Transcatheter Aortic Valve Implantation: 6 and 12 Months Results From a Multicenter Study Using the JenaValve Second Generation Transcatheter Aortic Valve Implantation System

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Background: Transcatheter aortic valve implantation (TAVI) has emerged as an accepted treatment alternative for high risk patients with severe aortic stenosis. This study was designed to evaluate the safety and efficacy of transcatheter aortic valve implantation in high risk patients using the second generation JenaValve TAVI system. It consists of a biological porcine valve mounted on a self-expanding Nitinol stent. Retrieval capability, feeler guided anatomically positioning and clipping fixation on the diseased leaflets provide potential advantages compared to current TAVI systems.

Methods: This study enrolled a total of 73 patients of whom 67 patients (mean age 83±1.39; Euroscore 28±4.6) underwent elective TAVI at 7 German centers. Primary endpoint was all-cause mortality at 30 days. Procedural success, major adverse cerebrovascular and cardiac events, functional improvement, echocardiographic and valve performance were assessed at baseline, post-procedure, discharge, 30 days, 3, 6, and 12 months.

Results: 60 of 67 patients underwent successful TAVI with the JenaValve resulting in a procedural success of 89.6%. Pacemaker implantation for new onset conduction disorders was necessary in 6 patients (9.1%). No coronary ostium obstructions were seen. TAVI resulted in favorable reductions of mean transvalvular gradients (40±16 mmHg to 10.0±7.3 mmHg, p<.0001) and increase in valve opening area (0.7±0.2cm² vs. 1.7±0.6cm², p<.0001). None of the unsuccessful patients had immediate post procedural aortic regurgitation (≥ grade 2). Survival at 30 days and 6 months was 92.4% and 74.3% respectively. Stroke occurred in 4 patients (6.0%) at 6 months. NYHA Class improved significantly at 6 months after valve implantation (5.4% NYHA class I, 56.8% NYHA class II and 37.8% with class III). 12 months outcomes will be presented according to VARC criteria at the conference.

Conclusions: TAVI using the JenaValve system has proven to be an effective treatment option in high risk patients with aortic stenosis with good short and mid-term outcome. Anatomically correct positioning and clip-fixation of the native leaflet led to good hemodynamic function and favorably reduced paravalvular leak rates.

Transcatheter Aortic Valve Replacement: 3-Month Outcomes in 11 Patients at High Surgical Risk (REPRISE I)

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Background: The Edwards SAPIEN valve has been FDA-approved with its Retroflex delivery system for retrograde transfemoral (TF) treatment of inoperable patients with severe aortic stenosis, and is the only device clinically available for transcatheter aortic valve replacement (TAVR) in the United States (US). Because of insufficient iliofemoral vascular access, many patients are excluded from the TF approach. We explored transapical (TAO) TAVR as an alternate access strategy for these patients.

Methods: Twenty-five consecutive patients underwent TAO TAVR between January and April, 2012 at our site. All had symptomatic severe aortic stenosis, were inoperable, and had inadequate vascular access for TF delivery. Through a small upper sternotomy and direct insertion of the sheath into the ascending aorta, we delivered the valve using the Retroflex catheter. Procedural and 30-day outcomes were retrospectively compared with the first 25 patients treated by transapical (TA) access in our program.

Results: TAO TAVR was successfully performed in all patients. One perioperative death occurred, which was unrelated to the TAO approach. No other cardiovascular death was reported within 30 days. Compared with TA access, TAO TAVR had a similar all-cause mortality rate at 30 days, and was associated lower incidence of bleeding events, as well as shorter ICU length of stay.

<table>
<thead>
<tr>
<th>BASELINE DEMOGRAPHICS</th>
<th>Trans-Aortic Series</th>
<th>Trans-Apical Series</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age (Years) /SD</td>
<td>83 (± 16)</td>
<td>85 (± 16)</td>
<td>0.35</td>
</tr>
<tr>
<td>Male Gender</td>
<td>10 (40%)</td>
<td>15 (60%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Median STS Score /SD</td>
<td>8 (± 4.4)</td>
<td>10.8 (± 3.27)</td>
<td>0.009</td>
</tr>
<tr>
<td>Operable for conventional AVR</td>
<td>0%</td>
<td>0%</td>
<td>1.00</td>
</tr>
<tr>
<td>NYHA Class 3 &amp; 4</td>
<td>24 (96%)</td>
<td>25 (100%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Median AVE (cm2)</td>
<td>0.62 (± 0.15)</td>
<td>0.60 (± 0.12)</td>
<td>0.62</td>
</tr>
<tr>
<td>Median LVEF (%)</td>
<td>60 (± /16)</td>
<td>50 (± /15)</td>
<td>0.38</td>
</tr>
</tbody>
</table>

Conclusions: TAVR via the TAO approach, using the only commercially-available device in the US, is technically feasible and is associated with favorable outcomes in inoperable patients with severe aortic stenosis who are not candidates for TF access. In these patients, the TAO approach expands the current alternative options for TAVR access sites. Efforts directed towards enhancing the technologies and techniques associated with TAO TAVR should further improve the efficacy and safety of this procedure.
Methods: A multidisciplinary team of four members with experience in clinical medicine, engineering, business and software design received four weeks’ training in basic anatomy, physiology, market analysis, clinical needs finding and concept generation, intellectual property (I.P.), regulatory, reimbursement and business planning. The fellows jointly agreed an acceptance criteria e.g. market size, measurable endpoints to aid future decision making. For eight weeks the team were attached to tertiary care hospitals to understand the patient cycle of care and to meet all the stakeholders impacting in/out-patient care and to observe a range of in-hospital procedures. This resulted in nearly 2000 observations which were translated into 120 problem statements. These problems were researched in terms of incidence, prevalence, disease heredity, existing treatment effectiveness, market size etc. This insight and filtering against the acceptance criteria enabled further elimination. The remaining problems were translated into clinical needs statements and validated by speaking to key stakeholders, in-depth medical literature review and competitor analysis. As a result eight needs statements were emerged. The resultant concepts from brainstorming of the needs were screened against agreed need specifications and pre-existing I.P. Further literature and primary research, filtering and elimination led to a final need entitled: A cost effective, fast way to embolize a blood vessel. This had emerged from observing that current embolization devices are deficient e.g. need for multiple coils, migration, recanalization, and high prices.

Results: Funding was successfully applied for and secured from Enterprise Ireland to enable prototyping with proof of concept via bench testing and animal studies.

Conclusions: This multidisciplinary innovation research program brings together the key stakeholders involved with medical devices and enables the development of a rich network and expertise that will promote patient care through future medical device development.

TCT-107

TIARA - A Novel Catheter-Based Mitral Valve Bio-Prosthesis Short Term Pre-Clinical Results

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Background: A significant proportion of patients with severe mitral regurgitation (MR), have severe comorbidities and are not candidates for conventional surgery because of high operative risk. The field of percutaneous mitral valve (MV) repair is developing and many technologies are now under investigation. To date, trans-catheter valve implantation is limited to pulmonary and aortic valve replacement. The aim of our study was to demonstrate the safety and feasibility of minimally invasive trans-catheter implantation of a novel self-expanding MV specifically designed for the unique complex anatomical configuration of the mitral apparatus - the TIARA self-expanding bioprosthetic valve.

Methods: Using a trans-apical approach, TIARA valves were successfully implanted in 29/36 (81%) domestic swine with fluoroscope and 3D transesophageal echocardiographic (TEE) guidance. Follow-up varied from 90 minutes to 96 hours. The valves were delivered using a short flexible 30F delivery catheter.

Results: Total procedure time ranged from 17 to 26 minutes, and the prosthetic deployment time ranged from 5 to 13 minutes. In the 29 successful implantations, TEE demonstrated excellent function and alignment of the TIARA prosthesis, with no left ventricular outflow tract obstruction, no pericardial effusion, no encroachment on the aortic valve, and no trans-valvular gradients. Significant paravalvular leaks were only seen in cases of either MV annulus-prosthesis mismatch or failed implantation. Macroscopic evaluation of the explanted hearts demonstrated stable and secure positioning of the valves in all planes of the mitral apparatus with no evidence of injury to the ventricular or atrial walls.

Conclusions: We report our successful initial pre-clinical experience with the TIARA trans-catheter self-expanding mitral bioprosthetic valve. We have demonstrated that the implantation of the TIARA valve is a feasible, safe, and relatively straightforward procedure, which results in a stable and well-functioning mitral valve bioprosthesis. Successful completion of long-term pre-clinical trials of the TIARA is ongoing which will lead the way to human clinical trials.

TCT-108

Performance and Safety of the TRUE Dilatation® Balloon Valvuloplasty Catheter for Aortic Balloon Valvuloplasty in Patients Undergoing TAVI

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Background: Valvuloplasty (BAV) using the currently available balloons - to prepare the valve annulus for the implant of a transcatheter heart valve - is associated with balloon slippage and rupture in up to 17% of the cases, which carries an increased risk of stroke. The TRUE Dilatation® Balloon Valvuloplasty Catheter, constructed of an inner and an outer film layers that encompass a flexible matrix center embedded with high performance fibers, was developed to allow a fast and precise dilatation of the aortic valve in the absence of balloon rupture. It was aim of the present study to assess the performance of...