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 is not 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 pericaval 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 periprocedural 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
Background: Transcatheter aortic-valve implantation (TAVI) has rapidly evolved as a next generation heart-valve therapy concept. Long-term functionality proven, a cell based TEHV approach may represent a new paradigm for tissue repair when percutaneous implantation is not possible. We propose to overcome these limitations. We summarize our initial experience on engineered heart-valves (TEHV) with self-repair capacity have been repeatedly proposed to overcome these limitations. We summarize our initial experience on marrow stromal cell based TAVI in an adult sheep model.

Methods: Tri-leaflet TEHV generated from synthetic-scaffolds were integrated into self-expanding Nitinol stents, seeded with autologous marrow-stromal cells. Thereafter, in a series of animal experiments, TEHW were transapically delivered into the descending aorta (n=3) and the orthotopic aortic-valve position of adult sheep (n=16) using different delivery systems including a generic system and the anatomically-orienting JenaValve transapical TAVI System (JenaValve, Munich/Germany). Follow-up was up to two weeks. Positioning and functionality were assessed by angiography and echo before the TEHV underwent post-mortem gross examination and histology. CT scan was used to assess stent positioning.

Results: Transcatheter implantation of TEHV into the descending aorta (n=3) and into the orthotopic aortic-valve position (n=16) was successful in all animals. Fluoroscopy and echo confirmed sufficient positioning at the intended delivery site. All TEHW tolerated the loading-pressure of the systemic-circulation and no acute ruptures or tears occurred. Animals displayed intact and mobile leaflets. TEHW remained patent at the end of the procedure (mean trans-valvular gradient <10mmHg in all animals). Importantly, TEHW orthotopically implanted (n=16) entirely excluded the native aortic leaflets and did not compromise the coronary arteries. Histology was indicative for an early cellular-remodelling.

Conclusions: We demonstrate transcatheter based TEHV implantation into the aorta within a one-step intervention. Our data indicate the feasibility to combine the concept of TEHV and transcatheter delivery representing a key step towards clinical translation. Long-term functionality proven, a cell based TEHV approach may represent a next generation heart-valve therapy concept.

Use Of A Novel Echo-fluoroscopy Overlay System For Percutaneous Mitral Valve Intervention

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Background: Percutaneous mitral valve repair requires a close understanding of both fluoroscopy and periprocedural imaging. Real time 3D transesophageal echocardiography is often used for guidance. We report the use of 3D-echocardiography-fluoroscopy fusion for mitral valve repair.

Methods: Patients presenting to our center for mitral valve repair had their procedure performed using an echocardiographic-fluoroscopic overlay system. The EchoNaviga-tor (Philips, Inc) system requires transesophageal echocardiography, which is registered to fluoroscopy based on probe angle and position. Relevant structures can be marked on echocardiography and tracked with fluoroscopy. Procedural characteristics of these patients were collected.

Results: Nine patients at our center underwent percutaneous mitral valve repair with MitraClip (Abbott Vascular, Santa Clara, CA) using a novel 3D-echocardiographic-fluoroscopic overlay technology (EchoNavigator, Philips Inc.). The EchoNavigator system was useful for transseptal puncture, understanding mitral valve anatomy, sheath exchange, clip advancement, and post-deployment visualization.

Conclusions: The use of EchoNavigator echo-fluoroscopy overlay system is feasible and useful in MitraClip intervention.

THE MULTILAYER FLOW MODULATOR STENT FOR THE TREATMENT OF PERIPHERAL AND VISCERAL ANEURYSMS

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Background: Arterial aneurysms (An) are traditionally treated surgically, but more and more by interventional procedures with a high technical success rate, but some problems are not solved like protection of aneurysm rupture, endoleaks, stent thrombosis, collateral branch thrombosis. We used a new concept of stent, the Multilayer Flow Modulator (MFM) to treat An and try to avoid some drawbacks with endografts.

Methods: This MFM is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest in vitro (theoretical simulation), computerized fluid dynamics, Molecular Modelization and in vivo tested demonstrated that this MFM reduces the velocity in the aneurisal sac up to 90% by modifying the flow.