ORALS

TCT-97

Long term follow up of 134 patients with non valvular atrial fibrillation and contraindications to oral anticoagulation therapy, treated with the Ampatzer 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 antiplatelet therapy following the procedure and single antiplatelet therapy thereafter. Follow up was carried out by clinical 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 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±8 years 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 hemorragic 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 >=12 months. The rates of death, stroke, TIA 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 LAAO procedure.

TCT-98

Largest 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)/fluoroscopy 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 (LVPA) closure, 2 ventricular septal defect closure, 8 mitral transcatheter 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/tamponade n=1; persistent access site bleeding requiring surgical closure 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 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 generalizabilty 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 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, 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 ischemia (TIA in n=1334 or stroke in n=1666). 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=303). Within a total of 8,873 patient years of follow-up (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 strokes occurred. In 6 patients peripheral embolic events occurred. In 122 patients (4.3%) 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 Defects and Patent Foramen Ovale: A Perspective of Last Decade

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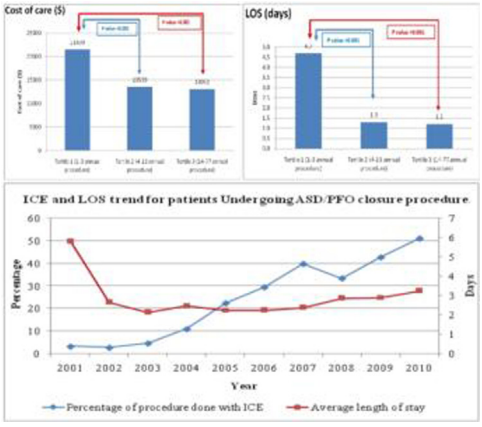
Background: We assessed the predictors of length of hospital stay (LOS) and cost of care related to percutaneous closure of ASD and PFO closure.
Methods: We examined the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample (NIS) database from 2001 to 2010 using ICD 9-CM code for percutaneous 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 is 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 for percutaneous ASD/PFO closure were 2.63±0.06 days and $16,635±225, respectively. LOS was increased (days, 95% CI, P-value) with presence of any complication (+2.47 days, 2.14-2.80, P 2 (+1.84 days, 1.48-2.20, P<0.001). Decrease in LOS was associated with use of higher operator volume tertile(-2.58 days, -3.04 - -2.12, P2) (1.17, 1.12-1.22, P<0.001). Decrease in cost was associated with higher annual operator volume tertile (0.84, 0.08 - 0.88, P<0.001).



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 LVPAs has been reported but long-term outcomes are unknown.
Methods: We reviewed all patients who underwent percutaneous LVPA 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 followup was obtained in all patients with assessment of survival and CHF. Followup 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 Amplazter devices in all cases. Large LVPA sacs were filled with embolization coils in 3 patients and thrombin injection in 1 patient. 12 of 14 patients were alive at mean followup 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 $\geq$ 1 NYHA class (mean change -0.8±1.3). 7 patients had followup CTAs $\geq$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 (PEA) has been a standard therapy for the treatment of Chronic Thromboembolic Pulmonary Hypertension (CTEPH), however, up to 40% of patients are considered non-operable 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:9, II:4, III:8, IV:0) and 25 non-operable patients, with mean pulmonary artery pressure (mPAP) $\geq$ 25mmHg in spite of under medical therapy, were performed BPA (67.8 ± 10.3 years old, San-Diego class I:0, II:3, III:15, IV:7). 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 mPAP and 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.

		Baseline	Post procedure	P value
BPA (n=25)	CO (L/min)	3.57 ± 0.91	4.44 ± 1.11	0.007
	mPAP (mmHg)	39.1 ± 6.9	22.5 ± 4.9	<0.0001
	PVR (dynes/s/cm-5)	746 ± 304	295 ± 117	<0.0001
	6MWD (m)	302 ± 100	380 ± 113	0.0004
	WHO Fc (I/II/III/IV)	(0/2/16/7)	(10/11/3/0)	0.0009
PEA (n=21)	CO (L/min)	3.35 ± 1.20	4.62 ± 1.67	0.007
	mPAP (mmHg)	44.6 ± 12.0	23.2 ± 6.2	<0.0001
	PVR (dynes/s/cm-5)	785 ± 291	267 ± 134	<0.0001
	6MWD (m)	NA	NA	
	WHO Fc (I/II/III/IV)	(0/1/13/7)	(11/7/1/0)	0.0007

Conclusions: BPA could be an effective treatment option for non-operable 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 transthoracic (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 post natally.
Results: Thirteen 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 overhaul 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.