Conclusions: Percutaneous PFO closure is safe and effective therapeutic approach for patients with atrial fibrillation and an underlying hypercoagulable disorder.

TCT-86
Efficacy And Safety Of Percutaneous Patent Foramen Ovale Closure In Patients With A Hypercoagulable Disorder
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Background: The presence of a patent foramen ovale (PFO) has been associated with an increased incidence of cryptogenic stroke. Patients who have a PFO and an associated thrombophilia may have an increased risk of cerebral ischemic events. Percutaneous PFO closure could be a safe and effective alternative therapeutic approach for these patients.

Methods: Consecutive patients who underwent PFO closure at a large academic center were evaluated. All patients underwent hypercoagulation testing with functional assays for homocysteine; proteins C and S; antithrombin III; factor II mutation; factor V-Leiden mutation; lipoprotein (a); elevated levels of antiphospholipids; including lupus anticoagulant (LAC), anticardiolipin (aCL). We compared the safety and efficacy of percutaneous PFO closure in this group of patients versus the group of patients without a hypercoagulable state.

Results: Of 728 consecutive patients with PFO undergoing percutaneous PFO closure, a hypercoagulable state was found in 234 patients (32.1%). There were no significant differences on baseline demographics or echocardiographic characteristics. There were no differences on success rate and complication rate between both groups. Follow up was available in 708 patients (97.3%). Median follow-up was 17 months. During follow-up there were no differences in TIA/stroke incidence (0.4% in the group with coagulation disorder and 0.6% in the non-hypercoagulable group, log rank test p =0.97).

Conclusions: Percutaneous PFO closure is safe and effective therapeutic approach for patients with cryptogenic stroke and an underlying hypercoagulable state.

TCT-87
Safety And Efficacy Of The MitraClip For The Treatment Of Patients With A Dilated Left Ventricle And Functional Mitral Regurgitation
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Background: Surgical treatment of functional mitral regurgitation (FMR) in the setting of heart failure has adequate short-term results however, late recurrence of mitral regurgitation is frequent and associated with high mortality. Patients with dilated left ventricles (LV) at baseline appear to be a higher risk for early mortality (17.9%) and readmission (Braun et al, 2008). We sought to determine the outcomes of patients with FMR and dilated ventricles treated with the MitraClip device.

Methods: Prospective data was collected on patients undergoing therapy with the MitraClip at the Montreal Heart Institute and Cedars Sinai Medical Center. Echo data was obtained pre- and post-procedure. Severity of MR was assessed echocardiographically in accordance with ASE Guidelines. Procedural success was defined as residual MR grade of 2+ or less. Dilated left ventricle was defined as a left ventricular end-diastolic dimension (LVEDD) ≥55mm. Mortality and hospital re-admission data was obtained from chart review and hospital administration databases.

Results: A total of 70 patients underwent transcathereter leaflet repair with the MitraClip at both centers during the study period. Ten were identified as having a dilated left ventricle and significant mitral regurgitation. Procedural success in this group of patients was 80% (n=8). In one patient, we were unable to grasp the leaflets and no clip was deployed; the patient subsequently died 12 days later from progressive renal failure while a second patient required mitral valve surgery for persistent severe MR. There were no procedural complications.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>LVEDD (mm)</th>
<th>EF (%)</th>
<th>MR pre-MitraClip</th>
<th>MR post-MitraClip</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>67</td>
<td>74</td>
<td>25</td>
<td>4</td>
<td>1</td>
<td>Unable to place clip, died 12d post-procedure</td>
</tr>
<tr>
<td>2</td>
<td>88</td>
<td>68</td>
<td>30</td>
<td>4</td>
<td>1</td>
<td></td>
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<tr>
<td>3</td>
<td>73</td>
<td>68</td>
<td>60</td>
<td>4</td>
<td>4</td>
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<td>4</td>
<td>77</td>
<td>66</td>
<td>20</td>
<td>3</td>
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<tr>
<td>5</td>
<td>79</td>
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<td>2</td>
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<tr>
<td>6</td>
<td>73</td>
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<td>20</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>70</td>
<td>70</td>
<td>20</td>
<td>3</td>
<td>3</td>
<td>MVR Day #2 post-procedure</td>
</tr>
<tr>
<td>8</td>
<td>64</td>
<td>68</td>
<td>25</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>82</td>
<td>75</td>
<td>20</td>
<td>3</td>
<td>1</td>
<td>At 6 month mod MR, NYHA class I no admission in hospital</td>
</tr>
<tr>
<td>10</td>
<td>56</td>
<td>81</td>
<td>42</td>
<td>4</td>
<td>2</td>
<td>At one and half years no admission for heart failure, grade 2 MR NYHA class I</td>
</tr>
</tbody>
</table>

TCT Abstracts/ORAL/Structural, Non-Valvular Intervention
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 lower than 50% and no revascularization procedures were enrolled in 14 U.S. and European sites. The device was deployed into the left ventricular 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 2.9 to 2.5 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
D237-238
Tuesday, October 23, 2012, 10:30 AM–12:30 PM
Abstract nos: 89-96

TCT-89
Timing, Predictive Factors and Prognostic Value of Cerebrovascular Events in a Large Cohort of Patients Undergoing Transcatheter Aortic Valve Implantation
Luis Nombela-Franco1, John Webb2, Peter De Jaegere3, Stefan Toggweiler4, Jan Nais Ratger1, Antonio Dogariu5, Ignacio Amat-Santos6, Anson Cheung7, Jian Ye8, Robert M A Van Der Boom9, Nicolas Van Mieghem10, Luis Benitez11, Ronald Binder12, Sergio Perez13, Javier Lopez14, Alberto San Roman15, Daniel Doyle16, Robert De Lorach17, Jonathon Leipsic18, Eric Dumont19, Josep Rodés-Cabau20
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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 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 (1-30 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: 4.4; 95% CI 0.93-20.16), and valve dislodgment/embolization (OR: 5.71; 95% CI: 1.21-25.69). new-onset atrial fibrillation (NOAF) (OR 2.8; 95% CI 1.1-6.73) was the only predictor of subacute CVEs. Late CVE 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 2.25-22.53) 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 event. 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
Marina Urena1, Michael Mok2, Vicenç Serra3, Eric Dumont3, Luis Nombela-Franco1, Robert De Lorach1, Daniel Doyle6, Albert Igual4, Eric Larose2, Ignacio Amat-Santos5, Melanie Coté4, Hug Cuellar4, Philippe Pibarot1, Peter De Jaegere3, François Philippot3, Ennio Garcia del Blanco3, Josep Rodes-Cabau1, Qatar Health and Lang Institute, Laval University, Quebec, Canada, 2Vall d’Hebron University Hospital, Barcelona, Spain, 3Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands

Background: The predictors of persistent LV's transient and 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 late 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 atroventricular 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-month 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-expansible and Self-expandable TAVI procedures: Predictors and Impact on clinical outcome - Insights from the FRANCE2 Registry
Eric Van Belle1, Francis Jutier2, Jean - Luc Auffray3, Marc Laskar2, Alain Leguerrier4, Bernard Lung5, Martine Gils6, Helene Eltchaninoff5, Carlo Barfut7, Jean Fajadet8, Pascal Leprince1, Alain Prat9, Emmanuel Teiger10, 1Hopital de Lille, Hospitale du littoral, Lille Cedex, France, 2CHRU Lille, Lille, France, 3Hopital cardiologique CHRU Lille, Lille, France, 4CHRU Limoges, Limoges, France, 5CHRU Rennes, Rennes, France, 6CHRU Bichat, Paris, France, 7CHRU Brest, Bret, France, 8CHRU Rouen, Rouen, France, 9Hospital cardiologique CHRU Lille, Lille, France, 10Clinique Pasteur, Toulouse, France, 11CHU La Pitié, Paris, France, 12Hopital Cardiologique, CHRU Lille, Lille, France, 13CHU Henri Mondor, Paris, France

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