TCT-768

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

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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±8.8 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 transhoracic 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

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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 decellularised 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

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TCT-770

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

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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 $\leq 10 \text{ kg}$.

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 \leq 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)

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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).