Early and Late Mortality in Patients Undergoing Transcatheter Aortic Valve Implantation: Comparison of the Novel EuroScore II with Established Risk Scores

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Key Words
Risk-scoring system · Aortic stenosis · Transcatheter aortic valve implantation

Abstract
Objectives: In the evaluation of patients considered for transcatheter aortic valve implantation (TAVI), the EuroScore II might be superior to established risk scores. Methods: We assessed the performance of the EuroScore II in predicting mortality in a cohort of 350 TAVI patients. Results: The EuroScore II and the logistic EuroScore were higher in nonsurvivors compared to survivors at 30 days (12.6 ± 1.8 vs. 7.5 ± 0.3%, \(p < 0.001\)) for EuroScore II, and 27.7 ± 2.8 vs. 22.1 ± 0.8%, \(p = 0.04\) for logistic EuroScore), while the STS-PROM score did not differ (7.3 ± 0.8 vs. 6.4 ± 0.3%, \(p = 0.09\)). The area under the curve (AUC) was 0.70 for the EuroScore II, 0.61 for the logistic EuroScore and 0.59 for the STS-PROM score for predicting 30-day mortality. Based on the estimated 30-day mortality risk, 3 risk groups were identified, a low-risk (EuroScore II ≤4%, 30-day mortality 1.2%), an intermediate-risk (EuroScore II between 4% and 9%, 30-day mortality 8.6%) and a high-risk group (EuroScore II >9%, 30-day mortality, 17.1%; \(p = 0.03\)). Regarding cumulative mortality, the AUC was 0.67 for the EuroScore II, 0.62 for the logistic EuroScore and 0.55 for the STS-PROM score for predicting mortality at total follow-up. Conclusions: In this patient cohort, the EuroScore II performed best in predicting short- and long-term mortality.

Introduction
Degenerative aortic stenosis (AS) is the most common valvular heart disease in Western communities and is continuously increasing in the aging population [1]. Without intervention, symptomatic AS has a poor outcome with an average survival of less than 4 years [2]. Until recently, surgical aortic valve replacement (AVR) has been considered as standard treatment for such patients [2, 3]. However, for patients not referred to open-heart surgery due to advanced age, severe comorbidities or an expected high operative mortality, transcatheter aortic valve implantation (TAVI) has become a less invasive treatment alternative [2, 4–6].
To predict morbidity and mortality after surgical procedures, different risk-scoring algorithms based on both patient history and functional status have been established. The most widely applied risk-scoring systems are the logistic European System for Cardiac Operative Risk Evaluation (EuroScore) and the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score. A novel version of the EuroScore, the EuroScore II, has recently been developed as the logistic EuroScore was known to overestimate mortality rates, in particular in high-risk patients [7–10]. In patients undergoing AVR, the STS score has been shown to better predict mortality compared to the logistic EuroScore [11, 12]. In addition to these well-established risk algorithms, several other risk-scoring systems such as the Cleveland Clinic Score or the Australian risk prediction model have been proposed as risk models in patients with valvular or coronary heart disease [13–16].

In the era of TAVI, it is of particular importance to identify patients with severe AS at high surgical risk who may benefit from this treatment. Accordingly, different risk algorithms are commonly used in addition to a comprehensive clinical risk stratification of an individual patient. TAVI is currently recommended for high-risk or inoperable patients including those with surgical contraindications, severe comorbidities or increased surgical risk [17]. However, the reliability of the established risk algorithms in patients evaluated for TAVI has recently been questioned. The logistic EuroScore, the STS-PROM score and the EuroScore II have not been validated to specifically predict mortality after TAVI. Despite the wide use of these risk scores in the context of TAVI, there is little data on the performance of the revised EuroScore II in comparison to the established risk models, i.e. the logistic EuroScore and the STS-PROM score. Indeed, prediction of mortality rates in patients evaluated for TAVI differs considerably among different scoring systems with conflicting results among different studies. In transthoracically treated patients, the study by Haensig et al. [18] showed that the STS-PROM score was a better predictor of 30-day mortality than the new EuroScore II, while another study did not confirm these results [19]. In the two most recent studies including both transapically and transfemorally treated patients, the EuroScore II tended to perform better with regard to discriminatory power compared to the logistic EuroScore and the STS-PROM score, in particular in the transfemorally treated patient cohort [20, 21].

The aim of this study was to further characterize the performance of the EuroScore II in comparison to the logistic EuroScore and the STS-PROM score in a larger TAVI population with regard to both early and late mortality, and to delineate different EuroScore II risk categories (low risk, intermediate risk and high risk) with respect to survival after TAVI.

### Methods

#### Patients and Procedures

The present study included 350 patients with severe AS (mean transaortic systolic pressure gradient of ≥40 mm Hg, or an aortic valve area of <1.0 cm² or <0.6 cm²/m²) undergoing TAVI at the University Hospital Zurich, Switzerland. All patients were evaluated for TAVI by a multidisciplinary board of interventional cardiologists, cardiac surgeons, cardiac anesthesiologists and imaging specialists (i.e. a ‘heart team’) [11]. In all patients, comprehensive clinical assessment, transthoracic and transesophageal echocardiography, coronary angiography and multislice computed tomography were performed before the procedure. The procedure was performed in the cardiac catheterization laboratory or the hybrid operation room. Procedural details have previously been reported [22]. In 341 patients, the procedure was performed under general anesthesia, and in 9 patients it was done under local anesthesia. The Medtronic CoreValve (26, 29 and 31 mm), the Edwards SAPIEN (23, 26 and 29 mm), and the Medtronic Engager (26 mm) prostheses were utilized. All scores were calculated online using the official websites and calculators (logistic EuroScore: http://euroscore.org/calcold.html; EuroScore II: http://euroscore.org/calc.html; STS-PROM score: http://riskcalc.sts.org/STSW ebRiskCalc273/de.aspx). The study was approved by the local ethical committee. Written informed consent was obtained from all patients.

#### Statistical Analysis

Continuous variables are presented as means ± standard error, or medians and interquartile range, as appropriate. Categorical variables are given as frequencies and percentages. Prognostic results are the numbers of events that occur over time. They were expressed: (1) in absolute terms (e.g. 30-day mortality rates), (2) in relative terms (e.g. risk from prognostic scores) and (3) in survival curves (cumulative events over time). Continuous variables were tested for differences with ANOVA or the Mann-Whitney/Kruskal-Wallis test, as appropriate. Categorical variables were tested by Pearson’s χ² test or Fisher’s exact test as appropriate. Correlation analysis of different scores was performed using Spearman’s correlation coefficient. Discriminatory power was assessed by receiver-operator characteristic (ROC) curve evaluation and the area under the curve (AUC) accompanied by 95% confidence intervals (CIs). Calibration, comparing the observed and the predicted probabilities for equal-sized quantiles of risk, was evaluated by the Hosmer-Lemeshow goodness-of-fit test. Cut-off points were calculated using exhausted χ² Automatic Interaction Detection (exhausted CHAID), a type of decision tree technique, based upon adjusted significance testing (Bonferroni testing). The Cox proportional hazards model was used to estimate the hazard ratio and CIs, respectively, to adjust for differing risk factor distributions between groups. A two-sided p
value of $<0.05$ was considered statistical significant. All statistical analyses were performed using IBM-SPSS version 20 (IBM Corp., Armonk, N.Y., USA) and R 2.15 for Windows.

### Results

#### Patient Characteristics

Mean age was 82.2 ± 7.1 years. Sex was equally distributed (48.9% male). Transfemoral procedures were performed in 83% ($n = 289$) of the patients and transapical procedures in 17% ($n = 61$), respectively. The CoreValve prosthesis was used in 65% ($n = 189$) of the patients, the Edwards SAPIEN prosthesis in 45% ($n = 158$) and the Medtronic Engager prosthesis in 1% ($n = 3$), respectively. Patients were at high surgical risk as expressed by a mean EuroScore II of 8.0 ± 0.3%, a mean logistic EuroScore of 22.6 ± 0.7% and a mean STS-PROM score of 6.5 ± 0.3%.

In patients treated with an Edwards SAPIEN prosthesis, mean EuroScore II was 8.3 ± 0.6%, mean logistic EuroScore 22.5 ± 1.1% and mean STS-PROM score 6.5 ± 0.3%. For all three scores, there were no significant differences between the two prosthesis types ($p = 0.85$ for logistic EuroScore, $p = 0.87$ for Euro-Score II, and $p = 0.80$ for STS-PROM score, respectively).

Half of the patients (i.e. 49.7% or 174/350) had a logistic EuroScore $>20\%$, and 14.6% (51/350) a STS-PROM score $>10\%$. The patient characteristics are summarized in table 1.

#### Predicted versus Observed Mortality at 30 Days

Thirty-day all-cause mortality was 9.1% without any significant difference between access sites (14.8% in transapically treated patients vs. 8.0% in transfemorally treated patients, $p = 0.09$) and prosthesis types (7.0% in patients treated with an Edwards SAPIEN prosthesis vs. 10.5% in patients treated with a Medtronic CoreValve prosthesis, $p = 0.18$).

Regarding risk score quartiles, the logistic EuroScore overestimated mortality, in particular in high-risk patients for whom mortality was overestimated by a factor 3.3. The STS-PROM score underestimated mortality, in particular in low-risk patients for whom mortality was 2.5 times higher than predicted (table 2). The EuroScore II and the logistic EuroScore were significantly higher in
patients who died within the first 30 days after the procedure compared to those who survived (12.6 ± 1.8 vs. 7.5 ± 0.3%, p < 0.001 for the EuroScore II; fig. 1a; and 27.7 ± 2.8 vs. 22.1 ± 0.8%, p = 0.04 for the logistic EuroScore; fig. 1b). The STS-PROM score did not differ between nonsurvivors and survivors at 30 days (7.3 ± 0.8 vs. 6.4 ± 0.3%, p = 0.09; fig. 1c).

All-cause mortality at 30 days was 12.0% in the first half of patients, and 6.3% in the second half (p = 0.07), reflecting the learning curve of the operators. In patients treated with an Edwards SAPIEN prosthesis, all-cause mortality at 30 days was 9.1% in the first half and 4.9% in the second half of patients (p = 0.31), and in those treated with a Medtronic CoreValve prosthesis, it was 13.7% in the first and 7.4% in the second half (p = 0.16), respectively. There was no significant difference with regard to 30-day all-cause mortality between prosthesis types (p = 0.35 in the first half, and p = 0.50 in the second half of patients, respectively).

Both logistic EuroScore as well as EuroScore II were significantly higher in the first half of patients compared

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**Table 2.** Risk quartiles of the EuroScore II, the logistic EuroScore and the STS-PROM score

<table>
<thead>
<tr>
<th></th>
<th>Patients at risk</th>
<th>Observed mortality, %</th>
<th>Predicted mortality, %</th>
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</thead>
<tbody>
<tr>
<td>EuroScore II</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st</td>
<td>85</td>
<td>1.2</td>
<td>2.23±0.08</td>
</tr>
<tr>
<td>2nd</td>
<td>91</td>
<td>8.8</td>
<td>4.62±0.08</td>
</tr>
<tr>
<td>3rd</td>
<td>87</td>
<td>10.3</td>
<td>8.07±0.13</td>
</tr>
<tr>
<td>4th</td>
<td>87</td>
<td>16.1</td>
<td>17.04±0.70</td>
</tr>
<tr>
<td>Log EuroScore</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st</td>
<td>87</td>
<td>4.6</td>
<td>8.89±0.30</td>
</tr>
<tr>
<td>2nd</td>
<td>88</td>
<td>9.1</td>
<td>15.89±0.24</td>
</tr>
<tr>
<td>3rd</td>
<td>88</td>
<td>10.2</td>
<td>24.05±0.29</td>
</tr>
<tr>
<td>4th</td>
<td>8</td>
<td>12.6</td>
<td>41.75±1.35</td>
</tr>
<tr>
<td>STS score</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1st</td>
<td>89</td>
<td>6.7</td>
<td>2.74±0.06</td>
</tr>
<tr>
<td>2nd</td>
<td>87</td>
<td>6.9</td>
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</tr>
<tr>
<td>3rd</td>
<td>90</td>
<td>8.9</td>
<td>5.86±0.08</td>
</tr>
<tr>
<td>4th</td>
<td>84</td>
<td>14.3</td>
<td>13.55±0.75</td>
</tr>
</tbody>
</table>

**Fig. 1.** Risk scores in survivors (S) and nonsurvivors (NS) after TAVI at 30 days (a-c) and at total follow-up (d-f). p ≤ 0.05 denotes a significant difference between survivors and nonsurvivors.
to the second half (24.3 ± 1.1 vs. 21.0 ± 1.0, p = 0.009 for the logistic EuroScore, and 10.0 ± 0.6 vs. 6.0 ± 0.3 for the EuroScore II, p < 0.001), while, in contrast, the STS-PROM score was lower in the first half of patients (5.7 ± 0.3 vs. 7.3 ± 0.5, p = 0.02).

Patients with a reduced left ventricular ejection fraction (LVEF) <35% had a higher observed 30-day mortality compared to those with a LVEF >35% (17.9 vs. 7.7%, p = 0.03). In patients with a LVEF <35%, both the EuroScore II as well as the logistic EuroScore were higher compared to patients with a LVEF >35% (13.1 ± 1.5 vs. 7.3 ± 0.3%, p < 0.001 for the EuroScore II, and 37.5 ± 2.8 vs. 20.4 ± 0.7%, p < 0.001 for the logistic EuroScore, respectively). The STS-PROM score did not differ significantly between patients with a LVEF <35% and those with a LVEF >35% (7.2 ± 0.8 vs. 6.2 ± 0.3%, p = 0.29).

Risk Score Performance in Predicting 30-Day Mortality

Spearman’s correlation coefficient revealed a moderate correlation between the EuroScore II and the logistic EuroScore (r = 0.59, p < 0.001), while both the EuroScore II and the logistic EuroScore only weakly correlated with the STS-PROM score (r = 0.30, p < 0.001 for the EuroScore II, and r = 0.32, p < 0.001 for the logistic EuroScore, respectively).

ROC curve analysis showed that all three risk scores were suboptimal in predicting 30-day mortality (fig. 2). The EuroScore II had a better predictive value compared to the logistic EuroScore or the STS-PROM Score. In ROC analysis, the AUC was 0.70 (95% CI 0.61–0.78, p < 0.001) for the EuroScore II, 0.61 (95% CI 0.50–0.72, p = 0.04) for the logistic EuroScore and 0.59 (95% CI 0.49–0.69, p = 0.09) for the STS-PROM score for predicting 30-day mortality. A cut-off value of 20% for the logistic EuroScore had a sensitivity of 0.63 and a specificity of 0.52 in predicting 30-day mortality. A cut-off value of 10% for the STS-PROM Score had a sensitivity of 0.22 and a specificity of 0.86 in predicting 30-day mortality. The Hosmer-Lemeshow test did not show any lack of calibration for all scores. Calibration by Hosmer-Lemeshow χ² was 10.3 (p = 0.15) for the EuroScore II, 12.1 (p = 0.25) for the logistic EuroScore and 2.6 (p = 0.96) for the STS-PROM score, respectively.

Risk Score Performance in Predicting Cumulative Mortality

Mean follow-up was 410 ± 22 days. Regarding cumulative mortality, the EuroScore II and the logistic EuroScore were significantly higher in patients who died compared to those who survived following TAVI (11.2 ± 1.0 vs. 7.1 ± 0.3%, p < 0.001 for the EuroScore II; fig. 1d; and 27.1 ± 1.7 vs. 21.4 ± 0.8%, p = 0.001 for the logistic EuroScore; fig. 1e). Regarding cumulative mortality, the STS-PROM score did not differ between nonsurvivors and survivors (6.7 ± 0.5 vs. 6.5 ± 0.3%, p = 0.09; fig. 1f). In ROC analysis for predicting cumulative mortality, the AUC was 0.67 (95% CI 0.61–0.74, p < 0.001) for the EuroScore II, 0.62 (95% CI 0.55–0.69, p = 0.001) for the logistic EuroScore and 0.55 (95% CI 0.48–0.62, p = 0.19) for the STS-PROM score.

Low-Risk, Intermediate-Risk and High-Risk TAVI Patients Based on EuroScore II Calculations

According to calculated optimal cut-off points for the EuroScore II, the patient cohort was divided into three groups: a low-risk group with a EuroScore II ≤4% and a 30-day mortality rate of 1.2%, an intermediate-risk group with a EuroScore II between 4 and 9% and a 30-day mortality rate of 8.6%, and a high-risk group with a EuroScore II >9% and a 30-day mortality rate of 17.1% (p = 0.03; fig. 3a). The Cox proportional hazards model
Discussion

This study demonstrates that in TAVI patients the EuroScore II outperformed the logistic EuroScore and the STS-PROM score with regard to discriminatory power in predicting all-cause mortality at 30 days as well as over the entire follow-up period. However, all three scores are not ideally suited to predict mortality in these patients. Nevertheless, based on estimated 30-day mortality risk as calculated by the EuroScore II, three different risk groups of mortality (low, intermediate and high risk, respectively) could be defined.

Despite the fact it has been primarily designed for patients considered for major cardiac surgery, in particular coronary artery bypass grafting, the logistic EuroScore has been widely used in patients evaluated for AVR [23]. However, a progressive loss of calibration of the logistic EuroScore has been observed over time with expected and observed mortalities diverging as both patient risk profiles and operative mortalities changed since its introduction in 1999 [23, 24]. It is well-known that in patients evaluated for AVR, the logistic EuroScore overestimates the risk of mortality, in particular in high-risk and in elderly patients [25]. Of note, these patients are potential candidates for transcatheter procedures (TAVI) in which optimal risk prediction for patient selection is particularly important. Previous studies have demonstrated that the logistic EuroScore clearly overestimated mortality in TAVI patients, in particular in those at high risk [19, 25, 26]. In line with these data, in our TAVI patient cohort, the logistic EuroScore clearly overestimated 30-day mortality, in particular in patients at high risk by a factor of 3.3. These findings are important since overestimation of the mortality risk might lead the heart team to select TAVI, although AVR would still have been feasible. Of note, current real-life registries demonstrate a general
trend towards lower risk patients selected for TAVI [27, 28]; based on our results such patients might be at an even lower risk than suggested by currently used risk scores. More importantly, overestimation of procedural risk might shift potential TAVI candidates to medical management.

In contrast to the logistic EuroScore, the STS-PROM score underestimated the observed 30-day mortality of 9.1%, predicting a 30-day mortality of 6.5%. In low-risk patients the mortality was 2.5 times higher than predicted. Previous studies have reported similar findings after cardiac surgery [12]. Piazza et al. [29] compared the performance of the logistic EuroScore to the STS score in TAVI patients. In line with observations in patients undergoing AVR, the STS score also had a better predictive ability than the logistic EuroScore in TAVI patients [11, 25, 29].

The EuroScore II was recently proposed as an updated version of the logistic EuroScore to improve risk prediction after cardiac surgery [8, 10, 30]. Variables such as poor mobility, NYHA functional class and diabetes were incorporated into the new risk model. Different categories of renal impairment, pulmonary hypertension and LVEF, as well as different grades of pulmonary hypertension were included into the risk algorithm. Reduced mobility due to neurological dysfunction or to musculoskeletal dysfunction was also added. Despite these efforts, a multicenter validation study demonstrated that the EuroScore II did not improve the performance in the higher tertiles of risk in patients undergoing major cardiac surgery [8, 30]. Moreover, Chalmers et al. [31] recently demonstrated that the EuroScore II failed to improve on the original logistic EuroScore model for isolated AVR and miscellaneous procedures.

Comparing the three scores in TAVI patients in this patient cohort, the EuroScore II outperformed the two other scores in predicting 30-day mortality with an AUC of 0.70 compared to 0.61 for the logistic EuroScore and 0.59 for the STS-PROM score, respectively. Moreover, both versions of the EuroScore were significantly different between nonsurvivors and survivors at 30 days, while the STS-PROM score was not. In line with the usual learning curve for establishing new procedures, mortality tended to be lower in the second half of patients. Interestingly, both versions of the EuroScore were lower in the second half of patients, while contradictory results were obtained for the STS-PROM score. Thus, the STS-PROM score in particular seems to address patient characteristics less well in the TAVI population. Patients with a reduced LVEF are an important subgroup of patients in the population evaluated for TAVI, and this subgroup is known to have an increased risk of mortality after TAVI. Both versions of the EuroScore correctly identified the increased risk of mortality in patients with reduced LVEF, while the STS-PROM score predicted similar 30-day mortality rates for both patient groups. In line with our findings two studies recently compared the performance of the EuroScore II in TAVI patients to the logistic EuroScore and the STS-PROM score with regard to short-term mortality. In both studies, the EuroScore II tended to have a better discriminatory power in 30-day mortality risk prediction compared to the logistic EuroScore, in particular in transfemorally treated patients [20, 21].

Based on the current data from our TAVI patient cohort, a low-risk, intermediate-risk and high-risk patient group was defined utilizing the EuroScore II. Patients with EuroScores below 4% comprised the low-risk group (observed 30-day mortality of 1.2%), those with values between 4 and 9% the intermediate risk group (observed 30-day mortality of 8.6%), and those with EuroScores above 9% the high-risk group (observed 30-day mortality of 17.1%), respectively. In addition to short-term outcome prediction, a subdivision of patients within these three risk groups significantly differentiated cumulative survival after TAVI. The proposed stratification into different risk groups might help in part to anticipate expected procedural complications and postinterventional mortality in individual patients evaluated for TAVI. However, risk categories and cut-off values for the EuroScore II need to be evaluated prospectively in large TAVI patients cohorts and better refined to further improve the predictive discriminative power of this score, which still performs below expectations.

With regard to long-term mortality prediction, both the EuroScore and the STS-PROM score have been shown to predict mortality after cardiac surgery for up to 14 years [32, 33]. Interestingly, the STS-PROM score performed nearly as well in predicting long-term survival after cardiac surgery compared to 30-day mortality [33]. In our TAVI patient cohort, the EuroScore II outperformed the logistic EuroScore and the STS-PROM score with regard to discriminatory power in the prediction of cumulative mortality. Interestingly, the EuroScore II predicted long-term mortality almost as well as short-term mortality. To our knowledge, this is the first study comparing the EuroScore II to established scores in predicting long-term outcome in TAVI patients. Hence, the EuroScore II can be used to estimate the likelihood not only of short-term, but also of long-term survival. Besides the prediction of short-term mortality, the ability to predict long-
term outcome after TAVI is important, and will even become more important with the aging of the population and the anticipated extension of transcatheter procedures to younger patients.

However, all currently available risk scores have substantial limitations. Predicted mortality varies considerably depending on the risk score utilized as different variables with diverse weighting are incorporated. All scores were derived from cardiac databases of patients undergoing cardiac surgery, mainly coronary artery bypass grafting, and both age and risk profiles of patients undergoing cardiovascular procedures have changed considerably since the logistic EuroScore and the STS-PROM score were established [34]. With regard to TAVI, patients evaluated for transcatheter procedures are somewhat different to those scheduled for heart surgery. Patients currently undergoing TAVI are a highly selected group of high-risk elderly patients with numerous comorbidities, and these risk characteristics were underrepresented in the patients in whom risk algorithms were established, and various additional variables such as liver disease, frailty, porcelain aorta, or previous radiotherapy are not included in current risk models [29, 35, 36]. In line with previous studies, all three evaluated scores overall had suboptimal discriminatory power and calibration in the TAVI patient population [29]. In our opinion, a risk-scoring system specifically developed for TAVI patients is imperative as it has the potential to: (1) improve patient selection for transcatheter versus surgical procedures and (2) enhance short- and long-term outcome prediction after TAVI. However, it is of utmost importance to emphasize the need for clinical assessment of patients, preferably by a multidisciplinary heart team.

A limitations of this study is its single-center design. However, comprehensive clinical data was available in all patients treated with both the Edwards SAPIEN and the Medtronic CoreValve prosthesis.

In conclusion, this study demonstrates that the EuroScore II is superior to both the logistic EuroScore and the STS-PROM score in predicting both short-term and cumulative long-term mortality in patients undergoing TAVI. Furthermore, this study emphasizes the specific need for a risk algorithm designed for TAVI patients, and the importance of a thorough clinical assessment which allows choice of an individualized strategy for each patient.

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