In summary, 16.4% of patients (group 1+3) were formally not treatable using TA VI. A substantial number of patients are not eligible due to oversized aortic annulus diameters. Consequently, the development of larger prostheses is crucial to embrace this not negligible minority of patients.

TCT-762

Predictive Factors and Prognostic Value of Periprocedural Myocardial Injury During Transcatheter Aortic Valve Implantation

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Background: Periprocedural myocardial injury (PMI) is a common complication during cardiac surgery and percutaneous coronary intervention and is an important predictor for postoperative cardiovascular morbidity and mortality. Very few data have been reported on the occurrence of myocardial damage associated with transcatheter aortic valve implantation (TA-AVI). Therefore, our purpose was to investigate the incidence, the predictive factors and clinical consequences of PMI during TA-AVI.

Methods: In a prospective observational single-centre study, we included 117 patients (age 81±8 years, 46 male), who had undergone a TA-AVI with the Medtronic-CoreValve® bioprosthesis. Serum CK-MB and cTnT levels were measured pre- and post-procedurally. Periprocedural myocardial injury was defined as a postprocedural CK-MB and/or cTnT level above 5 times the upper reference limit, as an increase of CK-MB and/or cTnT level above 5% from preprocedural levels or the occurrence of myocardial ischemia on the postprocedural electrocardiogram (ECG).

Results: Preprocedural hospitalization (OR: 9.96; 95%CI: 2.32-42.66) and left ventricular mass index (gr/m², OR: 1.02; 95%CI: 1.00-1.03). In the peri-procedural period (group 2) and 206 patients required no PPM during follow-up (group 3). The primary endpoint of the study was mortality at one year follow-up. Secondary endpoints included in-hospital mortality as well as rates of stroke and myocardial infarction in-hospital and at one year.

Conclusion: In this observational study, patients with severe aortic stenosis undergoing TA-AVI had a similar survival independent of the need of PPM implantation, which underlines the benign nature of this complication.

TCT-763

Aortic valve calcium scoring (AVCS) is a predictor of significant paravalvular aortic insufficiency in transapical aortic valve implantation

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Background: Transapical aortic valve implantation (TA-AVI) has evolved as a routine technique for selected high-risk patients. However, paravalvular leaks >1+ remain an unsolved issue using current generation of transcatheter valve devices. The aim was to study the impact of aortic valve calcification on paravalvular leaks and outcome using the Edwards SAPIEN™ prosthesis.

Methods: 120 consecutive patients (out of 307 TA-AVIs) with preoperative computed tomography, age 82.6±6.2 years, 75.0% female, were included. Implanted prosthetic valve sizes were 23 mm (n=31), and 26 mm (n=89), respectively. Mean logistic EuroSCORE was 30.1±15.5 and mean STS-Score 12.8±7.9. ECG-gated cardiac CT allowed to quantify the amount of calcification of aortic valve leaflets using a scoring analogous to the Agatston calcium scoring of coronary arteries (AVCS). Paravalvular leaks were assessed intraoperatively by echocardiography and angiography.

Results: All valves were implanted successfully. Mean AVCS in patients without paravalvular leaks (n=66) was 2704±1510, with mild paravalvular leaks (n=31) 3804±2739 (p=0.05) and with moderate paravalvular leaks (n=4) 7387±1044 (p=0.002). There was a significant correlation between AVCS and paravalvular leaks (r=0.33; p=0.001) indicating, of note, only a limited degree of linear dependence. No correlation was found to 30-day mortality, postoperative pacemaker-implantation and stroke-rate (r=0.040, p=0.671; r=0.117, p=0.232 and r=0.025, p=0.792). Overall 30-day mortality was 14.2%.

Conclusion: The AVCS identifies patients at risk for a relevant paravalvular leak. AVCS prior to TA-AVI might serve as an additional tool to reconsider the TA-AVI indication and valve size to reduce the risk of paravalvular leaks.

TCT-764

Transcatheter Aortic Valve Replacement: Outcome of Patients with Moderate or Severe Mitral Regurgitation

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Background: The influence of moderate or severe MR on TAVR outcomes is unknown.

Methods: This study included 535 consecutive patients undergoing TAVR with a balloon expandable valve at 2 centers. Patients with moderate or severe MR before TAVR were compared to patients with none or mild MR.

Results: A total of 149 patients (28%) presented with concomitant moderate or severe MR and 386 (72%) had none, trivial or mild MR. Patients with moderate or severe MR were older (median age 84 vs. 82 years, p = 0.01) and exhibited a higher risk profile (median STS score 8.2 vs. 7.4 %, p = 0.01). MR improved from moderate or severe to none or mild at discharge in 79/148 (53%) patients and worsened from none or moderate to severe in 16/379 (4%). Survival rates for patients with and without moderate or severe MR at baseline were 85.0% and 93.4% at 30 days, 72.3% and 79.2% at 1 year, and 53.4% and 51.8% at 3 years, respectively (log rank p = 0.038, Figure). Moderate or severe MR was an independent risk factor for mortality during the first 30 days (unadjusted HR 2.32 (95% CI 1.31, 4.11), p < 0.01, adjusted HR 2.25 (1.25, 4.05), p < 0.01), but not after 30 days (unadjusted HR 1.03 (0.57, 1.85), p = 0.92, adjusted HR 1.04 (0.57, 1.92), p = 0.85). 4% of the patients with moderate or severe MR at baseline and 5% of the patients with none or
mild MR at baseline were in NYHA class III or IV.

Conclusion: Moderate or severe MR in patients undergoing TAVR is associated with a higher short-term, but not long-term, mortality. MR improves in approximately half of the patients with moderate or severe MR post TAVR.

TCT-765
Transcatheter Aortic Valve Implantation – Multicenter Study Evaluating the Clinical Outcomes of Patients with PARTNER Trial Exclusions
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Background: The randomized PARTNER trial excluded patients with conditions frequently encountered in clinical practice.

Methods: 242 consecutive high-risk patients (STS >10) undergoing transcatheter aortic valve implantation (TAVI) were assessed. Patients were divided into a “PARTNER-exclusions” (PE) group (ejection fraction <20%, severe mitral regurgitation, creatinine >3 mg/dl and/or hemodialysis, significant coronary disease, recent cerebrovascular accident within 6 months, aneurysm diameter <16 mm, bicuspid aortic valve, aortic regurgitation >3+, prior valve surgery) and “no PARTNER exclusion” (NPE) group. The last 4 criteria were also sub-analyzed as “technical exclusions”.

Results: 12-month KM-survival estimates for the PE group were 68.1% vs. 78.2% for the NPE group (p=0.14). At 3-years this was 40 vs. 61.9%, p=0.04. The unadjusted HR for 3-year mortality for the PE group was 1.61 (95% CI 1.01-2.56), but when adjusted for baseline differences using a proportional hazard model this was no longer significant (HR for 3-year mortality for the PE group was 1.04, 95%CI 1.01-1.08; p<0.001). The univariate predictors of death were female gender (HR 1.58, 95%CI 1.05-2.36; p=0.03), female body mass index (HR 1.04, 95%CI 1.00-1.09; p=0.05), female age (HR 1.01-1.06; p=0.03), high creatinine levels (HR 1.36 ± 0.5, p<0.001), lower ejection fraction <35% (HR 1.45, 95%CI 1.0-2.06; p=0.03) and the wider QRS complex (HR 1.02, 95%CI 1.01-1.03; p=0.001). The multivariable predictors of death were female gender (HR 1.61, 95%CI 1.01-2.56; p=0.03) and the wider QRS complex (HR 1.45, 95%CI 1.0-2.06; p=0.03) were the univariate predictors of death post TAVI.

Conclusion: The main predictors of death after TAVI seem to be the female sex and a wider QRS complex. The NPE group represented a more favorable cohort with similar 1-year survival compared to the PE group. However, multivariable predictors of 3-year mortality were female sex and a wider QRS complex.

TCT-767
Gender differences in patients undergoing transcatheter aortic valve implantation with the Medtronic CoreValve System
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Background: Gender differences in patients undergoing surgical aortic valve replacement are well documented. Whether gender differences exist in patients undergoing TAVI is unknown.

Methods: From June 2007 to June 2010, we enrolled 333 consecutive patients who underwent Medtronic CoreValve implantation. Baseline characteristics and clinical outcomes were prospectively entered into a dedicated database and differences between genders were investigated. The primary end-point consisted of a composite outcome of 1-year mortality.Differences in survival outcomes between genders were estimated by Kaplan-Meier survival curves.

Results: 152 (46%) were male and 181 (54%) were female. Males had a larger left ventricular end-diastolic dimensions (51.5 ± 7.7 vs. 45.0 ± 7 mm, p=0.001) and aortic annulus size (23.4 vs. 21.3 mm, p<0.001), higher baseline creatinine levels (1.36 ± 0.5 vs. 1.07 ± 0.47 mg/dl, p<0.001), lower ejection fraction <35% (23.4 vs. 8.4%, p<0.001), and higher logistic EuroSCOREs (21.4 ± 14.4 vs. 17.4 ± 10.7%, p=0.007). A 26-mm CoreValve was implanted in 62% of females and a 29-mm CoreValve in 79% in males. Kaplan-Meier survival analyses did not demonstrate any differences between genders with regards to 30-day or 1-year mortality. Males were more likely to require post-implant dilatation (28.6 ± 6.5% vs. 8.4%, p<0.001) and higher logistic EuroSCOREs (21.4 ± 14.4 vs. 17.4 ± 10.7%, p=0.007). A 26-mm CoreValve was implanted in 62% of females and a 29-mm CoreValve in 79% in men.

Conclusion: In the current study, males undergoing TAVI had more comorbidities and higher logistic EuroSCOREs than females. There were no significant differences in 30-day or 1-year mortality between genders.