5 year results					
	Amplatzer (n=220)	Helex (n=220)	CardioSEAL-STARflex (n=220)	p-value	total (n=660)
Acute Complications					
Pericardial tamponade	1 (0.5%)	0	0	0.37	1(0.2%)
Device embolization	0	3 (1.4%)	0	0.049#	3 (4.5%)
Long-term Complications					
Thrombus formation	0	1 (0.5%)	11 (5%)	<0.0001*	12 (1.8%)
Atrial fibrillation	8 (3.6%)	5 (2.3%)	27 (12.3%)	<0.0001*	40 (6%)
Peripheral embolism	0	0	0	1	0
Non-neurological death	3 (1.4%)	4 (1.8%)	3 (1.4%)	0.90	10 (1.5%)
Recurrent Neurological Events					
TIA	0	4 (1.8%)	6 (2.7%)	0.058*	10 (1.5%)
Stroke	2 (0.9%)	4 (1.8%)	6 (2.7%)	0.36	12 (1.8%)
Cerebral Death	1 (0.5%)	1 (0.5%)	1 (0.5%)	1	3 (0.5%)
Complete PFO-closure	220 (100%)	213 (96.8%)	219 (99.5%)	0.004#	652 (98.8%)

*this represents the p-value comparing the CardioCEAL-STARflex device to both, the Amplatzer and the Helex device. There was no significant difference between the Amplatzer and Helex device.
#this represents the p-value comparing the Helex device to both, the Amplatzer and the CardioSEAL-STARflex device. There was no significant difference between the Amplatzer and CardioSEAL-STARflex device.

Conclusions: The periprocedural and long-term neurological event rates are low regardless of the device used. The recurrent neurological event rate was significantly higher after CardioSEAL-STARflex than after Amplatzer or Helex implantation. This has important implications regarding the interpretation of trials comparing PFO closure to medical management.

TCT-772

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

Paul Dunne[1], Oliver Monfredi[2], Bernard Clarke[1], Gerard Murphy[1], Vaikom Mahadevan[1]
[1]Manchester Royal Infirmary, Manchester, United Kingdom, [2]University of Manchester, Manchester, United Kingdom

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 contrast CT to assess the relationship of the coronary arteries to the proposed site of PPVI in 3 planes – axial, saggital 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, saggital 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.

TCT-773

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

Apostolos Tzikas[1], Daniel Aguirre[2], Daniel Velasco-Sanchez[3], Xavier Freixa[4], Marcela Alburquenque[5], Paul Khairy[4], John Bass[6], Juan Ramirez[5], Reda Ibrahim[4], Joaquim Miro[3]
[1]St Luke's Hospital of Thessaloniki, Thessaloniki, Greece, [2]Hospital de Niños Roberto del Río, na, na, [3]Hôpital Sainte-Justine, Montréal, QC, [4]Montreal Heart Institute, Montreal, QC, [5]Corominas Hospital, na, na, [6]Amplatz Children's Hospital, Minneapolis, MN

Background: Transcatheter closure of peri-membranous ventricular septal defects (pmVSDs) has been associated with a significant risk of complete heart block, leading most groups 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 9.3 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 9.4 ± 2.4 mm (range 5 – 14 mm). An eccentric device 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 ± 39 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.

TCT-774

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

Vasileios Thanopoulos[1], Andreas Giannopoulos[2], George Tsaousis[3]
[1]Iatrikon Medical Center, Marousi-Athens, -= Επιλ°γη´ =-, [2]Ahepa University Hospital, Thessaloniki, Greece, [3]Iatrikon Medical Center, Marousi-Athens, Greece

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 35 other patients were excluded from transcatheter closure because they did not fulfil 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 devise was permanently implanted in 72/78 patients. Complete occlusion of the communication at six month, 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 heart in 3 and 1 patients respectively. (sinus rhythm after device removal). Late (follow-up 6 months-10 years). Complete heart block was developed in one patient 4-year old with Down syndrome. No other patient developed heart block during the follow-up. Three patients developed mild aortic regurgitation. In one of them the regurgitation was not seen at the 1-year follow-up. No other complications were observed.
Conclusions: Transcatheter closure using the Amplatzer APMVSD occluder is as a safe and effective nonsurgical alternative that should be offered in properly selected patients with PMVSDs. It should be noted, however, that with the current design of the occluder-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.

TCT-775

Novel System for Detection of Cardiac Right to Left Shunts

Robert Sommer[1], Russell Brandwein[2], David Dobson[3], Eric Eggers[3], Andrew Eggers[3]
[1]Columbia University Medical Center, New York, USA, [2]Columbia Medical Center, New York, NY, [3]Cardiox Corporation, Columbus, OH

Background: The current "gold standard" for detection and quantification of right-to-left shunts (RLS) is transesophageal echocardiography (TEE). The Flow Detection System (FDS) (Cardiox Corp., Columbus, OH) is a new, 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 shunt 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 assessment by intra-cardiac echocardiography (ICE - Johnson & Johnson, NJ) performed during the catheterization.
Results: All ten study subjects with TCD-proven RLS exhibited a Shunt Conductance Index (SCI) > 0, reflecting the presence of a RLS (sensitivity = 100%). FDS was also in

POSTERS

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

UNES (Utah Nickel Elution Studies)

Muhammad Khan[1], Anwar Tandar[1], Div Verma[1], Amit Patel[2], Rajasekaran Soorappan[1], Joseph Muhlestein[3], Rodney Badger[1]
[1]University of Utah School of Medicine, Salt Lake City, UT, [2]Cardiovscular Regenerative Medicine, Salt Lake City, USA, [3]Intermountain Medical Center, Murray, UT

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-1xDulbecco's Phosphate-Buffered Saline (DPBS). Three device samples from each group were submerged 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±2.89 vs<0.01±0mg/L, p<.001,Figure1). Individual group comparisons by Bonferroni Multiple Comparisons test showed that nickel elution was statistically similar amongst devices other than AGA.

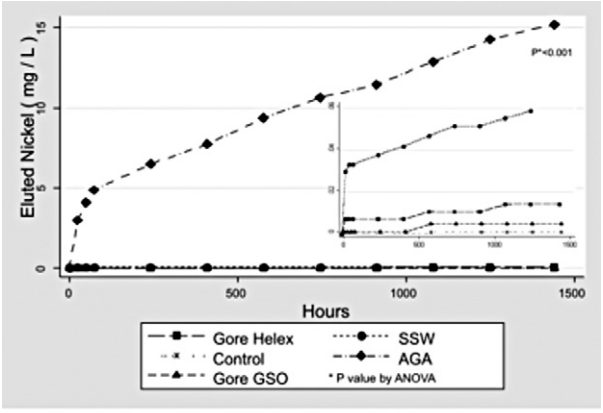


FIGURE 1: Nickel Elution Over 60 Days by Device Type. SSW: Sternal Wire, AGA: AGA Amplatzer Occluder"Cribriform" (30mm), Gore GSO: W.L. Gore GSO (30mm), Gore Helix: W.L. Gore Helex septal Occluder (30mm), Control: 1xDPBS (Dulbecco's Phosphate-Buffered Saline) Solution.
* P-value computed using ANOVA (Analysis of Variance Test)

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)

RONAN MARGEY[1], RONAN MARGEY[1], Sammy Elmariah[2], Brian Hynes[3], Pablo Renfigo-Moreno[3], Michael Jaff[4], Robert Schainfeld[5], Ignacio Inglessis[6], Igor Palacios[7]
[1]MASSACHUSETTS GENERAL HOSPITAL, BOSTON, MA, [2]Massachusetts General Hospital, Boston, MA, [3]Massachusetts General Hosptial, BOSTON, MA, [4]Harvard Medical School, Boston, USA, [5]Harvard Medical School, Newton, USA, [6]Massachusetts General Hospital, BOSTON, MA, [7]Associate Professor of Medicine. Harvard Medical School, Boston, USA

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 emboli,evaluating the relationship between high-risk PFO echo features,previously undiagnosed May-Thurner Syndrome,and hypercoagulability(cohort 1)compared to patients presenting with stroke(CVA)and/or transient ischemic attack(TIA)(cohort 2).
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 recorded.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 2lower extremity arterial emboli.772 patients are included in cohort 2.Cohort 1 had a higher incidence of May-Thurner syndrome(p=0.0005)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.

Risk Factor	Cohort 1 (N= 29)	Cohort 2 (N= 772)	p-Value
Age mean (SD)	48.0 (+/−14)	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 Aneursym	41.7%	25.5%	**0.08**
May-Thurner Syndrome	41.7%	15.1%	**0.0005**

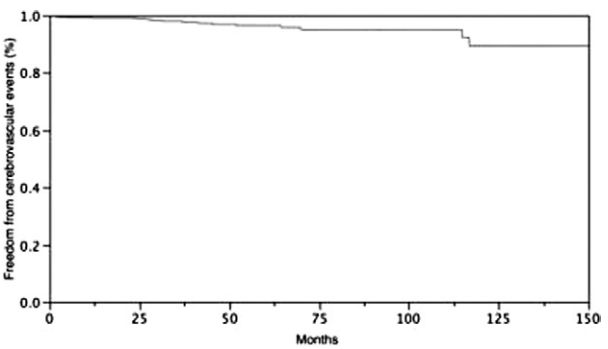
Conclusions: This is the largest series of PFO associated non-CVA/TIA paradoxical emboli,highlighting the need to screen for high risk PFO features and co-existantMay-Thurner syndrome.These patients can be treated successfully with transcatheter closure, with no recurrent events in follow-up.

TCT-778

Long-term Outcomes After Transcatheter Closure of Patent Foramen Ovale

Sammy Elmariah[1], Ignacio Inglessis[1], Pablo Rengifo[1], Ronan Margey[1], Suzanne Baron[2], Caitlin O'Callaghan[1], Ignacio Cruz-González[3], Zareh Demirjian[1], Ferdinando Buonanno[1], MingMing Ning[1], Scott Silverman[1], Eugene Pomerantsev[1], Robert Schainfeld[1], G. Dec[1], Igor Palacios[1]
[1]Massachusetts General Hospital, Harvard Medical School, Boston, MA, [2]Massachusetts General Hospital, MA, [3]Hospital Universitario de Salamanca, Salamanca, Castilla y Leon

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 36±35 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 (hazard ratio (HR)=12.5 (95% confidence interval: 3.56–43.6); p-value<0.0001) 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.