Conclusions: CoA stenting through the CA in neonates and infants was feasible safe and effective in the short-to-mid-term. New procedures should be performed during follow up to adjust for somatic growth, treat complications or repair intracardiac lesions.

TCT-168

Short Term follow up of Percutaneuos Closure Of Perimembranous Ventricular Septal Defects Using The Second Generation Amplatzer Occluders

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Background: No devices are currently available in the USA for percutaneous closure of perimembranous (Pm) ventricular septal defects (VSDs). The earlier device was withdrawn from clinical trial because of development of heart block possibly related to over sizing and/or device rigidity. New, softer devices are available for vascular occlusions as the Amplazer Vascular Plug II (AVP II) and the Amplatzer Duct Occluder II (ADO II). We previously submitted our initial experience in occluding Pm VSDs using AVP II & ADO II in 10 patients (pts) using AVP II in 6 and ADO II in 4. This is follow up (f/up) of these pts and additional pt.
Methods: F/up data of these pts. were reviewed specifically assessing for the development of heart block, residual flow through the device, presence of aortic insufficiency (AI) and device embolization or fracture or the occurrence of late adverse events (AE).
Results: Review of F/up data of these pts. was performed specifically assessing for the development of heart block, residual flow through the device, presence of aortic insufficiency (AI) and device embolization or fracture or the occurrence of late adverse events (AE).
Results: F/up clinical evaluations, chest x-rays and echocardiograms were available for all patients expect 1 who did not undergo chest x ray because of pregnancy. F/up period ranged from 0-13 months with a median of 5.5 + 5. New AI was seen in 3 patients graded as mild in 1 and trivial in 2. In 1 patient the AI could have been preexisting and masked by the VSD flow. 1 patient had mild new Tricuspid regurgitation. There was no incidence of device fracture or late embolization and no clinical evidence of hemolysis, sub-acute bacterial endocarditis or any serious AE. No patient developed heart block. In 1 patient with elongated tunnel type VSD, the device took the configuration of the defect. 1 patient had residual flow through the device which disappeared on follow up. I patient has additional small VSD.
Conclusions: In our series, percutaneous closure of PmVSDs using the softer new generation devices as the AVP II and the ADO II appears to be safe in the short term. Flow seen through the device usually disappears as the device endothelializes.

TCT-169

Exit Angiography and Intraoperative Stenting after Surgical Repair of Complex Congenital Heart Disease in a Hybrid Room: Impact on Management Strategies and Outcomes

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Background: Residual lesions after surgical repair of complex congenital heart disease (CHD) are poorly tolerated. An exit angiography (EA) after cardiopulmonary bypass (CPB) has been performed to promptly diagnose residual lesions, which may result in a change of the management strategy. We report our initial experience with EA and intraoperative stenting (IOS) in a dedicated hybrid suite (HS).
Methods: Patients (pts) with complex CHD were selected for EA at multidisciplinary meetings. All procedures were conducted in a dedicated HS in the OR. Catheters were advanced through sheaths secured by purse string sutures in the RVOT, SVC, MPA or ascending aorta. Stent delivery was guided by fluoroscopy after CPB completion.
Results: From 05/12 to 05/14, EA was performed in 22 pts (median age and weight: 0.9 years and 9.2 kg, respectively) after surgical repair (Glenn operations, unifocalization, bioprosthetic valve insertion, complex CoA). Twelve patients (55%) required IOS with 14 stents implanted in the PAs or descending aorta (1). The decision to implant a stent was made before hand in 4 pts and only after EA was performed in 8 pts (2 pts had undergone a failed redo surgical PA plasty under CPB after an initial EA). In all patients, stents were placed in the intended location and resulted in significant increase of vessel diameter from a median of 3.7 to 8.5 mm ($p < 0.001$). There were no deaths or vascular complications during the procedure. Of those 12 patients who underwent IOS, 8 pts had an uneventful early postoperative period. Two pts died in the ICU (1 pt with complex univentricular heart and 1 pt with HLHS in ECMO after Norwood-Glenn operation) and 1 patient each needed hemodialysis and pericardiocentesis, respectively, not related to EA or IOS. Of those 10 pts in whom IOS was not performed, surgical results were considered adequate and post-op course was uneventful.
Conclusions: EA and IOS were feasible, safe and effective. EA should be carefully planned before surgery in selected patients and may result in changes in management strategies. IOS probably results in better immediate surgical outcomes.

Left Atrial Appendage Exclusion

Washington Convention Center, Lower Level, Hall A

Saturday, September 13, 2014, 5:00 PM–7:00 PM

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TCT-170

Cost-effectiveness Analysis Of Left Atrial Appendage Occlusion Device Compared With 7 Oral Anticoagulants For Stroke Prevention In Atrial Fibrillation

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Background: Transcatheter left atrial appendage occlusion (LAAO) is a promising therapy for stroke prophylaxis in non-valvular atrial fibrillation (NVAF) but its cost-effectiveness remains understudied.
Methods: A Markov decision analytic model was used to compare cost-effectiveness of LAAO with 7 alternative strategies: Aspirin alone, Clopidogrel plus Aspirin, Warfarin, Dabigatran (110 and 150mg), Apixaban, and Rivaroxaban. This model simulates a cohort of 65-year-old NVAF patients moving between different health statuses in each Markov cycle of 1 year. The time horizon was lifetime (85 years old). Health states include AF without event, with event before, ischemic cerebrovascular events, hemorrhage, myocardial infarction, vascular or non-vascular deaths. To estimate discounted (3%) lifetime costs, quality-adjusted life years (QALYs) and incremental cost-effectiveness ratios (ICERs). Base-case data were derived from ACTIVE, RE-LY, PROTECT-AF and PREVAIL trials. One-way sensitivity analysis varied by HAS-BLED scores and time horizons, and probabilistic sensitivity analysis (PSA) using Monte Carlo simulations were conducted to assess parameter uncertainty.
Results: Compared with Aspirin alone, Clopidogrel plus Aspirin, Warfarin, Dabigatran 110mg, LAAO was cost-effective with an ICER of $3,921, $2,226, $3431, and $58 per QALY gained, respectively; however, LAAO was dominant to Dabigatran 150mg, Apixaban, and Rivaroxaban strategies (i.e. less costly and more effective). Sensitivity analysis demonstrated significant performance in ICERs of LAAO against oral anticoagulant drugs for patients with increasing HAS-BLED scores and within the varied time horizons (5, 10, and 15 years), and LAAO strategy was cost-effective over 99% of the Monte Carlo simulation using a cost-effectiveness threshold of US$50,000/QALY.
Conclusions: Transcatheter LAAO strategy is considered cost-effective as compared with 7 other antithrombotic strategies for prevention of stroke in patients with NVAF regardless of their risks of ischemic stroke.

TCT-171

Avoidance of Major Bleeding with WATCHMAN Left Atrial Appendage Closure compared with Long-Term Oral Anticoagulation: A Pooled Analysis of Randomized Trials

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Background: WATCHMAN left atrial appendage (LAA) closure is a novel approach to preventing stroke in patients with atrial fibrillation (AF) that could reduce the longer-term risk of bleeding compared with anticoagulation. We compared the temporal incidence of major bleeding beyond the immediate procedural period in the randomized trials of the device.
Methods: Landmark analyses of time-to-first major bleed in the PROTECT-AF, PREVAIL, and pooled trials were performed for 3 periods: (1) from 8-to-45 days post-procedure, during which WATCHMAN patients received warfarin; (2) from 46-to-180 days, during which WATCHMAN patients received dual antiplatelet therapy (DAPT); and (3) beyond 180 days, when WATCHMAN patients were eligible to receive aspirin alone. Major bleeding was site-reported and adjudicated as a serious adverse event by the Clinical Events Committee.
Results: After the periprocedural period, the risk of major bleeding did not differ significantly between study arms when WATCHMAN patients received warfarin or DAPT. Beyond 6 months, the bleeding risk was significantly lower with the device strategy compared with long-term warfarin (Hazard Ratio [HR] 0.30 [95% Confidence Interval (CI): 0.17-0.53), a finding that was consistent across trials (PROTECT-AF: HR 0.31 [95% CI: 0.16-0.61]; PREVAIL, HR 0.27 [95% CI: 0.09-0.79]).