Predicting 5-Year Clinical Outcomes After Transcatheter or Surgical Aortic Valve Replacement (a Risk Score from the SURTAVI Trial)

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Risk prediction scores for long-term outcomes after transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR) are lacking. This study aimed to develop preprocedural risk scores for 5-year clinical outcomes after TAVI or SAVR. This analysis included 1,660 patients at an intermediate surgical risk with severe aortic stenosis randomly assigned to TAVI (n = 864) or SAVR (n = 796) from the SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trial. The primary end point was a composite of all-cause mortality or disabling stroke at 5 years. The secondary end point was a composite of cardiovascular mortality or hospitalizations for valve disease or worsening heart failure at 5 years. Preprocedural multivariable predictors of clinical outcomes were used to calculate a simple risk score for both procedures. At 5 years, the primary end point occurred in 31.3% of the patients with TAVI and 30.8% of the patients with SAVR. Preprocedural predictors differed between TAVI and SAVR. Baseline anticoagulant use was a common predictor for events in both procedures, whereas male sex and a left ventricular ejection fraction <60% were significant predictors for events in patients with TAVI and SAVR, respectively. A total of 4 simple scoring systems were created based on these multivariable predictors. The C-statistics of all models were modest but performed better than the contemporary risk scores. In conclusion, preprocedural predictors of events differ between TAVI and SAVR, necessitating separate risk models. Despite the modest predictive value of the SURTAVI risk scores, they appeared superior to other contemporary scores. Further research is needed to strengthen and validate our risk scores, possibly by including biomarker and echocardiographic parameters. © 2023 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/) (Am J Cardiol 2023;200:78−86)

Transcatheter aortic valve implantation (TAVI) has become an alternative to surgical aortic valve replacement (SAVR) for the treatment of severe symptomatic aortic stenosis (AS) in patients of all surgical risk levels. As survival rates after TAVI increase and as indications are shifting to younger patients with lower risk, it has become more important to develop predictive tools focused on longer-term outcomes. Preprocedural risk prediction models can guide the decision for whether a patient should undergo TAVI or SAVR and can help in the expectation management for both patients and clinicians. Traditional scores such as the Society of Thoracic Surgery (STS) Predicted Risk of Mortality (STS-PROM) score or the European System for Cardiac Operative Risk Evaluation (EuroSCORE) II have been developed to predict periprocedural mortality for surgical procedures.[1,2] As such, they have suboptimal performance when applied to TAVI populations and have poor discrimination for longer-term outcomes.[1,3−6] In addition, contemporary scores include several variables and therefore are not always easy and practical to use in daily clinical practice. Few studies on risk predictors in patients who underwent TAVI have recently been published. However, relatively small cohorts or only patients with low-flow, low-gradient AS have been included.[7,8] The SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trial randomly allocated patients with symptomatic severe AS who were at an intermediate surgical risk to either self-expanding, supra-annular TAVI, or SAVR. In the present analysis, we aimed to develop simple SURTAVI risk scores based on the preprocedural variables to effectively stratify risk at 5 years after TAVI or SAVR.

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See page 84 for Declaration of Conflict of Interest.

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Methods

The SURTAVI trial details, including the inclusion and exclusion criteria, have been previously reported.[9] In brief, 1,660 patients with severe symptomatic severe AS who were deemed to be at an intermediate operative risk (3% to 15%) by a multidisciplinary screening committee based on the STS-PROM score and other coexisting co-morbidities underwent attempted TAVI with a supra-annular, self-expanding CoreValve or Evolut R bioprosthesis (Medtronic, Minnesota) or SAVR (surgeons discretion). Patients were enrolled from June 19, 2012, to June 30, 2016, at 87 centers in Canada, Europe, and the United States. The SURTAVI trial followed the principles of the Declaration of Helsinki and Good Clinical Practice. Each institutional review board or ethics committee approved the trial protocol and all patients provided written informed consent.

Patient assessments were performed at baseline; hospital discharge; 30 days; 6, 12, and 18 months; and annually through 5 years after the procedure. An independent clinical events committee adjudicated all the adverse clinical events and an independent core laboratory evaluated the available echocardiograms at baseline, discharge, 6 and 12 months, and 2 and 5 years.[10] The preprocedural clinical characteristics, medications, echocardiographic parameters, and frailty factors used to derive the risk scores were obtained from the screening and baseline data collected on the Case Report Form and Clinical Study Report.

The primary end point of this analysis was the composite of all-cause mortality or disabling stroke at 5 years. The secondary end point was the composite of cardiovascular mortality or hospitalization for aortic valve disease or worsening heart failure at 5 years. Complete definitions of both end points can be found in the original SURTAVI 5-year publication.[11]

Our primary analysis cohort included patients who underwent an attempted TAVI or SAVR (modified intention-to-treat population). Categorical variables are reported as counts and percentages and compared using the chi-square or Fisher's exact test, where appropriate. Continuous variables are presented as mean ± SD and compared using the Student's *t* test.

A univariate analysis was performed using the Cox proportional hazards for the TAVI and SAVR cohorts separately and for each study end point. The selection of the variables included in the univariate model was based on clinical relevance and included preprocedural demographic and clinical characteristics, medications, frailty factors, and echocardiographic parameters. Variables with >10% missing data were not considered (Supplementary Tables 1 and 2).

The multivariable model was built using the best Akaike information criterion (AIC) subsets to ensure that the variables considered in the univariate analysis with the best discriminative performance were selected. To make the score easy to use in the clinical setting while not compromising its accuracy, a total of 5 variables were fitted. The multivariate models were ranked by AIC from the smallest to the largest, and the final 5-variable model was chosen to be the one with the smallest AIC for the TAVI and SAVR cohorts separately and for each study end point.

The 5-variable multivariate models were used to calculate the SURTAVI risk scores based on a weighted calculation of the parameter estimates associated with each of the predictor variables. The risk levels were defined as low (quantile 1 [Q1]), medium (Q2 and Q3), and high (Q4). Kaplan−Meier estimates for each study end point and patient cohort were plotted by risk level. The discriminative performance of the SURTAVI risk scores were assessed with Harrel C-statistic and compared with the traditional STS-PROM score. Receiver-operator characteristic (ROC) curves were also calculated. The results were considered statistically significant when the $p < 0.05$. Supplementary Figure 1 shows the statistical method flow chart implemented in this study. All statistical analyses were performed using the SAS software, version 9.4 (SAS Institute, Cary, North Carolina) and R (R Core Team, 2021).

Results

The SURTAVI 5-year outcomes have been previously reported.[11] A total of 1,660 patients underwent an attempted TAVI (n = 864) or SAVR (n = 796). The mean age was 79.8 ± 6.2 years, 43.6% were women, and the mean STS-PROM was 4.5 ± 1.6%.

The clinical 5-year follow-up was available for 93.7% (n = 503) of the patients with TAVI and 95.5% (n = 426) of the patients with SAVR (Supplementary Figure 2). The echocardiographic 5-year follow-up was available for 72.6% (n = 390) and 70.0% (n = 312) of patients with TAVI and SAVR, respectively. At 5 years of follow-up, the primary end point occurred in 31.3% (n = 255) of patients with TAVI and 30.8% (n = 217) of patients with SAVR (hazard ratio [HR] 1.02, 95% confidence interval [CI] 0.85 to 1.22, p = 0.85). In the TAVI cohort, 30.0% of the patients (n = 243) died compared with 28.7% (n = 200) in the surgery cohort (HR 1.06, 95% CI 0.88 to 1.28, p = 0.55), and 4.1% of the patients who underwent TAVI (n = 31) versus 5.8% (n = 40) of those who underwent surgery experienced a disabling stroke (HR 0.69, 95% CI 0.43 to 1.10, p = 0.12).

Cardiovascular mortality was similar between groups; TAVI 17.8% (n = 136) versus SAVR 17.4% (n = 116; p = 0.84). Hospitalizations for aortic valve disease or worsening heart failure at 5 years occurred in 23.9% (n = 180) of the patients with TAVI and 20.8% (n = 136) of the patients with SAVR (p = 0.13).[11]

Baseline clinical characteristics, medications, and echocardiographic parameters of patients with and without the primary end point are listed in Table 1 and with and without the secondary end point in Supplementary Table 3. The univariate preprocedural predictors of the primary and secondary end points are listed in Supplementary Tables 4 and 5, respectively.

The multivariate preprocedural parameters associated with the primary end point are listed in Table 2. The significant predictors in the TAVI group included: male sex (HR 1.47, 95% CI 1.12 to 1.93, p = 0.006), chronic lung disease (HR 1.52, 95% CI 1.18 to 1.967, p = 0.001), 5 m gait speed >6 seconds (second) or wheelchair-bound (HR 1.59, 95% CI 1.23 to 2.07, p <0.001), and anticoagulant use (HR 1.68, 95% CI 1.28 to 2.22, p <0.001). The multivariate model also included a history of diabetes, which interestingly, in

Table 1
Baseline characteristics of TAVI and SAVR patients with and without the primary endpoint

	All-cause mortality or disabling stroke at 5 years			
	TAVI		SAVR	
	No Event (N=609)	Event (N=255)	No Event (N=579)	Event (N=217)
Baseline Characteristics				
Age, years	79.7 ± 6.1	80.3 ± 6.6	79.4 ± 6.0	80.6 ± 6.2
Male	331 (54.4)	167 (65.5)	301 (52.0)	137 (63.1)
NYHA class III/IV	361 (59.3)	159 (62.4)	328 (56.6)	135 (62.2)
Diabetes mellitus	217 (35.6)	79 (31.0)	192 (33.2)	85 (39.2)
Creatinine level >2 mg/dl	7 (1.1)	7 (2.7)	12 (2.1)	5 (2.3)
History of hypertension	561 (92.1)	240 (94.1)	523 (90.3)	196 (90.3)
Prior stroke	38 (6.2)	19 (7.5)	36 (6.2)	21 (9.7)
Prior TIA	40 (6.6)	18 (7.1)	31 (5.4)	15 (6.9)
Peripheral vascular disease	190 (31.2)	76 (29.8)	165 (28.5)	73 (33.6)
Cerebrovascular disease	107 (17.6)	44 (17.3)	83 (14.3)	47 (21.7)
Chronic lung disease/COPD	192 (31.6)	113 (44.5)	187 (32.3)	80 (36.9)
Pre-existing pacemaker	56 (9.2)	31 (12.2)	55 (9.5)	24 (11.1)
Coronary artery disease	365 (59.9)	176 (69.0)	364 (62.9)	147 (67.7)
Prior CABG	96 (15.8)	40 (15.7)	93 (16.1)	44 (20.3)
Prior PCI	126 (20.7)	58 (22.7)	113 (19.5)	56 (25.8)
Prior myocardial infarction	81 (13.3)	44 (17.3)	80 (13.8)	31 (14.3)
Congestive heart failure	581 (95.4)	243 (95.3)	558 (96.4)	211 (97.2)
Angina	92 (15.1)	42 (16.5)	103 (17.8)	37 (17.1)
Atrial fibrillation/flutter	155 (25.5)	88 (34.5)	135 (23.3)	76 (35.0)
Home oxygen	8 (1.3)	10 (3.9)	13 (2.2)	8 (3.7)
BMI < 21 kg/m^2	13 (2.1)	7 (2.7)	19 (3.3)	2 (0.9)
5 m gait speed > 6 s or wheelchair bound	287 (49.0)	144 (59.0)	289 (52.2)	118 (55.7)
Grip strength < threshold	366 (62.5)	153 (62.4)	347 (61.6)	142 (66.7)
Falls in past 6 months	65 (10.7)	37 (14.5)	63 (10.9)	38 (17.5)
Baseline Medications				
SAPT	319 (52.4)	117 (45.9)	355 (61.3)	110 (50.7)
DAPT	149 (24.5)	68 (26.7)	51 (8.8)	37 (17.1)
Anticoagulants	109 (17.9)	77 (30.2)	110 (19.0)	66 (30.4)
Baseline Echocardiography (Core lab)				
LVEF < 60%	149 (24.5)	67 (26.3)	139 (24.1)	72 (33.5)
AVA, cm^2	0.76 ± 0.22	0.81 ± 0.26	0.77 ± 0.23	0.76 ± 0.20
AVAi, cm^2/m^2	0.40 ± 0.11	0.41 ± 0.12	0.40 ± 0.11	0.39 ± 0.10
Mean gradient, mmHg	47.6 ± 13.9	45.4 ± 13.5	47.75 ± 13.15	47.73 ± 14.91
Moderate/severe AR	20 (3.3)	7 (2.8)	19 (3.3)	5 (2.3)
Moderate/severe MR	26 (4.3)	13 (5.1)	30 (5.2)	5 (2.3)

Data presented as mean ± standard deviation or no. of patients (percentage).

AR = aortic regurgitation; AVA = aortic valve area; AVAi = aortic valve area index; BMI = body mass index; CABG = coronary artery bypass grafting; COPD = chronic obstructive pulmonary disease; DAPT = dual antiplatelet therapy; LVEF = left ventricular ejection fraction; MR = mitral regurgitation; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; SAPT = single antiplatelet therapy; TIA = transient ischemic attack.

the presence of all other factors, was associated with a lower risk of the primary end point, although not statistically significant (HR 0.79, 95% CI 0.60 to 1.04, p = 0.09).

The following baseline parameters were associated with the primary end point for patients with SAVR: older age (HR 1.04, 95% CI 1.02 to 1.07, p = 0.002), falls in the past 6 months (HR 1.61, 95% CI 1.13 to 2.29, p = 0.008), dual antiplatelet use (HR 2.20, 95% CI 1.53 to 3.17, p <0.001), anticoagulant use (HR 1.83, 95% CI 1.36 to 2.47, p <0.001), and left ventricular ejection fraction (LVEF) <60% (HR 1.59, 95% CI 1.20 to 2.12, p = 0.001).

The multivariate preprocedural parameters associated with the secondary end point are listed in Table 2. The significant predictors in the TAVI group included: male sex (HR 1.41, 95% CI 1.06 to 1.78, p = 0.02), previous myocardial infarction (HR 1.62, 95% CI 1.15 to 2.28, p = 0.006), atrial fibrillation/flutter (HR 1.70, 95% CI 1.31 to 2.22, p <0.001), and a larger aortic valve area (AVA) (HR 2.16, 95% CI 1.24 to 3.75, p = 0.006). In addition, previous coronary artery bypass grafting (CABG), in the presence of all other factors, was associated with a lower risk of the secondary end point in patients with TAVI (HR 0.55, 95% CI 0.37 to 0.81, p = 0.003).

The following baseline parameters were associated with the secondary end point for patients with SAVR: New York Heart Association class III/IV (HR 1.49, 95% CI 1.12 to 1.99, p = 0.006), cerebrovascular disease (HR 1.68, 95% CI 1.22 to 2.32, p = 0.001), home oxygen (HR 3.13, 95% CI 1.77 to 5.53, p <0.001), anticoagulant use (HR 1.65, 95%

Table 2
Multivariable pre-procedural predictors of the primary and secondary endpoint

		All-cause mortality or disabling stroke at 5 years		
		Parameter Estimate	HR (95% CI)	p-value
TAVI	Male	0.38	1.47 (1.12, 1.93)	0.006
	Chronic lung disease/COPD	0.42	1.52 (1.18, 1.97)	0.001
	5 m gait speed > 6 s or wheelchair bound	0.47	1.59 (1.23, 2.07)	<0.001
	Anticoagulants	0.52	1.68 (1.28, 2.22)	<0.001
	Diabetes mellitus	-0.24	0.79 (0.60, 1.04)	0.09
SAVR	Age	0.04	1.04 (1.02, 1.07)	0.002
	Falls in past 6 months	0.48	1.61 (1.13, 2.29)	0.008
	DAPT	0.79	2.20 (1.53, 3.17)	<0.001
	Anticoagulants	0.61	1.83 (1.36, 2.47)	<0.001
	LVEF < 60%	0.47	1.59 (1.20, 2.12)	0.001
		Cardiovascular mortality or hospitalization for valve disease or worsening heart failure at 5 years		
		Parameter Estimate	HR (95% CI)	p-value
TAVI	Male	0.34	1.41 (1.06, 1.87)	0.02
	Prior myocardial infarction	0.48	1.62 (1.15, 2.28)	0.006
	Atrial fibrillation/flutter	0.53	1.70 (1.31, 2.22)	<0.001
	AVA, cm^2	0.77	2.16 (1.24, 3.75)	0.006
	Prior CABG	-0.61	0.55 (0.37, 0.81)	0.003
SAVR	NYHA class III/IV	0.40	1.49 (1.12, 1.99)	0.006
	Cerebrovascular disease	0.52	1.68 (1.22, 2.32)	0.001
	Home oxygen	1.14	3.13 (1.77, 5.53)	<0.001
	Anticoagulants	0.50	1.65 (1.23, 2.22)	<0.001
	LVEF < 60%	0.33	1.39 (1.04, 1.84)	0.03

AVA = aortic valve area; CABG = coronary artery bypass grafting; COPD = chronic obstructive pulmonary disease; DAPT = dual antiplatelet therapy; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

CI 1.23 to 2.22, p <0.001), and LVEF <60% (HR 1.39, 95% CI 1.04 to 1.84, p = 0.03).

Based on the parameter estimates from the 5 multivariate predictors per outcome and per patient cohort, a weighted risk score calculation was performed (Table 3). The mean weighted risk score for the primary end point was 0.6 ± 0.4 for patients with TAVI and 3.5 ± 0.5 for patients with SAVR. For the secondary end point, the mean weighted risk score was 0.9 ± 0.4 for patients with TAVI and 0.5 ± 0.4 for patients with SAVR. The 3-level SURTAVI risk score system effectively stratified patients who were at low risk (Q1), medium risk (Q2 to Q3), and high risk (Q4) of the primary end point and secondary end points (Figure 1). The C-statistic for the primary end point was 0.61 (95% CI 0.58 to 0.64) for patients with TAVI and 0.61 (95% CI 0.58 to 0.65) for patients with SAVR. The C-statistic for the secondary end point was 0.59 (95% CI 0.56 to 0.63) for patients with TAVI and 0.62 (95% CI 0.59 to 0.66) for patients with SAVR.

Table 3
Weighted risk score calculation

	All-cause mortality or disabling stroke at 5 years
TAVI	(0.38 * male) + (0.42 * chronic lung disease) + (0.47 * 5 m gait speed > 6 s or wheelchair bound) + (0.52 * anticoagulants) − (0.24 * diabetes)
SAVR	(0.04 * age) + (0.48 * falls in past 6 months) + (0.79 * DAPT) + (0.61 * anticoagulants) + (0.47 * LVEF< 60%)
	Cardiovascular mortality or hospitalization for valve disease or worsening heart failure at 5 years
TAVI	(0.34 * male) + (0.48 * prior myocardial infarction) + (0.53 * atrial fibrillation) + (0.77 * AVA) − (0.61 * prior CABG)
SAVR	(0.40 * NYHA class III/IV) + (0.52 * cerebrovascular disease) + (1.14 * home oxygen) + (0.50 * anticoagulants) + (0.33 * LVEF< 60%)

AVA = aortic valve area; CABG = coronary artery bypass grafting; DAPT = dual antiplatelet therapy; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

The C-statistic of the STS-PROM score for the primary end point was 0.55 (95% CI 0.52 to 0.58) for patients with TAVI and 0.57 (95% CI 0.54 to 0.60) for patients with SAVR. The C-statistic of the STS-PROM score for the secondary end point was 0.52 (95% CI 0.49 to 0.55) for patients with TAVI and 0.56 (95% CI 0.53 to 0.60) for patients with SAVR. The ROC curves for the risk score and the STS-PROM score can be found in Supplementary Figure 3. Supplementary Figure 4 represents the ROC curves for the SURTAVI risk score, STS-PROM score, and EuroSCORE for the all-cause mortality at years 1 and 5.

Discussion

To the best of our knowledge, this study is the first to develop a treatment-specific risk score for patients with TAVI and SAVR using prospective randomized preprocedural data with long-term follow-up. The main findings of this work are as follows: (1) preprocedural predictors of 5-year outcomes after TAVI and SAVR differ, suggesting the need of treatment-specific risk scores. (2) Baseline

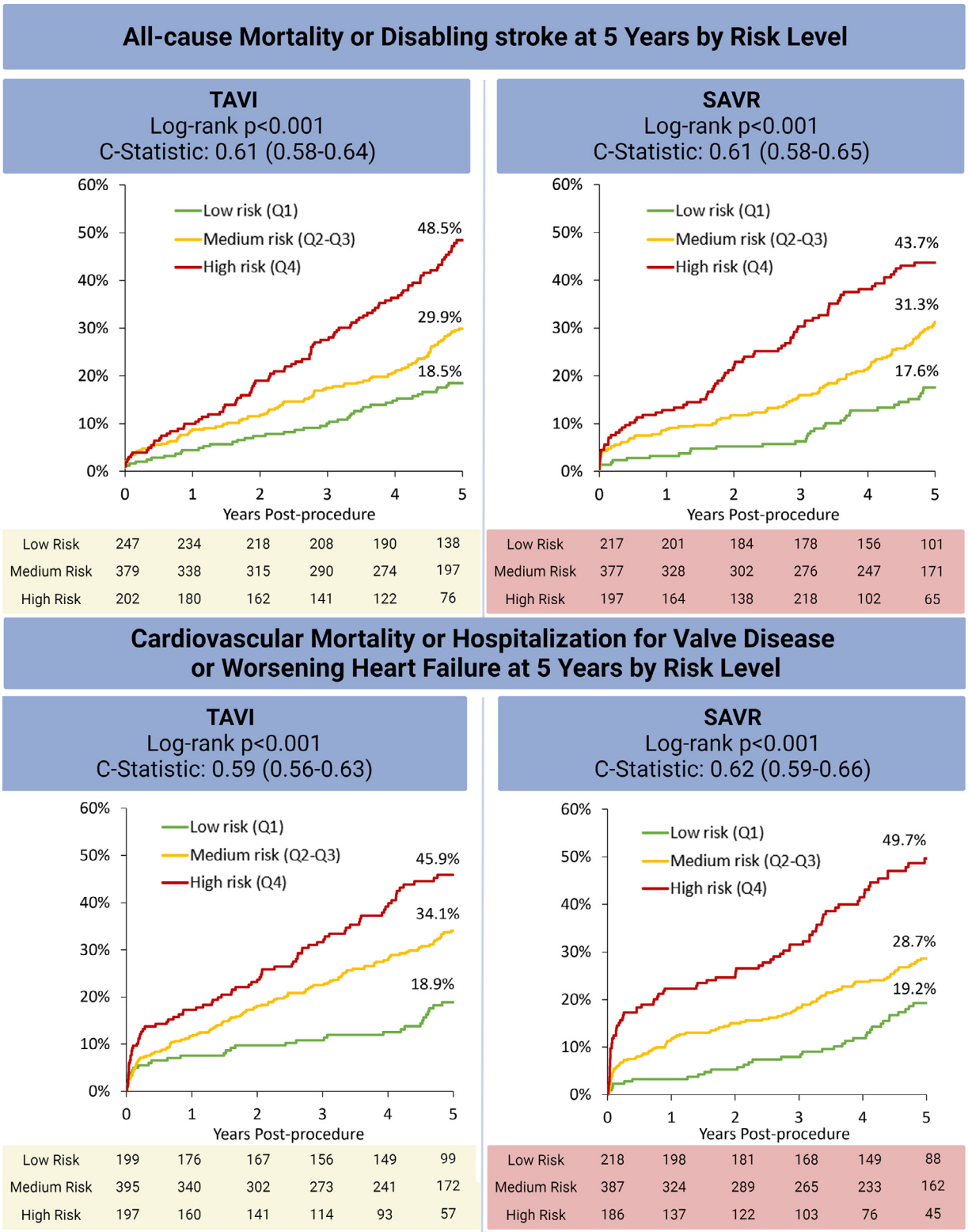

Figure 1. KM curves for the primary and secondary end points for TAVI and SAVR patients. Kaplan−Meier estimates of the 3-level SURTAVI risk score effectively stratified patients who were at low, medium and high risk of the primary and secondary end points. C-statistic shows the discriminative performance of the SURTAVI risk score.

anticoagulant use was a common predictor of adverse events in patients with TAVI and SAVR. (3) Male sex was a common predictor for worse outcomes in patients with TAVI, whereas a baseline LVEF <60% was a common predictor for worse outcomes in patients with SAVR. (4) Our

risk models had a modest predictive value but were more robust than other currently available risk scores.

Patients enrolled in the SURTAVI trial were eligible for either TAVI or SAVR and had an intermediate surgical perioperative risk. However, according to our analysis, the baseline parameters discriminative of the adverse outcomes differ between the TAVI and SAVR procedures. This suggests that the development of specific risk scores for TAVI and SAVR populations could help identify patients at a higher risk after aortic valve replacement (AVR).

Anticoagulant therapy before AVR was a common predictor for the primary end point after TAVI and SAVR and for the secondary end point after SAVR. In a previous report, anticoagulants were also predictive for adverse outcomes after TAVI in the women-only WIN-TAVI (Women's InterNational transcatheter aortic valve implantation) cohort.[12] This suggests that the use of anticoagulants at baseline potentially represents an "umbrella" marker for patients with more co-morbidities and therefore poor outcomes. The indications for anticoagulant use in patients who underwent AVR include stroke reduction in patients with atrial fibrillation and peripheral vascular disease or prevention of venous thromboembolism.[13,14] Separately, these factors were not selected as multivariate predictors. This suggests that, on their own, these variables may be underpowered as a predictor but are powered when combined in the "umbrella" term of anticoagulant use. Another potential reason can be the increased risk of bleeding with anticoagulant use, which could lead to higher mortality rates.[15,16] The interruption of anticoagulants during the procedure can also lead to an increased risk of ischemic complications, such as stroke, and therefore mortality. The ongoing POPular PAUSE (Periprocedural Continuation Versus Interruption of Oral Anticoagulant Drugs During Transcatheter Aortic Valve Implantation) trial (NCT04437303) will evaluate the possibility of the latter.

Male sex was associated with the primary and secondary outcomes in patients with TAVI only. It has become clear that the outcomes after TAVI differ between sex; although, data are conflicting and depends on the outcome studied.[17,18] In previous studies, men had a higher all-cause mortality risk after TAVI than women.[19,20] A possible explanation can be the difference in co-morbidities and thus a different risk profile between sexes before TAVI, such as higher rates of diabetes, coronary artery disease, previous myocardial infarction, percutaneous coronary intervention, and CABG in men.[21] In a review study, a "TAVI survival benefit" was seen in women who had better outcomes compared with SAVR, but this was not seen in men.[22] A recent meta-analysis confirmed this differential response of women and men to TAVI versus SAVR.[23] The exact reason for this difference is a still matter of speculation. Women may have better outcomes after TAVI, but the male sex as an adverse predictor for outcomes has not been shown in a large, randomized cohort before. A gender-specific approach and studies in patients with AS may help in gaining more insight into this question.

A baseline LVEF <60% was associated with the primary and secondary end points in patients with SAVR only. A reduced LVEF has been shown as a predictor for worse outcomes after SAVR in previous studies.[24,25] According to a study that randomly allocated patients to TAVI versus SAVR, patients with a normal LVEF (>50%) had favorable outcomes after TAVI, leading to lower mortality rates.[26] However, in the patients with a reduced LVEF, the type of treatment did not affect the mortality rate. A reduction in ejection fraction can be a marker of advanced AS and remodeling. Because AS contributes to left ventricular pressure overload and leads to ventricular hypertrophy, it may eventually result in a reduction in systolic function and decompensation.[25] In the European Society of Cardiology guidelines, an LVEF <50% in patients with AS without symptoms is an indication for AVR.[4] Thus, many patients with reduced ejection fraction get referred for AVR. Our study showed that an LVEF <60% had a poor discrimination for patients with TAVI, but it appeared to be associated with higher event rates after SAVR. More research is needed to confirm this finding.

A larger AVA was associated with the secondary end point in patients with TAVI, which may seem counterintuitive.[4] The inclusion criteria in the SURTAVI trial were AVA $\leq$1.0 cm^2 or AVA index (AVAi) <0.6 cm^2/m^2 and mean gradient >40 mm Hg or maximum velocity >4 m/s.[9] The AVAi was similar between the event and no-event groups in TAVI, but the AVA was larger in the event group. This may indicate a larger body mass index and body surface area in the event group. Although AVA and AVAi were included as candidate variables in the multivariate model, AVAi was not selected per best AIC subsets.

The 5-meter gait speed >6 seconds or wheelchair-bound was a predictor for events after TAVI, whereas falls in past 6 months was a predictor for events after SAVR. This might indicate that different frailty measurement tools predict events after both procedures. In general, these frailty measurement tools play a role in choosing the optimal treatment and tend to bias us to choose TAVI. Multiple studies showed the role of these tools in outcome prediction after either TAVI or SAVR, but a comparison between both procedures has not been made with the previously mentioned frailty measurements tools.[27−29] More data-driven evidence should be gathered to determine the best (combination of) objective measurement tools in assessing the risk for TAVI versus SAVR.

The C-statistics of the SURTAVI risk scores showed a good discrimination and an acceptable, although modest, discriminative performance capability. That said, the predictive value of the SURTAVI risk scores appears to be superior to several of the contemporary periprocedural risk scores, such as the STS-PROM and EuroSCORE.[30,31] In addition, our scores are simple and easy to use, with only 5 variables included per score (Figure 2). The models can be further improved in the future by including additional echocardiographic parameters (e.g., stroke volume index, contractile reserve, right ventricular function), and biomarkers. The addition of these parameters may increase the proportion of events that can be predicted with the model. The clear spread of the 3 risk levels in the Kaplan−Meier curves shows that the SURTAVI risk scores effectively stratified patients who were at low, medium, and high risk of the clinical end point but to its applicability and performance needs to be validated in external cohorts.

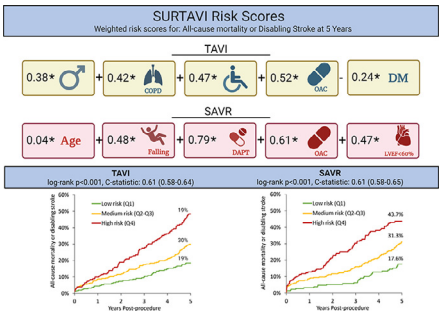

Figure 2. Central Illustration Title: Preprocedural risk scores for 5-year clinical outcomes after TAVI or SAVR. Weighted risk scores for all-cause mortality or disabling stroke at 5 years for TAVI and SAVR patients. Kaplan−Meier estimates of the 3-level SURTAVI risk score effectively stratified patients who were at low, medium and high risk of the primary end point. C-statistic shows the discriminative performance of the SURTAVI risk score. COPD = chronic obstructive pulmonary disease; DAPT = dual antiplatelet therapy; DM = Diabetes Mellitus; Falling = history of falling in last 6 months; OAC = oral anticoagulants.

As TAVI becomes an accepted alternative treatment in younger patients and those at a lower risk, having a preprocedural risk score to help in choosing the most appropriate procedure for each patient may be of importance. Such a score would be analogous to the SYNTAX (Synergy between percutaneous coronary intervention with Taxus and Cardiac Surgery) score in 3-vessel coronary disease in the preprocedural risk assessment of mortality and event rate after percutaneous coronary intervention and CABG. This score also shows modest long-term predictive ability but is widely used since its introduction more than a decade ago. Multiple validations of this score have been performed, showing a wide range of C-statistics for 1-year prediction.[32−34] A meta-analysis showed a C-statistic of 0.62 and 0.71 for its 5-year follow-up prediction.[35] Since then, multiple adjustments have been made to improve the prediction, showing the ability of risk scores to be improved over time by adding more (clinical) parameters.[36,37]

Limitations of the study include its retrospective post hoc nature. The SURTAVI trial excluded patients at a low or high surgical risk and patients with paradoxical low-gradient AS, end-stage renal disease, severe chronic obstructive pulmonary disease, and frailty. These factors are frequently present in the older high-risk patient population that is usually treated with TAVI in real-world daily clinical practice. Performing such an analysis and model validation and further adjusting the model in an all-comers population will be needed to make it applicable to daily clinical practice. Furthermore, because the SURTAVI includes patients with an intermediate-risk only, based on the STS score, a comparison with the STS score is more difficult and perhaps unfair. However, because the STS score is the most frequently used risk prediction score, we still find this comparison valid and useful. This study aimed to provide a preprocedural risk prediction tool, which can aid clinical decision making in the heart team, and patient-oriented shared decision making. Therefore, periprocedural factors were not included. Because the current risk scores showed a low performance, this might suggest that procedural factors might have a higher accurate performance than preprocedural factors alone. In previous research, the predictiveness of periprocedural factors has been shown.[38,39] Future research should focus on the exact rate of the impact of these periprocedural factors. The size of the dataset was limited, which may have affected the model's performance. Some potentially important and mechanistic variables, such as left and right ventricular echocardiographic and imaging parameters and biomarkers, were not collected and could not be included in the predictive model. These parameters are especially crucial in describing the extent of disease in patients with aortic valve disease and heart failure and therefore necessary to improve the model discrimination.[4,40,41] To make the model more robust and accurate, these additional variables may have to be added in future investigations. Finally, this was primarily a feasibility study, and a prospective external validation of the score is required to verify how the model performs in the real-world population.

In conclusion, preprocedural predictors of 5-year adverse outcomes after TAVI and SAVR differ, suggesting the need for treatment-specific risk scores. The calculation of such risk scores can help in informed clinical decision making for heart teams and patients. Anticoagulant therapy for concomitant medical conditions before AVR appears as a common marker of poor 5-year outcomes after TAVI and SAVR. The discriminative value of this simple and novel SURTAVI risk score system can potentially be further refined by the addition of more extensive echocardiographic and biomarker parameters. Further validation in external cohorts is required.

Declaration of Competing Interest

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consultant fees from Medtronic. Dr. Gada serves as a consultant for Abbott Vascular, BD, Boston Scientific, and Medtronic. Dr. Li is an employee and shareholder of Medtronic. Dr. Hanson is an employee and shareholder of Medtronic. Dr. Deeb serves on an advisory board for Medtronic and has received institutional grant support from Boston Scientific, Edwards LifeSciences, and Medtronic; he receives no personal remunerations. Dr. Voors has received institutional grant support from Medtronic. Dr. Reardon has received fees to his institution from Medtronic for consulting and providing educational services. Dr. van Bergeijk has no conflicts of interest to declare.

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Supplementary materials

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