MINI-FOCUS ON TAVI

CLINICAL RESEARCH

A 3-Center Comparison of 1-Year Mortality Outcomes Between Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement on the Basis of Propensity Score Matching Among Intermediate-Risk Surgical Patients

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Objectives This study sought to compare all-cause mortality in patients at intermediate surgical risk undergoing transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR).

Background Physicians are selecting “lower” surgical risk patients to undergo TAVI. No clinical data exist about the clinical outcomes of TAVI versus SAVR among intermediate-surgical-risk patients.

Methods We prospectively enrolled symptomatic patients with severe aortic stenosis who underwent TAVI or SAVR. Propensity-score matched pairs of TAVI and SAVR patients with Society of Thoracic Surgeons (STS) scores between 3% and 8% made up the study population. Primary endpoint was all-cause mortality at 1 year.

Results Between November 2006 and January 2010, 3,666 consecutive patients underwent either TAVI (n = 782) or SAVR (n = 2,884). Four hundred five TAVI patients were matched to 405 SAVR patients. Of matched TAVI patients, 99 (24%) patients had STS scores <3%, 255 (63%) had scores between 3% and 8%, and 51 (13%) had scores >8%. Among patients with STS scores between 3% and 8%, 20 (7.8%) versus 18 (7.1%) patients had died up to 30 days (hazard ratio: 1.12, 95% confidence interval: 0.58 to 2.15, p = 0.74) and 42 (16.5%) versus 43 (16.9%) patients had died up to 1 year (hazard ratio: 0.90, 95% confidence interval: 0.57 to 1.42, p = 0.64) after TAVI and SAVR, respectively. Effects of treatment on 1-year mortality were similar across all subgroups except for sex, with some evidence for a beneficial effect of TAVI in women but not in men (test for interaction p = 0.024).

Conclusions Cumulative all-cause mortality at 30 days and 1 year was similar among propensity-score matched TAVI and SAVR patients at intermediate surgical risk. (Surgical Replacement and Transcatheter Aortic Valve Implantation [SURTAVI]; NCT01586910) (J Am Coll Cardiol Intv 2013; 6:443–51) © 2013 by the American College of Cardiology Foundation
Recent evidence suggests that European centers undertaking transcatheter aortic valve implantation (TAVI) are selecting patients deemed to be at lower surgical risk than specified for the original CE mark label or those enrolled in the PARTNER (Placement of Aortic Transcatheter Valves) US Cohort A trial. It is unclear, however, whether “off-label” treatment of patients considered being at intermediate-surgical-risk would modify the effectiveness and safety of TAVI compared with surgical aortic valve replacement (SAVR). The SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trial is an investigator-initiated trial designed to randomize intermediate-surgical risk patients with severe aortic stenosis, defined by Society of Thoracic Surgeons (STS) scores between 3% and 8%, to either a self-expanding transcatheter aortic valve or SAVR. Currently, there are no data about the clinical outcomes of TAVI compared with SAVR among such patients. To inform the design and implementation of the SURTAVI trial, we conducted an analysis at 3 centers by matching patients undergoing TAVI and SAVR based on propensity scores with the aim of determining, first, the proportion of patients undergoing TAVI who are potentially eligible for the SURTAVI trial in present-day clinical practice; second, any differences in the effect of treatment between patients undergoing TAVI and SAVR for all-cause 30-day and 1-year mortality; and third, whether such effects vary across subgroups of patients as suggested by the PARTNER US Cohort A trial.

Abbreviations and Acronyms

\[CI = \text{confidence interval}\]
\[\text{EuroSCORE} = \text{European System for Cardiac Operative Risk Evaluation}\]
\[HR = \text{hazard ratio}\]
\[LVEF = \text{left ventricular ejection fraction}\]
\[NYHA = \text{New York Heart Association}\]
\[OR = \text{odds ratio}\]
\[\text{SAVR} = \text{surgical aortic valve replacement}\]
\[\text{STS} = \text{Society of Thoracic Surgeons}\]
\[\text{TAVI} = \text{transcatheter aortic valve implantation}\]

Methods

Patient selection and identification of the study population. Between November 2006 and January 2010 we prospectively enrolled over 3,500 consecutive symptomatic patients with severe aortic stenosis who underwent either TAVI or SAVR at Bern University Hospital, Bern, Switzerland; the German Heart Center, Munich, Germany; and Erasmus Medical Center, Rotterdam, the Netherlands. Patients were included if they had symptomatic severe aortic stenosis defined as an aortic valvular orifice area of <1.0 cm², a mean gradient across the aortic valve of 40 mm Hg or more, or a peak aortic-jet velocity of 4.0 m/s or more. Criteria for exclusion included: sepsis; hematologic disorders, such as bleeding or coagulopathy; estimated life expectancy of <1 year; a primary diagnosis of aortic valvular regurgitation; aortic valvular endocarditis; and the need for surgery on multiple valves or additional procedures involving the aortic root. We used propensity scores to match each patient undergoing TAVI to a comparable patient having SAVR (see the Statistical Methods section for further details). Matched pairs featuring TAVI patients with STS scores between 3% and 8% comprised the study population. The local ethical committees in all 3 centers approved the prospective collection of data, and all subjects gave written informed consent.

Study device and procedures. The TAVI was performed with standard techniques as previously described. Suitability for TAVI was confirmed by a combination of transesophageal echocardiography, multislice computed tomography, and angiography. Details of the anatomic criteria for selection of patients, the device, and procedural techniques are described in detail elsewhere (1). The site of interventional access was determined by anatomical characteristics, whereas SAVR was performed through a sternotomy or right lateral thoracotomy and followed standard routines, with single-mattressed sutures passed circumferentially through the valvular annulus to fix the bioprosthesis in a supra-annular position. Concomitant coronary revascularization was performed by either percutaneous or surgical techniques according to the discretion of the operator.

Data collection and study endpoints. We collected data on baseline characteristics for all patients, including the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE). The STS scores were prospectively collected for patients undergoing TAVI but not for those submitted for SAVR. Attempts retrospectively to calculate STS scores for those undergoing SAVR proved unreliable, because of incomplete collection of data at baseline. The
primary and secondary endpoints were all-cause 1-year and 30-day mortality, respectively. For patients with a suspected event, we systematically collected any relevant medical records, discharge letters, and documentation of hospital stay from the hospitals providing treatment and physicians in private practice.

**Statistical methods.** We compared the baseline characteristics of all patients with a chi-square test for categorical variables and unpaired Student t test for continuous variables. Variables associated with treatment selection varied by center. For example, we found that chronic obstructive pulmonary disease was associated with TAVI in Rotterdam (odds ratio [OR]: 2.26, 95% confidence interval [CI]: 1.09 to 4.70) but not in Bern (OR: 1.48, 95% CI: 0.86 to 2.53) or Munich (OR: 0.88, 95% CI: 0.58 to 1.31). Therefore, we derived propensity scores with separate multivariable probit models for each center, including age and sex along with center-specific pre-treatment variables that were associated at p < 0.10 in a multivariable model of all variables. The pre-treatment variables for Bern were logistic EuroSCORE, New York Heart Association (NYHA) functional class, hypertension, peripheral vascular disease, and pulmonary hypertension. Those for Munich were logistic EuroSCORE, NYHA, hypertension, left ventricular ejection fraction (LVEF), and pulmonary hypertension. In Rotterdam, we used logistic EuroSCORE, LVEF, peripheral vascular disease, chronic obstructive pulmonary disease, and history of cerebrovascular accident. Propensity scores were then matched with a caliper range of ±0.05 to obtain matched pairs of patients. We derived standardized differences between groups before and after propensity score matching by dividing differences in proportions and differences in means by the pooled SD, hence expressing all differences in SD units. A 0.20 SD unit corresponds to a small difference between groups (2), a 0.10 SD unit might indicate the smallest potentially meaningful difference (3). From the pairs created, those patients undergoing TAVI with STS scores between 3% and 8% were deemed potentially eligible for the SURTAVI trial.

Hazard ratios (HRs) of overall mortality at 30 days and 1 year were calculated with Cox proportional hazards models. In view of the results from the PARTNER US Cohort A trial, we performed pre-specified analyses stratified by the following variables: age (≤80 vs. >80 years), sex, logistic EuroSCORE (≤20% vs. >20%), STS score (≤4% vs. >4%), diabetes, LVEF (<30% vs. ≥30%), cerebrovascular event, peripheral vascular disease, pulmonary hypertension, and prior coronary arterial bypass graft surgery. Main

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**Figure 1. Patient Flow Chart**

A total of 255 transcatheter aortic valve implantation (TAVI) and 255 surgical aortic valve replacement (SAVR) patients were included in the main analysis. CI = confidence interval; STS = Society of Thoracic Surgeons.
Between November 2006 and January 2010, 3,666 consecutive patients with severe aortic stenosis underwent TAVI (n = 782) or SAVR (n = 2,884) (Fig. 1). The patients undergoing TAVI were older, more likely to be in NYHA functional class III or IV, had higher logistic EuroSCORE, and featured more comorbidities, such as hypertension, left ventricular dysfunction, cerebral and peripheral vascular disease, and pulmonary hypertension (Table 1, left), with 13 of 18 standardized differences above 0.10. From this cohort, we were able to propensity score match 405 patients undergoing TAVI with 405 patients undergoing SAVR, resulting in similar baseline characteristics between groups (Fig. 1, Table 1, right), with 3 of 18 standardized differences above 0.10. Of these, 99 TAVI patients had STS scores <3%, 255 (65%) had scores between 3% and 8%, and 51 had scores >8%. In Table 2, we present baseline characteristics of the propensity score-matched cohort (TAVI and SAVR) according to the stratification by STS scores, with significant trends across ordered groups for age, logistic EuroSCORE, NYHA, diabetes, left ventricular function, peripheral vascular disease, chronic obstructive pulmonary disease, pulmonary hypertension, and levels of creatinine. The STS score of propensity score-matched TAVI patients decreased from 6% (95% CI: 5.2% to 6.8%) to 4.3% (95% CI: 3.8% to 4.7%) from the first to the last quartile of the period of enrollment, respectively (p value for trend <0.001) (Fig. 2).
shown in Table 3. The mean age of TAVI and SAVR patients was 80.6 and 79.7 years, respectively. At baseline, 83.7% of patients undergoing TAVI and 86.3% of those undergoing SAVR were in NYHA functional class III or IV. The logistic EuroSCORE was 17.3% (SD 9.1%) for those undergoing TAVI and 17.6% (SD 11.7%) in the group submitted for SAVR. Severe left ventricular dysfunction, defined as an ejection fraction of $<$30%, was noted in one-tenth or less of patients. Among the 255 matched cases, 3 patients after TAVI and 8 after SAVR were lost to follow-up (Fig. 1).

**Mortality in patients potentially eligible for SURTAVI.** Among the 255 propensity score-matched pairs with STS scores between 3% and 8%, 20 TAVI patients (7.8%) and 18 SAVR patients (7.1%) had died up to 30 days (HR: 1.12, 95% CI: 0.58 to 2.15, $p = 0.74$) (Fig. 3). At 1 year, death had occurred in 42 patients undergoing TAVI (16.5%) and 43 patients undergoing SAVR (16.9%, HR: 0.90, 95% CI: 0.57 to 1.42, $p = 0.64$). Results from stratified analyses are shown in Figure 4. Treatment effects in terms of 1-year mortality were similar across all subgroups except for sex, with TAVI being more beneficial in women than in men ($p$ for interaction $= 0.027$).

**Mortality in overall cohort of propensity score-matched patients.** In the overall cohort of 405 propensity score-matched pairs, 33 TAVI patients and 25 SAVR patients died up to 30 days (HR: 1.29, 95% CI: 0.76 to 2.20, $p = 0.35$). At 1-year follow-up, there were 71 deaths in TAVI and 67 deaths in SAVR patients (HR: 1.02, 95% CI: 0.71 to 1.46, $p = 0.93$). When we stratified the overall cohort by STS score, we found little evidence for differences in HRs between the 191 pairs with STS scores $\leq$4% (HR: 0.75, 95% CI: 0.43 to 1.32) and the 214 pairs with STS scores $>$4% (HR: 1.26, 95% CI: 0.79 to 2.02, $p$ for interaction $= 0.17$). In the subset of the 99 propensity score-matched pairs ineligible for the SURTAVI trial because of STS scores $<$3%, HR were 0.75 (95% CI: 0.17 to 3.35, $p = 0.71$) at 30 days and 0.76 (95% CI: 0.34 to 1.75, $p = 0.53$) at 1 year. When stratifying the overall cohort by logistic EuroSCORE, we found an HR of 0.92 in the 279 pairs with a logistic EuroSCORE $\leq$20% (95% CI: 0.58 to 1.46) and an HR of 1.19 in the 126 pairs with a logistic EuroSCORE $>$20% (95% CI: 0.67 to 2.13), again with little evidence for a difference between groups ($p$ for interaction $= 0.50$).

**Discussion**

Our major findings are as follows: one-third of the patients undergoing TAVI in our current cohort had STS scores between 3% and 8% and were therefore potentially eligible for enrollment in the randomized SURTAVI trial. The proportion of such patients increased progressively over the enrollment period. The cumulative all-cause rates of mortality at 30 days and 1 year were comparable among the matched pairs of TAVI and SAVR patients deemed to be at intermediate risk. Finally, analysis of pre-specified subgroups showed that TAVI produced significantly was associated with improved outcomes for female but not for male patients.

In our study, we were able to match just over one-half of the overall cohort undergoing TAVI with patients submitted for SAVR with propensity score methodology. Of the 405 matched patients undergoing TAVI, 255 (63%) had STS scores between 3% and 8% and would therefore potentially qualify for enrollment in the randomized SURTAVI trial. Looked at from a different perspective, this would account for just over one-third of all our patients undergoing TAVI, specifically 255 of a total of 782 patients. Once anatomical criteria and discussions within the heart team are taken into account, however, it is highly likely that less than one-third of the patients undergoing TAVI would be eligible for the SURTAVI trial.

The STS scores for our surgical patients were not available, and these scores could not be calculated retrospectively from the existing databases. According to the STS database for the period 2006 through 2010, one-quarter of
patients undergoing isolated surgical replacement of the aortic valve and 45% of those undergoing such replacement combined with coronary arterial bypass grafting have STS scores between 3% and 8%, respectively (Michael Mack, MD, personal communication, August 9, 2011). We estimate, therefore, that approximately one-third of the patients undergoing SAVR in the United States would be eligible for enrollment in the SURTAVI trial.

From the first to the fourth quartile of our current enrollment period, the STS scores for propensity score-matched TAVI patients decreased from 6% to 4.3%. This points to an important shift in selection of patients and corroborates recent studies suggesting that increasingly younger patients, at lower surgical risk, are undergoing TAVI in Europe (4). The randomized SURTAVI trial will provide valuable information with regard to the safety and efficacy of TAVI as compared with SAVR among patients deemed to be at intermediate risk and will either confirm or refute current European practice for TAVI.

Inspection of the characteristics of our patients reveals that the matched cohort with STS scores between 3% and 8% differs considerably from the patients at high surgical risk enrolled in the PARTNER I US Cohort A (5). In fact, the characteristics of those enrolled in the PARTNER I US Cohort A more closely resemble our matched cohort with STS scores of 8%. The SURTAVI trial will enroll elderly patients of similar age but with less comorbidity, when compared with the PARTNER I study. Such a tendency toward the enrollment of “healthier” elderly patients seems sensible, given the clinical uncertainties that still surround issues of TAVI, such as paravalvular aortic regurgitation, stroke, and the durability of valves inserted transcutaneously.

The similar mortality outcomes not only mirror the results of the PARTNER I US Cohort A among patients at high surgical risk but also provide preliminary evidence of the lack of difference in mortality between patients at

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**Table 3. Baseline Characteristics of PS-Matched Patients With STS Scores 3% to 8%**

<table>
<thead>
<tr>
<th></th>
<th>TAVI (n = 255)</th>
<th>SAVR (n = 255)</th>
<th>Diff</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>80.6 ± 5.7</td>
<td>79.7 ± 4.9</td>
<td>0.167</td>
<td>0.059</td>
</tr>
<tr>
<td>Female</td>
<td>156 (61.2)</td>
<td>151 (59.2)</td>
<td>0.040</td>
<td>0.651</td>
</tr>
<tr>
<td>Logistic EuroSCORE (%)</td>
<td>17.29 ± 9.1</td>
<td>17.62 ± 11.7</td>
<td>-0.031</td>
<td>0.723</td>
</tr>
<tr>
<td>NYHA</td>
<td>0.842</td>
<td>0.905</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>7 (3.1)</td>
<td>10 (4.4)</td>
<td>-0.070</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>24 (10.6)</td>
<td>27 (11.9)</td>
<td>-0.042</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>145 (63.9)</td>
<td>139 (61.2)</td>
<td>0.055</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>51 (22.5)</td>
<td>51 (22.5)</td>
<td>0.000</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>79 (31.0)</td>
<td>60 (24.4)</td>
<td>0.147</td>
<td>0.1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>198 (76.8)</td>
<td>183 (80.6)</td>
<td>0.180</td>
<td>0.055</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>69 (26.6)</td>
<td>68 (26.0)</td>
<td>0.018</td>
<td>0.891</td>
</tr>
<tr>
<td>LVEF</td>
<td>0.404</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;50%</td>
<td>166 (65.1)</td>
<td>152 (59.6)</td>
<td>0.113</td>
<td></td>
</tr>
<tr>
<td>30%–50%</td>
<td>68 (26.7)</td>
<td>76 (29.8)</td>
<td>-0.070</td>
<td></td>
</tr>
<tr>
<td>&lt;30%</td>
<td>21 (8.2)</td>
<td>27 (10.6)</td>
<td>-0.081</td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>26 (10.2)</td>
<td>17 (6.7)</td>
<td>0.127</td>
<td>0.151</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>17 (6.7)</td>
<td>29 (11.7)</td>
<td>-0.165</td>
<td>0.064</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>48 (18.8)</td>
<td>41 (16.1)</td>
<td>0.072</td>
<td>0.414</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>52 (20.4)</td>
<td>57 (22.4)</td>
<td>-0.048</td>
<td>0.589</td>
</tr>
<tr>
<td>Creatinine (mg/dl)</td>
<td>1.16 ± 0.8</td>
<td>1.08 ± 0.7</td>
<td>0.116</td>
<td>0.191</td>
</tr>
</tbody>
</table>

Values are mean ± SD or n (%). The p values are from paired t test for continuous data and conditional logistic regression for dichotomous and ordinal data.

Abbreviations as in Tables 1 and 2.
SAVR with a mean logistic EuroSCORE of 17.2%, mortality at 30 days of 7.8% for 731 patients undergoing comorbidities. In this context, Grossi et al. (7) reported given the lower long-term risk related to coexisting vs. 24.2%, SAVR 17% vs. 26.8%), which can be expected, than those of the PARTNER US I Cohort A (TAVI 18.8% contrast, our mortality rates at 1 year are 5% to 10% lower wards) registry, with a 30-day mortality of 9.7% (6). By registries, including the recent experience from the PARTNER US Cohort A trial, at 7.9% as opposed to 3.4% for TAVI, and 7.1% versus 6.5% for SAVR. Our results, however, are well in line with those reported from other studies have also suggested that women have better short- and men have more pronounced left ventricular fibrosis, (15). Also, women undergoing TAVI have higher LVEF, SAVR, particularly in those patients with small aortic annuli (20). It has been observed that TAVI results in a lesser outcomes in the context of SAVR but not (or to a lesser extent) in the context of TAVI. Furthermore, women might be more prone to prosthesis–patient mismatch after SAVR (20). It has been observed that TAVI results in a lesser incidence of patient prosthesis mismatch compared with SAVR, particularly in those patients with small aortic annuli (15). Also, women undergoing TAVI have higher LVEF, and men have more pronounced left ventricular fibrosis, possibly making men less able to recover left ventricular function after TAVI (21,22). Single-arm observational studies have also suggested that women have better short- and long-term survival after TAVI (23,24).

We found no differences in treatment effects across subgroups, except for sex. In women, however, TAVI appeared more beneficial than in men, endorsing the findings from the PARTNER US Cohort A trial. In surgical series, female sex is often associated with worse outcomes (19). Women tend to have smaller body surface area, a smaller chest cavity, smaller (and more calcified) aortic annulus and root, and a more pronounced concentric remodeling. These conditions might predispose to worse outcomes in the context of SAVR but not (or to a lesser extent) in the context of TAVI. Furthermore, women might be more prone to prosthesis–patient mismatch after SAVR (20). Other studies based on propensity score matching have also reported similar outcomes in terms of mortality at 30 days and during longer-term follow-up extending to 3 years (8–14). Our study extends these observations to patients at intermediate risk and justifies the pursuit to perform randomized clinical trials. Lower transvalvular aortic gradients, larger effective orifice area, and lower rates of patient–prosthesis mismatch have been demonstrated in patients undergoing TAVI when compared with SAVR, even though paravalvular aortic regurgitation is more frequent after TAVI, with deleterious effect on survival (15,16). Nonetheless, TAVI is suggested to result in greater recovery of left ventricular function among those with reduced LVEF at baseline (17). A recent cost-effectiveness study using a Markov model, with data derived from real-world registry studies, noted a slightly increased cost of TAVI over SAVR, which was offset by a slightly higher gain in quality-adjusted life years (18). The authors concluded that TAVI satisfies current standards of cost-effectiveness relative to SAVR. (18). Our study now extends these inferences to patients at intermediate risk.

Figure 3. Cumulative Incidence of All-Cause Mortality

(A) Cumulative incidence (%) of all-cause 30-day mortality in TAVI (black line) and SAVR (blue line) patients. No difference in 30-day mortality between groups. (B) Cumulative incidence (%) of all-cause 1-year mortality in TAVI (black line) and SAVR (blue line) patients. No difference in 1-year mortality between groups. HR = hazard ratio; other abbreviations as in Figure 2.

intermediate surgical risk. That said, measured and unmeasured confounders might continue to limit observational comparisons and provide the rationale for planned randomized comparisons between these 2 treatment strategies.

The death rate at 30 days in our population was somewhat higher than previously reported for the patients in the PARTNER US Cohort A trial, at 7.9% as opposed to 3.4% for TAVI, and 7.1% versus 6.5% for SAVR. Our results, however, are well in line with those reported from other registries, including the recent experience from the FRANCE 2 (French Aortic National CoreValve and Edwards) registry, with a 30-day mortality of 9.7% (6). By contrast, our mortality rates at 1 year are 5% to 10% lower than those of the PARTNER US I Cohort A (TAVI 18.8% vs. 24.2%, SAVR 17% vs. 26.8%), which can be expected, given the lower long-term risk related to coexisting comorbidities. In this context, Grossi et al. (7) reported mortality at 30 days of 7.8% for 731 patients undergoing SAVR with a mean logistic EuroSCORE of 17.2%, which is directly comparable to the mortality of surgically treated patients in this study with a mean logistic EuroSCORE of 17.5%.

Other studies based on propensity score matching have also reported similar outcomes in terms of mortality at 30 days and during longer-term follow-up extending to 3 years (8–14). Our study extends these observations to patients at intermediate risk and justifies the pursuit to perform randomized clinical trials. Lower transvalvular aortic gradients, larger effective orifice area, and lower rates of patient–prosthesis mismatch have been demonstrated in patients undergoing TAVI when compared with SAVR, even though paravalvular aortic regurgitation is more frequent after TAVI, with deleterious effect on survival (15,16). Nonetheless, TAVI is suggested to result in greater recovery of left ventricular function among those with reduced LVEF at baseline (17). A recent cost-effectiveness study using a Markov model, with data derived from real-world registry studies, noted a slightly increased cost of TAVI over SAVR, which was offset by a slightly higher gain in quality-adjusted life years (18). The authors concluded that TAVI satisfies current standards of cost-effectiveness relative to SAVR. (18). Our study now extends these inferences to patients at intermediate risk.
study, because of the heterogeneity in clinical endpoint definitions across the 3 centers.

Data on frailty and on comorbidities—such as porcelain aorta and radiation disease, which might be associated with treatment decision and with prognosis—were neither collected in our study nor incorporated in STS and logistic EuroSCORE. Therefore, we cannot rule out residual confounding by these unmeasured characteristics. However, frailty is probably an infrequent finding in our matched-intermediate-risk cohort, whereas comorbidities such as radiation disease and porcelain aorta are typically found in <5% of patients undergoing TAVI.

Conclusions

Our results show that patients with severe aortic stenosis considered at intermediate surgical risk have similar overall mortality at 30 days and 1 year, irrespective of whether they are treated with TAVI or SAVR, and point to the need for dedicated randomized trials. The currently observed differences in treatment effects in men as opposed to women warrant further study.

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REFERENCES


Key Words: aortic stenosis | intermediate surgical risk | SAVR | surgical aortic valve replacement | SURTAVI | TAVI | transcatheter aortic valve implantation | transcatheter aortic valve replacement.