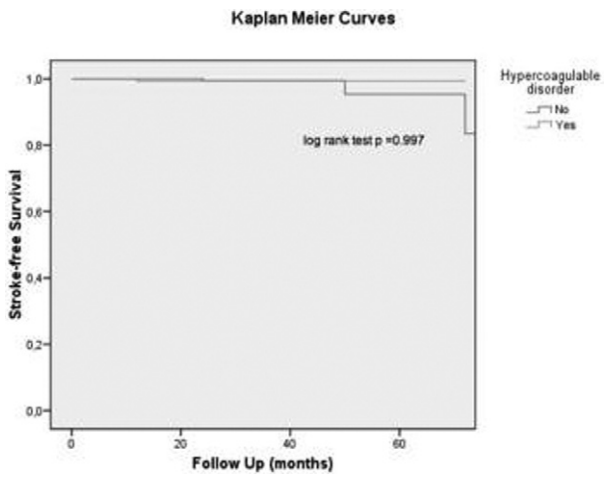
TCT-85

Efficacy And Safety Of Percutaneous Patent Foramen Ovale Closure In Patients With A Hypercoagulable Disorder

Jesus Herrero-Garibi[1], Ignacio Cruz-González[2], Pablo Rengifo[3], Ferdinando Bounanno[3], Maria Sánchez-Ledesma[2], Francisco Martín-Herrero[2], Igor Palacios[4]
[1]University Hospital of Burgos, Burgos, Spain, [2]University Hospital of Salamanca, Salamanca, Spain, [3]Massachusetts General Hospital, Boston, MA, [4]Associate Professor of Medicine. Harvard Medical School, Boston, MA

Background: The presence of a patent foramen ovale (PFO) has been associated with an increase 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 centre 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 month. 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 =0.997).



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

TCT-86

Results of the Amplatzer Cardiac Plug European Multicenter Prospective Observational Study

Jai-Wun Park[1], Jai-Wun Park[1], Horst Sievert[2], Wolfgang Schillinger[3], Lars Lickfett[4], Jose Ramon Lopez-Minguez[5], Heyder Omran[6], Mariano Valdes[7], Benno Hennen[8], Kevin Walsh[9], Oliver Ormerod[10], Peter Neuzil[11], Rainer Schraeder[12], Eulogio Garcia[13], David Hildick-Smith[14], Roman Lezaun[15]
[1]Asklepios Hospital Hamburg Harburg, Hamburg, Germany, [2]Cardio Vascular Center Frankfurt, Frankfurt, Germany, [3]Georg-August-University Göttingen, Göttingen, Germany, [4]Medizinische Klinik II des Universitätsklinikums Bonn, Bonn, Germany, [5]Hospital Universitario Infanta Cristina, Badajoz, Spain, [6]St.-Marien-Hospital, Bonn, Germany, [7]Hospital Universitario Virgen de la Arrixaca, Murcia, Spain, [8]Stadt Krankenhaus Pirmasens, Pirmasens, Germany, [9]Mater Misericordiae Hospital, Dublin, Ireland, [10]Oxford John Radcliffe Hospital, Oxford, Oxfordshire, [11]Homolka Hospital, Prauge, Czech Republic, [12]Kardiocentrum Frankfurt an der Klinik Rotes Kreuz, Frankfurt, Germany, [13]University of Madrid, Madrid, Spain, [14]Royal Sussex County Hospital, Brighton, United Kingdom, [15]Hospital de Navarra, Pamplona, Spain

Background: Many patients with atrial fibrillation (AF) at high risk for thromboembolic events are not candidates for long-term oral anticoagulation (OAC). The left atrial appendage (LAA) is the major site of thrombus formation in non-valvular AF. We report procedural results with 6 month follow-up for LAA occlusion with the AMPLATZER™ Cardiac Plug (ACP) (St. Jude Medical, Plymouth, MN).
Methods: A total of 197 patients underwent ACP implantation at one of 15 investigative centers in Europe in 2009-2011. 183 patients have completed their 6 month follow up visit. Study follow up requirements included echocardiographic assessment at baseline, pre-discharge 1 and 6 months post implant as well as rigorous neurological exam after a suspected stroke, TIA or systemic embolism.
Results: The majority of patients (57.9%) had a history of permanent AF, mean age was 74.20 ± 9.0, mean CHADS2 score 2.6 ± 1.3. Prior stroke or TIA was reported by 39.2% of patients. Patients were indicated for ACP therapy due to bleeding risk on oral anticoagulation (OAC) (79.8%), prior hemorrhage (8.9%) or prior stroke on Warfarin (11.3%). Only 3.9% of patients were on active OAC prior to implant. The ACP device was successfully implanted in 96.6% of patients with a closure rate of 99.5% at implant and 98.9% at six months. Device/procedure related safety events included: 0 (0.0%) periprocedural strokes, 3 (1.5%) serious pericardial effusions, 5 (2.4%) device related thrombus, and 3 (1.5%) device embolizations. The stroke rate was 1.98% at 101 patient years compared with a CHADS2 prediction of 5.6%.
Conclusions: Although warfarin has been shown to be effective for AF, many patients with AF are contraindicated for it. The ACP device is a good alternative for these patients based on the reported excellent implant success, LAA closure, and yields an acceptable safety profile. The rate of adverse events compares favorably with other LAA closure devices despite the high risk patients enrolled in the Study.

TCT-87

Safety And Efficacy Of The MitraClip For The Treatment of Patients With A Dilated Left Ventricle And Functional Mitral Regurgitation

Anita Asgar[1], Paul Khairy[2], Raoul Bonan[3], Anique Ducharme[1], Saibal Kar[4]
[1]Montreal Heart Institute, Montreal, Quebec, [2]Montreal Heart Institute, Montreal, QC, [3]Montreal University, Montreal, Canada, [4]Associate Professor at the David Geffen School of Medicine at UCLA, Los Angeles, USA

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) ≥65mm. Mortality and hospital re-admission data was obtained from chart review and hospital administration databases.
Results: A total of 70 patients underwent transcatheter 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.

Patient	Age	LVEDD (mm)	EF (%)	MR pre-MitraClip	MR post-MitraClip	Clinical Outcome
1	67	74	25	4	1	
2	88	68	30	4	1	
3	73	68	60	4	4	Unable to place clip, died 12d post-procedure
4	77	66	20	3	2	
5	79	76	20	4	2	
6	73	83	20	3	1	
7	70	70	20	3	3	MVR Day #2 post-procedure
8	64	68	25	3	2	
9	82	75	20	3	1	At 6 month mod MR, NYHA class I no admission in hospital
10	56	81	42	4	2	At one and half years no admission for heart failure, grade 2 MR NYHA class I

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

Marco Costa[1], Sinisa Gradinac[2], Ernest Mazzaferri[3], Horst Sievert[4], Igor Gregoric[5], Charles Davidson[6], Peter Berger[7], Albrecht Elsässer[8], Ron Waksman[9], Frank Smart[10], William Albernathy[11], William Abraham[12]
[1]Case Western Reserve University, Cleveland, OH, [2]Dedinje Cardiovascular Institute and Belgrade University Medical School, Belgrade, Yugoslavia, Belgrade, OH, [3]Ohio State University, Dublin, OH, [4]CardioVascular Center Frankfurt, Frankfurt, Germany, [5]St. Luke's Episcopal Hospital, Houston, TX, [6]Northwestern University Medical School, Chicago, USA, [7]Geisinger Center for Clinical Studies, Danville, PA, [8]Klinikum Oldenburg, Oldenburg, Germany, [9]Georgtown University, Washington, DC, [10]Louisiana State University, New Orleans, LA, [11]Duke University School of Medicine, Durham, NC, [12]Ohio State UNiveristy, Columbus, OH

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

D237-238

Tuesday, October 23, 2012, 10:30 AM–12:30 PM

Abstract nos: 89-96

ORALS

TCT-89

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

Luis Nombela-Franco[1], John Webb[2], Peter De Jaegere[3], Stefan Toggweiler[2], Jan Nuis Rutger[3], Antonio Dager[4], Ignacio Amat-Santos[5], Anson Cheung[2], Jian Ye[2], Robert M A Van Der Boon[3], Nicolas Van Mieghem[3], Luis Benitez[4], Ronald Binder[2], Sergio Perez[4], Javier Lopez[5], Alberto San Roman[5], Daniel Doyle[1], Robert De Larochelliere[1], Jonathon Leipsic[2], Eric Dumont[1], Josep Rodes-Cabau[1]
[1]Quebec Heart & Lung Institute, Laval University, Quebec, Canada, [2]St Pauls Hospital, University of British Columbia, Vancouver, Canada, [3]Thoraxcenter, Erasmus Medical Center, Rotterdam, Rotterdam, Netherlands, [4]4Angiografía de Occidente, SA, Cali, colombia, [5]Institute of Heart Sciences (ICICOR), University Clinic Hospital of Valladolid, Valladolid, Spain

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

Marina Urena[1], Michael Mok[1], Vicenç Serra[2], Eric Dumont[1], Luis Nombela-Franco[1], Robert De Larochelliere[1], Daniel Doyle[1], Albert Igual[2], Eric Larose[1], Ignacio Amat-Santos[1], Melanie Coté[1], Hug Cuellar[2], Philippe Pibarot[1], Peter De Jaegere[3], François Philippon[1], Bruno Garcia del Blanco[2], Josep Rodes-Cabau[1]
[1]Quebec Lung and Heart Institute, Laval University, Quebec, Canada, [2]Vall d'Hebron University Hospital, Barcelona, Spain, [3]Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands

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

Eric Van Belle[1], Francis Juthier[2], Jean - Luc Auffray[3], Marc Laskar[4], Alain Leguerrier[5], Bernard Lung[6], Martine Gilard[7], Helene Eltchaninoff[8], Carlo Banfi[9], Jean Fajadet[10], Pascal Leprince[11], Alain Prat[12], Emmanuel Teiger[13]
[1]University Hospital of Lille, Cardiological hospital, Lille Cedex, France, [2]CHRU Lille, Lille, France, [3]Hôpital cardiologique CHRU Lille, Lille, France, [4]CHRU Limoges, Limoges, France, [5]CHRU Rennes, Rennes, France, [6]CHRU Bichat, Paris, France, [7]CHRU Brest, Brest, France, [8]CHRU Rouen, Rouen, France, [9]Hopital cardiologique CHRU Lille, Lille, France, [10]Clinique Pasteur, Toulouse, France, [11]CHU La Pitié, Paris, France, [12]Hôpital Cardiologique CHRU Lille, Lille, France, [13]CHU Henri Mondor, Paris, France

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