**TCT-135**

Transcatheter Aortic Valve Replacement with Edwards Sapien Valve via Transcatheter Route: European Multicentre Experience

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**Background:** Edwards Sapien valve is usually implanted through either transfemoral (TF) or transapical (TA) route. We evaluate feasibility and results of implantation of Edwards Sapien valve through Transcatheter (TAo) route in patients with aortic stenosis.

**Methods:** Between January 2008 and May 2011 a total of 560 patients underwent TAVI using the Edwards Lifesciences SapienTM valve in our institutions, of which 58 patients (10.4%) underwent a TAo procedure using Ascendra delivery system. All patients were discussed in a multidisciplinary meeting and the decision for TAVI was based on high predictive risk for AVR. Patients with poor vascular access who were considered unsuitable for TF approach were considered for TAo approach if TAo approach was either not feasible (3/58) or desirable due to poor lung function (9/58), poor left ventricular function (6/58), fatty heart (2/58) and surgeons preference (28/58).

**Results:** Seven of these patients had also undergone at least one previous heart operation (12.1%).

**Results:** Mean age was 80 ±6.6y and 61% were female (n=23). Mean logistic Euroscore was 32 ±16 and STS score 8.09 ±3. M. The mean ejection fraction was 45 ±16 %, valve area 0.9 ±0.2cm² and peak gradient 67 ±19mmHg. All procedures were performed under general anaesthesia. Valve sizes used were 23mm (n=27, 40%), 26mm (n=29, 50%) and 29mm (n=2, 4%). Procedural success was achieved in all patients (100%). Post procedural mean and peak gradients were 6.2 and 11mmHg respectively. No valve migrations or structural valve failure were seen in any of the patients. 12-month all-cause survival was 92.2 ±3.8%. Valve orifice area and mean gradient showed statistical significance in this subgroup of patients was satisfactory with excellent short-term results.

**Conclusion:** Trans-aortic TAVI is a feasible and safe approach in the treatment of aortic stenosis using Edwards Sapien valve and Ascendra delivery system with low in-hospital complication rates. Despite high incidence of respiratory disease the outcome in this subgroup of patients was satisfactory with excellent short-term results.

**TCT-136**

Twelve-Month Results from the CoreValve Transcatheter Aortic Valve Replacement Australia-New Zealand Study

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**Background:** For patients with severe aortic stenosis at high risk for surgical replacement, transcatheter aortic valve implantation (TAVI) is a therapeutic option. We report twelve-month results from a multicenter study in Australia and New Zealand.

**Methods:** The CoreValve (Medtronic, Irvine, Calif.) Australia-New Zealand study is a fully monitored study with independent adjudication of adverse events. The study has enrolled 229 subjects at eight centers since 2008. Inclusion criteria included severe symptomatic aortic valve disease, age >80 or >65 with 1.2 high-risk co-morbidities or logistic EuroSCORE >20.

**Results:** Subjects were male 56%, age 84±6 years, logistic EuroSCORE 18±11, NYHA class III/IV 89%. Procedural success (successful implant without conversion to surgery or death) was 96.9%. Thirty-day all-cause mortality was 4.1% and the stroke rate was 1.9%. In 86 subjects after 12 months, all-cause survival was 88.0±4.5% and cardiac survival was 92.2±3.8%. Valve orifice area and mean gradient showed statistical improvements at 30 days and 12 months. No valve migrations or structural valve deterioration were reported. Aortic regurgitation grades at 12 months via echo were <2 in 94.0% of patients. Most (76.7%) improved >1 NYHA class at 12 months and improvements at 30 days and 12 months. No valve migrations or structural valve failure were seen in any of the patients. 12-month all-cause survival was 92.2 ±3.8%. Valve orifice area and mean gradient showed statistical significance in this subgroup of patients was satisfactory with excellent short-term results.

**Conclusion:** The 18Fr CoreValve TAVI prosthesis is safe and effective at twelve months in this monitored and adjudicated multicenter trial. Stable mortality and morbidity outcomes are within expectations for percutaneously treated subjects with severe symptomatic aortic stenosis in this very high-risk subgroup. Enrollment and long-term follow-up are ongoing and updated results, including vascular complications and pacemaker implants, will be forthcoming.

**TCT-137**

Comparison of Balloon-expandable and Self-expandable Bioprostheses for Transcatheter Aortic Valve Implantation

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**Background:** Recently Transcatheter Aortic Valve Implantation (TAVI) using balloon-expandable prostheses favorably compared to conservative management in inoperable patients and to surgery in high-risk patients. However, no data in comparison with surgery exists for self-expandable prostheses. We assessed prosthesis performance and clinical outcome of TAVI using self-expandable or balloon-expandable devices.

**Methods:** Valve performance and outcome were assessed in a prospective registry including all patients who underwent TAVI in our Department. The III generation CoreValve ReValving System was implanted between June 2007 and March 2009 (CoreValve, Medtronic Minneapolis, Minnesota, USA) and the Edwards SAPIEN/SAPIEN XT between April 2009 and May 2011 (ES. Edwards Lifesciences Irvine, CA, USA). Safety and efficacy end-points were expressed according to VARC definitions.

**Results:** One-hundred and ninety-eight patients underwent TAVI, 87 (43.9%) with CRS (82 transfemoral and 5 trans-subclavial), 111 (46.1%) with ES device (62 transfumal and 49 transapical).

**Conclusion:** TAVI using both self-expandable and balloon-expandable prostheses seems a safe alternative to surgery in high-risk aortic stenosis. However, prosthesis performance as well as 1-year effectiveness were higher using balloon-expandable devices.