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Transapical Aortic Valve Replacement With The JenaValve: Less Pravalvular Leackage And Higher Transvalvular Gradient

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Background: Transcatheter aortic valve implantation (TAVI) is an alternative treatment for high-risk patients with aortic valve disease. The JenaValve™, a second-generation TAVI-device, has recently received CE-approval for transapical implantation (TA-TAVI). Herein, we present early single-center clinical data of the initial 27 patients after TA-TAVI with the JenaValve™.
Methods: Between January 2011 and Mai 2012, 27 patients (age 80.9±7.1, 19 female, EuroScore 33.2 ±12.2%,) underwent TAVI with the JenaValve™. The primary endpoint was all-cause mortality at 30 days, secondary endpoints included procedural success and major adverse cardiac and cerebrovascular events. Echocardiographic valve function was evaluated on ambulantory visits at least once within the first 3 month after valve implantation.
Results: TA-TAVI was successfully performed in all patients with a mean radiation time of 11.4±8.4min. The average implanted device sizes included 23mm (n=8), 25mm (n=12) and 27mm (n=7), redilatation after deployment was necessary in 15/27 (55.6%). Angiographic evaluation demonstrated mild to moderate aortic regurgitation (AR) in one (3.7%) patient, wereas none or trivial AR were observed in 26 (96.3%) patients. Major adverse cardiovascular events within 30 days (according to VARC) occurred in 22.2% (death 14.8%, stroke 3.7%, pacemaker implantation for new onset conduction disturbances 3.7%). Survival at 3 month was 81.5% (n=24). Echocardiographic evaluation 3 month after implantation (n=18/23) demonstrated moderate AR in 1 (3.7%) patient and none or trivial AR in 11 (40%) and 6 (22.2%) patients, respectively. The mean transvalvular gradient at 1 and 3 month after implantation was 17.9±10.5mmHg and 16.8±10.8mmHg, respectively.
Conclusions: The JenaValve™ is a safe and effective for transapical TAVI of severe AS. Early echocardiographic data suggest valve function with a very low rate of significant paravalvular regurgitation, however, a higher mean transvalvular gradient compared to other TAVI devices.

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Transcatheter Aortic Valve Implantation with Edwards SAPIEN™ versus Medtronic CoreValve Revalving System® Devices: a Multi-Center Collaborative Study The PRAGMATIC Initiative – Pooled RotterdAm-Milano-Toulouse In Collaboration

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Background: Few data exists comparing transfemoral TAVI with Medtronic CoreValve® (MCV) (Medtronic, Minneapolis, Minnesota) vs. Edwards SAPIEN™/SAPIEN XT™ (ESV) (Edwards Lifesciences, Irvine, California) for severe aortic stenosis.
Methods: The prospective TAVI databases of 4 experienced centers in Europe were pooled and analyzed comparing transfemoral MCV vs. ESV. Due to differences in baseline clinical characteristics, a propensity score matching was performed. Study objectives were Valve Academic Research Consortium (VARC) outcomes at 30 days and one year.
Results: In total, 793 patients were included: 453 (57.1%) treated with MCV and 340 (42.9%) with ESV. After propensity matching 252 patients were identified in each group. In the matched cohort, at 30 days, there were no differences in all-cause mortality (MCV 8.7% vs. ESV 6.0%; Odds Ratio [OR] 1.511; 95% Confidence Interval [CI] 0.765-0.986; p=0.235), cardiac mortality (7.5% vs. 6.0%; OR 1.288; 95% CI 0.639-2.596; p=0.478), myocardial infarction (0.4% vs. 0.4%; OR 1.000; 95% CI 0.062-16.076; p=1.000) or device success (95.2% vs. 96.0%; OR 0.826; 95% CI 0.350-1.949; p=0.663). Of note, a trend toward more strokes was observed with MCV (3.6% vs. 1.2%; OR 3.074; 95% CI 0.822-11.491; p=0.095). Conversely, there was an advantage of the MCV group in major vascular complications (8.3% vs. 14.3%; OR 0.545; 95% CI 0.309-0.964; p=0.037), but not in life-threatening bleeding (12.3% vs. 12.3%; OR 1.000; 95% 0.588-1.702; p=1.000). Indeed, there was less need for PPM in the ESV group (22.6% vs. 6.8%; OR 4.024; 95% CI 2.266-7.143; p<0.001). At one year, there was no difference in all-cause (16.3% vs. 13.9%; OR 1.085; 95% CI 0.592-1.987; p=0.518) or cardiac mortality (8.7% vs. 7.9%; OR 1.085; 95% CI 0.592-1.987; p=0.783).
Conclusions: No differences between the 2 commercially available transfemoral TAVI devices were observed in VARC outcomes at 30 days and one year except for major vascular complications with ESV and need for PPM with MCV. A trend for less major strokes was observed with ESV. These results need to be confirmed in a randomized trial.

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Does the Logistic EuroSCORE II Better Predict Outcomes Following Transcatheter Aortic Valve Implantation? Results from the Milan Registry

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Background: To assess 30-day outcomes following transcatheter aortic valve implantation (TAVI) according to the STS score, logistic EuroSCORE and the new logistic EuroSCORE II.
Methods: All consecutive patients treated in our center by TAVI from November 2007 to May 2011, utilizing both commercially available valves, were analyzed. Patients were grouped by low-, intermediate- and high-risk (STS <3%, 3-8%, >8%; logistic EuroSCORE <10%, 10-20%, >20%; logistic EuroSCORE II <5%, 5-10%, >10%; respectively). Study endpoints were reported according to the Valve Academic Research Consortium (VARC) definitions. The C-statistic was performed to calculate the discriminative ability of the scores.
Results: A total of 417 patients were included: mean age was 79.5±7.5 years and 59.7% underwent implantation of Edwards SAPIEN™/SAPIEN XT™. According to STS, there were 17.7% patients in the low-, 49.2% in the intermediate- and 33.1% in the high-risk category. According to logistic EuroSCORE, there were 20.6% patients in the low-, 31.9% in the intermediate- and 47.5% in the high-risk category. According to logistic EuroSCORE II, there were 54.2% patients in the low-, 28.1% in the intermediate- and 17.7% in the high-risk category. Thirty-day mortality was 4.7% overall with no differences according to risk stratification: according to STS from low to high risk respectively 4.3% vs. 3.5% vs. 6.7% (p=0.392), logistic EuroSCORE 3.7%- vs. 2.3% - vs. 6.7% (p=0.167) and logistic EuroSCORE II 3.2% vs. 6.2% vs. 6.8% (p=0.307). The C statistic for 30 day mortality for STS, logistic EuroSCORE, and logistic EuroSCORE II were respectively 0.60, 0.66 and 0.62. All high-risk groups developed more acute kidney injury stage 3 (in high-risk STS 16.8%, logistic EuroSCORE 14.8% and logistic EuroSCORE II 17.6%) and stroke was more frequent in the high-risk logistic EuroSCORE II group (0% vs. 0.9% vs. 5.4%; p=0.001).
Conclusions: None of the available surgical risk scores were predictors of 30-day mortality following TAVI. Moreover, the C statistics showed poor discriminative ability of the scores for 30 day mortality. New scores are needed to help risk stratify TAVI patients.

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The effect of inflammation on left ventricular function after trancatheter aortic valve implantation

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Background: Trancatheter aortic valve implantation (TAVI) is an emerging treatment option for inoperable or high risk patients. After the procedure, most of patients show significant improvement of left ventricular function. However, the recovery of left ventricle is not immediately observed to all patients while to some others, it is temporarily deteriorated. Furthermore, some patients may elevate the levels of CRP and white blood cells (WBC) after TAVI. Elevated CRP has been associated with reduced left ventricular function. Therefore, we hypothesized that inflammatory parameters may influence left ventricular recovery after TAVI.
Methods: Data from consecutive patients who underwent TAVI were evaluated from an existed database. Blood samples were obtained before TAVI, 3 hours and daily for 5 days after the procedure. CRP as well as WBC were recorded. In addition, transthoracic echocardiogram was performed and obtained before TAVI and daily for 5 days after the procedure. Patients were separated into three groups according to left ventricle improvement (improved, unaffected, declined).
Results: Overall, data from 76 patients (80.37±5.36 years, 33 males (48.8%), AVA: 0.63±0.15 cm2) were analyzed. Out of them, in 29 patients (39.7%) LVEF improved, in 11 patients (15.1%) it declined and in 33 patients (45.2%) it remained unaffected. We performed ANNOVA test among three groups and we found significant differences between groups for CRPmax (p<0.01) and WBC1st day after (p<0.01). In particular, post-hoc analysis showed higher levels of CRPmax (70.2±49.28 vs. 120±22.36, p<0.01) and WBC1st day after (16333±4685 vs. 11748±3512, p<0.01) in patients with declined LVEF comparing to those with unaffected LVEF respectively. Similarly, post-hoc analysis recorded greater value for CRPmax (120±22.36 vs. 61.99±36.9, p<0.01) and WBC1st day after (16528±4890 vs. 10800±2687, p<0.01) in patients with declined LVEF when compared with those with improved LVEF.
Conclusions: In conclusion, inflammation as detected by simple indices such WBC and CRP may be associated with left ventricular function after TAVI.

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