**TCT-772**

**Role Of Non-ECG Gated Contrast CT In Preventing Percutaneous Pulmonary Valve Implantation-Related Coronary Compromise**

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**Background:** Percutaneous pulmonary valve implantation (PPVI) is a non-surgical transcatheter treatment for right ventricular to pulmonary artery conduit dysfunction. One of the rare but significant risks of this procedure is acute coronary occlusion following valve deployment. Proximity of coronary arteries has previously been assessed using time-consuming and costly ECG gated contrast CT scanning or MRI. We assessed the utility of non-ECG gated contrast CT scanning as an alternative for assessing the coronary position in patients planned to undergo PPVI.

**Methods:** We studied a series of 22 consecutive patients presenting to our institution for PPVI. The underlying diagnoses of these patients varied. In all of the patients, we used the rapid, highly-accessible and relatively cheap technique of non-ECG gated 32-slice CT scanning to assess the relationship of the coronary arteries to the proposed site of PPVI in 3 planes – axial, sagittal and coronal. Patients were only subsequently selected for PPVI if there was a distance of at least 3 mm between the main coronary vessels and region of proposed valve deployment.

**Results:** The mean age of patients selected for PPVI was 26. Non-ECG gated contrast CT scanning was found to be highly effective in detecting the position of the coronary arteries, allowing coronary identification in the axial plane 93% of the time, sagittal plane 87% of the time and in the coronal plane 87% of the time. No patient experienced acute coronary occlusion when the exclusion criteria of <3 mm between proposed valve deployment site and nearest distance of coronary artery was employed.

**Conclusions:** Non-ECG gated contrast CT is effective, rapid and cost-effective in allowing coronary characterisation before PPVI. A distance of 3 mm between coronary artery and valve implantation site seems to be a safe distance to avoid PPVI related coronary occlusion. More studies are required to assess this in further detail.

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**TCT-773**

**Transcatheter closure of perimembranous ventricular septal defect with the Amplatzer® Membranous VSD Occluder 2**

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**Background:** Transcatheter closure of peri-membranous ventricular septal defects (pmVSDs) has been associated with a significant risk of complete heart block, leading most patients to abandon the technique. Our objective was to describe the initial world experience of pmVSD closure with a newly designed occluder.

**Methods:** Patients with pmVSD underwent catheter closure using the Amplatzer® Membranous VSD Occluder 2 (AGA – St Jude, Minneapolis, MN, USA).

**Results:** Nineteen patients from the 4 centers initially involved worldwide were prospectively included and followed for at least 30 days (median 48, range 31 – 245 days).

Patients ranged in age from 1.4 to 62 years (median 6 years) and in weight from 0.3 to 96 kg (median 26 kg). The Qp/Qs ratio was (mean ± SD) 1.9 ± 1.6. The size of the defect on left ventricular side was 9.9 ± 3.5 mm (range 4.6 – 16 mm) and the orifice on right ventricular side was 8.1 ± 2.8 mm (range 3.9 – 14 mm) by echocardiography. Mean device size was 14 mm (range 5 – 14 mm). An eccentric defect was used in 9 patients (47%) and a concentric device in 10 (53%). A device was successfully implanted in 18 patients (95%). Procedural time was 122 ± 79 min (range 60 – 207 min). There were no significant procedural complications. Mild (0-2 mm) residual shunt was initially observed in 14 patients (78%). At last follow-up, mild residual shunt was still observed in only 3 patients (17%). There was no significant increase of aortic or tricuspid regurgitation. No patient showed any degree of AV block, although one patient developed a left anterior fascicular block. Holter evaluation was obtained in 13/18 patients, and was normal in all.

**Conclusions:** Transcatheter closure of pmVSD with the Amplatzer® pmVSD Occluder 2 is safe and effective. No conduction abnormalities or any other complications were observed on short-term follow of this initial human series.

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**TCT-774**

**Ten Year Experience with Transcatheter Closure of Perimembranous Ventricular Septal Defects Using the Amplatzer Asymmetric Perimembranous Ventricular Septal Defect Occluder in Children**

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**Background:** In this report we present 10-year experience with 78 patients (pts) with perimembranous ventricular septal defects (PMVSDs) who underwent transcatheter closure at 5 different Institutions with the Amplatzer asymmetric PMVSD occluder.

**Methods:** The age of the pts ranged from 0.3 to 15 years. During the study period 15 other patients were excluded from transcatheter closure because they did not fulfill the patient selection criteria (distance less than 2 mm from the PMVSD to the aortic valve, size of VSD in relation to patients age).

**Results:** The device was permanently implanted in 72/78 patients. Complete occlusion of the communication at six months, one-year, and 2-year follow-up was observed in 93%, 97%, and 97% patients, respectively. Main complications included: Early were observed in patients less than one year (body weight < 8 Kg) and included: a. Device embolization (2 patients-catheter and surgical removal, respectively), b. severe procedural bradycardia (5 pts) and c. Mobitz II and complete heart block in 3 and 1 patients respectively.

**Conclusions:** Transcatheter closure using the Amplatzer APMVSD occluder is a safe and effective nonsurgical alternative that should be offered in properly selected patients with PMVSDs. It should be used both for PMVSDs and for both VSDs, and the optimal device size and delivery system the procedure carries an increased risk in small patients less than one-year of age. Finally, due to anatomic reasons, this therapy cannot be offered to significant number of patients with these defects.

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**TCT-775**

**Novel System for Detection of Cardiac Right to Left Shunts**

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**Background:** The current “gold standard” for detection and quantification of right-to-left shunts (RLS) is transesophageal echocardiography (TEE). The Flow Detection System (FDS) (CardioSEAL, Columbus, OH) is a minimally invasive, diagnostic test, based on transdermal detection of Indocyanine Green (ICG) dye (Pulsion Medical Systems AG, Munich, Germany). The present study was performed to determine optimum ICG dosing and injection timing protocols, as well as the system’s accuracy in the detection of RLS.

**Methods:** Various ICG dosages and injection timing protocols were evaluated in eight (8) patients, with known RLS, to determine the optimal dose and injection timing to facilitate detection of RLS with FDS. 20 additional patients underwent testing with power m-mode transcranial Doppler (TCD) and subsequent FDS. Ten (10) patients with large RLS, (Spencer grades IV or V by TCD) were selected to comprise the study group. Ten (10) additional patients with Spencer grades 0 or I by TCD were selected to comprise a control group. All patients were evaluated just prior to a scheduled catheterization, with both TCD and FDS using the dosing and timing parameters developed in the initial cohort of eight patients. In the study group, results were also compared with RLS assessed by intra-cardiac echocardiography (ICE – Johnson & Johnson, NJ) performed during the catheterization.

**Results:** All ten study subjects with proven RLS exhibited a Shunt Conduction Index (SCI) > 0, reflecting the presence of a RLS (sensitivity = 100%). FDS was also in
agreement with ICE results in all ten. Nine (9) of ten (10) patients with TCD-negative RLS, had SCI = 0.

Conclusions: The Cardiox FDS, with the established dosage of ICG dye and timing protocols, provided consistent detection of significant RLS (Spencer Grades IV or V), with a good negative predictive value.

TCT-776

INES (Utah Nickel Elution Studies)
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Background: Percutaneous closure of ASD/ PFO has become a common procedure. Concerns exist regarding possible adverse outcomes with device implantation in patients allergic to nickel. Quantifying nickel elution by various devices is important.

Methods: We compared nickel elution behavior of 4 devices- AGA Amplatzer® Occluder “Cribriform” (AGA Medical Corporation; Plymouth, Minn), Gore GSO® and Gore Helex® Septal Occluder (W.L.Gore & Associates, Flagstaff, AZ), Sternalwire, and control:Duolite®c’s Phosphate-Buffered Saline (DPBS). Three device samples from each group were submerge in DPBS. Nickel elution was measured by blinded personal using Plasma Mass Spectroscopy at 24hours (h), 48h, 72h then weekly to 60 days.

Results: Nickel elution was significantly higher for AGA device compared to control group at all time points to 60 days (15.20 ± 8.99 vs <0.01 ±6.6; p<.001,Figure1). Individual group comparisons by Bonferroni Multiple Comparisons test showed that nickel elution was statistically similar amongst devices other than AGA.

Conclusions: There is significant variability of Nickel elution among the intra-atrial septal closure devices. AGA device has the greatest Nickel elution over 60 days. Clinical significance of nickel elution needs to be evaluated in clinical studies.

TCT-777

Non-Cerebrovascular Systemic Arterial Embolic Events from Paradoxical Embolization via Patent Foramen Ovale (PFO)
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Background: Paradoxical cerebral embolic events via PFO are well described. The frequency and impact of such embolization to other vascular beds is poorly defined. We describe a single center cohort of patients presenting with non-cerebrovascular paradoxical embolism, evaluating the relationship between high-risk PFO echo features, previously undiagnosed May-Thurner Syndrome, and hypercoagulability.

Methods: 801 patients who underwent transcatheter closure of PFO between 2001 and 2010 were retrospectively analyzed with clinical,procedural characteristics plus immediate and long-term follow-up record. Two-sided T tests and Fishers Exact test and Kaplan-Meier event free (death/cardiac death/CVA/TIA/arterial embolic event)survival analysis were performed.

Results: 801 closures were performed. Cohort 1 included 29 PFO closures(3.5% of total), with 6 acute myocardial infarctions (MI), 9 retinal emboli, 6 renal infarctions, 3 radial artery occlusions, 3 splenic infarcts, and 2 lower extremity arterial emboli. 772 patients are included in cohort 2. Cohort 1 had a higher incidence of May-Thurner syndrome (p=0.005) and were more likely to have an atrial septal aneurysm (p=0.08). Procedural success was 100%. In hospital 1 device embolization was successfully retrieved, no other in-hospital complications occurred. Effective defect closure was 100% with no significant residual shunting. Event-free survival in cohort 1 was 100%, median follow-up of 12.1 months (IQR 4.7, 23.7) compared with 97.4%, median follow-up of 25.3 months (IQR 11.6, 57.8) in cohort 2.

Conclusions: This is the largest series of PFO associated non-CVA/TIA paradoxical emboli, highlighting the need to screen for high risk PFO features and co-exist May-Thurner syndrome. These patients can be treated successfully with transcatheter closure, with no recurrent events in follow-up.

TCT-778

Long-term Outcomes After Transcatheter Closure of Patent Foramen Ovale
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Background: Percutaneous transcatheter closure of patent foramen ovale (PFO) is commonly performed for several indications despite conflicting data regarding the efficacy of this intervention. We examined the indications for as well as the immediate and long-term procedural outcomes of PFO closure in a large and diverse cohort of patients.

Methods: We report the outcomes of 801 consecutive patients (52% male, 50±14 years) who underwent PFO closure at our institution over a 13-year period after rigorous multidisciplinary evaluation.

Results: Indications for closure included cryptogenic cerebrovascular event (93%), hypoxemia (2%), peripheral embolism (3%), and other (2%). Procedural success was 99% with effective closure obtained in 95% of patients. At a mean follow-up of 30±33 months, 20 patients sustained a recurrent neurologic event (6 strokes, and 14 transient ischemic attacks) for a cumulative incidence rate of 0.83% per year (Figure). Only Eustachian valve prominence (R Honda) was associated with neurologic events, with a hazard ratio (HR) of 12.5 (95% confidence interval: 3.56–43.6; p-value=0.008) and moderate or severe residual shunt after closure (HR=5.36 versus no or trace shunt (95% CI: 1.21–23.85); p-value=0.03) were associated with neurologic events.

Conclusions: Transcatheter closure of PFO is safe and feasible in patients with several clinical indications. The efficacy of this intervention in patients with paradoxical embolism appears superb in this long-term observational study. Carefully selected patients with features suggestive of paradoxical embolism are the most likely to benefit from PFO closure and should be the focus of future investigation.

Risk Factor | Cohort 1 (N=29) | Cohort 2 (N=772) | p-Value | Age mean (SD) | 48.0 (+/-14.4) | 49.9 (+/-13.7) | 0.8 | Male Gender | 50% | 53.5% | 0.8 | Hypertension | 33.3% | 30.0% | 0.8 | Hyperlipidemia | 47.6% | 34.9% | 0.3 | Current or former Smoker | 25.0% | 34.2% | 0.3 | Family Hx of vascular disease | 0 | 10.4 | 0.1 | Diabetes | 4.2% | 5.7% | 0.7 | Hypercoagulable Disorder | 33.3% | 27.5% | 0.5 | Echo Tunnel Length (mm) | 8.2 (+/-4.4) | 11.1 (+/-4.7) | 0.9 | Atrial Septal Aneurysm | 41.7% | 25.5% | 0.08 | May-Thurner Syndrome | 41.7 | 15.1% | 0.0005

* FIGURE 1: Nickel Elution Over 60 Days by Device Type. SSS: Sternalwire, AGA: AGA Amplatzer® Occluder “Cribriform” (AGA Medical Corporation; Plymouth, Minn), Gore GSO® and Gore Helex® Septal Occluder (W.L.Gore & Associates, Flagstaff, AZ), Duolite®c’s Phosphate-Buffered Saline (DPBS). Three device samples from each group were submerge in DPBS. Nickel elution was measured by blinded personal using Plasma Mass Spectroscopy at 24hours (h), 48h, 72h then weekly to 60 days.

* P-value calculated using the unpaired t-test (assumptions of equal variances) of comparisons between the different devices.