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 using 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 centers.

Results: A total of 402 cases have been collected, mean age 81.2±6.4 years, 54.5% male, mean logistic EuroSCORE 25.8±16.1. 86% of patients were in NYHA functional class ≥ II. 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 encourage the 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 21–27mm 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 the need for a pacemaker will be available by the end of 2013.

Results: In a prespecified interim analysis conducted on the first 60 patients, mean age was 85.5 years, 63% were female, 75% were NYHA 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 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 valve deployment. 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.