

## RESEARCH ARTICLE

# Risk scores for prediction of 30-day mortality after transcatheter aortic valve implantation: Results from a two-center study in Norway

Didrik Kjørnås<sup>1</sup>  | Gry Dahle<sup>2</sup> | Henrik Schirmer<sup>3,4</sup> | Siri Malm<sup>5</sup> | Jo Eidet<sup>6</sup> | Lars Aaberge<sup>7</sup> | Terje Steigen<sup>1,8</sup> | Svend Aakhus<sup>9,10</sup> | Rolf Busund<sup>8,11</sup> | Assami Rösner<sup>1</sup>

<sup>1</sup>Department of Cardiology, University Hospital of North Norway, Tromsø, Norway

<sup>2</sup>Department of Cardiothoracic Surgery, Oslo University Hospital Rikshospitalet, Oslo, Norway

<sup>3</sup>Department of Cardiology, Akershus University Hospital, Lørenskog, Norway

<sup>4</sup>Institute of Clinical Medicine, University of Oslo, Oslo, Norway

<sup>5</sup>Department of Cardiology, University Hospital of North Norway, Harstad, Norway

<sup>6</sup>Department of Anesthesiology, Oslo University Hospital Rikshospitalet, Oslo, Norway

<sup>7</sup>Department of Cardiology, Oslo University Hospital Rikshospitalet, Oslo, Norway

<sup>8</sup>Institute of Clinical Medicine, UiT The Arctic University of Norway, Tromsø, Norway

<sup>9</sup>Department of Circulation and Imaging, Faculty of Medicine and Health Science, Norwegian University of Science and Technology, NTNU, Trondheim, Norway

<sup>10</sup>Clinic of Cardiology, St. Olavs University Hospital, Trondheim, Norway

<sup>11</sup>Department of Cardiothoracic and Vascular Surgery, University Hospital of North Norway, Tromsø, Norway

## Correspondence

Didrik Kjørnås, Department of Cardiology, University Hospital of North Norway, Sykehusveien 38, 9038 Tromsø, Norway. Email: didrikkj@gmail.com

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## Abstract

**Objectives:** Transcatheter aortic valve implantation (TAVI)-specific risk scores have been developed based on large registry studies. Our aim was to evaluate how both surgical and novel TAVI risk scores performed in predicting all cause 30-day mortality. In addition, we wanted to explore the validity of our own previously developed model in a separate and more recent cohort.

**Methods:** The derivation cohort included patients not eligible for open surgery treated with TAVI at the University Hospital of North Norway (UNN) and Oslo University Hospital (OUS) from February 2010 through June 2013. From this cohort, a logistic prediction model (UNN/OUS) for all cause 30-day mortality was developed. The validation cohort consisted of patients not included in the derivation cohort and treated with TAVI at UNN between June 2010 and April 2017. EuroSCORE, Logistic EuroSCORE, EuroSCORE 2, STS score, German AV score, OBSERVANT score, IRRMA score, and FRANCE-2 score were calculated for both cohorts. The discriminative accuracy of each score, including our model, was evaluated by receiver operating characteristic (ROC) analysis and compared using DeLong test where  $P < .05$  was considered statistically significant.

**Results:** The derivation cohort consisted of 218 and the validation cohort of 241 patients. Our model showed statistically significant better accuracy than all other scores in the derivation cohort. In the validation cohort, the FRANCE-2 had a significantly higher predictive accuracy compared to all scores except the IRRMA and STS score. Our model showed similar results.

**Conclusion:** Existing risk scores have shown limited accuracy in predicting early mortality after TAVI. Our results indicate that TAVI-specific risk scores might be useful when evaluating patients for TAVI.

## KEYWORDS

mortality, risk prediction, TAVI

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## 1 | INTRODUCTION

Aortic stenosis (AS) is the most common valvular heart disease requiring operative treatment and carries a dismal prognosis if left untreated.<sup>1,2</sup> Transcatheter aortic valve implantation (TAVI) is an established treatment option for patients with severe symptomatic aortic stenosis with intermediate or high risk for surgical aortic valve replacement (SAVR). While the risk factors for SAVR are known and incorporated into validated preoperative surgical risk scores,<sup>3-6</sup> they are not reliable in predicting early mortality after TAVI.<sup>7,8</sup> It is important to identify patients with unacceptable perioperative risk where the potential benefit of the procedure might be outweighed by unfavorable outcome and where conservative medical treatment alone might be more appropriate. Accordingly, several novel TAVI-specific risk scores have been developed,<sup>9-12</sup> but they have shown limited generalizability when applied in independent cohorts.<sup>12,13</sup> In a previously published study, we identified five independent risk factors of early mortality and created a model for predicting 30-day mortality after TAVI.<sup>14</sup> In the present study, we aimed to evaluate how our model, UNN/OUS (University Hospital of North Norway/Oslo University Hospital), performed compared to established surgical and previously published TAVI-specific risk scores. There has been a rapid development in the TAVI population with a trend toward treating lower risk patients.<sup>15</sup> Therefore, we wanted to explore the validity of our own model in a separate and more recent validation cohort.

## 2 | METHODS

### 2.1 | Derivation cohort

The derivation cohort is based on our previously published study which included patients with severe symptomatic AS that underwent TAVI at the University Hospital of North Norway (UNN) Tromsø and Oslo University Hospital (OUS) Rikshospitalet from February 2010 through June 2013.<sup>14</sup> All patients were found to have too high or unacceptable risk for SAVR based on surgical risk scores and evaluation by a cardiothoracic surgeon. A multidisciplinary heart team consisting of a cardiothoracic surgeon, cardiologist, and interventional cardiologist determined the patient suitability for TAVI considering cognitive function, comorbid status, and technical feasibility. Patients with life expectancy less than 12 months, low motivation for treatment, and/or inability to give informed consent were not offered TAVI. All procedures were done in general anesthesia via transfemoral (TF), transapical (TA), or transaortic (TAo) access. TF-TAVI was done via open access to the femoral artery, TA-TAVI was achieved through a small thoracotomy above the cardiac apex, and a small limited sternotomy were done to facilitate TAo-TAVI. Either the first-generation self-expanding Medtronic CoreValve (Medtronic Inc., Minneapolis, Minnesota, USA) or either first- or second generation Edwards SAPIEN-SAPIEN XT balloon-expandable valve (Edwards Lifesciences, Irvine, California, USA) was used at the discretion of the TAVI team and implanted during rapid pacing. Patient demographics, clinical

characteristics, and 30-day mortality were prospectively registered. All patients underwent preoperative transthoracic echocardiographic (TTE) evaluation. The aforementioned data were used for the calculation of risk scores. The surgical risk scores calculated were the EuroSCORE (European System for Cardiac Operative Risk Evaluation), Logistic EuroSCORE, EuroSCORE II, and STS (Society of Thoracic Surgeons) score.<sup>3-6</sup> The TAVI specific risk scores evaluated were the FRANCE-2 (French Aortic National CoreValve and Edwards registry) score, IRRMA (Israeli TAVR Registry Risk Model Accuracy) score, German AV (German Aortic Valve) score, and OBSERVANT (Observational Study of Appropriateness, Efficacy and Effectiveness of AVR-TAVR Procedures for the Treatment of Severe Symptomatic Aortic stenosis) score.<sup>9-12</sup> The TAVI-specific risk scores were developed based on French, Israeli, German, and Italian registries, respectively. The study was approved by the Regional Ethical Committees of North and South Norway. All patients gave written informed consent.

### 2.2 | Validation cohort

The validation cohort consisted of patients treated with TAVI between June 2010 and April 2017 at the University Hospital of North Norway (UNN), Tromsø. All patients were found eligible for TAVI based on the same criteria as above. However, some patients with acceptable risk for SAVR were offered TAVI at the discretion of the heart team based on technical aspects favoring TAVI and patient preference. Valve implantation was done through TF, TA, or TAo. The procedure was done using either a first-, second-, or third-generation Edwards SAPIEN-SAPIEN XT-SAPIEN 3 balloon-expandable valve (Edwards Lifesciences, Irvine, California) or one of the two types of self-expanding valves; first- or second-generation Medtronic CoreValve-EvolutR (Medtronic Inc., Minneapolis, Minnesota) or the St. Jude Portico (St. Jude Medical, Minnesota, USA). The procedures were performed under either general anesthesia for TA- and TAo- TAVI or local anesthesia and sedation in selected cases for TF-TAVI. Patient demographics, clinical characteristics, and 30-day mortality data were extracted retrospectively from the patients' electronic records and used for the calculation of surgical and TAVI-specific risk scores. The validation cohort study was approved by UNN's Data Protection Office.

### 2.3 | Clinical characteristics and echocardiographic parameters

All clinical and echocardiographic parameters were obtained and measured during the preoperative evaluation for TAVI occurring within 3 months of planned treatment. The presence of chronic obstructive pulmonary disease (COPD) was evaluated by spirometry and defined according to the GOLD classification. Chronic and paroxysmal atrial fibrillation/flutter, diagnoses by ECG, was grouped as one variable. Heart failure was defined as physician-documented clinical signs of heart failure in the form of unusual dyspnea on light exertion, orthopnea, fluid retention, rales on auscultation, or pulmonary edema

on chest X-ray less than 2 weeks prior to TAVI. Peripheral artery disease (PAD) was defined as claudication, previous amputation due to vascular insufficiency, previous reconstructive surgery or percutaneous intervention, abdominal aortic aneurism, and/or >50% stenosis in a peripheral artery diagnosed by computed tomography (CT) or angiographic imaging. Previous cerebrovascular events comprised both previous strokes and transient ischemic attacks. Conventional two-dimensional grey-scale echocardiographic images were obtained in the parasternal long- and short-axis view, as well as the apical four-, two-, and three-chamber views. Left ventricular ejection fraction (LVEF) was derived from the Simpson's biplane method. The degree of aortic regurgitation (AR) was estimated by the size of the regurgitation area by color Doppler, pressure half time, and diastolic velocities in descending aorta by Doppler-flow signal. The degree of mitral regurgitation (MR) was based on measurement and visual assessment of color Doppler images, vena contracta, and proximal isovelocity surface area. Systolic pulmonary artery pressure (SPAP) was derived from continuous wave Doppler measurements of tricuspid regurgitation (TR) and respiratory variation of the diameter of the inferior vena cava.

## 2.4 | Outcome

The primary endpoint of this study was all-cause mortality 30-days after TAVI. We did not distinguish between in-house mortality and mortality after discharge. Data on mortality are registered in the patients' electronic records, which are linked and automatically updated from the Norwegian Cause of Death Registry. As a result, none of the patients were lost to follow-up.

## 2.5 | Statistical analysis

Continuous data were tested for normality using Shapiro–Wilk and Kolmogorov–Smirnov tests in addition to evaluation of histograms and normal Q-Q plot. Categorical variables are presented as numbers (%) and continuous variables as mean  $\pm$  SD or median (interquartile range [IQR]) for normal and nonnormal distributed data, respectively. Continuous variables in the two cohorts were compared using independent *t*-test or Mann–Whitney *U* test as appropriate. Categorical variables were compared using Pearson's Chi-square test.

In the derivation cohort, univariable Cox regression analysis was performed for all-cause 30-day mortality. Variables with  $P < .15$  were selected and tested for interaction and linearity. A forward stepwise multivariable Cox regression analysis was performed for the identification of independent predictors of all-cause 30-day mortality where  $P < .05$  after multivariable adjustment was considered statistically significant. There was no imputation for missing data and multivariable analysis was performed on all available patients for each analysis. The final model was based on 213 patients. The predicted probabilities obtained from binary logistic regression were used in receiver operating characteristic (ROC) analysis to estimate the discriminative capacity (C-statistic) for the model and compare it to surgical and TAVI risk

scores in the same cohort. In the validation cohort, the C-statistic for our model was calculated as above based on the independent predictors identified in the derivation cohort. The difference in discriminative capacity between each individual risk score was evaluated by DeLong test, where  $P < .05$  was considered statistically significant. The Hosmer–Lemeshow test was performed to evaluate the calibration of our model in addition to the surgical and TAVI risk scores. All statistical analyses were performed using SPSS 24 (SPSS, Inc., Chicago, IL, USA) with the exception of DeLong test that was performed using SAS statistical software version 9.4.

## 3 | RESULTS

Patient demographics and clinical characteristics for both the derivation and validation cohort are shown in Table 1. Based on the derivation cohort consisting of 218 patients, we identified body mass index (BMI), SPAP above 60 mm Hg, PAD, TA-access, and heart failure as independent predictors of all-cause 30-day mortality.<sup>14</sup> Variables evaluated constituted both clinical and echocardiographic parameters. The logistic model generated from this cohort is shown in Table 2. Table 3 displays the respective C-statistics with 95% CI for each score, and Table 4 displays the results of DeLong test. The derivation cohort had a larger burden of comorbidities, more TA and TAO procedures, and higher 30-day mortality compared to the validation cohort (Table 1). The validation cohort consisted of 241 patients not included in the derivation cohort. Fourteen of these patients underwent intervention during the inclusion period of the derivation cohort. The remaining 227 patients underwent intervention after the inclusion period of the original study ended.

### 3.1 | Derivation cohort

Figure 1 shows the ROC curves for our model in addition to both surgical and TAVI risk scores. Our model showed statistically significant higher discriminative accuracy compared to all the other risk scores (Table 4). This, of course, is not unexpected since our model was developed from this cohort. The FRANCE-2 score, IRRMA score, and STS score had moderate-to-good discriminative accuracy when evaluating C-statistics alone (Table 3), but none of the risk scores demonstrated statistically significant better discriminative accuracy over the others. However, the difference in discriminative accuracy between the STS and IRRMA score and EuroSCORE 2, Logistic EuroSCORE, and EuroSCORE was borderline significant. Hosmer–Lemeshow test showed adequate calibration except for EuroSCORE ( $P = .024$ ) and Logistic EuroSCORE ( $P = .084$ ).

### 3.2 | Validation cohort

The ROC curves for the validation cohort are shown in Figure 1. Our model retained a high discriminative accuracy and the FRANCE-2

**TABLE 1** Preoperative demographics and clinical characteristics for the derivation and validation cohort

Variable	Reference cohort (N = 218)	Validation cohort (N = 241)	P value
Age (y)	82 ± 7	81 ± 8	.43
Female gender, n (%)	98 (45)	111 (46)	.81
Body mass index, (kg/m <sup>2</sup> )	26 ± 5	27 ± 5	.097
NYHA 4, n (%)	57 (26)	40 (17)	.012
HF < 2 wk, n (%)	96 (44)	87 (36)	.083
LVEF (%)	49 ± 12	51 ± 13	.22
A12, n (%)	38 (17)	30 (12)	.09
M12, n (%)	45 (21)	31 (13)	.019
Mean gradient (mm Hg)	52 ± 15	53 ± 15	.92
Atrial fibrillation/flutter, n (%)	100 (46)	89 (37)	.052
Hypertension, n (%)	148 (68)	138 (57)	.019
Porcelain aorta, n (%)	26 (12)	12 (5)	.007
Immunocompromised, n (%)	28 (13)	52 (22)	.014
Diabetes, n (%)	62 (28)	49 (20)	.043
SPAP			
<30 mm Hg	67 (31)	83 (34)	.40
30-60 mm Hg	130 (60)	126 (53)	.113
> 60 mm Hg	21 (9)	32 (13)	.222
Previous CABG, n (%)	95 (44)	70 (29)	.001
Previous SAVR, n (%)	9 (4.1)	4 (1.7)	.83
Previous PCI, n (%)	87 (40)	95 (39)	.92
Previous myocardial infarction, n (%)	82 (38)	77 (32)	.20
Previous cerebrovascular event, n (%)	52 (24)	35 (15)	.011
eGFR (ml/min)	54 ± 26	64 ± 24	<.001
COPD, n (%)	78 (36)	63 (26)	.025
Peripheral artery disease, n (%)	80 (37)	75 (31)	.21
Access, n (%)			
Transfemoral	122 (56)	209 (87)	<.000
Transaortic	28 (13)	10 (4)	.001
Transapical	68(31)	22(9)	<.000
Local anesthesia, n (%)	0 (0)	105 (44)	NA
STS score (6)	7.1 ± 4.5	6.3 ± 4.4	.68
EuroSCORE 2(5)	9.1 ± 7.5	8.1 ± 6.8	.031
Logistic EuroSCORE (4)	22 [19]	20 [22]	.210
EuroSCORE	11.0 ± 2.4	10.0 ± 2.5	.167
FRANCE-2 score (10)	3.4 ± 2.1	2.4 ± 1.8	<.000
IRRMA score (12)	0.8 ± 0.7	0.5 ± 0.6	<.000
OBSERVANT score (9)	3 [8]	0 [6]	.079
German AV score (11)	2.8 ± 0.8	2.7 ± 0.9	.124
Mortality, n (%)	19 (8.7)	10 (4.1)	.045

Note: Numbers are presented as n (%), mean ± SD, or median [IQR].

Abbreviations: A12, aortic insufficiency grade 2 or above; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; HF < 2 wk, physician-documented clinical signs of heart failure less than 2 wk prior to surgery in the form of unusual dyspnea on light exertion, orthopnea, fluid retention, rales on auscultation, or pulmonary edema on chest X-ray; LVEF, left ventricular ejection fraction; M12, mitral insufficiency grade 2 or above; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; SPAP, systolic pulmonary artery pressure.

score had a higher discriminative accuracy than in the derivation cohort (Table 3). The FRANCE 2 score had statistically significant better discriminative accuracy compared to all other scores with the exception of our model, IRRMA score, and STS score (Table 4). Our model showed similar results, but the discriminative accuracy was only borderline significant compared to the German AV score. The discriminative accuracy between the STS and IRRMA score and EuroSCORE 2 and EuroSCORE was borderline significant. The IRRMA score had also borderline significant better discriminative accuracy

than EuroSCORE 2. Based on Hosmer–Lemeshow test, all scores evaluated in this cohort displayed adequate calibration ( $P > .15$ ).

## 4 | DISCUSSION

Of the previously published risk scores evaluated in this study, the IRRMA and FRANCE-2 scores, both TAVI specific, obtained a similar or higher discriminative accuracy in both cohorts compared to the studies from which they were originally derived.<sup>10,12</sup> The FRANCE-2 score showed good discriminative accuracy in both cohorts and had statistically significant better discriminative accuracy compared to all but three scores (IRRMA score, STS score, and UNN/OUS) in the more recent validation cohort. Our model showed similar results and retained a high discriminative accuracy when applied to the validation cohort compared to the original and validated C-statistics of the surgical and TAVI risk scores evaluated in this study.

A study by Halkin et al<sup>12</sup> based on the Israeli TAVI registry including 1327 patients, from which the IRRMA score was derived, found that with the exception of the FRANCE-2 score, all risk scores had less predictive accuracy than in their original studies when applied to an independent cohort. None of the scores in this study attained a C-statistic  $>0.8$ . In contrast to our own model, which is based on a relatively low number of patients at only two centers, the FRANCE-2 score is derived from a national registry of 3833 patients. It has shown a better predictive accuracy than originally reported both in the IRRMA study and our cohort. Our model was developed from a wide range of clinical and echocardiographic parameters not incorporated in large registries, thus emphasizing the importance of the factors identified. Despite the differences in composition and number of risk factors included, our own model and FRANCE-2 scores share several common features indicative of factors important in predicting 30-day mortality after TAVI in elderly high-risk patients.

**TABLE 2** Logistic model for 30-d mortality based on the derivation cohort

	$\beta$ coefficient	OR	95% CI
Body mass index (kg/m <sup>2</sup> ) <sup>a</sup>	-0.37	0.69	0.56-0.86
HF < 2 wk	1.37	3.93	1.1-14.25
SPAP			
<30 mm Hg			
30-60 mm Hg	0.45	1.57	0.36-6.86
> 60 mm Hg	2.84	17.18	2.39-123
Peripheral artery disease	2.17	8.72	2.12-35
Access <sup>b</sup>			
Transfemoral			
Transaortic	- 0.62	0.54	0.049-6.01
Transapical	2.8	5.09	1.34-19.31
Constant	5.64		

Abbreviations: HF < 2 wk, physician-documented clinical signs of heart failure less than 2 wk prior to surgery in the form of unusual dyspnea on light exertion, orthopnea, fluid retention, rales on auscultation, or pulmonary edema on chest X-ray; SPAP, systolic pulmonary artery pressure.

<sup>a</sup>Analyzed as a continuous variable.

<sup>b</sup>Analyzed as a categorical variable.

**TABLE 3** C-statistic with 95% CI for surgical and TAVI risk scores and DeLong test for each risk score compared to our model (UNN/OUS)

	Derivation cohort		Validation cohort	
	C-statistic	95% CI	C-statistic	95% CI
UNN/OUS (14)	0.91	0.85-0.98	0.83	0.66-0.99
IRRMA score (12)	0.72	0.59-0.84	0.72	0.55-0.90
FRANCE-2 score (10)	0.69	0.57-0.80	0.82	0.69-0.95
STS score (6)	0.68	0.56-0.81	0.67	0.50-0.85
German AV score (11)	0.58	0.44-0.73	0.65	0.49-0.81
OBSERVANT score (9)	0.57	0.42-0.72	0.58	0.39-0.77
EuroSCORE 2(5)	0.56	0.42-0.70	0.53	0.37-0.70
EuroSCORE (3)	0.56	0.41-0.70	0.55	0.43-0.68
Logistic EuroSCORE (4)	0.55	0.41-0.70	0.55	0.40-0.70

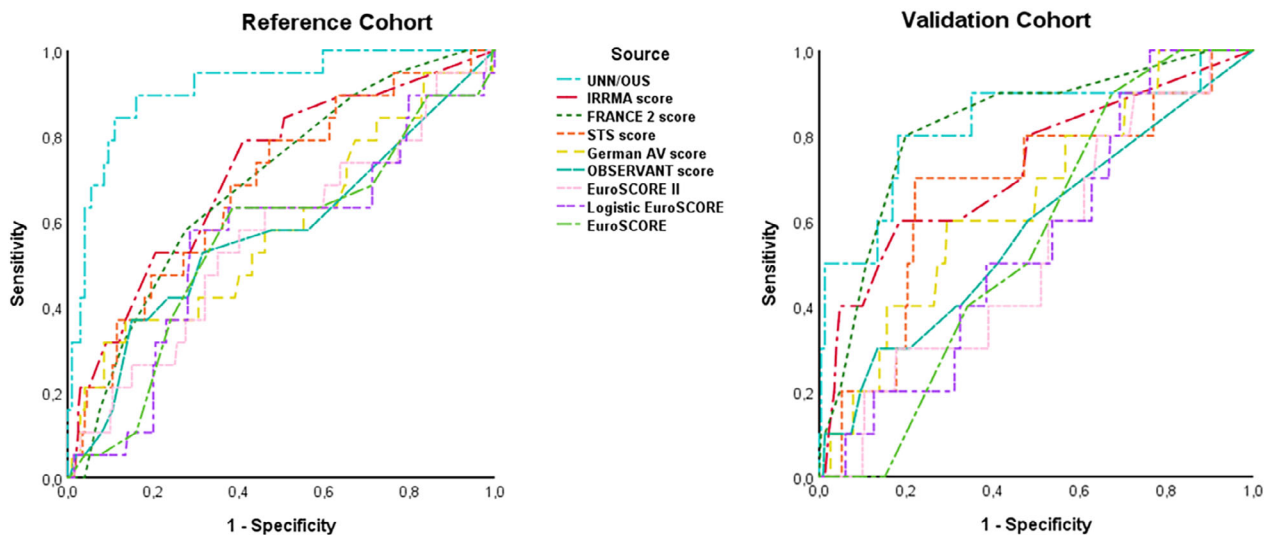
Abbreviations: EuroSCORE, European System for Cardiac Operative Risk Evaluation; FRANCE-2, French Aortic National CoreValve and Edwards registry score; German AV, German Aortic Valve score; IRRMA, Israeli TAVR Registry Risk Model Accuracy score; OBSERVANT, Observational Study of Appropriateness, Efficacy and Effectiveness of AVR-TAVR Procedures for the Treatment of Severe Symptomatic Aortic stenosis score; STS, Society of Thoracic Surgeons score; UNN/OUS, University Hospital of North Norway/Oslo University Hospital.

**TABLE 4** Results of DeLong test comparing the C-statistic between each risk score in the derivation and validation cohort

	UNN/OUS	FRANCE-2	IRRMA	German AV	OBSERVANT	STS	EuroSCORE	Log EuroSCORE	EuroSCORE 2
UNN/OUS	-	0.97	0.20	0.08	0.02	0.16	0.004	0.004	0.01
FRANCE-2	<0.001	-	0.16	0.03	0.009	0.11	<0.001	<0.001	0.003
IRRMA	0.001	0.61	-	0.43	0.03	0.63	0.06	0.05	0.07
German AV	<0.001	0.26	0.20	-	0.23	0.67	0.29	0.32	0.21
OBSERVANT	<0.001	0.15	0.10	0.89	-	0.17	0.82	0.79	0.63
STS	0.003	0.92	0.70	0.17	0.16	-	0.06	0.15	0.06
EuroSCORE	<0.001	0.11	0.06	0.59	0.85	0.07	-	0.90	0.74
Log EuroSCORE	<0.001	0.10	0.06	0.55	0.84	0.06	0.89	-	0.76
EuroSCORE 2	<0.001	0.16	0.07	0.75	0.91	0.05	0.86	0.83	-

Note: Validation cohort displayed in the upper right-hand corner in *italic*. Derivation cohort in lower left-hand corner.

Abbreviations: EuroSCORE, European System for Cardiac Operative Risk Evaluation; FRANCE-2, French Aortic National CoreValve and Edwards registry score; German AV, German Aortic Valve score; IRRMA, Israeli TAVR Registry Risk Model Accuracy score; OBSERVANT, Observational Study of Appropriateness, Efficacy and Effectiveness of AVR-TAVR Procedures for the Treatment of Severe Symptomatic Aortic stenosis score; STS, Society of Thoracic Surgeons score; UNN/OUS, University Hospital of North Norway/Oslo University Hospital.



**FIGURE 1** Receiver operating characteristic (ROC) curves for surgical and TAVI specific risk scores applied to the derivation and validation cohorts. EuroSCORE, European System for Cardiac Operative Risk Evaluation; FRANCE-2, French Aortic National CoreValve and Edwards registry score; German AV, German Aortic Valve score; IRRMA, Israeli TAVR Registry Risk Model Accuracy score; OBSERVANT, Observational Study of Appropriateness, Efficacy and Effectiveness of AVR-TAVR Procedures for the Treatment of Severe Symptomatic Aortic stenosis score; STS, Society of Thoracic Surgeons score; UNN/OUS, University Hospital of North Norway/Oslo University Hospital

Both American and European guidelines advocate for the use of surgical risk scores as part of the evaluation in patients considered for TAVI.<sup>16,17</sup> However, risk algorithms are accurate only for the population and treatment options for which they were developed and validated. Despite being a useful tool when considering patients for open surgery, they do not take into consideration the inherent differences between the two procedures in addition to the considerable diversity and severity of comorbidities often seen in the TAVI population. Our results support the previous findings that surgical risk scores are inaccurate in predicting early mortality after TAVI.<sup>7,8</sup>

Initially, TAVI was done primarily in patients with high or prohibitive risk for SAVR. This was the population from which the TAVI-specific risk scores evaluated in our study, including our own model, were developed. A limitation of existing risk scores, including our own model, is the lack of frailty measures, especially when considering patients with high or prohibitive risk for open surgery. TAVI is now performed in patients with intermediate risk for SAVR,<sup>15</sup> and results from the recently published PARTNER 3 and NOTION trials show promising results in low-risk patients.<sup>18,19</sup> However, the main challenge in clinical practice is evaluating patients with high comorbid burden that are not candidates for SAVR. In this setting, the question is

whether or not they will tolerate and/or benefit from interventional treatment. This might result in patients undergoing a procedure resulting in no additional benefit over medical therapy alone. These patients require a thorough multidisciplinary evaluation where objective risk scores are needed.

Expanding the indication for TAVI to include patients with intermediate or low surgical risk will make the comorbid burden more comparable to those currently treated with SAVR. However, due to the more invasive nature of the procedure and the use of general anesthesia and heart-lung machine, the inherent risks of surgical valve procedures will never be comparable with those of catheter-based interventions. In addition, there has been rapid development and improvement in valve and catheter technology as well as operator and center experience.<sup>20</sup> Therefore, continuous development, revision, and improvement in TAVI-specific risk scores are needed and must incorporate the heterogeneous comorbid profiles of these patients.

## 5 | LIMITATIONS

In contrast to larger registry studies, our model was based on relatively few patients treated with TAVI at only two centers, with a low number of clinical endpoints. The validity of our model is therefore uncertain and should serve as topic for further research prior to a conclusion of its clinical usefulness. As with previous existing risk scores, our model does not include frailty measures, which might have an impact on early mortality in the high-risk TAVI population. The validation cohort is not independent, since it was derived from new patients at one of the centers that generated the derivation cohort. Our primary endpoint was all cause 30-day mortality. In-hospital mortality beyond 30 days as well as postoperative morbidity was not evaluated in the current study.

## 6 | CONCLUSIONS

Existing risk scores have shown limited accuracy in predicting early mortality after TAVI. This study indicates that TAVI-specific risk scores may contribute to improving the preoperative evaluation of patients undergoing TAVI compared to surgical risk scores. Our results have the potential to aid in the further development of TAVI risk scores. Larger clinical studies and TAVI registries have to confirm their usefulness.

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### CONFLICT OF INTEREST

Rolf Busund is a proctor for Edwards Lifesciences and has received speakers fee from Abbot. Lars Aaberge is a proctor for Edwards Lifesciences. These affiliations were not involved in design, data

collection, analysis, data interpretation, or financial support of the current study.

### AUTHOR CONTRIBUTIONS

**Conceptualization:** Henrik Schirmer, Svend Aakhus, Assami Rösner

**Data curation:** Didrik Kjønnås, Gry Dahle, Jo Eidet, Svend Aakhus, Rolf Busund, Assami Rösner

**Formal analysis:** Didrik Kjønnås, Henrik Schirmer, Assami Rösner

**Funding acquisition:** Assami Rösner

**Investigation:** Didrik Kjønnås, Gry Dahle, Siri Malm, Jo Eidet, Lars Aaberge, Terje Steigen, Rolf Busund, Assami Rösner

**Methodology:** Didrik Kjønnås, Henrik Schirmer, Assami Rösner

**Project administration:** Assami Rösner

**Resources:** Gry Dahle, Siri Malm, Jo Eidet, Resources, Terje Steigen, Svend Aakhus, Rolf Busund, Assami Rösner

**Supervision:** Assami Rösner

**Validation:** Didrik Kjønnås, Assami Rösner

**Visualization:** Didrik Kjønnås, Assami Rösner

**Writing-original draft:** Didrik Kjønnås, Henrik Schirmer, Rolf Busund, Assami Rösner

**Writing-review & editing:** Didrik Kjønnås, Gry Dahle, Henrik Schirmer, Siri Malm, Jo Eidet, Lars Aaberge, Terje Steigen, Svend Aakhus, Rolf Busund, Assami Rösner

All authors have read and approved the final version of the manuscript.

All data used in the study are stored in an off-line central database with restricted access.

### TRANSPARENCY STATEMENT

Dr. Didrik Kjønnås affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, and no important aspects of the study have been omitted.

### DATA AVAILABILITY STATEMENT

The data used in our study can unfortunately not be shared, even upon request. The reason being that it contains sensitive information that could compromise patient anonymity and contain sensitive medical information. Law strictly regulates the access and distribution of such data.

### ORCID

Didrik Kjønnås  <https://orcid.org/0000-0002-7409-1713>

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