Conclusions: The ADVANCE study represents the largest, rigorously reported cohort of HRQoL findings in the TAVI literature. All HRQoL measures significantly improved compared with baseline at 1 and 6 months. An assessment of HRQoL by patient risk profile according to EuroSCORE will be presented at the meeting.

TCT-815
Prognostic Role Of Serum Cardiac Biomarker Elevation After Transcatheter Aortic Valve Replacement

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Background: The majority of patients have significant elevations in serum cardiac biomarkers after transcatheter aortic valve replacement (TAVR) however the prognostic significance of such elevations is unknown. Our aim was to assess incidence and prognostic power of biomarker elevations after TAVR.

Methods: Clinical data of patients with aortic stenosis who were subjected to TAVR was retrospectively analyzed. Myocardial necrosis markers cardiac troponin I (cTnI) and creatine kinase (CK-MB) were assessed during hospitalization.

Results: Among 150 TAVR patients, TA patients had significantly higher elevations both for cTnI (13.8±14.0 vs. 2.5±5.8, p<0.001) and CK-MB (28.4±24.2 vs. 7.4±8.6, p<0.001) compared with TF patients. Biomarker elevations in TA patients did not have any predictive power for patient outcome. However, by receiver operator curve analysis, for TF patients, post-procedural CK-MB (2-fold increase) had higher predictive power for 30-day mortality (area under the curve 0.85, p<0.001). Patients with high CK-MB had higher rates of post-procedural kidney injury (22% vs. 6%, p=0.026), in-hospital (22% vs. 0%, p<0.001), 30-day (27% vs. 15%, p=0.001), and 1-year mortality (41% vs. 18%, p=0.01).

Conclusions: Cardiac biomarker rise post-TAVR is common and more frequent among TA access patients. A 2-fold increase (>7 ng/ml) in CK-MB after TF-TAVR is a surrogate for poor long-term outcome.

TCT-816
Anticipated Utilization of Transcatheter Aortic Valve Replacement Reflects Cautious Optimism of the U.S. Interventional Cardiology Community

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Background: Transcatheter aortic valve replacement (TAVR) is the first major addition to the treatment of valvular heart disease in more than a decade, and the number of patients eligible for valve replacement is likely to increase significantly. As a consequence, little is known about expectations within the cardiology community regarding the utilization of this new therapy in clinical practice.

Methods: Four days after approval of the first TAVR device in November 2011 by the U.S. Food and Drug Administration (FDA), we emailed an online questionnaire to 201 interventional cardiologists involved in TAVR research and 461 recent members of the Society of Cardiovascular Angiography and Interventions to evaluate anticipated TAVR referral patterns. Follow-up reminders were sent during the next 4 weeks. Characteristics between respondents and clinicians were compared using chi-square and t-tests.

Results: Of 205 responses received (31%), the majority of respondents were male (90%), interventional cardiologists (86%), and working in academic practices (72%). Most respondents (90%) planned to refer patients for TAVR immediately after the devices are responsive. Although 75% of respondents anticipated referring less than one-fourth of their patients with severe aortic stenosis for TAVR, 68% believed that TAVR is equally efficacious as open-heart surgery, and 70% stated that no more data were needed to confirm TAVR is safe for clinical use. Although 75% of respondents anticipated referring less than one-fourth of their patients with severe aortic stenosis for TAVR, 68% believed that TAVR is equally efficacious as open-heart surgery, and 70% stated that no more data were needed to confirm TAVR is safe for clinical use. Although 75% of respondents anticipated referring less than one-fourth of their patients with severe aortic stenosis for TAVR, 68% believed that TAVR is equally efficacious as open-heart surgery, and 70% stated that no more data were needed to confirm TAVR is safe for clinical use.

Conclusions: These data provide insight into the expected utilization of TAVR after FDA approval in November 2011. Despite remarkable enthusiasm and media attention for TAVR over the past few years, our findings suggest cautious optimism among the U.S. interventional cardiology community regarding the uptake of this new approach to managing severe aortic stenosis.

TCT-817
Transcatheter Aortic Valve Replacement with a New Balloon Expandable Percutaneous Heart Valve

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Background: The SAPIEN 3 transcatheter heart valve (Edwards Lifesciences Inc., USA) incorporates an enhanced paravalvular sealing system, an active 3-dimensional coaptation positioning catheter, and is compatible with an ultra-low profile 14 French expandable sheath.

Methods: As a first-in-human trial the SAPIEN 3 transcatheter heart valve (Edwards Lifesciences Inc., CA, USA) was implanted in 15 patients with symptomatic severe aortic stenosis via femoral arterial access with a 14 French expandable sheath. Patients underwent transesophageal echocardiography and multidetector computed tomography both before and after valve implantation. Clinical and echocardiographic follow-up was obtained at 30 days. Outcomes were reported according to the Valve Academic Research Consortium guidelines.

Results: All 15 device implants were successful. Aortic valve area increased from 0.7 ± 0.2 cm2 to 1.5 ± 0.2 cm2 (p < 0.001) and mean trans-aortic gradient decreased from 42.2 ± 10.3 mmHg to 11.9 ± 5.3 mmHg (p < 0.001). No patient had more than mild paravalvular regurgitation. Hospital discharge occurred at 3 (2, 12) hospital days. At 30 days one patient had required a new pacemaker. There were no strokes, vascular complications, transfusions, or deaths. All patients were in NYHA functional class I or II at 30-day follow-up.

Conclusions: The ultra-low SAPIEN 3 transcatheter valve and delivery system may facilitate fully percutaneous implantation in a broader range of patients with the potential for more accurate positioning and less paravalvular regurgitation.
Conclusions: BAV can be utilized as a part of a complex therapy in severe AS in high risk patients. EBRT has no impact on prevention of restenosis after BAV.

TCT-819
Effect of Transfemoral Aortic Valve Implantation on Plasma Brain Natriuretic Peptide Levels and Its Predictive Value for 30-day and 1-year survival
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Background: To determine the effect of transfemoral aortic valve implantation (TF-TAVI) on plasma BNP levels and to evaluate their predictive value for 30-day and one-year survival.

Methods: Baseline BNP, peak BNP within 48 hours after TAVI and predischarge BNP were obtained in 104 patients who underwent TF-TAVI with complete one-year follow-up.

Results: BNP was elevated at baseline (298.2, IQR 145.8, 661.6 pg/ml) and showed an acute increase after TF-TAVI (508.9, IQR 253.3, 806.8 pg/ml) followed by regression towards baseline levels prior to discharge (327.2, IQR 159.2, 634.6 pg/ml), p < 0.001. Acute BNP increase (ΔBNPpeak–baseline) is significantly higher in 30 days non-survivors (277.1 IQR 252.1, 810 pg/ml) than in survivors (132.8 IQR 101, 301 pg/ml), p = 0.028, and is found to be independent predictor of 30 days survival. Kaplan-Meier (KM) survival analysis showed a reduced 30 days survival in patients with a ΔBNPpeak–baseline ≥ 248.9 pg/ml, p = 0.002. For 1-year survival, predischarge BNP level (250.8, IQR 152.9, 621.8 pg/ml in survivors vs. 591, IQR 354.5, 788 pg/ml in non survivors, p = 0.003) and ΔBNPdischarge–baseline (211.8 IQR – 521.5, –91.1 pg/ml in survivors vs. 108.4 IQR 12.2, 272.6 pg/ml in non survivors, p = 0.002) are independent predictors. KM analysis showed that 1-year survival is significantly lower in patients with a predischarge BNP ≥327.2 and a ΔBNPdischarge–baseline ≥ 38.3 than in those not fulfilling both criteria, p < 0.001.

Conclusions: BNP values are elevated in patients with severe, symptomatic aortic stenosis presenting for TF-TAVI. They further increase acutely after procedure and regress to baseline levels, usually prior to hospital discharge. Acute, postprocedural BNP increase is an independent predictor of reduced 30 days survival, while reduced 1-year survival is predicted by higher predischarge BNP levels and failure of BNP to decline at discharge below baseline BNP level.

TCT-820
Transcatheter Aortic Valve Implantation (TAVI) In Patients Unsuitable For A Transfemoral Approach: A Comparison Between Trans-apical and Trans-Axillary Approaches
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Background: Transcatheter aortic valve implantation (TAVI) is an accepted alternative in high-risk or inoperable patients with severe, symptomatic aortic stenosis. The trans-femoral (TF) approach is most widely used however is limited in those with peripheral vascular disease. The trans-apical (TA) and trans-axillary (TAX) approaches have been described for such patients with limited data on outcomes. This study reports our single center experience with both approaches and compares patient outcomes.

Methods: A retrospective study of patients undergoing TAVI from January 2010 to December 2011. Procedural and clinical outcomes were defined according to the VARC definitions.

Results: During the study period, 126 patients underwent TAVI at our hospital; 70 (55%) patients were done by TF, 41 (33%) by TA and 15 (12%) by the TAx. Indications for TAs or TA approach for TAVI in our institution were as follows: PVD in 34 patients (61%), suboptimal size of femoral arteries (arterial diameter <6 mm) in 23 (41%), AAA in 14 (25%), morbid obesity in 8 (14%). Procedural success, defined as implantation of the device with a reduction in aortic valve gradient and without the need for conversion to open heart surgery, was 93% (14/15) in TAs and 88% (36/41) in TA (p=1.00). In TAx group, two patients required retrieval of the devices and subsequent successful implantation of another valve with the same approach. Valve embolization occurred in three TAs cases requiring conversion to conventional AVR.

Table 1: Baseline Characteristics, and Outcomes of TAVI Patients (TAXs and TA)

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>TAX N (%)</th>
<th>TA N (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean ± SD</td>
<td>81.1±7.92</td>
<td>80.8±5.99</td>
<td>0.68</td>
</tr>
<tr>
<td>Male</td>
<td>13 (87)</td>
<td>22 (54)</td>
<td>0.03</td>
</tr>
<tr>
<td>Diabetes</td>
<td>6 (40)</td>
<td>16 (39)</td>
<td>0.95</td>
</tr>
<tr>
<td>Morbid obesity, BMI &gt; = 35</td>
<td>2 (13)</td>
<td>6 (15)</td>
<td>1.00</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>8 (53)</td>
<td>27 (66)</td>
<td>0.39</td>
</tr>
<tr>
<td>Abdominal aortic aneurysm</td>
<td>6 (40)</td>
<td>8 (20)</td>
<td>0.12</td>
</tr>
<tr>
<td>Diameter of femoral arteries&lt;=6mm</td>
<td>6 (40)</td>
<td>17 (41)</td>
<td>0.92</td>
</tr>
<tr>
<td>Previous stroke/TAX</td>
<td>2 (13)</td>
<td>4 (10)</td>
<td>0.70</td>
</tr>
<tr>
<td>NYHA functional class III-IV</td>
<td>13 (87)</td>
<td>37 (90)</td>
<td>0.65</td>
</tr>
<tr>
<td>Outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Successful procedure</td>
<td>14 (93)</td>
<td>36 (88)</td>
<td>1.00</td>
</tr>
<tr>
<td>In-hospital all-cause mortality</td>
<td>0 (0)</td>
<td>2 (5)</td>
<td>1.00</td>
</tr>
<tr>
<td>30-day all-cause mortality</td>
<td>0 (0)</td>
<td>5 (12)</td>
<td>0.31</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>-</td>
</tr>
<tr>
<td>Major bleeding complication</td>
<td>3 (20)</td>
<td>7 (17)</td>
<td>1.00</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>1 (7)</td>
<td>1 (2)</td>
<td>0.47</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Conclusions: In this single center series the trans-apical approach was associated with a trend towards higher procedural success, lower all-cause mortality and fewer bleeding complications than the trans-apical approach in patients with severe aortic stenosis. Larger randomized controlled trials will be required to determine the true superiority of one access site over the other.

TCT-821
Initial Experience With Transcatheter Implantation of the Prosthesis Edwards Sapien XT Without Previous Valvuloplasty in Patients with Severe Aortic Stenosis
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Background: Balloon valvuloplasty (BV) before transcatheter aortic implantation of the prosthesis has been considered a mandatory step before valve implantation. However, BV has been associated with complications such as atriointerventricular block, aortic insufficiency and stroke. We report 10 patients with severe aortic stenosis in whom direct transcatheter implantation of the SAPIEN XT system was performed.

Methods: From November 2011 to April 2012, 10 patients (35% of patients treated with Edwards SAPIEN XT in that period) were selected that met the following criteria: moderate calcification, homogeneous distribution of calcium, symmetrical opening of the valve and some degree of aortic insufficiency. The valve positioning was guided by TEE in all cases.

Results: All patients had symptomatic aortic stenosis of a native valve and high risk surgical; echocardiographic characteristics were: aortic annulus diameter ranged from 17 to 24 mm (determined by TEE). Six patients had the valve mildly calcified, in four patients the degree of calcification was moderate. All patients had symmetric opening of the stenotic aortic valve. Mild aortic regurgitation was present in seven patients, moderate in two and trivial in one. The native valve was crossed and the prosthetic aortic valve was properly positioned in all cases and implanted in the correct position in all cases. No patient underwent post-dilatation and only 1 patient had a mild periaprothesis regurgitation. There were no adverse events (death, need for pacemaker, myocardial infarction or stroke). At 30 days postprocedure all patients had significant clinical improvement.

Conclusions: Direct implantation of Edwards SAPIEN XT without prior balloon valvuloplasty in selected cases is feasible and safe. The number of patients in whom this technique is applicable and their impact on reducing complications has to be determined.