**TCT-97**

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

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**Background:** Left atrial appendage occlusion with the Amplatzer Cardiac Plug Device (ACP) (St Jude Medical, Minneapolis, MN) for non valvular atrial fibrillation (NVAF) and contraindications to oral anticoagulant therapy (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 antplatelet therapy following the procedure and single antplatelet therapy thereafter. Follow up was carried out by clinic visits 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 transthoracic echocardiography (TTE) 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. 26 patients had a follow up of 3 years. 110 patients had a follow up of > 3 years. 10 patients had a follow up of ≥ 5 years. The rate of death, stroke and systemic embolism 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 expected stroke rate was 8.6% versus an observed stroke rate of 1.5% (p=0.01).

**Conclusions:** Our follow up of patients treated with ACP device for NVAF and contraindications to OAC demonstrates the efficacy of the procedure in preventing stroke over a long time period (110 pts followed for >1 year), with a significant reduction of the risk of stroke as compared with the expected incidence. The imaging follow-up showed low incidence of significant residual leaks. We also confirm the feasibility and safety of the LAOO procedure.

**TCT-98**

Large single-Center Experience of Percutaneous Left Ventricular Transapical Access for Structural Heart Disease Interventions

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**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)/fluorescence fusion imaging (HeartNavigator, Philips, Netherlands) has been used to guide TA puncture.

**Results:** All TA were successfully performed for the following interventions: 74 mitral paravalvaral leak (PVL) closure, 6 aortic PVL closure, 14 left ventricular pseudoaneurysm (LVPA) closure, 2 ventricular septal defect closure, 8 mitral trans-catheter 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%): hemothorax n=5, pericardial effusion n=1, persistent access site bleeding requiring surgery n=1, non-fatal device migration n=3 (2 ventricular, 1 epicardial requiring surgical closure), and death n=2. One death occurred in a patient with supraventricular pulmonary hypertension developing pulseless 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 without 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

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**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 of a history of at least one presumed 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 antplatelet 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, questionnaires and phone calls, or 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=481), peripheral embolism (n=55), diving accident (n=36) or cryptogenic cerebral ischemic stroke (n=134). 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. We examined the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample (NIS) database from 2001 to 2010 using ICD 9-CM code for percutaneous ASD/PFO closure (35.52). Only adult (age > 18 year) patients with ASD/PFO (ICD 9-CM - 745.5) were included in study. We could not differentiate between ASD and PFO closure due to the 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. Comorbidity 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 related to percutaneous closure of ASD and PFO procedure were 1.17 days and $19,025 respectively. We examined the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample (NIS) database from 2001 to 2010 using ICD 9-CM code for percutaneous ASD/PFO closure (35.52). Only adult (age > 18 year) patients with ASD/PFO (ICD 9-CM - 745.5) were included in study. We could not differentiate between ASD and PFO closure due to the 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. Comorbidity 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.
Conclusions: In conclusion, ICE use and high operator volume are significant predictors of improved out come in ASD/PFO closure.

TCT-101
Long-term Outcomes of Percutaneous Left Ventricular Pseudoaneurysm Closure
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Background: Left ventricular pseudoaneurysms (LVPAs) may occur as sequelae of cardiac surgery, myocardial infarction (MI), or endocarditis, and may result in congestive heart failure (CHF) or rupture with sudden death. Percutaneous closure of LVSD has been reported, but long-term outcomes are unknown.

Methods: We reviewed all patients who underwent percutaneous LV closure at our center from 09/2008 to 02/2013. All patients had a pre-procedural helical CTA. LVPA size was measured on CTA in 3 perpendicular planes (x, y, and z), with x-plane being the largest diameter and y-plane being the largest perpendicular diameter. Clinical follow-up was obtained in all patients with assessment of survival and CHF. Follow-up CTA studies were reviewed to assess residual LVPA flow.

Results: 15 LVPA closures were performed in 14 patients (mean age 72; male 71%; CHF 79%; mean NYHA class 2.6). The etiology was post-surgical in 11 cases, post-MI in 2 cases, and endocarditis in 1 case. 10 had associated paravalvular leaks. The mean x-plane diameter was 34±20mm. Percutaneous access was transapical in 10, retrograde aortic in 2, and direct chest wall puncture in 2 cases. The LVPA ostium was closed with Amplatzer devices in all cases. Large LVPA sacs were filled with emboilization coils in 3 patients and thrombin injection in 1 patient. 12 of 14 patients were alive at mean follow-up of 717±467 days. 1 patient had persistent LVPA flow requiring a second closure at day 447. He had attempted surgical repair of an LVPA to bronchial fistula and died intraoperatively at day 448. 1 patient died of progressive CHF at day 741 after CTA at day 642 had shown no residual LVPA flow. 8 of 12 patients with heart failure had improvement of ≥ 1 NYHA class (mean change 1.3). 7 patients had followup CTAs ≥ 3 months post procedure (mean 24 ± 17 months). 6 of 7 followup CTAs had no residual flow into the LVPA. 1 patient had residual LVPA flow after 2 closure procedures.

Conclusions: Percutaneous LVPA closure can be performed safely with durable long-term results. The majority of patients with heart failure symptoms improve after closure. Followup CTA imaging demonstrates effective exclusion of LVPA flow in most cases.

TCT-102
Efficacy and Safety of Balloon Pulmonary Angioplasty for Non-operable Chronic Thromboembolic Pulmonary Hypertension in Comparison to Pulmonary Endarterectomy for Operable Patients
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Background: Pulmonary thromboendarterectomy (PTEH) has been a standard therapy for the treatment of Chronic Thromboembolic Pulmonary Hypertension (CTEPH), however, up to 40% of patients are considered non-operative due to distal types of thromboembolism or comorbidities, resulting in poor prognosis. Therefore, we performed balloon pulmonary angioplasty (BPA) for non-operable patients, and evaluated the efficacy of BPA in comparison with PEA.

Methods: We treated 46 CTEPH patients from November 2001 to May 2013. Operable 21 patients underwent PEA (56.8 ± 14.7 years old, San-Diego class I/II, II/II, III/III, IV/IV). BPA was repeated in 1 to 6 sessions to every patient depending on their severity. We evaluated hemodynamics by Swan-Ganz catheter at baseline and post procedure.

Results: PEA significantly improved hemodynamics in operable patients (Table). In non-operable patients, even BPA dramatically improved hemodynamic parameters such as a significant increase in cardiac output (CO) and decrease in pulmonary vascular resistance (PVR), which were accompanied with improved 6-minute walk distance (6MWD) and WHO-Fc as observed in PEA for operable patients. Reperfusion pulmonary injury occurred in 3 patients (14.3%) after PEA, and in 21 sessions (32.8%) after BPA with 3 sessions required emergent intubation. Two patients (9.5%) died after PEA due to persistent of right heart failure and 1 patient (4.0%) died after BPA due to systemic infection.

<table>
<thead>
<tr>
<th>BPA (n=25)</th>
<th>CO (L/min)</th>
<th>mPAP (mmHg)</th>
<th>PVR (dynes/cm²-s)</th>
<th>6MWD (m)</th>
<th>WHO Fc</th>
<th>PVR (dynes/cm²-s)</th>
<th>6MWD (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>3.57 ± 0.91</td>
<td>39.1 ± 6.9</td>
<td>746 ± 304</td>
<td>302 ± 100</td>
<td>(0/16/17/0)</td>
<td>10/11/9/0</td>
<td>0.0009</td>
</tr>
<tr>
<td>Post procedure</td>
<td>4.44 ± 1.11</td>
<td>22.5 ± 4.9</td>
<td>295 ± 117</td>
<td>380 ± 113</td>
<td>(0/1/14/7)</td>
<td>11/7/1/0</td>
<td>0.0007</td>
</tr>
</tbody>
</table>

Conclusions: BPA could be an effective treatment option for non-operative CTEPH to achieve dramatic improvement of hemodynamic and outcome parameters. The efficacy and safety for non-operable cases were equivalent to those of PEA for operable cases.

TCT-103
Is fetal aortic valvuloplasty effective to achieve a biventricular circulation after birth?
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Background: Critical aortic stenosis (AS) in utero is a severe disease that may evolve to hypoplastic left heart syndrome (HLHS) if not treated. Fetal aortic valvuloplasty (AV) has been performed in selected cases to avert this progression. However, more data is required to assess its impact on achieving a biventricular circulation (BVC), especially in patients with smaller left ventricles (LV). We report the immediate procedural results and the postnatal outcomes up to one year of age of fetuses who underwent AV.

Methods: Procedures were performed under spinal maternal block and fetal anesthesia between 23 to 34 weeks gestation through a transabdominal (maternal) and transplacental (fetus) approach under echo guidance. The LV apex was entered using 17/18 G Chiba needles and the valve was dilated with coronary angioplasty balloons (1-1.2 times the valve annulus). Serial echos were performed pre and postnatally.

Results: Thirty fetuses underwent the procedure. Five were severely hydropic, 4 had severe mitral regurgitation and gigantic left atrium (GLA), 3 had hypoplastic LVs (2 severe). Endocardial fibroelastosis was present in all (severe in 6). In all but 1 fetus the valve was successfully crossed and dilated. Satisfactory antegrade flow was observed in 12 cases, aortic insufficiency in 7 and pericardial effusion ± bradycardia in 9 fetuses requiring needle aspiration + atropine. There were no maternal complications. There were 2 early neonatal deaths after premature delivery because of severe hydrops (both with GLA), BVC was achieved in 3 neonates. All required aortic valvuloplasty. Three with smaller LV underwent aortic valvuloplasty + hybrid procedures, with 2 undergoing LV overhauls and a BVC @ 9 months of age. In the other a BVC is still contemplated. One neonate born at another institution died on the first day of life, 3 were managed as univentricular hearts and 1 had comfort care (no LV growth).

Conclusions: Fetal aortic valvuloplasty may improve overall neonatal and infancy outcomes. BVC was achieved in 30% of the cases with a chance of improving to a 50% rate. Neonatal outcomes seem to depend on the clinical and anatomical fetal presentation, with hydropic fetuses having worse outcomes.