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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 antiplatelet therapy following the procedure and single antiplatelet therapy thereafter. Follow up was carried out by clinical visit or phone contact. 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 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. TA, device related 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<0.001).

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.

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Longest 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 male, 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 paravalvaral leak (PVL) closure, 6 aortic PVL closure, 14 left ventricular pseudoaneurysm (LVPA) closure, 2 ventricular septal defect closure, 8 mitral trans-cather 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, persistent access site bleeding requiring surgery 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 pulsless 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.