TCT-119

Long-Term Follow-up After Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy in Young Adults

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Background: The objective of the study was to assess the long-term safety and efficacy of alcohol septal ablation (ASA) in young adults.

Methods: Data of 163 consecutive patients who underwent ASA at our institution from 2000 to 2010 were reviewed. Clinical follow-up was obtained at a mean of 3 years after ASA in patients aged between 18 and 40 years at the time of the procedure.

Results: During the study period, 21 patients (15%) aged between 18 and 40 years old (mean age 33.1±6.5, range 18-39 years) underwent ASA. Among them, 76% were treated with beta-blockers, 33% calcium-channel antagonists and 5% disopyramide. There were 6 patients (29%) with prior pacemaker, 1 patient (5%) with history of sudden death and implantable cardioverter-defibrillator (ICD) and 1 patient (5%) with prior myectomy. At baseline, mean New York Heart Association (NYHA) functional class was 2.2±0.5. Mean left ventricular outflow tract (LVOT) peak gradient and septal thickness were 89.3±33mmHg and 24.9±5.1mm, respectively. All procedures were performed with myocardial contrast echocardiography guidance. During ASA, 2.2±0.7ml of absolute alcohol was injected in 1.4±0.5 septal perforators. Final procedural success (defined as immediate LVOT peak gradient reduction >50%) was achieved in 20 patients (95%). There were no major complications. One patient (5%) required a temporary pacemaker for second-degree atrioventricular block. Mean peak CK was 934±468 IU/L. At a mean follow-up of 3.0±2.2 years, 2 patients (10%) failed to follow-up and 1 patient (5%) received a new ICD. ASA was performed in 2 patients (10%) and a new ICD was needed in 1 patient (5%), while 1 patient (5%) died at 30 days.

Conclusion: 2.0 years after the procedure (range 0.3-8.4), repeat ASA was performed in two patients (10%) and a new ICD was needed in 1 patient (5%), while 1 patient (5%) died at 30 days. There were no major complications. One patient (5%) required temporary pacemaker for second-degree atrioventricular block. Mean peak CK was 934±468 IU/L. At a mean follow-up of 3.0±2.2 years, 2 patients (10%) failed to follow-up and 1 patient (5%) received a new ICD. ASA was performed in 2 patients (10%) and a new ICD was needed in 1 patient (5%), while 1 patient (5%) died at 30 days.

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TCT-120

Mid-Term Outcomes Following Transcatheter Aortic Valve Replacement with Both Edwards SAPIEN™ and Medtronic CoreValve ReValving System®: Devices According to VARC Definitions: the Milan Experience

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Background: Our aim was to assess the outcomes of transcatheter aortic valve replacement (TAVR) according to the Valve Academic Research Consortium (VARC) definitions at 30 days and 1 year.

Methods: A total of 163 consecutive patients from our single-center prospective registry with aortic stenosis treated with TAVR from November 2007 to April 2011, via the transfemoral (TF), transapical (TAp), transaxillary (TAx) or transaortic (TAo) routes were included in the study. The procedural success defined as VARC 1A or higher and outcomes at 30 days and 1 year were compared between Edwards SAPIEN™ and Medtronic CoreValve ReValving System® (MCV) in differing device groups. The primary end-point was Valve Academic Research Consortium (VARC) success (VARC 1A or higher).

Results: A total of 305 patients were included: mean age was 79.4±7.3 years and Logistic EuroSCORE 24.2±17.0%. Mean clinical follow-up length was 279 (IQR 51-485) days. The most frequent access was TF (81.6%) followed by TAp (7.2%), TAx (7.2%) and TAo (1.0%). ESP was implanted in 60.7% of the patients. Thirty-day mortality was 4.7%, with a myocardial infarction rate of 1.3% and stroke of 1.0%. At multivariate analysis, body mass index and logistic EuroSCORE were significantly associated with an increased risk of 30-day mortality. Life-threatening bleeding occurred in 25.9% of the patients and 17.5% had major vascular complications. Accessing access type or type of valve, there was no difference in device success (92.5% overall), combined safety endpoint at 30 days (61.8%) or combined efficacy endpoint (72.0%) at one year follow-up. Conversely, there was a significantly high occurrence of conduction disturbances and/or atrhythmia (10.1% vs. 23.1%; p<0.006) as well as need of pacemaker (6.3% vs. 28.6%; p<0.001) with MCV as compared to ESV.

Conclusion: Routine TAVR using both ESV and MCV via a range of access appears feasible, with good overall device success and outcomes.

TCT-121

Late Structural Integrity of Balloon Expandable Stents used for Transcatheter Aortic Valve Replacement: Assessment by Multi-detector Computerized Tomography

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Background: Late bioprosthetic valve failure most commonly results from leaflet degeneration but may also be caused by gross deformity of the valve frame. Late structural integrity of the balloon expandable stents used in transcatheter aortic valve replacement (TAVR) is ill-defined. We evaluated stent circularity, expansion and evidence of frame fracture late post implantation using multidetector computerized tomography (MDCT).

Methods: Subjects greater than 1 year post implantation of a balloon expandable aortic valve underwent MDCT. Geometry of the stent frame was assessed for circularity, minimum (Dmin) and maximum (Dmax) external diameter and expansion ratio at three levels: inflow, mid and outflow. Circularly was defined as an eccentricity index (EI) (less than 0.1 (EI = 1 - Dmin/Dmax) and expansion ratio as a percentage of the measured cross sectional stent area divided by the expected area for a fully expanded valve.

Results: 48 patients underwent MDCT at an average 2.5 years (1.0-4.0yrs) post implantation including 34 Edwards SAPIEN valves, 7 SAPIEN XT valves and 7 CoreValve (CE) valves. 143 of 144 (99%) analyzed segments of the 48 valves were circular. There was no difference in eccentricity between valve type (CE: EI 1.8±1.1, SAPIEN: EI 2.7±2.2, XT 2.1±2.2, p=0.71) or from the inflow to outflow aspect of the stent (p=0.54). The mean external diameter of the 23 and 26 mm valves was 23.4±9.9mm and 25.9±0.9mm respectively. The average expansion ratio was 104.1±7.4% with a significant increase from the inflow to outflow level (100.5±7.6% vs 108.1±6.9%, p<0.001). The was no difference in ER between valve type (CE 106.6±7.2%, SAPIEN 104.7±6.2%, XT 103.8±8.4%, p=0.48). There were no cases of stent fracture.

Conclusion: Balloon expandable aortic valves have excellent rates of circularity and maintain full expansion without stent fracture late following implantation, thus supporting long term valve durability.

TCT-122

Short- and Long-Term Safety and Effectiveness of Transcatheter Aortic Valve Implantation in a Failing Surgical Aortic Bioprosthesis

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Background: The viability of transcatheter aortic valve implantation (TAVI) in patients with a failing previously-implanted surgical aortic bioprosthesis has been reported, mostly from single centers. We present results from a multicenter feasibility study in patients followed in one year after TAVI implant.

Methods: A total of 18 subjects implanted with the 18Fr CoreValve TAVI prosthesis (Medtronic, Irvine, Calif.) in a failing surgical aortic bioprosthesis at three centers in Germany. Subject inclusion requirements included >75 years old and either surgical risk with logistic EuroSCORE >15% or >1 high-risk co-morbidity.

Results: Implanted subjects were 79 ± 4 years old, 67% male, 78% NYHA class III/IV, logistic EuroSCORE 34 ± 14, and had failed surgical bioprosthesis from six manufacturers. The procedure was considered successful by the implanting physicians in 89% (16/18) of cases. One subject was converted to surgery during the procedure and another was successfully implanted after a second attempt. Mortality at 30 days and one year was 11% (2/18) and 28% (5/18). Two cardiac deaths occurred, including one within 30 days. Two subjects had strokes, both within 30 days. After 30 days and 12 months, 86% and 73% of subjects improved at least one NYHA class and the remainder had no change. Aortic regurgitation was grade 0 or 1 (none/mild) in 86% of patients at 30 days and in 100% of patients at 1 year. Aortic valve area and mean gradient showed a significant improvement at 30 days that was sustained through at least one year. A moderate improvement was observed in LVEF.

Conclusion: Most patients with a failing surgical bioprosthesis were successfully implanted with a TAVI prosthesis in this multicenter feasibility study. Outcomes at 30 days were within expectations for this very high-risk subgroup and improvements were sustained through twelve months.