Methods: Pre- and postprocedural MSCT was performed in 40 patients. TAVI size selection was done on the basis of annulus cross sectional measurements by MSCT so that the nominal TAVI device CSA always exceeded the anNuUs CSA. In preprocedural data sets we determined the valve calcium score, the CSA and the severity index of the aortic annulus. In postprocedural data sets maximum and minimum diameter and the degree of circularity at three levels (ventricular end, annulus, aortic end) was determined.

Results: The average expansion ratio of the Edwards Sapien XT device was 95% and the circularity Index was 97%. In multivariate regression analysis neither calcium score nor severity index of the native annulus were associated with under or non circular expansion of the device. The only parameter predicting underexpansion was the degree of oversizing. Underexpansion of the device was not associated with increased transaortic pressure gradients or with the incidence of paravalvular aortic regurgitation. The degree of oversizing was however positively associated with the incidence of new conduction disturbances. In the entire cohort no aortic regurgitation > mild was observed.

Conclusions: MSCT guided TAVI device sizing is associated with almost complete and symmetric expansion of the Edwards Sapien XT device and the absence of significant aortic regurgitation. Calcification or severity of the native annulus do not influence the expansion pattern. To rigorous device oversizing however is associated with new conduction disturbances and device underexpansion.

TCT-809
Impact of New Conduction Defect After TAVI on Left Ventricular Function at 1-Year Follow-up
Rainer Hoffmann1, Rüdiger Autschbach1, Ralf Hertertz1, Sharum Lotfi2, Nikolaus Mars3
1University Aachen, Aachen, Germany
2University Of Antwerp, Antwerpen, Belgium
3Antwerp University Hospital, Edegem, Belgium

Background: New left bundle branch block (LBBB) or need for permanent pacing due to LVOT block are based after aortic valve implantation (TAVI). This study evaluated the impact of new conduction defect after TAVI on the evolution of left ventricular (LV) function during one year follow-up.

Methods: A total of 90 consecutive patients treated with TAVI and 12 months echocardiographic follow-up were included in the study. In 39 patients a new conduction defect (new LBBB or need for permanent pacemaker activity) persisted one month after TAVI. In 51 patients no persistent new conduction defect was observed. 2D echocardiography using parasternal short-axis, apical 4-chamber and 2-chamber views was performed before TAVI and at 1 year follow-up to determine left ventricular volumes and ejection fraction based on Simpson’s rule. Speckle-tracking echocardiography was applied using standard LV short-axis images to assess the effect of new conduction defect on time-to-peak radial strain of different LV segments as parameter of LV dyssynchrony.

Results: New conduction defect resulted in marked heterogeneity in time-to-peak strain between the 6 analysed short-axis segments. During one year follow-up after TAVI there was a significant increase in LVEF in patients without new LBBB (53±11% pre to 59±10% at follow-up, p<0.001), while there was no change in LVEF in patients with new conduction defect (52±11% pre to 51±12% at follow-up, p=0.740). Change in LV endystolic volume was also significantly different between patient groups (1=10.14 vs. 11.2±15.7 ml, p=0.042). New conduction defect was an independent predictor of reduced LVEF at 12 months follow-up after TAVI.

Conclusions: LVEF improves after TAVI for treatment of severe aortic stenosis in patients without new conduction defect. In patients with a new conduction defect after TAVI, there is no improvement in LVEF at follow-up.

TCT-810
Assessment of Doubtful Aortic Stenosis by Measuring Simultaneous Transaortic Pressure: A Pilot Study With Fractional Flow Reserve Guidewire
Romain Chopard1, Marie-France Seronde1, Sebastien Janin1, Philippoktimon Plastaras3, Nicolas Meneveau1, Francois Schiele1
1University Hospital Besancon, Besancon, France
2University of Antwerp, Turnhout, Antwerp,
3Antwerp University Hospital, Edegem, Belgium
4University Hospital Antwerp, Antwerp, Belgium

Background: Transthoracic echocardiography (TTE) is the reference technique for measuring simultaneous transaortic pressure using a fractional flow reserve (FFR) guidewire in doubtful aortic stenosis.

Methods: Between January 2009 and December 2011, 57 patients with symptoms possibly related to severe AS that was poorly evaluated by echocardiography underwent right and left heart catheterization for assessment of aortic valve area with the Gorlin & Gorlin formula. Transaortic pressure was obtained by 2 invasive methods, namely conventional pullback method from the left ventricle (LV) towards the aortic valve (AV) with subsequent computerized superposition of the pressure curves, and (2) simultaneous method using a FFR wire introduced into the LV (SM).

Results: Reasons for inaccurate assessment by echocardiography were atrial fibrillation (75%) and/or low LV ejection fraction (38%). Results of evaluation of mean aortic valve gradient and aortic valve area are summarized in the table below. Agreement between methods (using the kappa coefficient) for severe aortic stenosis defined by an aortic-valve area < 0.6 cm²/m² was 0.36 between SM and PM, 0.07 between SM and TTE, and −0.12 between PM and TTE. These findings led to a decision to change therapeutic strategy in 8 patients (14%).

Conclusions: Simultaneous measurement of trans-aortic pressure using a FFR guidewire is feasible and may be an attractive and accurate method for evaluation of doubtful aortic stenosis.
The primary endpoint is freedom from all-cause mortality @ 30 days, secondary endpoints were device success and safety according to the VARC criteria. Data are monitored and events adjudicated by independent committees (DMC, CEC). All echocardiograms 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 84.9 ± 7.95 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

Klaudija Bijuklic1, Thilo Tuebler2, Hendrik Treede3, Hermann Reichenpflüger4, Reginald Loo5, Eberhard Grube6, Joachim Schofer7

1Medical Care Center, Hamburg, Germany, 2Medical Care Center Prof, Mathey, Prof. Schofer, Hamburg, Germany, 3Hamburg University, Hamburg, Germany, 4University Heart Center Hamburg, Ham, Hamburg, 5University of California, Davis, Sacramento, USA, 6University Hospital Bonn, Bonn, Bonn, 7Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany

**Background:** The Direct Flow Medical (DFM) valve is repositionable and retrievable. The nonmetallic 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

Johan Bosmans1, Ulrich Gerckens2, Peter Wenaes3, Corrado Tamburino4, Stephen Brecker5, Robert Buehrmensch5, Axel Linke6

1University Hospital Antwerp, Antwerp, Belgium, 2Bonn Community Hospital, Bonn, Germany, 3University Hospital Bern, Bern, Switzerland, 4University of Catania, Catania, Italy, 5St. George’s Hospital, London, United Kingdom, 6ISAR Heart Center, Munich, Germany, 7University Hospital Leipzig, Leipzig, Germany

**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 represents 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 were evaluated using the SF-12 and the EQ-5D, 2 general validated questionnaires. Results of the measurements at baseline, 1 and 6 months are reported.

**Results:** Baseline clinical characteristics were: 50.6% female, age 81±14.5 years, mean EuroSCORE 19.2±12.4, 79.6% NYHA class II/III, 22.6% CPOD, 21.4% prior CABG, 14.6% renal failure, and 12.9% cerebral vascular 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.