POSTERS

Joachim Schofer1, Jean Fajadet2, Antonio Colombo3, Silvio Klugmann4, Severe Aortic Stenosis - Results from the DISCOVER Trial 30-day Outcome of the 18 F-Direct Flow Medical Valve in Patients with TCT-812
driver is length of stay and valve cost. Costs decrease marginally over time. Most patient
Milan, Italy, 5Medical Care Center Prof Mathey, Prof Schofer, Hamburg, Germany.

Previous pacemaker 2 (2.3%) .071 12 with pm. Continuous variables Mean (sd) Spearman rho’s p-value

Mediastinal radiation 6 (7.0%) .919

Previous CABG 25 (29.1%) .898

Previous valve surgery 4 (4.7%) .743

Previous PCI 17 (19.8%) .371

Year of intervention .091

2007-2009 43 (50.0%) 47.77

2010 20 (26.7%) 44.12

2011 23 (23.3%) 32.44

Continuous variables Mean (sd) Spearman rho’s p-value

age (years) 81.8 (6.6) .989

log euroscore 25.6 (15.2) .559

AVA (cm²) 0.6 (0.15) .556

Mean grad (mmHg) 25.2 (17.0) .824

LVEF (%) 59.4 (12.7) .899

Conclusions: Total hospitalisation costs of TAVI amount to about €40,000. Main cost
driver is length of stay and valve cost. Costs decrease marginally over time. Most patient characteristics are not significantly related to total hospitalisation costs.

TCT-812
30-day Outcome of the 18 F-Direct Flow Medical Valve in Patients with Severe Aortic Stenosis - Results from the DISCOVER Trial

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Background: For currently available percutaneous aortic valve prosthesis, device design limitations and potential misplacement can lead to significant aortic regurgitation, which can result in severe complications and have an impact on long-term survival. The Direct Flow Medical (DFM) valve is repositionable and retrievable and has non metallic inflatable cuff with a conformable design that results in better valve sealing. Compared to the first generation, the new 18F prosthesis, has a smaller profile, increased radial force and better handling. We report the first series of high risk patients who received the 18F DFM transfemoral prosthesis for severe aortic stenosis. Aim of the study was to test the safety and performance of the 18F Direct Flow Medical valve in high risk patients with severe aortic stenosis.

Methods: In this prospective, multicenter, non-randomized clinical trial 100 symptomatic patients with severe aortic stenosis and a logistic EuroSCORE ≥ 20% will be enrolled.

The primary endpoint is freedom from all-cause mortality at 30 days, secondary endpoints were device success and safety according to the VARC criteria. Data are monitored and events adjudicated by independent committees (DMIC, CEC). All echo-cardiograms and angiograms were assessed by an independent Core Laboratory.

Results: The study started in January 2012 in 5 centers in Europe. Five additional centers will follow. As of May 2012, 25 patients have been enrolled (mean age 84.9y, 76-95 yrs, mean logistic Euro-Score 27.9%, mean STS 11%). The primary endpoint of freedom from death at 30 days was achieved in all 25 patients. The valve was retrieved and reimplanted in 4 patients. At present, 10 pts had core lab evaluation, revealing a mean transvalvular gradient at 30 days of 11 mmHg. There was no aortic regurgitation in 8 pts and 2 had trace aortic regurgitation.

Conclusions: The 18F DFM valve can be safely implanted, repositioned and, if necessary retrieved in high risk patients with severe aortic stenosis. Preliminary results suggest excellent hemodynamic performance with abolishing significant aortic regurgitation. The results of the completed study will be available at TCT 2012.

TCT-813
Long-term performance of a transfemorally implantable nonmetallic, retrievable and repositionable aortic valve in patients with severe aortic stenosis 4 Year Follow-Up of the 22 F-Direct Flow Medical Valve

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Background: The Direct Flow Medical (DFM) valve is repositionable and retrievable. The non metallic inflatable and conformable design of the valve results in better sealing but in less radial force which may have an impact on stability and valve function over time. Aim of the study was to evaluate the 4-year clinical and echocardiographic outcome of the first generation 22F-DFM percutaneous aortic valve.

Methods: From 2007 to 2008 31 symptomatic high-risk for surgery patients (mean age 82±4y) with severe aortic stenosis and a mean logistic EuroSCORE of 29±7% were the subject of this analysis. Clinical, echocardiographic and hemodynamic follow-up were obtained during 4 years.

Results: Survival rates were 81%, 69%, 60%, and 54% at 1,2,3,4 years, respectively. At 4 years, 83% of the patients, who survived, were in NYHA-class I, 17% in class II. Echocardiography revealed a significant decrease of the mean gradient from baseline (49.1±13.8 mmHg) to 30 days (19.1±6.8 mmHg, p< 0.001), which remained stable over 4 years. At 4-year follow-up, 80% of the patients had no aortic regurgitation, 20 % had trace aortic regurgitation.

Conclusions: In this preliminary series, the first generation of the nonmetallic, repositionable and retrievable 22F-DFM valve was associated with acceptable clinical outcome and stable hemodynamic performance with no aortic regurgitation in the majority of patients.

TCT-814
Health Related Quality of Life Following Transcatheter Aortic Valve Implantation: Results from the CoreValve ADVANCE Study

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Background: Percutaneous transcatheter aortic valve implantation (TAVI) is associated with favorable safety and efficacy outcomes in older patients at high risk for surgical AV replacement. Health Related Quality of life (HRQoL) can be at least, if not more, important than quantity of life in an elderly patient population, often frail, and with multiple comorbidities. The Medtronic CoreValve ADVANCE is a prospective, multicenter, 100% monitored study evaluating “real world” patients with severe aortic stenosis treated with the CoreValve System (Medtronic, Minneapolis, MN). The HRQoL measures collected in the ADVANCE study represent the largest, rigorously reported cohort of HRQoL findings in the TAVI literature.

Methods: From March 2010 to July 2011, the ADVANCE study enrolled 1015 patients at 44 experienced centers in Western Europe, Asia, and South America. HRQoL measures collected in the ADVANCE study represents the largest, rigorously reported cohort of HRQoL findings in the TAVI literature.

Results: Baseline clinical characteristics were: 50.5% female, age 81.1±6.4 y, log EuroSCORE 19.2±12.4, 79.6% NYHA Class II/III, 22.6% CDFP, 21.4% prior CABG, 14.6% renal failure, and 12.9% cerebrovascular disease. Compared with baseline, physical and mental summary score (PCS and MCS) measures and the EQ-5D index significantly improved at 1 and 6 months.

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JACC Vol 60/17/Suppl B October 22–26, 2012 TCT Abstracts/POSTER/Aortic Valve Disease and TAVR
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<0.01) 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) 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. 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 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%), most common specialties were interventional cardiologists (86%) and hematology (72%). Most respondents (90%) planned to refer patients for TAVR immediately after the devices are available versus 98% of clinical cardiologists (p<0.05). The majority of respondents (90%) were confident in referring less than one-fourth of their patients with severe aortic stenosis for TAVR, 86% believed that TAVR is equally efficacious as open-heart surgery, and 11% believed that moderate-risk percutaneous intervention patients are also 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 multidector 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=16 Gy).

Results: 168 patients (age=82.6y, LogEuroscore=22.1%) underwent BAV. After BAV we observed an increase in AVA (0.59 to 0.70 cm2, p=0.05), a decrease in mean transvalvular gradient (4.78 to 3.64 mmHg, p=0.05), without change of LV function (EF 53.3 to 53.7%, 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).