a multidisciplinary, multimodality, but minimalist (3M) approach could improve current outcomes.
Methods: With the addition of a second implanting site within a single Vancouver program, patients considered high risk for surgery, but relatively low risk for TAVR, were rigorously screened with functional and cognitive assessments, echocardiography, angiography with aortography, and computed tomography (CT). From a potential pool of 228 accepted transfemoral patients between August 2011 and April 2013, 52 patients underwent SAPIEN XT (Edwards Lifesciences Inc., CA, USA) valve implantation utilizing percutaneous arterial access. Area based CT sizing, with balloon under filling when appropriate, was utilized. The final 17 cases were performed without intubation or sedation. Thirty day outcomes are reported according to the VARC-2 guidelines.
Results: The mean patient age was 83 ± 7 years with a mean STS score of 8.6 ± 3.7%. Mortality at 30 days was 1.9% (1/52). The median LOS was 1 day (1, 9) with a mean LOS of 1.8 days. Thirty two patients (62%) were discharged one day post TAVR. Aortic valve area increased from 0.67 ± 0.14 cm2 to 1.70 ± 0.28 cm2 ($p<0.001$) and the mean gradient decreased from 43 ± 17 mmHg to 9 ± 3 mmHg ($p < 0.001$) at 30 days. Two patients (3.8%) were re-admitted within the first 30 days: one patient underwent elective pacemaker implantation for pre-existing type 2 AV block on day 7 and one patient with advanced fibrotic lung disease was readmitted with worsening respiratory symptoms on day 15. At 30 days, there were no major vascular complications or strokes and 98% (50/51) were NYHA class I or II with mild or less paravalvular regurgitation.
Conclusions: Rigorous patient screening and improvements in procedural guidance and device selection permits safe next day discharge in high risk patients. The 3M approach may help facilitate TAVR in a broader range of lower risk patients.

TCT-119

European Multi-Center Experience with Direct Aortic Transcatheter Aortic Valve Implantation with a Self Expandable Valve

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Background: Transcatheter aortic valve implantation (TAVI) has been designed to treat elderly patients with severe aortic stenosis at high risk for surgery. The safety and effectiveness of TAVI have been demonstrated in numerous studies. The self-expanding CoreValve prosthesis is implanted retrogradely with vascular access usually via the femoral or subclavian arteries. However, in certain patients these access routes are either not possible or are deemed to carry a high risk of vascular injury. The aim of this report is to describe the European experience use of a direct aortic approach (DAA) for TAVI in a high risk population and evaluate the impact of any potential learning curve.
Methods: This multi-centre experience comprises patients treated in the 18 centres in 9 countries in Europe and in Israel, a standard dataset was circulated. between center.
Results: A total of 402 cases have been collected, mean age 81,2±6.4 years, 54% male, mean logistic EuroSCORE 25.8±16.1. 86% of patients were in NYHA functional class ≥ III. Peripheral vascular disease was present in 73% of cases. 58 % of patients had coronary artery disease and 22% of the patients had undergone previous coronary artery bypass surgery. The procedure was performed in 130 of cases through a right anterior mini-thoracotomy in the 2nd intercostal space and via an upper hemi-sternotomy in the others. A size 29mmCoreValve was implanted in 171 patients. Procedural success was achieved in 96% of cases. There were two procedural deaths and 30 day mortality was 9%. The incidence of stroke was 2% and 56 patients (13.9%) required a new permanent pacemaker. Median post-operative hospitalization was 8 days.
Conclusions: Direct aortic access is a feasible approach for TAVI with the self-expanding CoreValve prosthesis. These initial and provisional results with this technique are encouraging given the high risk patient cohort (with a particularly high incidence of concomitant vascular disease) and the fact that this series includes each unit's initial experience

TCT-120

Need for Permanent Pacemaker Following Implantation of the Repositionable Second-Generation LOTUS™ Device for Transcatheter Aortic Valve Replacement: Results From the Pivotal REPRISE II Trial

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Background: An increased incidence of conduction disturbances requiring permanent pacemaker implantation has been reported with some devices following transcatheter aortic valve replacement (TAVR). The repositionable and fully retrievable Lotus Aortic Valve Replacement System (Boston Scientific, Natick, MA) is being evaluated in the REPRISE II study. This analysis will evaluate the incidence and predictors of the need for a permanent pacemaker following implantation of the Lotus Valve.
Methods: REPRISE II is a prospective, single arm, multicenter study of symptomatic patients with calcified aortic valve stenosis and an aortic annulus of 19-27mm who were at high risk for surgery. A total of 120 patients were enrolled and implanted with a transfemoral 23mm or 27mm Lotus Valve. The primary device performance endpoint is the mean aortic valve pressure gradient at 30 days post implant, and the primary safety endpoint is all-cause mortality at 30 days. Echocardiography, CT, and EKG data were evaluated by independent core labs; results including univariate and multivariate predictors of need for a pacemaker will be available by the time of presentation.
Results: In a prespecified interim analysis conducted on the first 60 patients, mean age was 85.5 years, 63% were female, 75% were NHYA Class III/IV at baseline, and mean STS score was 6.4±3.0%. Thirty-day follow-up data were available for 58 patients (1 patient withdrew consent and 1 died). In this analysis, 17/58 (29.3%) patients required a newly implanted pacemaker: 15 for 3rd degree AV block, 1 for 1st degree AV block with right bundle branch block (RBBB) and left anterior fascicular block, and 1 for AF with slow ventricular rate. Of these, 7 (41.2%) had baseline PR interval prolongation, 4 (23.5%) had baseline RBBB, and 10 (58.8%) had new conduction disturbances immediately after valvuloplasty. Eleven of the 17 patients (64.7%) still had a paced rhythm at 30 days.
Conclusions: The incidence and predictors of the need for a permanent pacemaker post-implantation for the full 120-patient cohort in REPRISE II will be available for the first time at TCT 2013.

TCT-121

First Human Transcatheter Aortic Valve Implantation of the Colibri Heart Valve, A Pre-mounted, Pre-packaged, Low Profile Ready for Use, Dry Valve in a 14 French Delivery System. Six Months Follow up.

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Background: The 24 mm sized Colibri TAVI valve is pre-mounted and compressed upon its delivery balloon catheter at manufacture and is packaged within a 14 French introducer, sterilized and ready for use into the patient. We report the results and early clinical follow-up of the first human implantation of the Colibri Heart Valve pre-mounted, pre-packaged TAVI valve in an initial feasibility study.
Methods: An elderly, frail, hypertensive, bedbound female patient with minimal effort dyspnea and recurrent syncope (functional class 4) was referred for treatment. Echo-Doppler showed severe aortic stenosis with peak gradient = 154 mmHg (mean 89 mmHg), aortic valve area (AVA) = 0.7 cm2 and preserved left ventricular ejection fraction of 60%. Surgical valve replacement was not available to her. The minimum diameter of the femoral arteries was approximately 5.0 mm, precluding transfemoral approach with available TAVI systems. The local institutional ethics board approved the procedure as a humanitarian application.
Results: The Colibri valve was implanted in the cardiac catheterization laboratory by transfemoral approach. Mean aortic gradient decreased to 12 mmHg and AVA increased to 2.3 cm2 with mild paravalvular leak (PVL). The patient experienced symptomatic relief. Follow-up echocardiogram performed at 7 days showed trace PVL and transvalvular mean gradient of 12 mmHg. At 6-month follow-up she is NYHA Class 1 and echocardiogram showed no aortic insufficiency/PVL, mean gradient of 9 mmHg and AVA of 2.3 cm2.
Conclusions: Transfemoral implant of the Colibri ready for use transcatheter aortic valve in its 14 Fr delivery sheath is feasible and efficient. Clinical outcomes at 6 months after implantation showed sustained benefits suggesting that the Colibri TAVI technology can enable the successful transfemoral treatment of patients with small femoral arteries.