TCT-97
Long term follow up of 134 patients with non valvular atrial fibrillation and contraindications to oral anticoagulation therapy, treated with the Amplatz Cardiac Plug Device for left atrial appendage occlusion

Miroslava Stolcova, Marco Rezzaighi, Francesco Meucci, Cataldo Palmieri, Umberto Paradosi, Luigi E. Pastorizela, Gabriele Rosso, Sergio Bertis, Gianmario Saon
1Careggi Hospital, Firenze, Italy, 2Fondazione Gaetano Monasterio, Massa Hospital, Massa, Italy, 3Careggi Hospital, Florence, Italy, 4Fondazione Toscana Fondazione Gaetano Monasterio, Massa Hospital, Massa, Italy, 5Santa Maria Annunziata Hospital, Firenze, Italy

Background: Left atrial appendage occlusion with the Amplatz Cardiac Plug Device (ACP) (St Jude Medical, Minneapolis, MN) for non valvular atrial fibrillation (NVAF) and contraindications to oral anticoagulant (OAC) is showing to be feasible and safe but there is lack of data as for the long term follow up.

Methods: We report the follow up of 134 patients treated with ACP device from 1/2009 to 12/2012 in two Italian centers. Most patients received short-term (1-3 months) dual antiplatelet therapy following the procedure and single antiplatelet therapy thereafter. Follow up was carried out by clinical visit or phone contact at 1, 6 and 12 months and yearly thereafter. A total of 93(72.6%) patients received imaging follow-up 6 months after the procedure either by transesophageal echography(TEE) or by cardiac CT scan. The presence of device thrombosis and residual leak were evaluated.

Results: Mean age and median CHADS2 were 76±6 and 3 respectively. The procedure was successful in 96% of the patients. Main complications were pericardial effusion (4.4%) with 2 cases of cardiac tamponade (1.4%), 1 hemorrhagic stroke and 1 TIA. Median follow up was 22 months (range 1.4 – 53.6). The longest follow up was 4 years for 4 patients. 20 patients had a follow up of 3 years. 110 patients had a follow up of >6 months. TA was closed using an Amplatzer device in 28 cases (67.5%), device thrombosis and residual effusion at follow-up were 5.5%, 1.5%, 2.3% and 0% respectively. The presence of peri-device leak was observed in 5.4% of patients at 6-months imaging follow-up. No massive leak was observed. There was one case of device thrombosis that resolved after 1 month of anticoagulation. The imaging follow-up showed low incidence of significant residual leaks. We also confirm the feasibility and safety of the LAOO procedure.

TCT-98
Longest Single-Center Experience of Percutaneous Left Ventricular Transapical Access for Structural Heart Disease Interventions

Chad Kligcr 1, Leandro C. Maranan 2, Sonnit Sharma 3, Robert Kumar 3, Vladimir Jelinin 4, Itzhak Kronzon 1, Anja Summers 5, Carlos E. Rui 5
1Lenox Hill Heart and Vascular Institute-North Shore LJI Health System, New York, NY, 2Lenox Hill Heart & Vascular Institute, New York, NY, 3Lenox Hill Heart and Vascular Institute, New York, NY, 4Professor of Pediatrics and Medicine, New York, NY

Background: Percutaneous left ventricular transapical access (TA) can be utilized for a multitude of diagnostic and interventional procedures in structural heart disease (SHD). With advancements in imaging and device technology, applicability of this approach is expanding. We present our growing experience in utilizing TA for structural heart interventions.

Methods: We evaluated patients at our center, from April 2008 to June 2013, who presented for SHD intervention. Ninety four TA were performed in 80 consecutive patients (54 males, 71±30 years) with 4 patients having double TA during the same intervention and 10 patients having repeat TA during subsequent SHD interventions (double TA n=13). Since August 2010, computed tomographic angiography (CTA)/fluorescopy fusion imaging (HeartNavigator, Philips, Netherlands) has been used to guide TA puncture.

Results: All TA were successfully performed for the following interventions: 74 mitral paravalvular leak (PVL) closure, 6 aortic PVL closure, 14 left ventricular pseudoaneurysm (LVP) closure, 2 ventricular septal defect closure, 8 mitral transcatheater valve-in-valve implantations, and 10 combined procedures. Average initial final sheath sizes were 6F and 7F (range 5F-12F). TA was closed using an Amplatzer Ductal Occluder n=86, Amplatzer Vascular Plug II n=3, Muscular VSD Occluder n=3, and coils n=2. Complications occurred in 13 cases (14%): hemorrhotax n=5, pericardial effusion n=2, persistent access site bleeding requiring surgery n=2, non-fatal device migration n=3 (2 ventricular, 1 epicardial requiring surgical closure), and death n=2. One death occurred in a patient with suprasystemic pulmonary hypertension developing pulseeless electrical activity and one death occurred after PVL closure in the setting of untreated critical aortic stenosis and epicardial device migration. There was no significant difference in complications associated with use of fusion imaging (with 10% vs within 17.6%, p=0.29).

Conclusions: TA is useful in multiple SHD interventions. Despite fusion imaging, complications still occur. More reliable TA closure devices may further improve the safety and generalizability of this approach for more complex SHD interventions.

TCT-99
Long-term recurrent ischemic event rates after percutaneous closure of patent foramen ovale in patients with paradoxical embolism

Marius Hornung 1, Jennifer Franke 1, Stefan C. Bertog 2, Dani Ild 3, Ilona Hofmann 4, Laura Vaskelyte 1, Horst Siever 1
1CardioVascular Center Frankfurt, Frankfurt, Germany

Background: Patients with a patent foramen ovale (PFO) and a history of paradoxical embolism are at risk to suffer from recurrent events even if the PFO was closed percutaneously. This study investigated the long-term results of a high-volume center.

Methods: PFOs were closed in patients with a history of at least one assumed paradoxical embolism (TIA, stroke or peripheral embolism) or a diving accident. The type of closure device was chosen due to availability and operator's decision. All patients were prescribed a dual antiplatelet therapy (aspirin and clopidogrel) for the first 6 months after the procedure. Echocardiographic studies were performed at 4 weeks and 6 months after the index procedure. Patients were evaluated for residual shunts and the incidence of potential adverse events. All patients were followed annually through office visits, telephone calls, and by contacting the referring physicians.

Results: Between August 1998 and December 2012 percutaneous closure of patent foramen ovale was performed in 2831 patients. The mean age of patients was 50±13 years. 55% were male (n=1551). Indication for PFO-closure was a history of migraine (n=1481), peripheral embolism (n=55), diving accident (n=36) or cryptogenic cerebral ischemic event (n=38). The Amplatzer device was used in 1334 patients (38.0%) and the CardioSEAL-STARFlex device in 563 patients (19.9%) suffered from recurrent neurological events before percutaneous PFO-closure. We used 23 different types of closure devices. The most commonly used occluders were the Amplatzer (n=914), the Helex (n=470), the Premere (n=409) and the CardioSEAL-STARFlex device (n=318). Within a mean follow-up of patient years (mean follow-up duration: 38 months), there were 89 recurrent embolic events. This compares to an annual event rate of 1.0%. 29 patients suffered from recurrent TIA, and in 54 patients an ischemic stroke occurred. In 6 patients peripheral embolic events occurred. In 122 patients (0.4%) a second device implantation was performed to close a residual shunt.

Conclusions: The results of this study represent the clinical experience of a European high-volume center in PFO-closure and show a favorable and much lower annual recurrent event rate compared to previously published randomized trials.

TCT-100
Effect of Intra cardiac echocardiography and yearly operator volume on Length of Stay and Cost of Care for Percutaneous Closure of Atrial Septal Septal and Patent Foramen Ovale: A Perspective of Last Decade

Shilpkumar Arora 1, Nileshkumar J. Patel 2, Ankit Chothani 3, Neeraj Shah 2, Kathan Mehta 4, Peeyush Grover 5, Vikas Singh 6, Abhishek J. Deshmukh 7, Ankath Rathod 8, Dhyaval B. Kadhada 9, Ghanashyamthi T. Savani 2
1Careggi Hospital, Firenze, Italy, 2Fondazione Gabriele Monasterio, Massa Hospital, Massa, Italy, 3Lenox Hill Heart & Vascular Institute, New York, NY, 4Professor of Pediatrics and Medicine, New York, NY

Background: We examined the Stroke and Cost of Care due to Patent Foramen Ovale (PFO) and other non-structural heart defects during the past decade. The Transcatheter Closure of Patent Foramen Ovale (TCT-99) Project's Nationwide Inpatient Sample (NIS) database from 2001 to 2010 using ICD 9-CM code for percutaneous ASD/PFO closure (53.52). Only adult (age ≥ 18 years) patients with ASD/PFO (ICD 9-CM - 745.5) were included in study. We could not differentiate between ASD and PFO closure due to same ICD9 code for both procedures. NIS represents 20% of all US hospitals. Cost to charge ratio files were merged with NIS to calculate cost of care. Cost was adjusted for inflation in reference to 2010. Comorbid conditions were defined by Charlson's Comorbidity Index (CCI). Hierarchical multilevel regression models were generated to determine independent predictors of LOS and cost of care.

Results: Total of 7,107 (weighted n=34,990) percutaneous ASD/PFO closure procedures were analyzed. Average LOS and cost of care per percutaneous ASD/PFO closure were 2.63±0.06 days and $16,635±1,225, respectively. LOS was increased (days, 95% CI, P-value) with presence of any complication (+2.47 days, 2.14-2.80, P < 0.001). Decrease in LOS was associated with use of higher operator volume tertile (+2.58 days, -3.04 - +2.12, P1 (1.17, 1.1-2.12, P < 0.001). Decrease in cost was associated with higher annual operator volume tertile (0.84, 0.08 - 0.88, P < 0.001).