POSTERS

Congenital Heart Disease and Acquired Structural Defects

(Abstract nos 711 - 726)

TCT-711

Large Devices for Transcatheter Closure of Atrial Septal Defects in Adult Patients: the REPERA Multicenter Registry

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Background: Percutaneous closure of atrial septal defects (ASD) has established as treatment of choice in most patients. Large and complex defects (multiperforated, rim deficient, septal aneurysm) often require very large devices. Success rate, incidence of early and late complications and potential predictors of failure in this setting are not well known.
Methods: Multicenter registry of adult patients with an ASD who have undergone percutaneous intervention with large devices (from 26 to 40 mm). Clinical, echocardiographic and procedural data were analyzed, as well as clinical follow-up. All data were collected retrospectively.
Results: We included 302 adult patients from 14 hospitals, mean age 48 years (17-79), 62% females, 86% were in sinus rhythm. ASD median size was 24 mm (unstretched), 16% had septal aneurysm, 6% were multiperforated, and 45% had at least one deficient rim (28% retroaortic, 6% anterosuperior, 6% inferior, 5% posterior). Echocardiographic imaging during intervention was intracardiac in 51%, and transesophageal/3D (TEE) in 49%. Stretching balloon was used in 32% of defects (mean defect size 27±4 mm). Most devices were Amplatzer ASD (99%), the rest were Occlutech (1%), with a mean size of 31±4 mm. Immediate success was achieved in 91% of patients. The device was not released in 13 patients (4,3%), and early embolization happened in 11 patients (3,6%). In 4 patients (1,3%) significant device malposition was discovered early after deployment. Other minor complications were atrial fibrillation (1%), cerebral ischemia (0,7%) and cardiac tamponade (0,7%). No mortality was related to the procedure. Follow-up has been 52±36 months. Late severe complications were embolization or malposition (1,3%) and perforation (0,3%), and all of them required surgery. Atrial tachyarrhythmias (7,7%) were the most frequent complications during follow-up. Univariant analysis showed that an absent or deficient inferior rim is significantly associated with lower success rate (p<0,05).
Conclusion: Transcatheter closure of large and complex ASD with large devices (≥26 mm) is feasible and safe, with a low rate of complications. Device not released and early embolization were the main causes of failure. A deficient inferior rim is an independent predictor of device failure.

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Percutaneous Paravalvular Leak Closure Abates Heart Failure Symptoms, Reduces NT-proBNP Plasma Concentration and Left Ventricle Size

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Background: Paravalvular leak (PVL) is a complication of heart valves prostheses implantation which may provoke heart failure (HF) and deteriorate patients' survival. Less invasive than surgical treatment, the percutaneous PVL closure is auspicious but requires further investigation.
Methods: We enrolled 23 consecutive patients referred to our institution due to PVL present at prosthesis in aortic (AV group; n=12) or mitral (MV group) position. All patients presented with symptomatic heart failure corresponding to NYHA classes 4 (24%), 3 (75%) and 2 (1%). Consequently, percutaneous PVL closure procedures were scheduled via transfemoral, transseptal or transapical access, depending on PVLs' features. End diastolic and systolic values of left ventricle (LV) diameters (EDD, ESD) and volumes (EDV, ESV) were obtained by transthoracic echocardiography and indexed to body surface area (EDDi, ESDi, EDVi, and ESVi, respectively). PVL closure was performed with Amplatzer Vascular Plugs II or III.NT-proBNP plasma concentration and LV dimensions were determined initially and in one month follow-up.
Results: The successful PVL closure rate was 83%. In majority of patients implantation of a single plug proved sufficient but in 5 cases two were required. The mean procedure time reached 68 minutes in AV group and 160 minutes in MV group. After a month we noted a reduction from 3 to 1 in median NYHA class (p<0.05) and a drop in mean NT-proBNP (pg/mL) plasma concentration from 870 to 345 (p<0.05) in all patients. LV dimensions markedly decreased in AV group (EDVi: 122 vs. 85 ml*; ESVi: 47 vs. 36 ml*; EDDi: 32 vs. 32ml ESDi: 20 vs. 18ml*; *-p<0.05) while in MV group they remained unaffected (EDVi: 90 vs 96ml; ESVi 39 vs. 42 ml; EDDi: 35 vs. 36 ml; ESDi: 23 vs. 22).
Conclusion: Percutaneous PVL closure improves exercise tolerance and reduces NT-proBNP plasma concentration regardless of lesion original location. Additionally, elimination of aortic PVL reduces left ventricle size.

TCT-713

Safety and Performance Of a New Ceramic-coated Double-disc Patent Foramen Occluder: One and Six-month Follow-up

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Background: Though percutaneous patent foramen ovale (PFO) closure is performed with increasing frequency worldwide, certain risks such as thrombus formation and incomplete endothelialization remain. The Spider™ PFO Occluder was designed to minimize these risks. The aim of this clinical trial was to assess safety, efficacy and technical handling of this novel ceramic-coated double-disc PFO occluder.
Methods: The Spider™ PFO occluder is a self-expandable double-disc device with a ceramic coated nitinol wire mesh and an integrated expanded polytetrafluoroethylene (ePTFE) membrane on the right atrial side and ceramic coated nitinol anchors and an ePTFE patch on the left atrial side. Study patient assessments were conducted at baseline, periprocedure and discharge and at one and six-month follow-up.
Results: Fifty-one patients (mean age 52 ± 14 years; 63% male) were enrolled in the prospective, multicenter clinical trial. Implantation was successful in all patients. Mean procedural time was 30.0 ± 8.6 minutes. No periprocedural or in-hospital complications occurred. Total follow-up time ranged from 5 to 12 months. Four patients (8%) had paroxysmal atrial fibrillation at one-month follow-up. One patient suffered a pulmonary embolism at the 6-month follow-up. Otherwise, no procedure or device related adverse events occurred. Importantly, there were no recurrent embolic events. At the one-month follow-up 63% (32/51) of all patients had no residual shunt with contrast transesophageal echocardiography during Valsalva maneuver. Of all patients who underwent six-month follow-up to date 77% (36/47) had no residual shunt during Valsalva maneuver.
Conclusion: Initial results with the novel Spider™ PFO occluder show that the device is safe to use for percutaneous closure of PFO. Although the overall complication rate was low, there was a high incidence of atrial fibrillation during the one month-follow up. The closure rate needs further investigation.

TCT-714

Percutaneous Transcatheter Pulmonary Valve Implantation Induces a Reduction of B-Type Natriuretic Peptide at 30 days

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Background: High levels of B-Type Natriuretic Peptide (BNP) in patients with congenital heart disease (CHD) correlate with the right ventricular volume load and predict poor outcome. Surgical pulmonary valve replacement induces an immediate postoperative increase followed by a reduction of BNP levels at long term. The aim of the present study was to evaluate whether transcatheter pulmonary valve implantation has also an impact on BNP levels.
Methods: Patients treated in our institution by implantation of a transcatheter pulmonary valve were prospectively included in the study. BNP was measured before, 24 hours and 30 days after the procedure. A cardiac magnetic resonance imaging was performed at baseline and at 3 months.
Results: Between september 2010 and april 2011, 10 patients (7 males, mean age 17 ± 3 yrs) were treated in our institution by transcatheter pulmonary valve implantation using the Melody Valve. CHD was tetralogy of Fallot in 6 patients, common arterial trunk in 2, transposition of the great arteries in 1 and previous Ross intervention in another one. All the procedures were successfull with two complications (distal pulmonary hemorrhage due to the stiff wire, treated successfully by coil embolization and positive pressure ventilation).The transvalvular gradient decreased from 31 ± 14 to 10 ± 6 mmHg (p<0.0001) with no significant residual pulmonary regurgitation. BNP significantly decreased from 42 ± 34 to 20 ± 16 pg/ml at 30 days without any significant change at 24 hours (28 ± 19 pg/ml, p=NS vs baseline). Right ventricular volume significantly decreased from 132 ± 25 ml/m squarre to 101 ± 25 ml/m squarre (p=0.02) at 3 months follow-up. Decrease of BNP at 30 days (-27 ± 22 pg/ml) correlated well with the reduction of right ventricular volume (-29 ± 25 ml/m squarre) at 3 months (r = 0.59).
Conclusion: Percutaneous transcatheter pulmonary Melody valve is a safe and effective procedure, inducing a decrease of BNP levels at 30 days and resulting in reduced right ventricular volumes at 3 months.