

HRQoL Measure	Baseline (BL)	1 Mo	p value (1 Mo vs BL)	6 Mos	p value (6 Mos vs BL)
EQ-5D Summary Index*	0.62	0.72	<0.001	0.72	<0.001
SF12-PCS†	32.82	39.00	<0.001	39.74	<0.001
SF12-MCS†	46.18	48.51	<0.001	49.98	<0.001

*EQ-5D: from 0 [death] to 1 [perfect health].
†SF-12: from 0 to 100, with a higher score reflecting a better HRQoL

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 high 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. 1.5%, 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 cardiologists involved in TAVR research and 461 recent members of the Society of Cardiac Angiography and Interventions to evaluate anticipated TAVR referral patterns. Follow-up reminders were sent during the next 4 weeks. Characteristics between researchers 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 clinically available, 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 11% believed that moderate-surgical risk patients should also be referred for TAVR. When comparing groups of respondents, those involved in TAVR research studies were more conservative with regard to anticipated referral patterns, as 81% would refer as soon as TAVR is clinically available versus 98% of clinical cardiologists (p<0.01).

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 coaxial 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 transthoracic 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.



TCT-818

Balloon Aortic Valvuloplasty In Severe Aortic Stenosis And Prevention Of Restenosis In Elderly

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Background: Balloon aortic valvuloplasty (BAV) is a palliative treatment for severe aortic stenosis (AS). Restenosis after BAV can be resolved with another BAV or with TAVI. We presented our experience with BAV and the results of RADAR-SLO study where we evaluated the external beam radiation (EBRT) for prevention of restenosis.

Methods: Inclusion criteria for BAV were severe AS, increased operative risk, bridge to surgical AVR/TAVI, urgent non-cardiac surgery. The severity of AS and LV function was assessed with invasive and echocardiographic evaluation. In RADAR-SLO study we randomized patients 2:1, the first group was treated with EBRT (total dose=16Gy).

Results: 168 patients (age=82.6y, LogEurosc=22.1%) underwent BAV. After BAV we observed an increase in AVA (0.59 to 0.70cm², p<0.05), a decrease in mean transvalvular gradient (47.8 to 38mmHg, p<0.05), without change of LV function (EF 53.3 to 54.9%, p=0.75). The most common complications involved peripheral arterial accesses (4.8%). BAV was performed in patients with CAD (N=17) concomitant with PCI and in patients with carcinoma (N=7) that underwent major non-cardiac surgery. During 6 months follow up a restenosis of dilated valve occurred (restenosis rate 59%). Recurrence of symptoms was resolved with another BAV (2 BAV N=22, 3 BAV N=3) or TAVI (N=22). During the follow up a trend towards better outcome was noted in the TAVI patients. There was no impact of EBRT on restenosis and on survival rate (Fig.1).