measurements to follow-up, there was no significant improvement in CFR immediately post TAVI (mean % ΔCFR pre TAVI to immediately post TAVI 8.6%, 95% CI -23.0 – 40.3%, p=0.41).
Conclusions: TAVI does improve coronary flow dynamics as measured by CFR. This improvement does not occur immediately, but requires a period of time post-TAVI to manifest. The improvement in coronary flow reserve may represent a mechanism by which both symptoms and prognosis improve following TAVI.

TCT-734

Percutaneous Implantation of Stent Grafts in the Management of Vascular Complications in Transfemoral Transcatheter Aortic Valve Implantation

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Background: Vascular complications remain to be the most prevalent adverse event associated with transfemoral TAVI and related to increased morbidity and mortality. Percutaneous implantation of stent grafts in the management of access-site related vascular complications is not widely studied.
Methods: Among 379 patients who underwent TAVI from November 2007 to December 2011 for severe aortic stenosis, transfermoral access was performed in 314 patients. 10 cases received surgical closure and consequently pure percutaneous transfemoral TAVI was performed in 304 patients. We described the clinical outcomes of this patient cohort who developed access-site related vascular complications and were subsequently managed by percutaneous implantation of stent grafts. We also compared their baseline clinical and procedural characteristics, as well as in-hospital outcomes with those without vascular complications.
Results: Access site-related vascular complications occurred in 68 (22%) patients. 8 patients were managed surgically and 18 by manual compression. The remaining 42 patients with access site-related complications were managed by percutaneous means, in which 29 were treated solely by implantation of stent grafts. Overall, stent graft implantation was successful in all cases. The rate of VARC-defined endpoints was similar between patients managed by stent graft implantation and those free of vascular complications. After a median follow-up of 19.2months, 9 patients underwent Duplex ultrasonography of the intervened limb and the remaining patients underwent clinical assessment. Duplex ultrasonography revealed no evidence of obstructive flow. Moreover, no patient experienced lower limb ischemic symptoms during follow-up.
Conclusions: Access-site related vascular complications in transfemoral TAVI can be managed by implantation of stent grafts with an encouraging technical success rate and safety profile. The clinical outcomes in these patients are similar to those who have undergone transfemoral TAVI without vascular complications. However, more dedicated imaging and larger clinical trials are needed to define the applicability of stent grafts in the treatment of vascular complications in TAVI.

TCT-735

Can we Predict Post-Procedural Paravalvular Leak After Edwards Sapien Transcatheter Aortic Valve Implantation?

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Background: Post-procedural PVL ≥ 2 has been shown to be associated with worse mid-term outcomes after TAVI. Valve calcification and optimal valve sizing may play an important role in this setting. This study sought to identify predictive factors of post-procedural paravalvular leak (PVL) $\geq$2 after transcatheter aortic valve implantation (TAVI) with the Edwards valve.
Methods: A total of 176 Edwards TAVI patients (aged 83.4±7.4 years, Logistic EuroSCORE 18.8±12.0, transfemoral 54.5%) who had preprocedural multislice computed tomography (MSCT) were studied. In order to assess the role of valve calcification, a new Valve Calcification Index (VCI) was defined using MSCT as aortic root calcification volume / aortic annulus area. Optimal valve sizing was defined as the valve diameter / calculated annulus average diameter (CAAD) by MSCT.
Results: After post dilatation, performed in 16.7% of cases, a PVL $\geq$ 2 was observed in only 12.5% of cases. The 1-year estimated survival of both PVL < 2 and PVL $\geq$ 2 groups were 95.3±2.1% vs 79.0±10.8% (log-rank p=0.02), respectively. Only the VCI, odds ratio [OR] 2.11, 95% confidence interval [CI] 1.27 to 3.51, p<0.01) and the valve diameter / CAAD (OR 0.57, 95% CI 0.38 to 0.87, p=0.01), were identified as independent predictors of post-procedural PVL $\geq$ 2. A score predicting post-procedural PVL $\geq$ 2 (PVL score) was determined by assigning one point when the Valve / CAAD ratio was < 1.05 and one point when VCI was > 2.05, and summing all points accrued. Area under receiver-operator characteristic curves of PVL score were 0.70 (95% CI 0.58 to 0.82, p<0.01). The incidence of PVL $\geq$ 2 in patients with a PVL score of 0 was 5.5%, 1 was 16.7% and 2 was 38.5%, respectively.
Conclusions: The only predictors of PVL $\geq$ 2 after Edwards valve implantation are the valve diameter / CAAD and VCI. The use of these two simple parameters, could become an excellent tool to predict the risk of PVL.

TCT-736

Interim results of the JUPITER Registry on long-term performance and safety of the Transapical JenaValve

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Background: Transcatheter aortic valve implantation (TAVI) has emerged as an accepted treatment option for high-risk patients with severe aortic stenosis. The second generation transapical JenaValve with its unique fixation system enabling anatomically correct positioning received CE-mark in September 2011. This registry was designed to evaluate long-term safety and efficacy of the transapical JenaValve TAVI system in high-risk patients in a real world setting.
Methods: The registry will enroll a total of 180 patients undergoing TAVI with the transapical JenaValve system and will follow them for a period of five years. Endpoints are defined according to Valve Academic Research Consortium (VARC) with the primary endpoint 30-day mortality and secondary endpoints safety, device success, effectiveness and quality of life at up to 5 years.
Results: In the JUPITER-Registry, so far 56% of the patients, i.e. a total of 101 patients underwent elective TAVI at 11 European centres. Currently procedural outcome is available on 88 patients (mean age 80.8±6.1 years; EuroSCORE 24.9±13.5%), of whom 84 underwent successful TAVI using the JenaValve resulting in a procedural success of 95.5%. 2 patients were converted to surgical AVR, 2 patients to a valve-in-valve procedure. 30 day all-cause mortality was 14.9%, cardiovascular mortality 4.7%. TAVI resulted in favourable reduction of mean transvalvular gradients (40.4±14.4mmHg vs. 8.1±4.9mmHg, p< 0.0001). No or trace paravalvular leakage (PVL) was present in 80.2% of patients, mild PVL in 17.4% and moderate PVL in 2.3%. None of the patients had severe post procedural aortic regurgitation (> grade 2). Complete 30-day results according to VARC criteria of 75 % of the patients, i.e. 135 patients will be presented at the conference.
Conclusions: Interim results of the JUPITER registry demonstrate that TAVI using the JenaValve system results in high procedural success, excellent hemodynamics and low incidence of paravalvular leakage. Thirty-day mortality in this very high-risk group is slightly high in this interim analysis, but final results remain to be seen when data for all 180 patients are available.

TCT-737

MONITORING THE LEARNING CURVE AND QUALITY OF CARE IN TAVI PROCEDURES BY CUSUM ANALYSIS

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Background: Starting a TAVI program mandates to keep efficacy and safety competitive in relation to conventional surgery, while implementing a procedure that requires new skills and close cooperation between different specialties. In this complex scenario, monitoring the overall and individual performance is essential. The aim of the present study was to apply control charts (CUSUM curves) to monitor the performance of the TAVI team and to enhance the quality control for that procedure.
Methods: The first 90 patients undergoing TAVI at our institution were prospectively monitored, using risk-adjusted CUSUM curves. Predicted risks of failure for individual patients were derived from the literature. The following endpoints were considered: (1) Technical device success (TDS); (2) 30-days mortality (HM); (3) 30-days freedom from adverse events (FAE).
Results: All patients received a Sapien valve via a transapical (43) or transfemoral (47) approach. median age was 80.6 years, the median Euroscore and STS score were 24.1 and 9.82. The TDS and the HM CUSUM curves showed an initial cluster of 3 (TDS) and 2 (HM) failures in the first 12 procedures, probably reflecting the traversing of the learning curve. Consecutively we experienced a period of good performance and the process came in control at operation number 29 (TDS) and 26 (HM). The FAE curve behaved similarly, but a steep upward trend was observed starting from patient 38, and the boundary line was crossed at the 45th patient, indicating that the procedure was going out of control. An internal audit identified as possible causes of failure an inappropriate patients' selection and the lack of a dedicated "Post-procedural care" team. The correction of these problems led to a downward shift of the CUSUM curve,