrenic block copolymers (BCPs) consisting of alternating blocks of glassy and rubbery polymer have been proposed. In order to optimize a transcatheter valve fabricated from BCPs, we sought to quantify the effect of design change on hydrodynamic function.

METHODS Transcatheter aortic valves (23mm) were fabricated from 3 BCPs: poly(styrene-block-isobutylene-block-styrene); SIBS, poly (styrene-block-isoprene-block-styrene); SIS and poly(styrene-block-ethylene-propylene-block-styrene); SEPS. A polyurethane (Elast-Eon) was used for comparison. Five design parameters were evaluated (stent attachment, free-edge geometry, leaflet thickness, modulus and molecular orientation) across 4 pulsatile flow rates (3.9 -7.1 L/min), with hydrodynamic function reported as effective orifice area (cm2), mean pressure gradient (mmHg), total regurgitant fraction (%) and energy loss (mJ).

RESULTS Figure 1 presents the relationship between thickness and hydrodynamic function for each polymer at a simulated cardiac output of 5.0L/min. Controlling for modulus, leaflet thickness was inversely correlated with EOA (B1=-2.223, p<0.001) and total regurgitant fraction (B1=-24.415, <0.001), and positively correlated with mean pressure gradient (B1=30.796, <0.001). Adopting the ISO-5840 minimum performance requirements, the estimated maximum leaflet thickness using SIS, SIBS, SEPS and Elast-Eon was 0.38 mm, 0.30 mm, 0.36 mm, 0.35 mm, respectively. Pairwise comparison revealed a significant difference between a plano-concave and plano-convex profile for EOA (+13.37%, p<0.001), transvalvular pressure (-18.15%, p<0.001) and total regurgitation (-14.33% ± 0.46, p<0.001). Domain orientation parallel to the leaflet base demonstrated a significant improvement in EOA at low flow rates (+4.21% and +6.00% at 3.9L/min and 5.0 L/min, respectively). Conversely, perpendicular orientation demonstrated a significant reduction in total regurgitation and closed valve energy loss. At low flow rates, including 5L/min, material selection did not effect hydrodynamic function for a given thickness. Likewise, no difference was observed with a change in leaflet-stent attachment.