5.9±5.4%, log EuroSCORE-I 13.9±7%). The mean age was 82.4±5.3 years old, 62% were female, and 70% were in NYHA class III. The implanted valve sizes were 26mm in 7 cases and 29mm in 57 patients. Implantation was successfully completed in 64 patients. One-month follow-up is completed in 97.1% of patients (echocardiographic examination was performed for 88% of the patients and NYHA is assessed for 90% of patients). The preliminary echocardiographic hemodynamic performance revealed: A mean aortic valve area increase from 0.7±0.2cm2 at baseline to 1.9±0.4cm2 at 30 days ($p < 0.0001$). Mean transaortic gradient decreased from 37.7±14.4mmHg at baseline to 6.4±2.5mmHg at 30 days post-procedure ($p < 0.0001$). Paravalvular aortic regurgitation at one-month follow-up was none/trace (0) in 32%, mild (1+) in 64%, moderate (2+/3+) in 4% and severe (4+) in 0% of patients. Survival at 30 days was 98.5%. NYHA class I/II was observed for 77% of patients (improvements to NYHA class I/II were found in 61% of the patients). The freedom from all strokes was 94%, from major vascular complications was 95.6%, from acute kidney injury stage 2/3 was 97.1% and from new permanent pacemaker implantation was 85%, respectively.

CONCLUSION This novel self-expanding transcatheter valve has been shown to be safe and effective at one month with significant hemodynamic improvements, low paravalvular regurgitation, low incidence of major complications in a higher surgical risk population requiring treatment for severe, symptomatic aortic stenosis. Final clinical and echocardiographic data up to 6 months follow-up will be available upon presentation.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-42

An Early Feasibility Study to Assess Safety and Effectiveness of the Transfemoral JenaValve Pericardial TAVR System in the Treatment of Patients With Symptomatic Severe Aortic Stenosis (AS)

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BACKGROUND The aim of this study is to demonstrate the feasibility of use of a new self-expanding transcatheter heart valve with unique locator technology which anatomically aligns and 'clips' the bioprosthesis over the native aortic valve with resultant minimal paravalvular leak and a low transvalvular pressure gradient. This new device is anticipated to improve outcomes for patients with severe aortic stenosis and eventually, those with aortic regurgitation.

METHODS Fifteen patients with severe aortic stenosis were enrolled at three centers in Germany and New Zealand. Prior to valve implantation, patients underwent CT and echo assessment. Clinical and echo follow-up was obtained post-procedure, at 30 days, and at regular follow-up to 2 years. A screening committee was used for patient selection and a core lab performed the imaging analyses. An academic, independent safety committee reviewed and adjudicated adverse events. The primary endpoint is all-cause mortality at 30 days. Secondary endpoints of safety and performance using VARC2 definitions are collected to 2 years post-procedure.

RESULTS Fifteen patients underwent implantation of the study valve via a femoral approach and 11 patients thus far have returned for 30-day follow-up. Technical success was 93.3%. Paravalvular leak immediately post treatment was none/trace in 5 patients (35.7%) and mild in 9 (64.3%). To date, in patients who have reached 30-day follow-up, the aortic valve area increased from 0.7 ± 0.2 cm2 at baseline to 2.2 ± 0.4 cm2 at 30 days and the mean transvalvular pressure gradient decreased from 49.3 ± 16.0 mmHg to 5.0 ± 0.5 mmHg. At 30 days, paravalvular leak is none/trace in 7 patients (63.0%) and mild in 4 (37.0%). No moderate or severe leak is reported. One patient required permanent pacing and survival at 30 days is 100%. Of the patients who have returned for 30-day visits, all exhibit in New York Heart Association Functional Class I (54.5%) or Class II (27.3%).

CONCLUSION Transcatheter aortic valve replacement using this new device is feasible and can lead to good outcomes. Patients are currently returning for 30 day and 6 month visits. Safety and performance results of this CE-Mark trial will be presented at TCT 2018.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-43

First-in-human experience of a novel transradial device for embolic deflection during transcatheter aortic valve replacement

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BACKGROUND The average stroke rate in contemporary transcatheter aortic valve replacement (TAVR) studies is 4.4%. The majority of the TAVR studies are non-randomized registries, hence, neurological outcomes may be underreported. Over 50% of all TAVR related strokes occur during the procedure or on the same day – with over half of them being major strokes.

METHODS The ProtEmbo System (Protembis GmbH, Germany) is an intra-aortic filter device that deflects embolic material arising during TAVR away from the cerebral circulation. The safety and feasibility of the first generation ProtEmbo System was tested in a first-in-human study in AS patients indicated for TAVR (n=4). The primary safety endpoint was in-hospital procedural safety, defined as occurrence of all MACCE based on VARC-2 criteria, including device-related safety outcomes. The primary feasibility endpoint was defined as technical success. The secondary efficacy endpoint was defined as the reduction in number and volume of new cerebral lesions assessed on DW-MRI prior to discharge at day 3 and day 30, compared to baseline and comparison subjects.

RESULTS The ProtEmbo System could successfully be delivered, deployed and retrieved in all patients, with no device-related adverse events. The device covered all three side branch vessels of the aortic arch as assessed by angiographic analysis. There was minimal to no interference with other devices used in the index procedure. The histopathology core lab analysis revealed no safety or biocompatibility concerns. The MRI core lab analysis revealed a 50% reduction in number of new lesions versus a comparison subject (1-1). When adjusting for baseline lesions, the reduction in new lesions was as high as 87% for protected versus unprotected TAVR.

CONCLUSION This first-in-human study could demonstrate the initial safety and feasibility of the first generation ProtEmbo System. The device could be implanted quickly in all patients and it was easy to use. The ProtEmbo System demonstrated a reduction in the number of new cerebral lesions versus a comparison subject. Comprehensive data analysis of this study will be available for presentation for the first time at TCT 2018.

CATEGORIES OTHER: Pre-Clinical/First In-Human Studies

TCT-44

Comparative effectiveness and safety of five leading new-generation TAVI devices: 12-month results from the RISPEVA Study

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BACKGROUND Transcatheter aortic valve implantation (TAVI) for aortic stenosis is beneficial in inoperable or high-risk patients. Several new-generation TAVI devices have been recently introduced, but comparative analyses are lacking. Equipoise cannot yet be assumed among them. We aimed to compare such five leading new-generation TAVI devices exploiting data collected in the prospective multicenter RISPEVA Study.