wall. LV performance was evaluated before (baseline) and immediately after device implantation by echo.

Results: TCVR was successfully performed in all the animals. Immediately after the procedure and compared to baseline, LV end-systolic volume was decreased by 54% (26.9±8.7 vs. baseline 60.1±22.5ml, p<0.01) and end-diastolic volume decreased by 34% (54.5±11.0 vs. baseline 85.6±20.6ml, p<0.05). Ejection fraction was significantly increased by 19.8% (51.9±9.5% vs. baseline 31.4±9%, p<0.001) and stroke volume was preserved (27.5±6.9 vs. baseline 25.3±3.8ml, p=NS).

Conclusions: Minimally invasive thoracoscopically assisted TCVR is feasible and resulted in significant improvement in cardiac volume and ejection fraction in an ovine infarction model.

TCT-126
First-in-human experience with a novel high flow percutaneous heart pump
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Background: High-risk percutaneous coronary interventions (HRPCI) involving complex disease and/or depressed cardiac function have become increasingly common. The potential benefit from short-term mechanical circulatory support is suggested by observations that intraprocedural hemodynamic compromise may impact completeness of revascularization and contribute to adverse events. We report outcomes from a First in Human trial using the HeartMate PHP™ (Percutaneous Heart Pump) in patients undergoing HRPCI. PHP is a catheter-based axial flow pump designed to provide partial left ventricular support of up to 5 lpm and is rapidly delivered percutaneously via typical femoral insertion. The 12F catheter contains a distal collapsible covered nitinol cannula with an integrated impeller that expands to 24F when deployed across the aortic valve.

Methods: 10 patients with complex coronary disease and reduced LV function (EF from 26% - 34% prior to PCI) underwent elective HRPCI while on PHP support. Device success, defined as the deployment, use and removal of PHP without device failure; and peri-procedural measures of hemodynamics and cardiac performance were evaluated. Major adverse safety and efficacy events were assessed during PHP use and at 30 days.

Results: Among the first 3 patients, PHP was successfully deployed in all patients without complications. There was no peri-procedural or follow-up echocardiographic evidence of aortic regurgitation or valve abnormalities. All patients remained hemodynamically stable while on support and all planned target lesions were revascularized. The PHP was successfully removed in all cases and there were no adverse patient events while on device support through 30 days. (Outcomes on the full patient series will be presented when complete.)

<table>
<thead>
<tr>
<th>CARDIAC INDEX</th>
<th>MAP</th>
<th>PCWP</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>On Support</td>
<td>Baseline</td>
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<tr>
<td>Pt #1</td>
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<tr>
<td>Pt #2</td>
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<tr>
<td>Pt #3</td>
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<td>3.26</td>
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</table>

Conclusions: In a First in Human trial involving patients undergoing HRPCI, hemodynamic support using the HeartMate PHP is feasible and safe.

TCT-127
Trans-Auricular Intra-Pericardial Tricuspid Annuloplasty (TRAIPTA)
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Background: Functional tricuspid regurgitation (TR) is clinically significant. TR predicts mortality independent of LVEF, age or pulmonary artery pressure. Persistent TR after mitral valve surgery is an independent poor prognostic sign. Tricuspid valve repair is usually an adjunct to other surgery. We present TRAIPTA, a novel percutaneous treatment of functional TR. We demonstrate pre-clinical feasibility in swine.

Methods: Through the femoral vein and under X-ray guidance, the pericardial space is accessed by puncture through the right atrial appendage (Panel A). A custom memory-shape delivery device positions a suture circumferentially in the AV groove (Panel B) and used to deploy a semi-rigid device to apply direct compression to the tricuspid annulus. The suture is tightened to achieve the desired degree of annuloplasty (Panel C), then secured and cut. The atrial appendage access is closed with an occluder.

Results: In naive swine, trans-auricular pericardial access was easy and safe. The TRAIPTA device is consistently delivered to the AV groove, tension can be selectively applied to the tricuspid annulus, and RV geometry importantly altered.

Conclusions: Percutaneous treatment of functional TR is feasible in swine using TRAIPTA.

TCT-128
Transcatheter Implantation of Self-Expandable Vena Cava Valves for Treatment of Tricuspid Regurgitation: First-Human-Case Description
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Background: Despite the recent advances in interventional treatment of heart valve disease, no transcatheter approach is established for severe tricuspid regurgitation (TR). Single valve implantation into the inferior vena cava (IVC) has been suggested, which however only partially resolves the hemodynamic sequelae of TR. After extensive preclinical evaluation, we herein report the first human case of bi-caval self-expanding valve implantation (CAVI) in the superior (SVC) and inferior vena cava.

Methods: CAVI was performed in a 83-year-old patient with severe TR, chronic right heart failure and congestive hepatopathy. Two self-expanding pericardial valves were custom-made to fit to the anticipated implantation zones in the caval veins of this patient. Both devices were implanted under fluoroscopy using a 27F-catheter and deployed at the level of the cavo-atrial junction of the SVC and the IVC. To protect the hepatic veins from backward flow, the inferior valve was aligned just above the hepatic vein inflow and deployed with the valve protruding into the right atrium (RA).

Results: After deployment and during 3-month follow-up excellent valve function was observed. The procedure resulted in a marked reduction of the pressure in the SVC and IVC from 27/14mmHg and 28/15mmHg to 21/7mmHg and 13/6mmHg at 3 month, respectively. After implantation symptoms of right heart failure resolved and did not recur during follow-up and synthetic liver function recovered. The patients physical capacity improved with an increase in distance covered in 6-minute-walk-test from 20m before implantation to 200m at 3 month.

Conclusions: In this first-in-man experience, transcatheter CAVI proved feasible and resulted in persistent hemodynamic and clinical improvement. Further confirmatory experience with longer follow-up is required to evaluate the clinical benefit of the procedure.

TCT-129
Percutaneous Transfemoral Management of Severe Secondary Tricuspid Regurgitation with Edwards Sapien XT Bioprosthesis in patients with severe heart failure: first in man experience
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Background: Severe tricuspid regurgitation (STR) is a common final pathway in advanced stages of heart failure (HF) and associated with increased morbidity and mortality. The prevalence of moderate to severe TR is 35% in HF patients occurring in 1.6 Mio patients in the US. In advanced TR stages, the surgical risk is prohibitively high, alternative approaches are therefore required. Here we describe the feasibility as well as peri-procedural and short-term outcomes of a novel first-in-man single caval and dual caval approach for implantation of the Edwards Sapien XT.

Methods: Vena cava inferior (VCI) single valve approach: to guarantee stable placement we prepared a landing zone by implanting a self-expanding 30/60-mm Sinus XI, Stent in the IVC segment downstream of the RA. To further downsize the