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Early Outcomes With Direct Flow Medical Versus 1°-Generation Transcatheter Aortic Valve Devices: A Single-Center Propensity-Matched Analysis

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Background: The aim of this study was to compare TAVI outcomes with the new-generation Direct Flow Medical (DFM) versus the Medtronic CoreValve (MCV) and Edwards SAPIEN XT (ESV) devices.
Methods: From November 2007 to March 2014 all consecutive patients who underwent transfemoral TAVI with DFM, MCV or ESV in our center have been included. Because of differences in baseline characteristics a propensity score matching among patients treated in the same time span was performed. Endpoints were defined according to VARC-2 criteria at 30 days.
Results: Overall, 496 patients were included: 44 (8.7%) treated with DFM, 179 (36.9%) with MCV and 273 (54.4%) with ESV. Rigorous propensity-score matching identified 41 patients in each group. A higher device success endpoint was observed in DFM (DFM 100% vs. MCV 61% vs. ESV 85.4%; $p < 0.001$). This was attributed to a significantly lower incidence of moderate-to-severe post-procedural aortic regurgitation (PPAR; 0% vs. 24.4% vs. 15.4%; $p = 0.014$), valve embolization (0% vs. 7.3% vs. 0%; 0.041) and need for a 2° valve implantation (0% vs. 7.3% vs. 0%; $p = 0.041$). Of note, a more frequent need of balloon post-dilation, secondary to moderate-to-severe PPAR immediately after valve implantation, was observed with MCV and ESV (0% vs. 39% vs. 34%; $p < 0.001$). No differences were present in post-procedural mean gradient (7.5 ± 4.4 vs. 6.5 ± 5.8 vs. 4.9 ± 4.1 mmHg; $p = 0.139$). Interestingly, DFM was associated with a trend to less acute kidney injury stage II or III (2.4% vs. 14.6% vs. 4.9%; $p = 0.081$), this finding was probably related to a numerically lower contrast medium dose used during DFM implantation (100 ± 50.3 vs. 123.2 ± 66.9 vs. 113.1 ± 58.9; $p = 0.219$). Conversely, incidence of permanent pacemaker implantation with DFM was lower than MCV but higher as compared to ESV (17.1% vs. 34.1% vs. 7.3%; $p = 0.001$). Finally, no differences were observed at 30 days in cardiovascular mortality (0% vs. 2.4% vs. 0%; $p = 0.365$) and early safety composite endpoint (4.9% vs. 17.1% vs. 14.6%; $p = 0.203$).
Conclusions: DFM was associated with higher rates of device success and a lower incidence of PPAR. New generation devices solve several of the limitations of earlier generation devices.

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Clinical Impact and Evolution Of Mitral Regurgitation Following Transcatheter Aortic Valve Replacement: A Meta-Analysis

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Background: Mitral regurgitation (MR) is a common entity in patients with aortic stenosis undergoing transcatheter aortic valve replacement (TAVR), but its influence on outcomes remains controversial. The purpose of this meta-analysis was to assess the clinical impact of and changes in significant (moderate-severe) MR in patients undergoing TAVR, overall and according to valve design (self-expandable [SEV] vs. balloon-expandable [BEV]).
Methods: All national registries and randomized trials published between 2002 and 2013 were identified and pooled using meta-analytical guidelines to establish the impact of moderate or severe MR on mortality after TAVR. Studies reporting changes in MR after TAVR on an individual level were electronically searched and used for the analysis.
Results: Eight studies including 8015 patients (SEV: 3474 patients; BEV: 4492 patients) were included in the analysis. The overall 30-day and 1-year mortality was increased in patients with significant MR (OR: 1.49, 95% CI: 1.16-1.92; HR: 1.32, 95% CI: 1.12-1.55, respectively), but a significant heterogeneity across studies was observed ($P < 0.05$). The negative effect of MR on 1-year mortality was more evident in patients who had received a SEV (HR: 1.62, 95% CI 1.23-2.14) than those who had received a BEV (HR: 1.22, 95% CI 0.98 to 1.51). Changes in MR over time were evaluated in 9 studies including 1278 patients. Moderate-severe MR (SEV: 326 patients; BEV: 192 patients) improved in 50.5% of the patients at a median follow-up of 180 (30-360) days after TAVR, and the degree of improvement was greater in patients who had received a BEV (66.7% vs. 40.8% in the SEV group, $P=0.001$).
Conclusions: Concomitant moderate-severe MR was associated with increased early and late mortality following TAVR. A significant improvement in MR severity was detected in half of the patients following TAVR, and the degree of improvement was greater in those patients who had received a BEV. The results of the present meta-analysis provide further insight into the effects of and changes in MR in patients undergoing TAVR, and this may be of help in the clinical decision-making process and procedural planning for such a challenging group of patients.

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One-Year Outcomes With the Fully Repositionable and Retrievable Lotus™ Transcatheter Aortic Replacement Valve in 120 High-Risk Surgical Patients With Severe Aortic Stenosis: Results From the REPRISE II CE-Mark Study

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Background: The repositionable and fully retrievable Lotus™ Valve (Boston Scientific, Natick, MA, USA) was designed to facilitate accurate positioning and minimize paravalvular regurgitation in patients with severe aortic stenosis who are at high or extreme surgical risk. The device is CE-marked based on favorable efficacy and safety outcomes at 30 days in the prospective, single-arm, multicenter REPRISE II trial. This analysis will present the first report of 1-year outcomes from the full cohort of patients in REPRISE II.
Methods: The study enrolled 120 symptomatic patients aged ≥70 years at 14 centers in Australia and Europe. Patients had severe calcific AS and were deemed to be at high or extreme risk for surgery based on assessment by the Heart Team.
Results: The mean age was 84.4±5.3 yrs, 57% (68/120) were female, and mean STS Score was 7.1±4.6. The mean baseline aortic valve area was 0.7±0.2cm^2, and the mean aortic valve pressure gradient was 46.4±15.0mmHg. All patients were successfully implanted with a Lotus Valve and 6-month follow-up data or death was available in 99.2% (119/120). The primary performance endpoint of 30-day mean aortic valve pressure gradient was 11.5±5.2mmHg, as assessed by an independent core lab, and was significantly less than the performance goal of 18 mmHg ($P < 0.001$). The primary safety endpoint of 30-day all-cause mortality was 4.2%. At 6 months, the VARC Safety Composite rate was 20.2% (24/119), all-cause mortality was 8.4% (10/119), disabling stroke was 3.4% (4/119), disabling bleeding was 5.0% (6/119), with no repeat procedures for valve-related dysfunction. A total of 29.4% (35/119) patients had new permanent pacemaker implantation due to new or worsened conduction disturbance. Mean 6-month aortic valve gradient was 11.4±4.6mmHg and mean aortic valve area was 1.7±0.4cm^2. By independent core lab adjudication, 80.9% patients had no/trivial paravalvular aortic regurgitation at 6 months.
Conclusions: The Lotus Valve has demonstrated minimal paravalvular regurgitation and low rates of death and stroke at 6 months. One-year results for the full 120 patients in the REPRISE II trial will be presented for the first time at TCT 2014.