POSTERS

TCT-768

Noninvasive cardiac arrhythmia therapy using High-Intensity Focused Ultrasound (HIFU) ablation

Qi Wu[1], Qi Zhou[2], Que Zhu[2], Shunkang Rong[3], Qi Wang[4], Rui Guo[2], Changming Deng[2], Dichuan Liu[2], Gang Yang[5], Yonghong Jiang[2], Zhigang Wang[2], Han Lei[6], Tong-Chuan He[7], Zhibiao Wang[8], jing huang[9]
[1]the Second Affiliated Hospital of Chongqing medical University, Chongqing, Chongqing, [2]the Second Affiliated Hospital of Chongqing Medical University, Chongqing, Chongqing, [3]the Second Affiliated Hospital of Chongqing Medical University, Chongqing, chongqing, [4]State Key Laboratory of Ultrasound Engineering in Medicine Co-Founded by Chongqing and the Ministry, Chongqing, Chongqing, [5]the Second Affiliated Hospital of Chongqing Medical University, Chongqing, Chongqig, [6]the First Affiliated Hospital of Chongqing Medical University, Chongqing, Chongqing, [7]The University of Chicago Medical Center, Chicago, IL, [8]National Engineering Research Center of Ultrasound Medicine, Chongqing, Chongqing, [9]The second affiliated hospital of chongqing medical university, Chongqing, Chongqing

Background: To investigate the feasibility and safety of transthoracic HIFU ablation for blocking cardiac electrical conduction in a canine model.
Methods: Degreasing, degassing and establishment of artificial pleural effusion were induced in 21 canines. We used HIFU to target the right side of the central fibrous body guided by echocardiography. 10 canines received ablation only, 8 canines received ablation and cardiac pacing for 2h, while 3 canines received ablation and cardiac pacing for 3 months. At each endpoint, the targeted tissues were retrieved for gross, histological and immunohistochemical evaluation.
Results: Complete atrioventricular block (AVB) was achieved in all 21 canines using 400W×22.5±8.8s HIFU energy after acoustic coupling was improved. Recovery of AV conduction was observed neither in the 8 canines with cardiac pacing for 2h, nor in the 3 canines which were maintained with cardiac pacing for 3 months. The ablation lesion had a clear margin at the top part of interventricular septum with a necrosis of the conduction fiber in all analyzed animals whereas small fibrosis of the target regions within intact endothelium was found in the animals maintained for 3 months. No other complications were observed except that mild hemorrhagic injury in the inferior lobe of left lung was found in one animal.
Conclusions: Our findings indicate that the transthoracic HIFU for blocking cardiac conduction is specific, safe and efficient, lending itself as a potentially novel approach for arrhythmia therapy.

TCT-769

Functional Performance and Structural Maturation of Decellularised Pericardial Valves in Central Venous Position: An Experimental Study

Alexander Lauten[1], Adrian Laube[1], Markus Ferrari[1], Harald Schubert[2], Sabine Bischoff[2], Arthur Lichtenberg[3], Hans Figulla[1], Payam Akhyari[3]
[1]University Heart Center Jena, Jena, Germany, [2]Institute of Laboratory Animal Science, Jena, Germany, [3]Department of Cardiovascular Surgery, Duesseldorf, Germany

Background: Patients with severe tricuspid regurgitation (TR) represent a therapeutic challenge. Combining the excellent (pre-)clinical experience with decellularized heart valves and the transcatheter valve implantation results, we sought to evaluated the functional and structural outcome of decelluarised pericardial tissue valves(dTV) in the venous circulation using a chronic animal model of TR.
Methods: 8 decellularized pericardial tissue valves were implanted in the inferior(IVC) and superior(SVC) vena cava in a sheep model of severe TR. The devices were assembled using self-expanding nitinol stents and bovine pericardia decellularized by an established protocol (n=8). Glutaraldehyde-fixed(GA) tissue served as control(GA-TV, n=8). Prior to implantation, severe TR was created by pulmonary banding and papillary muscle avulsion. Valve implantation was performed by means of a 21F-catheter. After 6 month, valve function and structural maturation were analysed by echocardiography, histology, immunohistology and electron microscopy.
Results: Device was successful in all animals. After valve implantation, cardiac output increased significantly from 4.4 l/min to 5.1 l/min ($p<0.05$) and competent valve function was verified by angiography. At 6 month, angiographic and echocardiographic evaluation revealed moderate to severe regurgitation in all nTV. In contrast, 5 out of 8 dTV showed excellent function with only minor regurgitation. In these animals autopsy revealed preserved structural integrity of the valve with tender leaflets without signs of thrombosis or calcification. In contrast, nTV leaflets showed severe valve degeneration with large calcification areas. Microscopic and histologic analysis confirmed endothelial repopulation of the leaflets in both valve types. However, in dTV additional interstitial reseeding was noted.
Conclusions: In the venous low-pressure circulation, decellularized tissue valves show superior functional performance compared to native pericardial tissue valves. Macroscopic and microscopic analysis suggests preserved structural integrity and advanced endothelial and interstitial repopulation without evidence of degradation in decellularized tissue valves.

PFO, ASD, and Congenital Heart Disease

Hall D

Tuesday, October 23, 2012, 8:00 AM–10:00 AM

Abstract nos: 770-778

TCT-770

Transcatheter Device Closure Of Atrial Septal Defect In Infants And Young Children

Edwin Francis[1], Raman Krishnakumar[1], Shine Kumar[1]
[1]Amrita Institute of Medical Sciences, Cochin, Kerala

Background: Transcatheter closure of atrial septal defect (ASD) is the procedure of choice for central fossa-ovalis defects. There is limited information on safety and follow-up of transcatheter closure of ASD in young children. To describe our institutional experience on transcatheter closure of atrial septal defect in infants and children weighing ≤10 kg.
Methods: Records of 56 patients weighing ≤10 kg (mean age: 28.70 ± 9.54 months, range 4 - 50 months; mean weight: 8.98 ± 1.29 kg, range 4 - 10 Kg) who underwent transcatheter closure of ASD in our Institute (January 2007- December 2011) were reviewed.
Results: The study population represented 8.6 % of our total experience in this period. Indications for closure included failure to thrive (75.1%), recurrent respiratory infections (39.4%) and or heart failure (7.2 %). Case selection was through trans-thoracic echocardiography. The ASD size was 14.66 ± 3.27mm (range 9-23 mm) and mean pulmonary artery pressure was 27 ± 6.42 mm of Hg. Closure was achieved in all with mean fluoroscopy time of 8.61 ± 6.75 minutes; device size ranged from 9 to 24 mm. General anesthesia and transesophageal echo guidance was utilized in 22 (39.3%). One patient had embolisation of device immediately after release and was surgically retrieved. Transient ECG abnormalities included first degree AV block (2) and junctional rhythm (3). All had normal sinus rhythm at 24 hrs after procedure. On follow up (median 6 months; range 1-53 months) all were symptom free with over all improved weight z scores (from -2.00 ± 0.0 to -1.81 ± 0.29; $p < 0.008$), normal ECGs and satisfactory device positions on echocardiograms.
Conclusions: The immediate and short-term follow up results of transcatheter device closure of ASD are encouraging and suggest that the indications can be broadened to include selected children ≤ 10 Kg.

TCT-771

Long-term results of a comparison of three patent foramen ovale closure devices in a randomized trial (Amplatzer versus CardioSEAL-STARflex versus Helex occluder)

Marius Hornung[1], Jennifer Franke[1], Stefan Bertog[1], Margaret Taaffe[1], Laura Vaskelyte[2], Undine Pittl[3], Ilona Hofmann[4], Horst Sievert[5]
[1]CardioVascular Center Frankfurt, Frankfurt am Main, Germany, [2]CardiVascular Center, Frankfurt, Germany, [3]CardioVascular Center, Frankfurt, Germany, [4]Cardiovascular Center, Frankfurt, Germany, [5]CardioVascular Center Frankfurt, Frankfurt, Germany

Background: Percutaneous patent foramen ovale (PFO)-closure for secondary stroke prevention is discussed controversially, and long-term data comparing different closure devices are very limited.
Methods: This is a prospective trial comparing procedural complications and long-term results after PFO closure in 660 patients with cryptogenic stroke randomized to three different closure devices: Amlpatzer (AGA Medical, Golden Valley, Minnesota), Helex (W.L. Gore and Associates, Flagstaff, Arizona) and CardioSEAL-STARflex (NMT Medical, Boston, Massachusetts), 220 patients per group). Patients were monitored for recurrent cerebral ischemia (stroke, TIA or Amaurosis fugax), death and rate of complete PFO closure during 5 year follow-up (including periprocedural events).
Results: We examined 660 patients (361 men, 299 women, mean age 49.3+/−1.9 years). All PFO closures were successful technically. The procedure was complicated by pericardial tamponade requiring surgery in 1 patient (Amplatzer device) and device embolization in 3 patients (all Helex devices).

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