Conclusions: Experience with the MitraClip in patients with a dilated left ventricle suggests that the procedure is safe and feasible in most patients. Mortality and heart failure-related hospital rates are low. This therapy may be an alternative to surgery in this high-risk group of patients.

TCT-88

Three-year Clinical Outcomes of the First-In-Human Experience with Percutaneous Ventricular Restoration Using the Parachute Device in Patients with Ischemic Heart Failure and Dilated Left Ventricle

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Background: Left ventricle (LV) remodeling after anterior wall myocardial infarction leads to increased LV volumes, myocardial stress and ultimately congestive heart failure (CHF). Treatment options are limited for these high morbidity and mortality risk population.
Methods: The study included 39 patients with ischemic CHF class II-IV (NYHA), akinetic or dyskinetic wall abnormality, ejection fraction between 15 and 40% and no revascularization options were enrolled in 14 U.S. and European sites. The device was deployed into the left ventricle apex to partition off the damaged myocardium. Warfarin and ASA treatment for 1-year post implant. All events were adjudicated and CT, EKG and echo data were analyzed by independent core labs.
Results: End-diastolic volume was 127.5cc pre-procedure, 106.7cc at 6-month and 114.7cc at 2 years by echo (p=0.74 6M vs 2Y). There were no strokes and worsening CHF or death occurred in 32.9% (per Protocol n=34) or 29.5% (treated pts, n=31) of patients at 2 years. Average NYHA class reduced from 2.6 to 1.9 with 87% of patients reporting improvement in symptoms at 12 months. Adjudication of 3-year clinical events will be completed in July 2012 and will be available for presentation.
Conclusions: Sustained 2-year improvement in symptoms and LV volume was observed after PVR using the ParachuteTM device in patients with ischemic CHF and anterior LV dilatation. Three-year clinical data will provide important insights into long-term safety of this novel therapy.

Transcatheter Aortic Valve Replacement I

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TCT-89

Timing, Predictive Factors and Prognostic Value of Cerebrovascular Events in a Large Cohort of Patients Undergoing Transcatheter Aortic Valve Implantation

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Background: Recent studies have raised major concerns about an increased risk of cerebrovascular events (CVE) following transcatheter aortic valve implantation (TAVI). The objective of this study was to evaluate the timing, predictive factors and prognostic value of CVE following TAVI.
Methods: A total of 1061 consecutive patients who underwent TAVI with a balloon- (64%) or a self- (36%) expandable valve in 5 centers were included. CVEs were defined using the VARC criteria and further classified according to timing with respect to the TAVI procedure as acute (≤24 hours), subacute (1 to 30 days), and late (>30 days). All baseline, procedural, and follow-up data were prospectively recorded.
Results: CVEs occurred in 54 patients (5.1%; stroke: 4.2%, TIA: 0.9%) within 30 days following TAVI, and were acute and subacute in 54% and 46% of cases, respectively. The predictors of acute CVEs were balloon postdilation (BPD) of the valve prosthesis (OR: 2.46, 95% CI: 1.07-5.67) and valve dislodgment/embolization (OR: 4.36, 95% CI: 1.21-15.69); new-onset atrial fibrillation [NOAF] (OR 2.72, 95% CI 1.10-6.73) was the only predictor of subactute CVEs. Late CVEs occurred in 35 patients (3.6%; stroke: 2.1%, TIA: 1.5%) at a median follow-up of 12 (3-23) months. The independent predictors of late CVEs were chronic AF (HR: 2.62, 95% CI 1.34-5.11) and peripheral vascular disease (HR: 2.07, 95% CI 1.05-4.08). Major stroke was independently associated with 30-day (OR 7.43, 95% CI 2.45-22.53) and late (HR: 1.75, 95 CI% 1.01-3.03) mortality.
Conclusions: In a large cohort of patients undergoing TAVI, the rate of acute and subacute CVEs was 2.7% and 2.4%, respectively. While mechanical factors such as further stretching of the valve prosthesis with BPD and valve embolization were the predictors of acute CVEs, atrial arrhythmias (NOAF) determined a higher risk for subacute events. Late events were mainly determined by chronic AF and peripheral vascular disease. The occurrence of major stroke was associated with an increased early and late mortality. These results provide important insights for the implementation of preventive measures for CVEs following TAVI.

TCT-90

Predictive Factors and Long-Term Clinical Consequences of Persistent Left Bundle Branch Block Following Transcatheter Aortic Valve Implantation with a Balloon-Expandable Valve

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Background: The predictors of persistent(vs transient or absent)left bundle branch block (LBBB)after transcatheter aortic valve implantation(TAVI)with a balloon-expandable valve(BEV)and its clinical consequences are unknown. The aim of this study was to evaluate the predictors and prognostic value of new-onset persistent LBBB in patients undergoing TAVI with a BEV.
Methods: A total of 202 consecutive patients with no baseline ventricular conduction disturbances or previous permanent pacemaker implantation (PPI) who underwent TAVI with a BEV were included. Patients were on continuous ECG monitoring during hospitalization and 12-lead ECG was performed daily until hospital discharge. No patient was lost at a median follow-up of 12 (6-24) months, and ECG tracing was available in 97% of patients. The criteria for PPI were limited to the occurrence of high degree atrioventricular block (AVB) or severe symptomatic bradycardia.
Results: New-onset LBBB was observed in 61 patients (30.2%) immediately after TAVI, and had resolved in 37.7% and 57.3 % of them at hospital discharge and at 6 to 12-months follow-up, respectively. Baseline QRS duration (p=0.037) and prosthesis ventricular depth (p=0.017) were independent predictors of persistent LBBB. Persistent LBBB at hospital discharge was associated with a decrease in left ventricular ejection fraction (p=0.001) and poorer functional status (p=0.034) at 1-year follow-up. Patients with persistent LBBB and no PPI at hospital discharge had a higher incidence of syncope (16.0% vs. 0.7%, p=0.001) and complete AVB requiring PPI (20.0% vs. 0.7%, p<0.001), but not of global mortality, cardiac mortality or sudden death during the follow-up period (p>0.20 for all). New-onset LBBB was the only factor associated with PPI following TAVI (p<0.001).
Conclusions: Up to 30% of the patients with no prior conduction disturbances developed new LBBB following TAVI with a BEV, although it was transient in more than one third of them. Longer baseline QRS duration and a more ventricular positioning of the prosthesis were associated with a higher rate of persistent LBBB, which in turn determined a higher risk for complete AVB and PPI but not mortality or sudden death at 1-year follow-up.

TCT-91

Peri-valvular Aortic Regurgitation in Balloon-expendable and Self-expendable TAVI procedures: Predictors and Impact on clinical outcome - Insights from the FRANCE2 Registry

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Background: A significant perivalvular aortic regurgitation (AR) is observed in 10-20% after a successful TAVI procedure. The prognostic value and the predictors of such