TCT-154
Patient and Healthcare System Benefits of Contemporary Transcatheter Aortic Valve Implantation (TAVI) Practice


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BACKGROUND TAVI is now the treatment of choice for patients presenting with severe symptomatic aortic stenosis who are deemed to be inoperable or of high surgical risk. During the last few years, rapid improvements have been made to TAVI devices coupled with greater operator and institutional experience. We sought to determine the patient and healthcare benefits of contemporary TAVI practice.

METHODS A retrospective analysis was conducted of all patients that underwent transfemoral TAVI between November 2007 and May 2015 at San Raffaele Scientific Institute, Milan, Italy. The first 150 patients treated were allocated to the early experience group (EE), and the last 150 patients to the contemporary practice group (CP).

RESULTS Patients were older in the EE group (85.1 vs. 81.5 years, p<0.001) and of higher risk (10.8 vs. 9.7, p=0.003) when compared to the CP group. In the EE group, general anesthetic (22.7% vs. 5.3%, p<0.001) and surgical cut-down (4% vs. 0%, p<0.001) were more frequent in comparison to the CP group. Procedure times were also longer in the EE group (104.4 vs. 74.6 minutes, p=0.004) as was the volume of contrast used (208.8 vs. 76.9 milliliters, p<0.001). This translated into a significant reduction in hemoglobin drop (2.4 vs. 1.7 grams/deciliter, p=0.02) but without a significant impact upon plasma creatinine rise (0.23 vs. 0.18, p=0.6). As a consequence of these improvements patient length of stay was significantly shorter in the CP group (7.2 vs. 9.4 days, p=0.04).

CONCLUSIONS Advances in TAVI technology, coupled with greater operator and institutional experience has resulted in significant improvements in contemporary TAVI practice. In our single high-volume center experience, this has translated into shorter, less invasive procedures that have resulted in a significantly shorter length of stay. These improvements have resulted in advantages to both patients (e.g. reduced risk of nosocomial infection) and the healthcare system with reduced economics costs coupled with benefits of improved patient flow enabling greater number of patients to be treated.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Quality of life, TAVR

TCT-155
Transfemoral aortic valve replacement with the repositionable Lotus valve compared with the balloon-expandable Edwards Sapien 3 valve

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BACKGROUND Moderate or severe aortic insufficiency (AI) after transcatheter aortic valve implantation (TAVI) with first generation devices increased acute and long-term mortality. Post-dilation in order to improve procedural outcome increased acute stroke rate. Second generation devices are designed to reduce the risk for relevant AI and offer more control regarding valve positioning. We compared the repositionable Lotus valve with the balloon-expandable Edwards Sapien 3 valve regarding acute and 30 days outcomes (Clinical Trial Registration: NCT02162069).

METHODS We evaluated post-procedural AI, need for post-dilation, rate of permanent pacemaker implantation, and device success according to VARC criteria in 221 patients with severe aortic stenosis undergoing transfemoral TAVI. The repositionable Lotus valve (N=71) or the balloon-expandable Edwards Sapien 3 (ES3) valve (N=150) were implanted. Baseline parameters did not differ between Lotus and ES3 group with: pulmonary disease 57% vs 57% (p=0.99), NYHA III or IV in 79% vs 84% (p=0.30), aortic valve area by echocardiography 0.82±0.49 cm2 vs 0.80±0.28 cm2, STS and Euro-Scores. For sizing a 256 multislice computed tomography (MSCT, Philips Brilliance iCT) with retrospective ECG triggering was done. Measurements were performed in systole and area and perimeter derived diameters of the annulus and left ventricular outflow tract were measured. Baseline MSCT data did not differ with area derived annulus diameter of 24.7±1.7mm in the Lotus group and 24.7±2.6mm in the ES3 group (p=0.89). Perimeter derived diameter was 25.3±1.7mm vs 25.4±1.6mm (p=0.75). Number of area and perimeter derived diameters of the LVOT were 24.6±2.2mm vs 24.7±2.7mm (p=0.73) and 25.4±2.3mm vs 25.7±2.9mm (p=0.44), respectively. Measurements were performed with a dedicated software (memosio 7.0 software, Pie Medical Imaging, Maasstricht, The Netherlands).

RESULTS Post TAVI there was no moderate or severe AI, no need for post-dilation or use of a second valve in both groups. Contrast amount was 107±38ml for Lotus and 87±25ml for ES3 implantation (p<0.05). There was no moderate or severe AI by echocardiography one day after TAVI in both groups. There were no death, stroke, annulus rupture or coronary obstruction. Device success did not differ between groups and need for pacemaker implantation was significantly higher with Lotus compared with ES3, respectively. Mean regurgitation index was 29.1±9.2 vs 25.2±9.7 for Lotus vs ES3 (p=0.01), mean aortic gradient by echocardiography 12.0±3.4mmHg vs 12.6±4.9mmHg (p=0.39).

CONCLUSIONS TAVI with the repositionable Lotus Valve System and the balloon-expandable Edwards Sapien 3 demonstrated similar acute and 30 days results. With both second generation TAVI devices there was no moderate or severe aortic insufficiency and no need for post-dilation. Device success was similar between groups while need for permanent pacemaker was significantly higher with the Lotus Valve.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Transcatheter aortic valve implantation

TCT-156
Outcomes After Transcatheter Aortic Valve Implantation Using a Novel Balloon-Expandable Transcatheter Heart Valve: A Single Center Experience

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BACKGROUND Recently, a novel balloon-expandable transcatheter heart valve (THV), the SAPIEN 3 (S 3) has been introduced. While preliminary data on clinical performance with this device is...
promising, information regarding outcome at 30 days is limited. We evaluated outcomes after TAVI with S3 THV with particular emphasis on the updated Valve Academic Research Consortium (VARC-2) criteria.

METHODS 261 consecutive patients undergoing transfemoral TAVI with S3 THV at our center were enrolled and outcome according to the VARC-2 criteria was analyzed at 30 days.

RESULTS Mean age was 81±6 years and median logistic EuroScore was 10% [8-21]. Follow-up at 30 days was available for 260 patients. VARC-2 defined device success was achieved in 251 (96%) of patients; 5 (2%) cases developed moderate paravalvular leakage. At 30 days, one patient (0.4%) died due to a noncardiac cause and 8 (3%) patients suffered from a disabling (n = 4) or non-disabling stroke (n = 4). Life-threatening bleeding and major vascular complications occurred in 12 (5%) and 7 (3%) of the cases, respectively. From discharge to 30 days, 5 (2%) patients were hospitalized due to valve-related symptoms or worsening of heart failure. The VARC-2 composite early safety endpoint at 30 days* was 12% [8-21]. Follow-up at 30 days was available for 260 patients; 5 (2%) cases developed moderate paravalvular leakage. At 30 days, one patient (0.4%) died due to a noncardiac cause and 8 (3%) patients suffered from a disabling (n = 4) or non-disabling stroke (n = 4). Life-threatening bleeding and major vascular complications occurred in 12 (5%) and 7 (3%) of the cases, respectively.

CONCLUSIONS Our objective was to estimate the impact of availability of transcatheter heart valve replacement (TAVR) therapy on overall heart valve replacement volumes and aortic valve disease mortality over a longer-term horizon, using the German healthcare system as a reference case, which was among the first systems adopting TAVR therapy in routine care.

METHODS We collected therapy- and age-specific procedure volumes from records of the German Federal Statistics Office for TAVR and surgical aortic valve replacement (SAVR) procedures for years 2009-2013. Relevant ICD-10 diagnosis-based information about discharges and hospital-based mortality were obtained for the same period. We computed therapy-specific and total procedure volumes and growth stratified by 5-year age increments and in total. Discharge and mortality data for aortic valve disease hospitalizations was assessed to obtain an estimate of changes in per-case mortality.

RESULTS Overall procedure volumes grew from 26,466 in 2009 to 33,235 in 2013 (+26%). This growth was driven by TAVR (3,411 to 10,814; +217%), while SAVR volumes remained stable (23,055 to 22,421; -3%). In patients 75 years or older, an overall procedure growth of 51% was observed (12,168 to 18,318), with volumes in older patient segments growing more heavily (+62% in >80-year olds; +101% in >85-year olds). Across all elderly age groups, SAVR volumes decreased (-20% in >80 year olds; -37% in >85 year olds), while they grew in selected younger patients groups (highest growth +30% in age group 60-64 yrs.). Concurrently, total aortic valve disease hospital discharges grew by 26%, from 44,161 to 55,748, while mortality per hospitalization case decreased by 5% between 2009 and 2013.

CONCLUSIONS Five-year real world data from the German healthcare system demonstrate that the availability of TAVR has led to substantial growth in aortic valve replacements. TAVR substantially increased volumes in the elderly population, and partially replaced SAVR treatments in this subgroup. Concurrently, increased therapy utilization in patients previously left untreated was associated with a reduction in overall mortality of aortic valve-related hospitalizations. Further analysis is warranted to compare these data with the German Registry as well as replicate them in other countries, if possible stratified by pre-procedural surgical risk.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-158 Fully Percutaneous Transthoracic Left Atrial Entry and Closure to Deliver Large Caliber Transcatheter Mitral Valve Implants

TCT-157 The Impact of transcatheter aortic valve replacement on therapy utilization and case volumes in Germany, 2009-2013

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CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-158 Fully Percutaneous Transthoracic Left Atrial Entry and Closure to Deliver Large Caliber Transcatheter Mitral Valve Implants

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BACKGROUND To overcome limitations of transapical and transseptal access to deliver large caliber transcatheter implants to the mitral valve, we hypothesized that the left atrium could be accessed through the posterior chest wall by displacing the lung with CO2 under imaging guidance.

METHODS We tested fully percutaneous transthoracic left atrial access in 12 animals (10 pigs and 2 sheep) and 3 human cadavers under real-time magnetic resonance imaging (n = 10) or x-ray fluoroscopy plus C-arm computed tomographic (n = 2) guidance. We also simulated transthoracic trajectories to the left atrium on human contrast-enhanced cardiac computed tomographic angiograms.

RESULTS Animals were survived for median 7.5 days (Q1-Q3, 7–8.5 days). The pleural space was insufflated with CO2 to displace the lung, an 18-26G sheath was delivered to the left atrium, and the left atrial port was closed using an off-the-shelf nitinol cardiac occluder (Amplatz Atrial Septal Occluder) successfully in 12/12 animals. There was no procedural mortality and no important change in hemodynamics (heart rate, mean arterial pressure and expired CO2). Median bleeding into the pericardium and pleura were 55mL (40–73mL) and 10mL (10–75mL) respectively, which were immediately anticoagulation-transfused. No clinically significant pericardial effusion was observed at follow-up. We also successfully accessed and closed the left atrium in 3 human cadavers under real-time magnetic resonance imaging (n = 1) or X-ray fluoroscopic guidance (n = 2). A theoretical trajectory to the left atrium, assuming the right lung...