Transcatheter Aortic Valve Implantation
With the Edwards SAPIEN Versus the Medtronic CoreValve Revalving System Devices
A Multicenter Collaborative Study: The PRAGMATIC Plus Initiative (Pooled-Rotterdam-Milano-Toulouse In Collaboration)

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Objectives
The aim of this study was to compare outcomes after transfemoral transcatheter aortic valve implantation with the Medtronic CoreValve (MCV) versus the Edwards SAPIEN/SAPIEN XT transcatheter heart valve (ESV) for severe aortic stenosis.

Background
No large matched comparison study has been conducted so far evaluating both commercially available devices.

Methods
The data from databases of 4 experienced European centers were pooled and analyzed. Due to differences in baseline clinical characteristics, propensity score matching was performed. Study objectives were Valve Academic Research Consortium outcomes at 30 days and 1 year.

Results
In total, 793 patients were included: 453 (57.1%) treated with the MCV and 340 (42.9%) with the ESV. After propensity matching, 204 patients were identified in each group. At 30 days, there were no differences in all-cause mortality (MCV, 8.8% vs. ESV, 6.4%; hazard ratio [HR]: 1.422; 95% confidence interval [CI]: 0.677 to 2.984; p = 0.352), cardiovascular mortality (MCV, 6.9% vs. ESV, 6.4%; HR: 1.083; 95% CI: 0.496 to 2.364; p = 0.842), myocardial infarction (MCV, 0.5% vs. ESV, 1.5%; HR: 0.330; 95% CI: 0.034 to 3.200; p = 0.339), stroke (MCV, 2.9% vs. ESV, 1.0%; HR: 3.061; 95% CI: 0.610 to 15.346; p = 0.174), or device success (MCV, 95.6% vs. ESV, 96.6%; HR: 0.770; 95% CI: 0.281 to 2.108; p = 0.611). Additionally, there were no differences in major vascular complications (MCV, 9.3% vs. ESV, 12.3%; HR: 0.735; 95% CI: 0.391 to 1.382; p = 0.340) or life-threatening bleeding (MCV, 13.7% vs. ESV, 8.8%; HR: 1.644; 95% CI: 0.878 to 3.077; p = 0.120). MCV was associated with more permanent pacemakers (22.5% vs. 5.9%; HR: 4.634; 95% CI: 2.373 to 9.050; p < 0.001). At 1 year, there were no differences in all-cause mortality (MCV, 16.2% vs. ESV, 12.3%; HR: 1.374; 95% CI: 0.785 to 2.407; p = 0.266) or cardiovascular mortality (MCV, 8.3% vs. ESV, 7.4%; HR: 1.145; 95% CI: 0.556 to 2.361; p = 0.713).

Conclusions
No differences between the 2 commercially available transfemoral transcatheter aortic valve implantation devices were observed at the adjusted analysis in Valve Academic Research Consortium outcomes except for the need for permanent pacemakers with the MCV. (J Am Coll Cardiol 2013;61:830–6) © 2013 by the American College of Cardiology Foundation

For high-risk patients with severe symptomatic aortic stenosis, transcatheter aortic valve implantation (TAVI) has emerged as an effective alternative (1–5). Since its introduction, 2 devices have been in widespread use throughout Europe. The first is the Medtronic CoreValve (MCV) (Medtronic Inc., Minneapolis, Minnesota), a nitinol self-expandable porcine pericardial tissue valve. The other is the balloon-expandable Edwards SAPIEN/SAPIEN XT transcatheter heart valve (ESV) (Edwards Lifesciences, Irvine, California), composed initially of
stainless steel and now of a cobalt chromium frame with bovine pericardial leaflets.

Currently, a substantial body of data has been published regarding outcomes following TAVI (1–8). However, so far, no large comparison has been performed to assess differences between currently available valve types. The aim of this multicenter collaborative registry was therefore to compare 30-day and 1-year Valve Academic Research Consortium (VARC) outcomes after transfemoral (TF) TAVI with MCV versus ESV.

Methods

Patients. The PRAGMATIC Plus (Pooled-RotterdamAm-MilAno-Toulouse In Collaboration) initiative is a collaboration of 4 European institutions with established TAVI experience. The baseline characteristics and clinical outcomes from a series of 944 patients who underwent TAVI were collected since the introduction of the respective local TAVI programs until July 2011: 1) San Raffaele Scientific Institute, Milan, Italy (N = 330); 2) Clinique Pasteur, Toulouse, France (N = 224); 3) Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands (N = 206); and 4) Hôpital Rangueil, Toulouse, France (N = 184). After the VARC publication, clinical outcomes were adjudicated, and all data pooled in a dedicated database.

Patient eligibility for TAVI at each center was described previously (9–11).

Procedures. Patients were included in this analysis if femoral access was used. Both TAVI devices, commercially available at the onset of the study, were used: the 18-F sheath–compatible MCV (except 5 cases with the 21-F device) and the ESV, using 22-/24-F sheaths until mid 2010 when the Novaflex delivery catheter and the ESV-XT downgrading to 18-/19-F device was introduced. Sheath size was entered in the propensity matching as a dichotomous variable, thus, excluding the initial devices in the adjusted analysis. Valve choice was at operator discretion.

Study endpoints. The study endpoints were defined according to VARC (12). Residual aortic regurgitation (AR) was evaluated by either transthoracic or transesophageal echocardiography at all centers.

All patients provided written informed consent for the procedure and data collection according to the policy of each hospital.

Statistical analysis. The analysis was performed according to valve type. Continuous variables are expressed as mean ± SD and analyzed with the Student t test or Wilcoxon rank sum test depending on the variable distribution. Categorical variables were compared with the chi-square test with Yates correction for continuity or the Fisher exact test. Because of the nonrandomized nature of the study, to reduce treatment selection bias and potential confounding, we performed rigorous adjustment for significant differences in baseline characteristics with propensity-score matching. The score was calculated by performing a multiparsimonious multivariable logistic regression with valve type as the dependent variable. The following covariants were selected: age, sex, body mass index, logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation), Society of Thoracic Surgeons score, previous MI, coronary artery bypass graft, or percutaneous coronary intervention, coronary artery disease, hypertension, chronic obstructive pulmonary disease, diabetes mellitus, peripheral vascular disease, chronic kidney disease, cerebrovascular disease, ejection fraction ≤35%, aortic annulus diameter, and sheath size. The C-statistic for the propensity score model was 0.67, and the Hosmer-Lemeshow goodness-of-fit was 0.33, confirming good calibration. To identify matched pairs, we used the following algorithm: 1:1 optimal match with a ±0.01 caliper and no replacement. Clinical outcomes in the matched population were analyzed with Cox proportional hazards regression stratified on matched pairs. Multivariable Cox proportional hazards regression modeling was performed to determine the independent predictors of study objectives with purposeful selection of covariates. Variables associated at univariate analysis (all with a p value ≤0.1) and those judged to be of clinical importance were eligible for inclusion into the multivariable model-building process. The goodness-of-fit of the Cox multivariable model was assessed with the Grennesby-Borgan-May test. Results are reported as hazard ratio (HR) with associated 95% confidence interval (CI) and p value. Survival was recorded by Kaplan-Meier analysis with the log-rank method used for comparison. All statistical analyses were performed with STATA (version 9.0, StataCorp, College Station, Texas). A p value of <0.05 was considered statistically significant.

Results

Overall, 793 patients were treated with a TF access strategy: 453 (57.1%) with an MCV and 340 (42.9%) with an ESV. Baseline characteristics of the overall population are reported in Table 1.

Unadjusted VARC outcomes in the overall population. At 30 days, 34 patients (7.5%) died after receiving an MCV compared with 17 (5.0%) after receiving an ESV; cardiovascular death was, respectively, 28 (6.2%) and 17 (5.0%). Online supplementary Table 1 shows predictors of mortality. Major stroke occurred in 16 MCV (3.5%) and 5 (1.5%) ESV patients. Patients who had a stroke more frequently
had valve embolization or required a second valve (Online Table 2).

Five patients (1.1%) with an MCV and 1 (0.3%) with an ESV had a periprocedural MI. Coronary obstruction occurred in only 1 patient in each group. Valve embolization occurred in 30 MCV patients (6.6%) and in no ESV patients, and there was a need for a second valve in 20 MCV (4.4%) versus ESV 2 (0.6%) patients. Residual mild AR was observed in 89 MCV patients (19.6%) versus 37 ESV patients (10.9%); moderate AR occurred in 8 MCV patients (1.8%) versus 5 ESV patients (1.5%), and severe AR in 1 MCV patient (0.2%) versus 1 ESV patient (0.3%). Figure 1 illustrates the impact of AR on unadjusted survival. The device was successful in 424 MCV patients (93.6%) and in 327 ESV patients (96.2%).

Major vascular complications and life-threatening bleeding occurred, respectively, in 41 (9.1%) and 53 (11.7%) of MCV patients versus 50 (14.7%) and 48 (14.1%) ESV patients. At 1 year, 79 patients (17.4%) in the MCV group died versus 46 (13.6%) in the ESV group; 42 (9.3%) versus 26 (7.6%), respectively, were cardiac deaths. Figure 2 illustrates unadjusted survival curves in the overall population.

### Propensity-matched analysis

After propensity-score matching was performed, there were 204 matched pairs of patients in each group. Baseline characteristics of the matched groups are shown in Table 2. In the propensity model, because sheath size was a dichotomous variable, only newer generation devices were included.

<table>
<thead>
<tr>
<th>VARC outcomes for the matched groups</th>
<th>MCV (n = 204)</th>
<th>ESV (n = 204)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day all-cause mortality</td>
<td>8.8%</td>
<td>6.4%</td>
<td>0.142</td>
</tr>
<tr>
<td>Cardiovascular mortality</td>
<td>6.9%</td>
<td>6.4%</td>
<td>0.842</td>
</tr>
<tr>
<td>Spontaneous MI</td>
<td>0.5%</td>
<td>1.5%</td>
<td>0.339</td>
</tr>
<tr>
<td>Stroke</td>
<td>2.9%</td>
<td>1.0%</td>
<td>0.174</td>
</tr>
</tbody>
</table>

Values are n (%) or mean ± SD.

AVA = aortic valve area; CAGB = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; ESV = Edwards SAPIEN/SAPIEN XT transcatheter heart valve; EuroSCORE = European System for Cardiac Operative Risk Evaluation; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MCV = Medtronic CoreValve; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease; STS score = Society of Thoracic Surgeons predicted risk of mortality score.

### Table 1 Baseline Characteristics of the Overall Population

<table>
<thead>
<tr>
<th></th>
<th>MCV (n = 453)</th>
<th>ESV (n = 340)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>80.9 ± 6.7</td>
<td>81.6 ± 7.3</td>
<td>0.125</td>
</tr>
<tr>
<td>Male</td>
<td>251 (55.4)</td>
<td>168 (49.4)</td>
<td>0.094</td>
</tr>
<tr>
<td>NYHA functional class III/IV</td>
<td>373 (82.3)</td>
<td>273 (80.8)</td>
<td>0.572</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>21.4 ± 12.6</td>
<td>23.0 ± 13.8</td>
<td>0.089</td>
</tr>
<tr>
<td>STS score</td>
<td>8.1 ± 6.2</td>
<td>8.9 ± 6.5</td>
<td>0.066</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>75 (16.6)</td>
<td>46 (13.5)</td>
<td>0.241</td>
</tr>
<tr>
<td>Previous MI</td>
<td>88 (19.4)</td>
<td>41 (12.1)</td>
<td>0.005</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>108 (23.9)</td>
<td>59 (17.4)</td>
<td>0.037</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>128 (28.3)</td>
<td>101 (29.7)</td>
<td>0.656</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>129 (28.5)</td>
<td>94 (27.6)</td>
<td>0.797</td>
</tr>
<tr>
<td>Hypertension</td>
<td>292 (64.5)</td>
<td>244 (71.8)</td>
<td>0.030</td>
</tr>
<tr>
<td>GFR &lt; 60 ml/min</td>
<td>267 (58.9)</td>
<td>217 (64.2)</td>
<td>0.133</td>
</tr>
<tr>
<td>COPD</td>
<td>147 (32.5)</td>
<td>110 (32.4)</td>
<td>0.977</td>
</tr>
<tr>
<td>PVD</td>
<td>75 (16.6)</td>
<td>65 (19.3)</td>
<td>0.327</td>
</tr>
<tr>
<td>Annulus, mm</td>
<td>23.5 ± 2.3</td>
<td>22.7 ± 1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AVA, mm²</td>
<td>0.7 ± 0.2</td>
<td>0.7 ± 0.2</td>
<td>0.822</td>
</tr>
<tr>
<td>LVEF &lt; 35%</td>
<td>80 (17.7)</td>
<td>59 (17.4)</td>
<td>0.910</td>
</tr>
</tbody>
</table>

Values are n (%) or mean ± SD.

AVA = aortic valve area; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; ESV = Edwards SAPIEN/SAPIEN XT transcatheter heart valve; EuroSCORE = European System for Cardiac Operative Risk Evaluation; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MCV = Medtronic CoreValve; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease; STS score = Society of Thoracic Surgeons predicted risk of mortality score.

### Figure 1 Freedom From All Cause and Cardiac Mortality According to AR

Freedom from all-cause (A) and cardiovascular (B) mortality at 1 year according to the grade of aortic regurgitation (AR). The green line represents no/trace AR, the blue line mild AR, and the red line moderate/severe AR.
Furthermore, there were no differences in major vascular complications (MCV, 9.3% vs. ESV, 12.3%; HR: 0.735; 95% CI: 0.391 to 1.382; p = 0.340) or life-threatening bleeding (MCV, 13.7% vs. ESV, 8.8%; HR: 1.644; 95% CI: 0.878 to 3.077; p = 0.120). Consequently, no difference was observed in 30-day VARC combined safety (MCV, 26.5% vs. ESV, 23.0%; HR: 1.203; 95% CI: 0.766 to 1.887; p = 0.422).

Conversely, as expected, there was less need for a PPM after treatment with an ESV (MCV, 22.5% vs. ESV, 5.9%; HR: 4.634; 95% CI: 2.373 to 9.050; p < 0.001).

No significant differences were found in residual moderate/severe AR (MCV, 1.5% vs. ESV, 0.5%; HR: 3.015; 95% CI: 0.311 to 29.243; p = 0.341) or indeed residual mild AR (MCV, 17.3% vs. ESV, 11.7%; HR: 1.569; 95% CI: 0.887 to 2.776; p = 0.122). Supplementary Online Table 3 illustrates the degree of residual AR. Furthermore, there was no difference in the aortic valve area after the procedure (1.77 ± 0.41 mm Hg vs. 1.71 ± 0.32 mm Hg; HR: 1.525; 95% CI: 0.752 to 3.092; p = 0.242).

Notably, there was no significant increased need for a second valve (MCV, 2.9% vs. ESV, 1.0%; HR: 3.061; 95% CI: 0.610 to 15.346; p = 0.174) with MCV despite 11 patients (5.4%) versus no patients (p = 0.001) undergoing embolization. However, this was not reflected in device success, which was similar between groups (MCV, 95.6% vs. ESV, 96.6%; HR: 0.770; 95% CI: 0.281 to 2.108; p = 0.611).

At 1 year, there were no differences in all-cause (MCV, 16.2% vs. ESV, 12.3%; HR: 1.374; 95% CI: 0.785 to 2.407; p = 0.266) or cardiovascular mortality (MCV, 8.3% vs. ESV, 7.4%; HR: 1.145; 95% CI: 0.556 to 2.361; p = 0.713). No difference was also observed in the combined efficacy endpoint (MCV, 32.4% vs. ESV, 25.6%; HR: 1.389; 95% CI: 0.903 to 2.136; p = 0.135). Kaplan-Meier survival curves are shown in Figure 3.

Table 2  
Baseline Characteristics of the Propensity-Matched Population

<table>
<thead>
<tr>
<th></th>
<th>MCV (n = 204)</th>
<th>ESV (n = 204)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>82.1 ± 6.0</td>
<td>81.8 ± 7.8</td>
<td>0.656</td>
</tr>
<tr>
<td>Male</td>
<td>92 (45.1)</td>
<td>100 (49.0)</td>
<td>0.427</td>
</tr>
<tr>
<td>NYHA functional class III/IV</td>
<td>169 (82.8)</td>
<td>163 (80.3)</td>
<td>0.507</td>
</tr>
<tr>
<td>Logistic EuroSCORE, %</td>
<td>22.1 ± 12.2</td>
<td>21.7 ± 13.7</td>
<td>0.778</td>
</tr>
<tr>
<td>STS score, %</td>
<td>9.3 ± 7.2</td>
<td>8.9 ± 7.0</td>
<td>0.538</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>25 (12.3)</td>
<td>24 (11.8)</td>
<td>0.879</td>
</tr>
<tr>
<td>Previous MI</td>
<td>19 (9.3)</td>
<td>22 (10.8)</td>
<td>0.621</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>27 (13.2)</td>
<td>31 (15.2)</td>
<td>0.571</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>69 (33.8)</td>
<td>63 (30.9)</td>
<td>0.525</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>58 (28.4)</td>
<td>56 (27.5)</td>
<td>0.825</td>
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<tr>
<td>Hypertension</td>
<td>154 (75.5)</td>
<td>145 (71.1)</td>
<td>0.314</td>
</tr>
<tr>
<td>GFR &lt; 60 ml/min</td>
<td>128 (62.7)</td>
<td>123 (60.3)</td>
<td>0.611</td>
</tr>
<tr>
<td>COPD</td>
<td>58 (28.4)</td>
<td>59 (28.9)</td>
<td>0.913</td>
</tr>
<tr>
<td>PVD</td>
<td>47 (23.0)</td>
<td>41 (20.0)</td>
<td>0.470</td>
</tr>
<tr>
<td>Annulus, mm</td>
<td>22.7 ± 2.3</td>
<td>22.9 ± 1.8</td>
<td>0.417</td>
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<tr>
<td>AVA, mm²</td>
<td>0.7 ± 0.2</td>
<td>0.7 ± 0.2</td>
<td>0.250</td>
</tr>
<tr>
<td>LVEF &lt; 35%</td>
<td>29 (14.2)</td>
<td>32 (15.7)</td>
<td>0.677</td>
</tr>
</tbody>
</table>

Values are n (%) or mean ± SD.  
Abbreviations as in Table 1.
Discussion

The main findings of our study are as follows. 1) There were no differences in 30-day or 1-year mortality between MCV and ESV; 2) moreover, there were no differences in combined safety and efficacy endpoints between valves; 3) as expected, there was a greater need for PPM after MCV implantation.

TAVI is now an acceptable treatment option for those deemed at high risk of surgical aortic valve replacement. There are currently 2 commercially available devices avail-

<table>
<thead>
<tr>
<th>Table 3</th>
<th>VARC Outcomes in the Propensity-Matched Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>No. (% of Events)</td>
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<tr>
<td>---------</td>
<td>-----------------------------------------------------</td>
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<tr>
<td>30 days</td>
<td>All-cause mortality</td>
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<tr>
<td></td>
<td>Cardiac mortality</td>
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<tr>
<td></td>
<td>Spontaneous MI</td>
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<tr>
<td></td>
<td>Major stroke</td>
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<td></td>
<td>Major vascular</td>
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<tr>
<td></td>
<td>Life-threatening bleeding</td>
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<td>Major bleeding</td>
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<tr>
<td></td>
<td>Acute kidney injury stage 3</td>
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<tr>
<td></td>
<td>Device success</td>
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<tr>
<td></td>
<td>Combined safety</td>
</tr>
<tr>
<td>1 Year</td>
<td>All-cause mortality</td>
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<tr>
<td></td>
<td>Cardiac mortality</td>
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<td></td>
<td>NYHA functional class III/IV</td>
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<td></td>
<td>Rehospitalization</td>
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<tr>
<td></td>
<td>Mean gradient, mm Hg</td>
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<td></td>
<td>Moderate-severe AR</td>
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<tr>
<td></td>
<td>Combined efficacy</td>
</tr>
</tbody>
</table>

AR = aortic regurgitation; CI = confidence interval; VARC = Valve Academic Research Consortium; other abbreviations as in Table 1.

Figure 3

Freedom From All-Cause and Cardiac Mortality at the Propensity-Matched Analysis

Freedom from all-cause (A) and cardiovascular (B) mortality in the propensity-matched population at 1 year. The green line represents MCV and the blue line the ESV. Abbreviations as in Figure 2.
able for TF: MCV and ESV. A number of studies have provided a comparison, including the FRANCE 2 (French Aortic National CoreValve and Edwards) registry (8) and the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) registry (7). In addition, it is important to understand that these registries report only unadjusted analyses and do not take into account the significant differences at baseline.

In our series, the adjusted all-cause mortality at 30 days (MCV, 8.8% vs. ESV, 6.4%) is similar to the unadjusted all-cause mortality reported in the FRANCE 2 (8) and the U.K. TAVI registries (7). It is also comparable with that reported by several initial registries, varying from 0.9% to 11.0% for ESV and 6.0% to 15.2% for MCV via transfemoral approach (1,13,14). Furthermore, at 1 year, there remained no differences in all-cause mortality between valves (MCV, 16.3% vs. ESV, 13.9%), which was favorable compared with other studies (7,8). No difference was also observed at 1 year in the combined efficacy endpoint.

Importantly, there was no difference in major vascular complications after matching for sheath size (MCV, 9.3% vs. ESV, 12.3%). It was previously demonstrated that major vascular complications were improved with the introduction of the newer device (15). Nevertheless, the introduction of smaller sheaths is warranted to reduce complications further. The introduction of the Edwards SAPIEN 3 will reduce the sheath size to 14/16-F, with similar improvements expected with the MCV.

In our series, the 2.6% incidence of stroke seems acceptable compared with previous experience (1.2% to 5.0%) (3,5,6–8,16). Of note, patients who had a stroke more frequently had valve embolization or needed a second valve. At the center with the highest rate of stroke, the rate of embolization was 10.4%. It is possible that the process of recapturing and the subsequent retrieval of the valve and delivery system through the aorta could have played a role.

As previously reported (7,16), there was a greater need for PPM with the MCV, likely related to valve structure and design.

The U.K. TAVI registry demonstrated in the comparison between valve types (unadjusted) an increased risk of moderate/severe AR with the MCV (MCV, 17.3% vs. ESV, 9.6%; p = 0.001) (7). Importantly, in our study in both unadjusted and adjusted analyses, no differences were observed in the incidence of residual AR of any grade between valve types. In addition, our data confirm that moderate/severe AR is associated with increased 1-year mortality. There is growing evidence in the current literature that moderate/severe AR is correlated with higher mortality (8,17–19). Notably, the presence of residual AR in our study significantly affected both all-cause and cardiac mortality (Fig. 1). In fact, the freedom from all-cause and cardiac mortality was significantly lower with moderate/severe AR compared with nil/trivial or mild AR.

The presence of residual AR is one of the limitations of the currently available TAVI devices, and paravalvular leaks need to be decreased to improve outcomes further. In addition, facilitation of accurate positioning, device retrieval, and reduction of the delivery catheter diameter will continue to improve outcomes. Overall, our results are encouraging, showing no difference between commercially available valve types except for a greater need for a PPM with the MCV, but clearly longer term follow-up in the setting of an adequately powered randomized clinical trial is needed.

**Study limitations.** Due to the nonrandomized and retrospective nature of this study, the findings are subject to selection bias and confounding with regard to the preprocedural risk of the patient. In an aim to minimize these biases, propensity-score matching was performed; however, hidden bias may remain due to the influences of unmeasured confounders.

The lack of a central core laboratory and adjudication committee means potential reporting bias and is a further limitation. Finally, the clinical follow-up duration limits conclusions on valve durability.

**Conclusions**

No differences between the 2 commercially available TF TAVI devices were observed in the adjusted analysis in the study population in VARC outcomes at 30 days and 1 year, except for the need for a PPM with the MCV. These results need to be confirmed in a randomized trial.

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**REFERENCES**


Key Words: Aortic stenosis ▪ aortic valve implantation ▪ Edwards SAPIEN transcatheter ▪ Medtronic CoreValve.

APPENDIX

For supplemental tables, please see the online version of this article.