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Validation of transcatheter aortic valve implantation risk scores in relation to early and mid-term survival: a single-centre study

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Abstract

OBJECTIVES: The aim of this study was to validate recently proposed risk scores for the prediction of mortality up to 1 year after transcatheter aortic valve implantation (TAVI), using a self-expandable valve (CoreValve).

METHODS: In this single-centre study, 225 consecutive patients with severe symptomatic aortic valve stenosis, who underwent TAVI between December 2007 and January 2015, were included. Conventional surgical risk scores (logistic EuroSCORE, EuroSCORE II and STS score) were calculated as well as newly proposed TAVI risk scores (TAVI₂-SCORE, STT Score and OBSERVANT score). Medium-term survival of the patients was assessed up to 1 year after TAVI.

RESULTS: The median age was 82 (77–86) years and 45.3% were male. Patients were categorized into 'non-high risk' or 'high risk' according to logistic EuroSCORE >20%, EuroSCORE II >8%, STS score >10%, TAVI₂-SCORE >2, STT score >12% and OBSERVANT score >6. Thirty-day and 1-year survival rates were significantly different between 'non-high-risk' and 'high-risk' patients according to the STS score (1 year: low: 84.4% vs high: 67.0%, $P = 0.010$) and according to OBSERVANT score (1 year: low: 85.2% vs high: 68.4%, $P = 0.005$). In contrast, TAVI₂-SCORE and STT score did not discriminate 'non-high-risk' and 'high-risk' patients. This was confirmed by Cox regression analysis [STS score >10%: hazard ratio: 2.484 (1.206–5.115), $P = 0.014$; OBSERVANT score >6: hazard ratio: 2.532 (1.295–4.952), $P = 0.007$].

CONCLUSIONS: In this single-centre study, OBSERVANT and STS score most accurately predicted early and mid-term survival in patients undergoing TAVI, using a self-expandable valve (CoreValve).

Keywords: Aortic valve stenosis • Transcatheter aortic valve implantation • Risk scores

INTRODUCTION

Recently, transcatheter aortic valve implantation (TAVI) has been proved to be a reasonable alternative for the treatment of severe, symptomatic aortic stenosis in 'high-risk' patients, not considered for surgical valve replacement [1–3]. According to the guidelines, patient selection for TAVI relies on the multidisciplinary heart team, evaluating technical aspects of the procedure, as well as the procedural risk of the patient. As already reported before, surgical risk scores [logistic EuroSCORE, EuroSCORE II and Society of Thoracic Surgeons (STS) score] could be helpful, but are limited for these purposes [4–9]. Recently, new risk scores have been developed, specifically for patients suffering from severe, symptomatic aortic valve stenosis undergoing TAVI. The TAVI₂-SCORE [10], the Survival postTAVI (STT) score [11] and the Observational Study of Appropriateness, Efficacy

And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis (OBSERVANT) score [12] have all been derived from baseline parameters (see [Supplementary Table 1](#)) and have all been outperforming conventional surgical risk scores for prediction of mortality after TAVI. The aim of this study was to validate these recently proposed risk scores for the prediction of mortality up to 1 year after TAVI.

METHODS

In this single-centre study, we included consecutive patients with severe symptomatic aortic valve stenosis, refused for surgical aortic valve replacement as decided by the local heart team, who underwent TAVI using the Medtronic CoreValve prosthesis between December 2007 and January 2015.

Baseline patient demographic data, cardiovascular risk factors, symptoms, quantification of aortic valve severity, medication and laboratory variables were collected.

Variables included in the conventional risk scores were previously described [13]. They were calculated using web-based systems [14–16]. Newly proposed TAVI risk scores (TAVI₂-SCORE, STT score and the OBSERVANT score) were calculated for each patient. The STT score was calculated using the online application [17]. Patients were categorized ‘high risk’ or ‘non-high risk’ according to a logistic EuroSCORE of >20%, a EuroSCORE II of >8%, an STS score of >10%, a TAVI₂-SCORE of >2, an STT score of >12% and an OBSERVANT score of >6 [10–12, 18].

Major adverse cardiac and cerebrovascular events (MACCEs) that occurred within 30 days after the procedure were reported according to the standardized endpoints of the Valve Academic Research Consortium 2 [19]. Medium-term survival of the patients was assessed up to 1 year after TAVI.

Statistical analysis

According to the distribution of the data (evaluated by histograms, QQ-plots and Kolmogorov–Smirnov test), continuous variables are presented as mean ± standard deviation (SD) or as median (Q1–Q3) and tested with Student’s *t*-test or the Mann–Whitney *U*-test. Categorical variables are presented as *n* (%) and were tested with the Pearson χ^2 or Fisher’s exact test (when at least one cell of the cross tabs had an expected count of less than 5). A contingency analysis by kappa values was performed to assess the agreement of ‘non-high-risk’ and ‘high-risk’ classification between different risk scores. Kaplan–Meier curves were constructed to evaluate survival, and differences between the groups of risk scores were tested based on the log-rank test. Cox regression analysis determined predictors of mortality. Statistical analyses were conducted with SPSS version 20.0 (IBM Corporation, New York, USA).

RESULTS

Two hundred and twenty-five consecutive patients were included in this study. The median age was 82 (77–86) years old, 45.3% (*n* = 102) were male and the mean body mass index was 26.9 ± 4.8 kg/m². They were all suffering from severe, symptomatic aortic valve stenosis, based on significantly reduced aortic valve area (0.64 ± 0.18 cm²), with a mean and peak gradient of 44 ± 15 and 69 ± 25 mmHg, respectively. The median left ventricular ejection fraction was 60 (50–62)%. Different comorbidities were present: 21.3% of the patients had diabetes (*n* = 48), 17.8% chronic obstructive pulmonary disease (*n* = 40) and 63.1% hypertension (*n* = 142). Previous procedures, such as percutaneous coronary intervention, coronary artery bypass grafting and valve surgery, were done in, respectively, 62 (27.6%), 68 (30.2%) and 10 (4.4%) patients. Of the total, 15.6% of the patients (*n* = 35) had a previous myocardial infarction and 7.1% (*n* = 16) had a permanent pacemaker at baseline. Median logistic EuroSCORE, EuroSCORE II and STS score were 15.3 (10.1–23.5), 5.1 (2.9–8.8) and 6.3 (5.6–8.2)%, respectively. The different parameters composing the new risk scores are described in Table 1, together with their prevalence.

Figure 1A describes the categorization of the TAVI patients as ‘non-high risk’ or ‘high risk’ according to the different risk scores. Agreement between these risk scores to categorize patients as ‘non-high-risk’ and ‘high-risk’ is visualized in Fig. 1B. The agreement

Table 1: Description of the different parameters of the new risk scores

TAVI ₂ -SCORE	
Porcelain aorta [1 point]	22 (9.8)
Anaemia: haemoglobin <10 g/dl [1 point]	11 (4.9)
Left ventricular dysfunction: left ventricular ejection fraction <35% [1 point]	10 (4.4)
Recent myocardial infarction: <90 days before TAVI [2 points]	5 (2.2)
Male sex category [1 point]	102 (45.3)
Critical aortic valve stenosis: mean aortic valve gradient ≥70 mmHg [1 point]	18 (8.0)
Old age: >85 years [1 point]	64 (28.4)
Renal dysfunction: creatinine clearance <30/kg/min [1 point]	18 (8.0)
Survival posT TAVI score	
Glomerular filtration rate (ml/min/1.73 m ²)	58.6 ± 21.0
Systolic pulmonary arterial pressure >50 mmHg	47 (20.9)
Previous stroke	22 (9.8)
OBSERVANT score	
Glomerular filtration rate <45 ml/min [6 points]	60 (26.7)
Critical state [5 points]	0 (0.0)
Pulmonary hypertension: systolic pulmonary arterial pressure >60 mmHg [4 points]	22 (9.8)
Diabetes mellitus [4 points]	50 (22.2)
New York Heart Association class 4 [4 points]	31 (13.8)
Prior balloon aortic valvuloplasty [3 points]	12 (5.3)
Left ventricular dysfunction: left ventricular ejection fraction <40% [3 points]	20 (8.9)

Data are presented as *n* (%) of mean ± standard deviation.

TAVI: transcatheter aortic valve implantation; OBSERVANT:

Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

between logistic EuroSCORE and EuroSCORE II was the strongest (kappa = 0.642, *P* = 0.001). The OBSERVANT score agreed with EuroSCORE II (kappa: 0.143, *P* = 0.027) and STS score (kappa: 0.245, *P* = <0.001). The number of similarly classified patients was the lowest in logistic EuroSCORE and the STT score (*n* = 140; kappa = -0.074, *P* = 0.155).

The incidence of procedure-related MACCEs according to the risk scores is summarized in Tables 2 and 3. Procedural mortality occurred in 6 patients, 30-day mortality in 17 patients and 1-year mortality in 38 patients. Logistic EuroSCORE and EuroSCORE II categorized most patients who died during the procedure as high risk. Most patients who died during 30 days and 1 year after TAVI were categorized as high risk according to the logistic EuroSCORE and the OBSERVANT score (Fig. 2). In Fig. 3, Kaplan–Meier curves represent mortality during 1 year after TAVI, according to the different risk scores. Survival between the ‘non-high risk’ and the ‘high-risk’ group of the STS score and the OBSERVANT score was significantly different, based on the log-rank test. Furthermore, Cox regression analysis confirmed these results (Table 4). Using three risk groups (low–moderate–high) according to the STS and the OBSERVANT score, a stepwise increase in mortality was seen according to the OBSERVANT score (Fig. 4).

DISCUSSION

This study is, to the best of our knowledge, the first to compare the six available risk scores in patients with severe, symptomatic aortic valve stenosis. The three conventional surgical risk scores (logistic EuroSCORE, EuroSCORE II and STS score) correlated the most to each other. The OBSERVANT score agreed with EuroSCORE II and

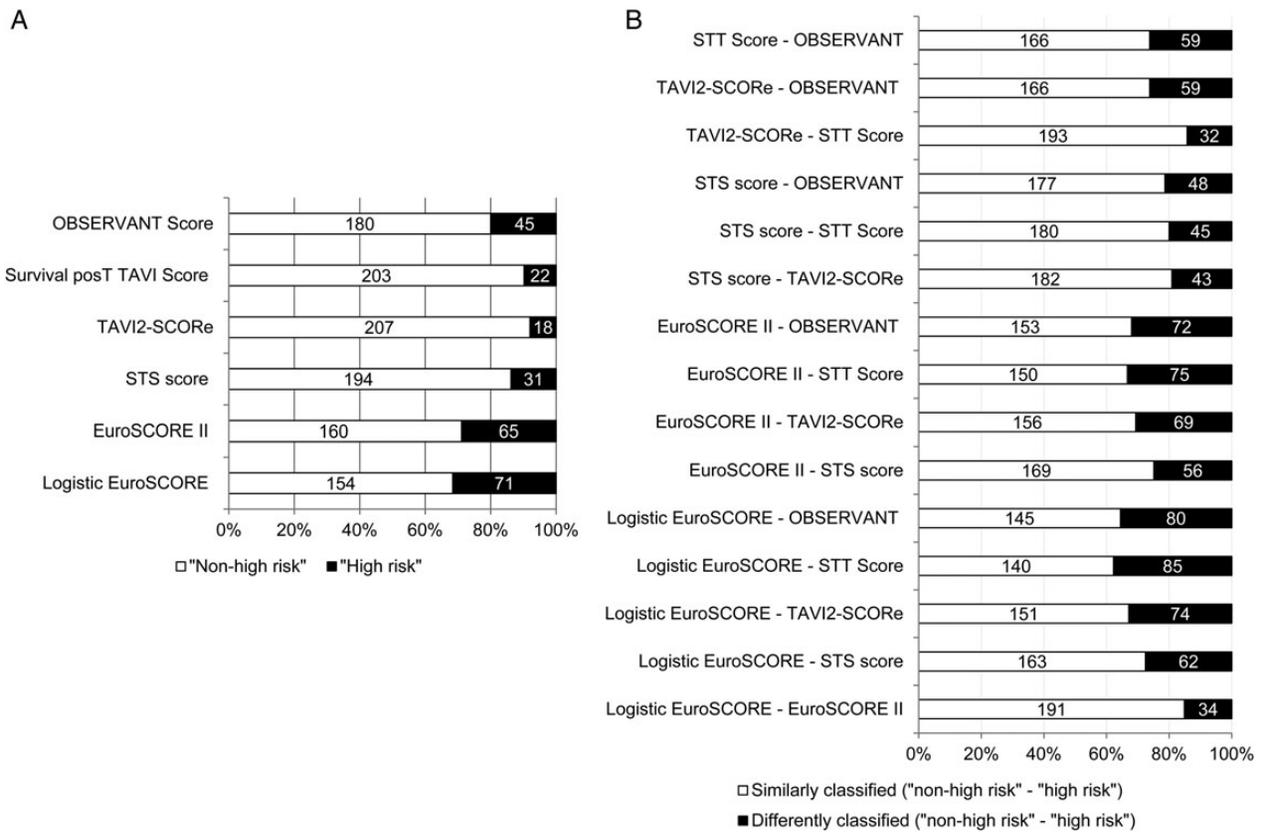


Figure 1: (A) Categorization of the TAVI patients in 'non-high risk' or 'high risk' according to risk scores. Logistic EuroSCORE: ≤ 20 , >20 ; EuroSCORE II: ≤ 8 , >8 ; Society of Thoracic Surgeons (STS) score: ≤ 10 , >10 ; TAVI₂-SCORE ≤ 2 , >2 ; Survival postT TAVI (STT) score: ≤ 12 , >12 ; and OBSERVANT score: ≤ 6 , >6 . Numbers represent the patients in that group. (B) Agreement between the different risk scores in the categorization of TAVI patients. TAVI: transcatheter aortic valve implantation; EuroSCORE: European System for Cardiac Operative Risk Evaluation; OBSERVANT: Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

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Table 2: Major adverse cardiovascular and cerebral events (MACCEs) within 30 days after the procedure, according to logistic EuroSCORE, EuroSCORE II and STS score

	Logistic EuroSCORE			EuroSCORE II			STS score		
	$\leq 20\%$	$>20\%$		$\leq 8\%$	$>8\%$		$\leq 10\%$	$>10\%$	
MACCEs									
Stroke or transient ischemic attack	8 (5.2)	1 (1.4)	0.279	6 (3.8)	3 (4.6)	0.720 ^d	8 (4.1)	1 (3.2)	1.000 ^d
Life-threatening bleeding	4 (2.6)	4 (5.6)	0.265 ^d	6 (3.8)	2 (3.1)	1.000 ^d	6 (3.1)	2 (6.5)	0.304 ^d
Major bleeding	10 (6.5)	5 (7.0)	1.000 ^d	10 (6.3)	5 (7.7)	0.769 ^d	11 (5.7)	4 (12.9)	0.134 ^d
Minor bleeding	25 (16.2)	14 (19.7)	0.521	26 (16.3)	13 (20.0)	0.501	33 (17.0)	6 (19.4)	0.749
Major vascular complications	3 (1.9)	4 (5.6)	0.211 ^d	3 (1.9)	4 (6.2)	0.109 ^d	5 (2.6)	2 (6.5)	0.248 ^d
Minor vascular complications	46 (29.9)	18 (25.4)	0.485	47 (29.4)	17 (26.2)	0.627	56 (28.9)	8 (25.8)	0.726
Aortic regurgitation grade II-IV ^a	31 (23.7)	12 (21.4)	0.739	33 (24.6)	10 (18.9)	0.399	37 (22.8)	6 (24.0)	0.898
New pacemaker ^b	42 (29.2)	26 (40.0)	0.122	50 (33.8)	18 (29.5)	0.549	57 (31.8)	11 (36.7)	0.602
Survival									
Procedural success	152 (98.7)	67 (94.4)	0.081 ^d	158 (98.8)	61 (93.8)	0.059 ^d	190 (97.9)	29 (93.5)	0.194 ^d
Alive 30 days post-TAVI	145 (94.2)	63 (88.7)	0.153	150 (93.8)	58 (89.2)	0.270 ^d	183 (94.3)	25 (80.6)	0.017 ^d
Alive 1 year post-TAVI ^c	101 (80.2)	53 (80.3)	0.981	105 (79.5)	49 (81.7)	0.732	135 (82.8)	19 (65.5)	0.031

EuroSCORE: European System for Cardiac Operative Risk Evaluation; STS: Society of Thoracic Surgeon; TAVI: transcatheter aortic valve implantation. ^an = 187, ^bn = 209, ^cn = 192, ^dFisher's Exact Test.

STS score. A higher TAVI₂-SCORE was related to higher incidence of significant aortic regurgitation post-TAVI and a higher OBSERVANT score was related to more minor bleeding events post-TAVI. A higher logistic EuroSCORE and EuroSCORE II were related to higher

procedural mortality, whereas a higher STS score and OBSERVANT score were related to 30-day and 1-year mortality.

As mentioned by Debonnaire *et al.* [10], TAVI risk scores should predict 30-day, as well as 1-year mortality post-TAVI in order to

Table 3: Major adverse cardiovascular and cerebral events (MACCEs) within 30 days after the procedure, according to TAVI₂-SCORE, survival post TAVI score and OBSERVANT score

	TAVI ₂ -SCORE			Survival post TAVI score			OBSERVANT score		
	≤2	>2		≤12%	>12%		≤6	>6	
MACCEs									
Stroke or transient ischemic attack	9 (4.3)	0 (0.0)	1.000 ^d	8 (3.9)	1 (4.5)	1.000 ^d	8 (4.4)	1 (2.2)	0.691 ^d
Life-threatening bleeding	8 (3.9)	0 (0.0)	1.000 ^d	8 (3.9)	0 (0.0)	1.000 ^d	7 (3.9)	1 (2.2)	1.000 ^d
Major bleeding	14 (6.8)	1 (5.6)	1.000 ^d	15 (7.4)	0 (0.0)	0.372 ^d	12 (6.7)	3 (6.7)	1.000 ^d
Minor bleeding	35 (16.9)	4 (22.2)	0.525 ^d	33 (16.3)	6 (27.3)	0.232 ^d	27 (15.0)	12 (26.7)	0.064
Major vascular complications	6 (2.9)	1 (5.6)	0.447 ^d	6 (3.0)	1 (4.5)	0.518 ^d	4 (2.2)	3 (6.7)	0.145 ^d
Minor vascular complications	62 (30.0)	2 (11.1)	0.089	57 (28.1)	7 (31.8)	0.712	55 (30.6)	9 (20.0)	0.160
Aortic regurgitation grade II-IV ^a	36 (21.1)	7 (43.8)	0.058 ^d	39 (23.4)	4 (20.0)	1.000 ^d	34 (23.1)	9 (22.5)	0.933
New pacemaker ^b	60 (31.3)	8 (47.1)	0.182	60 (31.4)	8 (44.4)	0.259	50 (30.1)	18 (41.9)	0.143
Survival									
Procedural success	202 (97.6)	17 (94.4)	0.397 ^d	198 (97.5)	21 (95.5)	0.465 ^d	176 (97.8)	43 (95.6)	0.345 ^d
Alive 30 days post-TAVI	192 (92.8)	16 (88.9)	0.633 ^d	187 (92.1)	21 (95.5)	1.000 ^d	171 (95.0)	37 (82.2)	0.008 ^d
Alive 1 year post-TAVI ^c	142 (80.7)	12 (75.0)	0.527 ^d	141 (80.6)	13 (76.5)	0.750 ^d	127 (83.6)	27 (67.5)	0.023

TAVI: transcatheter aortic valve implantation; OBSERVANT: Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

^an = 187, ^bn = 209, ^cn = 192, ^dFisher's Exact Test.

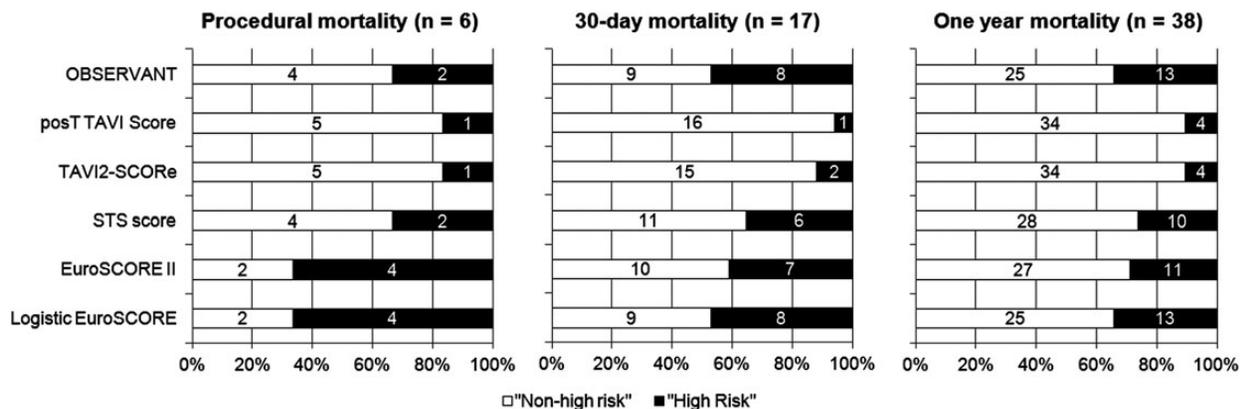


Figure 2: Categorization of the patients deceased during the procedure (left panel), during 30 days after TAVI (middle panel) and during the 1-year follow-up (right panel) in the 'non-high-risk' or 'high-risk' group. Numbers represent the patients in that group. STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation; EuroSCORE: European System for Cardiac Operative Risk Evaluation; OBSERVANT: Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

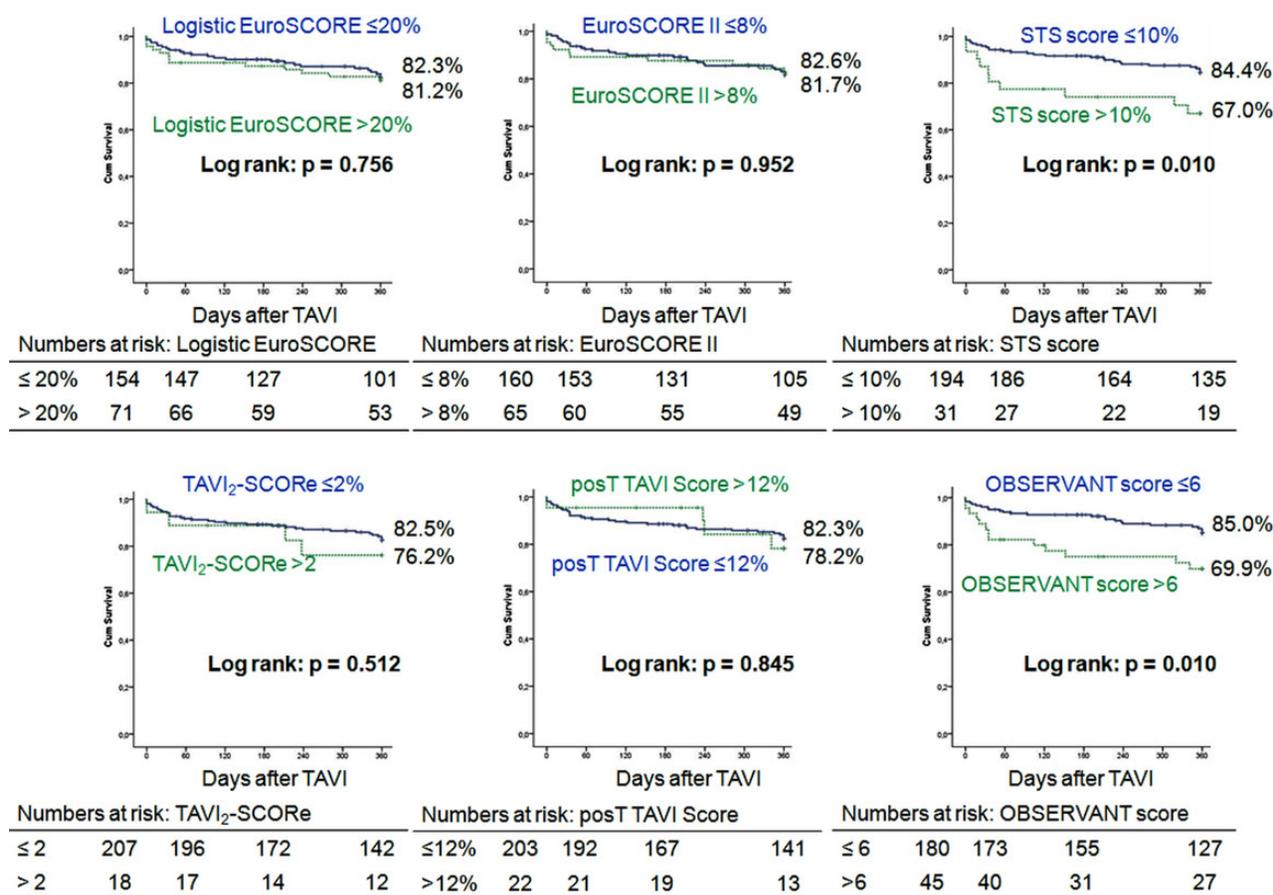
allow proper risk assessment and optimal patient selection, together with evaluation of cost-benefits for a given treatment. Due to the unavailability of TAVI-specific risk scores, conventional surgical risk scores were used for this purpose. Of the three conventional risk scores, only the STS score could significantly discriminate patients with good and limited mid-term prognosis in this patient cohort. Nevertheless, the STS score was not developed for TAVI and calculation of the STS score is time-consuming, involving more than 40 parameters that need to be available. Therefore, the development of specific TAVI risk scores remains of valuable importance.

Recently, three risk tools were proposed as specific TAVI risk scores.

The TAVI₂-SCORE was developed in patients who underwent TAVI with the Edwards SAPIEN system at the Leiden University Medical Center (Leiden, Netherlands; n = 207) and Centro Cardiologico Monzino IRCCS (Milan, Italy; n = 304) between November 2007 and November 2012 (n = 511) [10]. Mortality

within 30 days occurred in 29 patients (29 of 511, 5.7%), and within 1 year in 80 patients (80 of 471, 17.0%). In contrast to our data, 1-year survival was not significantly different between low- and high-risk patients according to the STS score. We assume that this might be partly explained by a remarkably high percentage of high-risk patients according to the STS score of >10% (90% of their cohort) in comparison with our data (14% in the present study).

Porcelain aorta and anaemia are two parameters representing more TAVI-specific risk factors, not included in the conventional risk scores. In their study cohort, 12% of patients had an elevated risk (TAVI₂-SCORE >2), and 1-year survival was significantly different between the two groups of patients (TAVI₂-SCORE ≤2: 88% vs TAVI₂-SCORE >2: 54%; P < 0.001). In comparison with our study, less patients (8%) were at high risk and the TAVI₂-SCORE could not differentiate patients with good and bad prognosis at 30 days, nor at 1 year post-TAVI. The TAVI₂-SCORE was developed in patients undergoing TAVI with the Edwards SAPIEN system. In our patient cohort, the Medtronic CoreValve system was used. Therefore, the



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Figure 3: Kaplan-Meier survival curves according to the risk score. STS: Society of Thoracic Surgeons; EuroSCORE: European System for Cardiac Operative Risk Evaluation; OBSERVANT: Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

Table 4: Predictors of mortality up to 1 year after TAVI

Cox regression	Thirty days				One year			
	Hazard ratio	95% CI		P-value	Hazard ratio	95% CI		P-value
		Lower	Upper			Lower	Upper	
Logistic EuroSCORE (%)	1.016	0.981	1.053	0.364	1.001	0.975	1.028	0.930
Logistic EuroSCORE $> 20\%$	1.964	0.758	5.090	0.165	1.107	0.566	2.165	0.766
EuroSCORE II (%)	1.061	0.997	1.129	0.060	1.034	0.984	1.086	0.190
EuroSCORE II $> 8\%$	1.756	0.668	4.614	0.253	0.979	0.485	1.973	0.952
STS score (%)	1.118	1.018	1.228	0.020	1.108	1.036	1.185	0.003
STS score $> 10\%$	3.555	1.315	9.614	0.012	2.484	1.206	5.115	0.014
TAVI ₂ -SCORE	0.913	0.544	1.532	0.729	0.959	0.684	1.346	0.810
TAVI ₂ -SCORE > 2	1.596	0.365	6.977	0.535	1.411	0.501	3.978	0.514
postT TAVI score (%)	0.991	0.905	1.085	0.841	1.021	0.998	1.045	0.075
postT TAVI score $> 12\%$	0.573	0.076	4.318	0.589	1.109	0.393	3.125	0.845
OBSERVANT score	1.155	1.046	1.275	0.004	1.095	1.020	1.175	0.012
OBSERVANT score > 6	3.743	1.444	9.704	0.007	2.356	1.205	4.607	0.012

TAVI: transcatheter aortic valve implantation; EuroSCORE: European System for Cardiac Operative Risk Evaluation; STS: Society of Thoracic Surgeon; OBSERVANT: Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

predictive value of the TAVI₂-SCORE might not be extrapolated to our patient population.

The STT score was derived from baseline characteristics of patients who underwent TAVI with the Edwards SAPIEN system or

the Medtronic CoreValve system at six institutions (Turin, Catania, Padova, two centres in Milan and Utrecht) [11]. The STT score was externally validated in an independent cohort of Bologna. All patients were treated between January 2007 and December 2012.

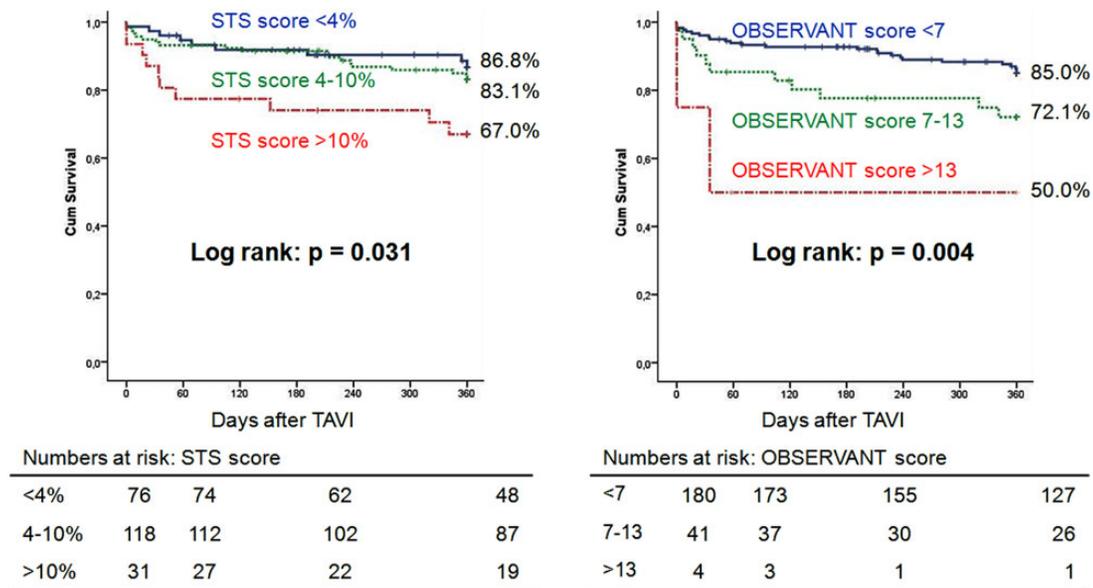


Figure 4: Kaplan–Meier survival curves of low-, moderate- and high-risk patients according to Society of Thoracic Surgeons (STS) and OBSERVANT score. TAVI: transcatheter aortic valve implantation; OBSERVANT: Observational Study of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis.

Mortality within 30 days occurred in, respectively, 60 patients (60 of 1067, 5.6%) and 13 patients (13 of 177, 7.3%), and within 1 year in, respectively, 165 patients (165 of 1067, 15.4%) and in 63 patients (63 of 177, 35.6%). No differences were found in the logistic EuroSCORE and the STS score between patients who survived and patients who died within 1 year post-TAVI. No Kaplan–Meier curves were included in the manuscript to compare survival between low- and high-risk patients. In our study, the STT score could neither differentiate patients with good and bad prognosis at 30 days, nor at 1 year post-TAVI.

The OBSERVANT score was derived from baseline characteristics of patients who underwent TAVI with the Edwards SAPIEN system or the Medtronic CoreValve system at 95 Italian institutions ($n = 1256$) [12]. The OBSERVANT score was externally validated on an independent cohort ($n = 622$). All patients were treated between December 2010 and June 2012. Mortality within 30 days occurred in, respectively, 77 patients (77 of 1256, 6.1%) and 37 patients (37 of 177, 5.9%). In their study cohort, 41.9% had an elevated risk. In comparison with our study, less patients (23.6%) were at high risk. The 30-day mortality was significantly different between the two groups of patients (OBSERVANT score ≤ 6 : 2.4% vs OBSERVANT score > 6 : 11.4%; $P < 0.001$). This observation was confirmed in our study: OBSERVANT score ≤ 6 : 5.0% vs OBSERVANT score > 6 : 17.8%; $P = 0.008$. Moreover, this risk estimation could be extrapolated to 1-year mortality (at least in our study cohort) and in contrast to the STS score, the OBSERVANT score showed a good stepwise increase in 30-day as well as in 1-year mortality, based on three risk groups. The fact that the OBSERVANT score, containing only seven parameters, was more significantly predictive than the time-consuming STS score favours its clinical applicability.

An important parameter, not included in any of these risk scores, but suggested in the literature to estimate the risk specifically in TAVI patients, is frailty [20, 21]. However, since there is no general definition of frailty available, further research is necessary in order to compose optimal criteria to evaluate frailty in aortic

valve stenosis. Also, red cell distribution width gained interest in the risk estimation of TAVI patients [9, 22–23].

The discordances between survival of ‘high’-risk patients in various TAVI cohorts underline the need of validation in external large real-world populations before a new risk score should be used in everyday clinical practice. Ideally, this risk score is a simple and accurate tool that can be used both in patients treated with a balloon-expandable TAVI prosthesis as well as in patients treated with a self-expandable system.

Limitations of the study

This study was based on a single-centre population, including a limited number of patients and only one type of transcatheter aortic valve implanted (Medtronic CoreValve). Results can therefore not be extrapolated to other types of valves. Use of the CoreValve frame is indeed associated with typical problems, potentially influencing the final results of our study. Based on the results of the Belgian TAVI Registry [24] and the randomized CHOICE trial [25], comparing transfemoral TAVI with balloon-expandable vs self-expandable transcatheter valve, more patients develop significant aortic regurgitation and new conduction disturbances within 30 days after CoreValve implantation. Because aortic regurgitation post-TAVI is a predictor of mortality, this could potentially bias the results. Nevertheless, according to the survival curves reported in both studies, no differences in mortality between patients implanted with balloon-expandable and self-expandable valve were found.

Finally, grouping of the patients within the evaluated score systems is somewhat ‘author-dependent’. However, for our analysis, we respected the risk cohorts as published by the different authors, taking into account that the number in some of the patient subgroups were too limited for meaningful statistical analysis. Keeping this in mind, according to the actually available guidelines, TAVI has been proven to be a reasonable alternative for the

treatment of severe, symptomatic aortic stenosis in 'high-risk' patients, we decided to focus primarily on 'high-risk' compared with 'non-high-risk' patients.

CONCLUSION

In this single-centre study, the OBSERVANT and STS score most accurately predicted early and mid-term survival in patients undergoing TAVI, using a self-expandable valve (CoreValve). However, further validation in large external patient cohorts using different valve frames is needed.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

Conflict of interest: Johan M. Bosmans is a part-time clinical proctor for Medtronic CoreValve.

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