TCT-79

Myocardial Recovery in Ambulatory Heart Failure Patients Treated with the C-Pulse Cardiac Assist System: A Single Center Experience

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Background: The C-Pulse System is an implantable, non-blood contacting device designed to provide long-term counterpulsation therapy for patients with advanced heart failure. Results from a recently completed a 20 patient IDE prospective study demonstrated improvements in NYHA class and quality of life with a low incidence of adverse events. We describe our single center experience in a subgroup of patients undergoing implantation of the C-pulse system who showed signs of myocardial recovery allowing for successful discontinuation of device support.
Methods: Between July 2010 and April 2012, six patients underwent implantation of the C-Pulse device at a single institution under the feasibility study. Safety endpoints included death, aortic disruption, neurologic events, myocardial infarction, and major infection at 6 months. Quality of life was assessed using the MLWHF and the KCCQ.
Results: Mean age was 50 years (range 34-71) and 83% were male. All patients were NYHA class III at baseline, with non-ischemic etiology in 83% (5/6). Two patients were inotrope dependent. There were no deaths, no neurologic events, aortic disruptions, myocardial infarctions, or mediastinal infections. One patient was transitioned to an implantable LVAD at 97 days post implant for worsening heart failure symptoms. Two patients remain clinically stable on device support (1178 and 982 days). Three patients showed clinically significant improvement allowing for discontinuation of device support with explantation of the percutaneous lead (mean duration of support 659 days, range 534-793 days). In the patients weaned, mean ejection fraction increased from 18.3% to 29.3% with a mean reduction in LVEDD of 1.1cm. Mean follow up time post-weaning was 335 days (range 52-565 days). There have been no readmissions for recurrent heart failure.
Conclusions: Long-term counterpulsation therapy with the C-pulse system has shown feasibility, preliminary safety and efficacy in patients with moderate to severe ambulatory heart failure, with the potential for sufficient myocardial recovery to allow for discontinuance of device support in a significant number of patients in our single center experience.

TCT-80

In-Vivo Long Term Evaluation of a Novel Mitral Valve Regurgitation Therapy: Experience in a Preclinical Large Animal Model

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Background: The MitraSpacer™ (Cardiosolutions, Inc.) is a novel approach to address mitral regurgitation by introducing a dynamic spacer with characteristics that constantly adjust to the instantaneous hemodynamics of the mitral apparatus and left atrium (LA). The purpose of this study was to evaluate the safety of the MitraSpacer™ within the mitral valve apparatus in the Yucatan miniature swine model.
Methods: Four (4) Yucatan miniature swine were enrolled in this study. Through a left thoracotomy, the shaft of the MitraSpacer™ was introduced into the left ventricular (LV) apex and advanced in to the LA avoiding the chordae tendineae. Once the device was in place, the balloon was partially filled to the desired volume with an iopromide/saline mix introduced by a subcutaneous access port. After implantation, all animals were survived up to 90 days.
Results: Following implantation, device performance was assessed by fluoroscopy and echocardiography. The volume within the balloon shifted during the cardiac cycle in all cases following the direction of blood flow and applied pressure. All enrolled animals survived up to 90 days for terminal imaging and tissue harvest. Echocardiographic data showed no change in LV ejection fraction from baseline to 90 days, 61.25±1.7% and 58.09±3.6% (p=0.2) respectively, and slight changes in LA and LV volumes consistent with the rate of growth of the animal over time. Cardiac performance was maintained and no functional or structural changes to the mitral apparatus were observed over 90 days by serial imaging. In addition, there were no observations of disruption in LV diastolic function, pulmonary vein inflow, or tricuspid regurgitation.
Conclusions: In a healthy porcine model, the feasibility of chronic (up to 90 days) placement of the MitraSpacer™ was demonstrated. In contrast to currently used mitral valve repair/replacement devices, the subcutaneous port of this device allows for post-implantation adjustment of the balloon volume, making it potentially ideal for treatment of patients with mitral regurgitation due to left ventricular dysfunction.

TCT-81

Ex-Vivo Simulator for Training, Teaching, and Testing of Transcatheter Valve Therapies Based on the Principle of a Passive Beating Heart

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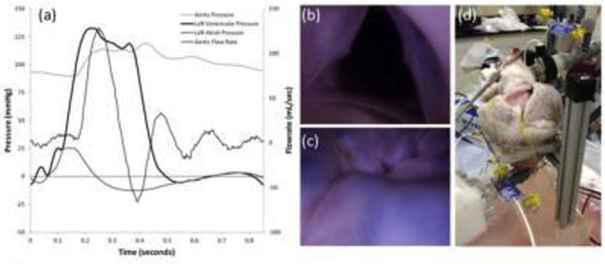
Background: Commercially available in-vitro cardiac simulators offer testing opportunities for transcatheter valve therapies (TVT) as they are able to replicate the physiological flow and pressure accurately. These simulators lack the anatomical similarity needed for some transcatheter device testing as well as training and teaching physicians. The ex-vivo simulator combines the anatomical similarity with physiological flow and pressure signatures.
Methods: The left side of a porcine heart was incorporated into a circulatory loop and driven by a pulsatile pump. Compliances were added to achieve physiological pressure and flow signatures and native movement of the mitral (MV) and aortic (AV) heart valve. Pressure transducers acquire the aortic, ventricular and mitral real-time pressures. A flow meter measures the cardiac output of the simulator. Access sites at aorta, atrium and apex allow the insertion of TVT devices as well as endoscopic visualization.
Results: The pressure differences over the MV and AV are comparable to physiological values. The characteristics of the valves such as orifice area as well as the duration of opening and closing comply with those in native hearts.



(a) Flow and pressure signatures; endoscopic images: (b) opened aortic valve, (c) closed mitral valve; (d) pig heart connected to ex-vivo simulator

Conclusions: The ex-vivo simulator reliably duplicates the movement of the MV and AV. Hence it is a cost-effective, and user-centric bench top model suitable for testing TVT and training and teaching of TVT methods. Advantages are the time associated with each trial especially in comparison with animal tests and the low experimental costs while still being able to test in an intact heart.

TCT-82

Thoracoscopically Assisted Transcatheter Ventricular Restoration Reverses Left Ventricle Remodeling in the Chronic Anteroseptal Aneurysmal Ovine Model

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Background: Surgical ventricular reconstruction has been used to treat heart failure patients with large ventricular aneurysms. This study assessed the feasibility and efficacy of performing minimally invasive thoracoscopically assisted transcatheter ventricular restoration (TCVR) in an anteroseptal ovine infarction model.
Methods: Anteroseptal scar was achieved by percutaneous coil-occlusion of the left anterior descending artery. Two months after occlusion, TCVR was performed in five sheep via a minimal left thoracotomy and right external jugular catheter intervention. Under endoscopic and fluoroscopic guidance, trans-interventricular septal puncture was performed at the epicardial border of the scar using a proprietary needle, and a guidewire was externalized via a snare placed in the right ventricle from the right external jugular vein. An internal anchor with a tether was inserted over the wire and positioned on the right ventricular septum and an external anchor was deployed on the LV anterior epicardium. Serial pairs of anchors were placed and LV walls were plicated to completely exclude the scar through apposition of the antero-lateral wall to the septum and exclusion of the intervening wall segment. LV performance was evaluated before (baseline) and six weeks after device implantation by echo.
Results: All animals survived with no procedural or device-related complications. Compared to baseline, LV end-systolic volume was decreased by 46% (34.0±16.8 vs. baseline 62.0±20.9ml, p< 0.001) and end-diastolic volume decreased by 32% (60.9±18.3 vs. baseline 89.5±18.0, p< 0.01) 6 weeks post TCVR. Ejection fraction was significantly increased by 14% (46±9% vs. baseline 32±9%, p< 0.01) and stroke volume was preserved (26.9±3.9 vs. baseline 27.5±4.6ml, p=NS).
Conclusions: A thoracoscopically assisted TCVR procedure is safe and effective. A significant and presumably clinically important reduction in LV volume can be