


openheart Clinical value of the 20% logistic EuroSCORE cut-off for selecting TAVI candidates: a single-centre cohort study analysis

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ABSTRACT

Background A logistic European System for Cardiac Operative Risk Evaluation (logEuroSCORE) $\geq 20\%$ is frequently recognised as a finite criteria for transcatheter aortic valve implantation (TAVI) reimbursement, despite guideline modifications to reflect the appropriacy of TAVI in selected lower-risk patients. The aim was to evaluate the clinical value of this threshold cut-off in TAVI patients and to identify factors associated with mortality in those below this threshold.

Methods We analysed data from a single-centre, German, observational, TAVI-patient registry, gathered between 2008 and 2016. Patients were stratified by logEuroSCORE (\geq or $< 20\%$) for comparisons. Logistic regression was performed to identify predictors of mortality at 1 year, with this analysis used to generate a calculated ('real') risk value for each patient.

Results 1679 patients (logEuroSCORE $< 20\%$: n=789; logEuroSCORE $\geq 20\%$: n=890) were included. LogEuroSCORE $< 20\%$ patients were significantly younger (80.1 vs 81.6 years; $p < 0.001$) and less comorbid than logEuroSCORE $\geq 20\%$ patients, with a higher rate of transfemoral TAVI (35.6% vs 26.1%; $p < 0.001$) and predilation (70.0% vs 63.3%; $p = 0.004$). Patients with a logEuroSCORE $< 20\%$ experienced more vascular complications (3.4% vs 1.5%; $p = 0.010$). One-year survival was 88.3% in the logEuroSCORE $< 20\%$ and 81.8% in the logEuroSCORE $\geq 20\%$ group ($p = 0.005$), with the calculated mortality risk falling within 2% of the logEuroSCORE in just 12.9% of patients. In the logEuroSCORE $< 20\%$ group, only coronary artery disease was significantly predictive of 1-year mortality (OR 2.408; 95% CI 1.361 to 4.262; $p = 0.003$).

Conclusions At our institution, patients with a logEuroSCORE $< 20\%$ selected for TAVI have excellent outcomes. The decision not to reimburse TAVI in such patients may be viewed as inappropriate.

INTRODUCTION

The European System for Cardiac Operative Risk Evaluation (EuroSCORE) was first introduced in 1999 as a tool for predicting the likelihood of operative mortality in cardiac

Key questions

What is already known about this subject?

► A logistic European System for Cardiac Operative Risk Evaluation (logEuroSCORE) $\geq 20\%$ is frequently recognised as a finite criteria for transcatheter aortic valve implantation (TAVI) reimbursement, despite guideline modifications to reflect the appropriacy of TAVI in selected lower-risk patients.

What does this study add?

► Aim was to evaluate the clinical value of this threshold cut-off in TAVI patients in Germany and to identify factors associated with mortality in those below this threshold.
► At our institution, the outcomes of patients with a logEuroSCORE $< 20\%$ selected for TAVI by our multidisciplinary Heart Team were excellent, with good periprocedural safety and high rates of medium-term survival.

How might this impact on clinical practice?

► Given the overwhelming evidence that the logEuroSCORE is inaccurate for identifying TAVI-associated mortality risk, we suggest that such non-specific scores should be given less importance when evaluating an individual's suitability for TAVI, with additional risk factors and the expert opinion of the Heart Team given greater weight.
► From a clinical perspective, coronary artery disease may deserve particular attention in patients with a logEuroSCORE $< 20\%$ being considered for TAVI.

surgical patients.¹ The score takes into account a total of 17 objective risk factors encompassing patient-related, cardiac and operation-related variables. In Germany, it is one of the most widely used tools for preprocedural assessment of patients with severe symptomatic aortic stenosis (AS) being considered for aortic valve replacement (AVR).

The advanced age and multimorbidity of the AS population means that surgical AVR (SAVR) is typically a high-risk procedure.² In

recent years, transcatheter AVR (TAVI) has been widely adopted as a lower-risk, minimally invasive alternative. In their initial 2008 statement, European authorities proposed an arbitrary 20% logistic EuroSCORE (logEuroSCORE) cut-off as a rough guide for identifying high-risk patients that may be more suited to TAVI than SAVR.³ However, in the same consensus document, the authors emphasised the score's modest accuracy and promoted its use in conjunction with informed clinical judgement. Current 2017 European guidelines now recommend that TAVI be considered in all patients with a logEuroSCORE $\geq 10\%$, as well as in those with a score below this threshold but with additional significant risk factors.⁴ As such, conventional risk-stratification tools should be supplemented by a Heart Team's professional opinion when identifying good TAVI candidates. Despite these evidence-based guideline revisions, a logEuroSCORE of 20% continues to be recognised as the lower limit for TAVI candidates.⁵

The present real-world analysis aimed to evaluate the clinical value of the 20% logEuroSCORE cut-off for identifying good TAVI candidates at our site. Factors associated with post-TAVI mortality in patients with a logEuroSCORE $< 20\%$ were also explored, so as to aid clinical decision-making.

METHODS

The present study is a post hoc analysis of data from a single-centre, German, observational registry that was originally established as part of a quality assurance initiative. The registry's methodology has been previously described.^{6,7} Briefly, patients with severe AS undergoing TAVI between 2008 and 2016 were consecutively enrolled after providing their written informed consent to participate.

Patients

All patients with a diagnosis of severe, symptomatic AS that were scheduled to undergo TAVI at the Bad Rothenfelde Heart Centre were included. For the present analysis, patients without stated values for logEuroSCORE were excluded. No further inclusion/exclusion criteria applied.

The decision to perform TAVI was taken by the resident Heart Team, independently from the registry. In line with European guidelines, this decision was based on the patient being judged to be at high risk for SAVR following a comprehensive assessment that took into account the logEuroSCORE and other important risk factors, such as frailty, porcelain aorta and sequelae of chest radiation.⁴ The choice of access route was governed by the 'best for transfemoral (TF)' principle, which has been previously described.⁷ Briefly, unless a patient had all of the attributes comprising an ideal candidate for TF-TAVI, transapical (TA)-TAVI was preferentially performed.

For the present analysis, patients were divided into those with a logEuroSCORE of $< 20\%$ and those with a logEuroSCORE of $\geq 20\%$.

Procedures and documentation

Baseline patient demographics, cardiac history, comorbidities and echocardiographic parameters were recorded prior to TAVI. Coronary artery disease (CAD) in our dataset is a clinical diagnosis which was not revalidated in the context of this registry. A logEuroSCORE value, the components of which are outlined in online supplementary table 1, was calculated for each patient, as previously described.¹

A trans-oesophageal echocardiography, coronary angiography and a CT scan were performed to aid access route and transcatheter heart valve size selection. All TAVI procedures were performed under general anaesthesia, according to standard site protocol. Peri-procedural details and complications were documented and patients were followed up over the subsequent year. This period included outpatient visits or telephone interviews at 30 days, 6 and 12 months, during which data on vital status, complications and cardiovascular health were documented.

Statistics

Baseline and peri-procedural data were analysed using descriptive statistics, with continuous variables presented as means with SD and categorical variables presented as absolute numbers with percentages (%). Comparisons between patients with a logEuroSCORE $< 20\%$ and those with a logEuroSCORE $\geq 20\%$ were carried out using a Student's t-test or Mann-Whitney U test for continuous variables and a χ^2 or Fisher's exact test for categorical variables. One-year Kaplan-Meier survival estimates were generated for each group and presented with a p value calculated by Breslow test. Multivariate logistic regression including all documented baseline variables as covariables was carried out to identify predictors of mortality within the year following TAVI in the total study population, as well as in the logEuroSCORE $< 20\%$ group separately. These data are presented as ORs with 95% CIs and p values.

To retrospectively determine each patient's 'calculated risk' of all-cause mortality at 1 year, output data from the regression analysis for the total population were entered into SPSS, alongside individual baseline patient data. This analysis generated a value for the 'real' probability of death at 1 year for each patient, expressed as a percentage (%). Appendix 1 No calculated risk was generated for patients missing data for any of the baseline variables. Each patient's calculated risk was compared with their logEuroSCORE-predicted risk, with values within $\pm 2\%$ considered comparable.

All statistical analysis was carried out using IBM SPSS, V.24.0 (IBM, Armonk, New York, USA), with a p value of < 0.05 considered to be statistically significant.

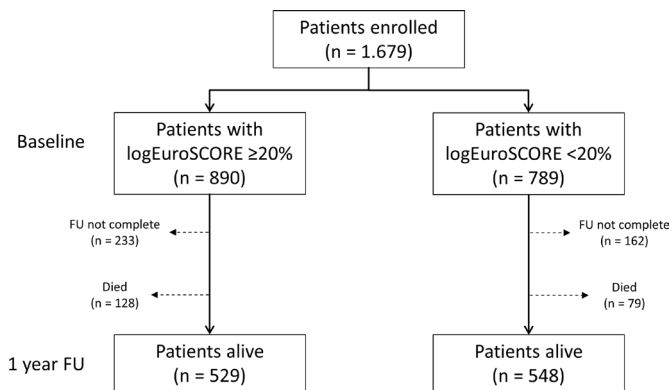


Figure 1 Patient flow. 'FU not complete' comprises all patients with a follow-up of <1 year or patients lost to follow-up. FU, follow-up; logEuroSCORE, logistic European System for Cardiac Operative Risk Evaluation.

RESULTS

A total of 1679 patients met the study inclusion criteria and underwent TAVI at our centre (figure 1). The

baseline logEuroSCORE was <20% in 789 patients (47.0%) and ≥20% in 890 patients (53.0%).

Baseline patient characteristics

Compared with patients with a logEuroSCORE ≥20%, patients with a logEuroSCORE <20% were younger ($80.1\% \pm 6.3\%$ vs $81.6\% \pm 5.4\%$; $p < 0.001$), had experienced fewer prior cardiac events/surgeries and were generally less comorbid (table 1). In addition, a significantly lower proportion were in New York Heart Association (NYHA) class III/IV (78.1% vs 84.2%; $p < 0.001$). The mean left ventricular ejection fraction (LVEF) was higher in the logEuroSCORE <20% group ($57.4\% \pm 10.3\%$ vs $49.9\% \pm 13.9\%$; $p < 0.001$), as were the peak (79.2 ± 23.5 vs 73.5 ± 26.1 mm Hg; $p < 0.001$) and mean (49.5 ± 15.7 vs 45.3 ± 17.1 ; $p < 0.001$) transvalvular gradients.

Peri-procedural details

Although TA was the most common access route in both groups (62.6% and 72.1%, respectively), a higher

Table 1 Baseline patient characteristics

	logEuroSCORE ≥20% mean±SD or n/N (%) (n=890)	logEuroSCORE <20% mean±SD or n/N (%) (n=789)	P value
Age (years)	81.6±5.4	80.1±6.3	<0.001
Female gender	458/890 (51.5)	444/789 (56.3)	0.048
Cardiac history			
Prior MI	207/884 (23.4)	82/772 (10.6)	<0.001
Prior cardiac surgery*	315/890 (35.4)	107/788 (13.6)	<0.001
Prior stroke	210/890 (23.6)	54/788 (6.9)	<0.001
Comorbidities			
AF	414/890 (46.5)	267/789 (33.8)	<0.001
Hypertension	844/890 (94.8)	738/789 (93.5)	0.256
CAD	593/883 (67.2)	374/772 (48.4)	<0.001
Mitral valve insufficiency (>II°)	54/888 (6.1)	19/785 (2.4)	<0.001
Porcelain aorta	266/884 (30.1)	212/773 (27.4)	0.232
Pulmonary hypertension	362/889 (40.7)	158/788 (20.1)	<0.001
COPD	204/890 (22.9)	140/789 (17.7)	0.009
Diabetes mellitus	304/890 (34.2)	214/789 (27.1)	0.002
Kidney insufficiency	581/888 (65.4)	379/789 (48.0)	<0.001
Dialysis	36/888 (4.1)	10/789 (1.3)	<0.001
NYHA class III or IV	726/861 (84.3)	579/741 (78.1)	0.001
LVEF (%)	49.9±13.9	57.4±10.3	<0.001
Peak AV gradient (mm Hg)	73.5±26.1	79.2±23.5	<0.001
Mean AV gradient (mm Hg)	45.3±17.1	49.5±15.7	<0.001
STS score (%)	11.8±10.1	8.0±8.3	<0.001
LogEuroSCORE (%)	34.5±13.0	12.6±4.3	<0.001

*Not including percutaneous coronary intervention.

AF, atrial fibrillation; AV, aortic valve; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; logEuroSCORE, logistic European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons.

Table 2 Peri-procedural details

	logEuroSCORE $\geq 20\%$ n/N (%) (n=890)	logEuroSCORE $< 20\%$ n/N (%) (n=789)	P value
Access route			<0.001
TF	232/890 (26.1)	281/789 (35.6)	
TA	642/890 (72.1)	494/789 (62.6)	
Other	16/890 (1.8)	14/789 (1.8)	
Valve type			0.007
SAPIEN/SAPIEN XT	735/890 (82.6)	646/789 (81.9)	
ACURATE	142/890 (16.0)	142/789 (18.0)	
Others	13/890 (1.5)	1/789 (0.1)	
BAV predilation	563/890 (63.3)	552/789 (70.0)	0.004
Complications			
Conversion to surgery	4/890 (0.4)	6/789 (0.8)	0.530
Major vascular complications	13/871 (1.5)	27/785 (3.4)	0.010
PPI	66/869 (7.6)	69/782 (8.8)	0.363
New arrhythmia	244/871 (28.0)	233/784 (29.7)	0.444
Moderate-to-severe PVL	9/857 (1.1)	9/750 (1.2)	0.776
AKI requiring dialysis	7/858 (0.8)	3/771 (0.4)	0.349
Postdilation	146/889 (16.4)	149/788 (18.9)	0.182
In-hospital mortality	26/880 (3.0)	21/788 (2.7)	0.721

AKI, acute kidney injury; BAV, balloon aortic valvuloplasty; logEuroSCORE, logistic European System for Cardiac Operative Risk Evaluation; PPI, permanent pacemaker implantation; PVL, paravalvular leak; TA, transapical; TF, transfemoral.

proportion of the logEuroSCORE $< 20\%$ group underwent TAVI via the TF route compared with the logEuroSCORE $\geq 20\%$ group (35.6% vs 26.1%; $p < 0.001$) (table 2). The vast majority of patients received a SAPIEN/SAPIEN XT valve (82.3% overall). Balloon aortic valvuloplasty (BAV) predilation was more frequently performed in the logEuroSCORE $< 20\%$ group than the logEuroSCORE $\geq 20\%$ group (70.0% vs 63.3%; $p = 0.004$).

The rates of conversion to surgery, permanent pacemaker implantation (PPI), new arrhythmia, moderate/severe paravalvular regurgitation (PVL), acute kidney

injury (AKI) requiring dialysis and balloon post-dilation were low and statistically comparable between groups (table 2). Though rare overall, major vascular complications were significantly more common in patients with a logEuroSCORE of $< 20\%$ than in those with a logEuroSCORE of $\geq 20\%$ (3.4% vs 1.5%; $p = 0.010$).

Survival

No statistical significant difference was found for in-hospital mortality between the two groups (3.0% (logEuroSCORE $\geq 20\%$) vs 2.7% (logEuroSCORE $< 20\%$); $p = 0.721$) (table 2). At 1 year post-TAVI, the estimated survival rate was significantly higher for patients with a logEuroSCORE $< 20\%$ than for those with a logEuroSCORE $\geq 20\%$ (88.3% vs 81.8%; $p = 0.005$) (figure 2). At 5 years post-TAVI, the estimated survival rate stayed significantly higher for patients with a logEuroSCORE $< 20\%$ (57.1% vs 44.3%; $p = 0.005$) (online supplementary figure 1).

Predictors of mortality at 1 year

In the overall population, atrial fibrillation (AF; OR 1.758; 95% CI 1.267 to 2.439; $p = 0.001$), CAD (OR 1.559; 95% CI 1.054 to 2.306; $p = 0.026$), kidney insufficiency (OR 1.458; 95% CI 1.021 to 2.084; $p = 0.038$) and NYHA class III/IV (OR 1.824; 95% CI 1.099 to 3.027; $p = 0.020$) were independent predictors of mortality at 1 year (table 3). A higher LVEF was protective, although the effect size was small (OR 0.985; 95% CI 0.972 to 0.998; $p = 0.020$).

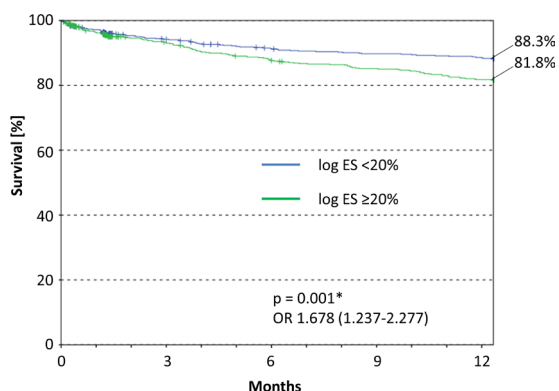


Figure 2 Kaplan-Meier survival curves for the year after TAVI. logES, logEuroSCORE.

Table 3 Predictors of mortality at 1 year post-TAVI in the overall study population

	Univariate OR (95% CI)	P value	Multivariate OR (95% CI)*	P value
Age (years)	0.997 (0.973 to 1.021)	0.779	1.002 (0.972 to 1.033)	0.903
Female gender	0.796 (0.591 to 1.072)	0.134	1.156 (0.811 to 1.646)	0.422
Cardiac history				
Prior MI	1.333 (0.923 to 1.924)	0.125	0.979 (0.638 to 1.502)	0.922
Prior cardiac surgery†	1.220 (0.882 to 1.687)	0.229	0.881 (0.588 to 1.320)	0.540
Prior stroke	1.062 (0.707 to 1.597)	0.771	0.875 (0.561 to 1.364)	0.556
Comorbidities				
AF	2.140 (1.584 to 2.892)	<0.001	1.758 (1.267 to 2.439)	0.001
Hypertension	1.390 (0.705 to 2.743)	0.342	0.879 (0.427 to 1.808)	0.725
CAD	1.638 (1.188 to 2.258)	0.003	1.559 (1.054 to 2.306)	0.026
Mitral valve insufficiency (>II°)	1.225 (0.624 to 2.404)	0.555	0.929 (0.453 to 1.905)	0.841
Porcelain aorta	1.194 (0.864 to 1.649)	0.283	1.117 (0.786 to 1.588)	0.537
Pulmonary hypertension	1.475 (1.074 to 2.027)	0.016	1.353 (0.958 to 1.909)	0.086
COPD	1.383 (0.980 to 1.950)	0.065	1.156 (0.792 to 1.687)	0.451
Diabetes mellitus	1.861 (1.354 to 2.559)	<0.001	1.238 (0.876 to 1.750)	0.226
Kidney insufficiency	1.156 (0.721 to 1.854)	0.546	1.458 (1.021 to 2.084)	0.038
NYHA class III or IV	2.233 (1.372 to 3.634)	0.001	1.824 (1.099 to 3.027)	0.020
LVEF (%)	0.976 (0.966 to 0.987)	<0.001	0.985 (0.972 to 0.998)	0.020
Peak AV gradient (mm Hg)	0.989 (0.983 to 0.995)	0.001	1.000 (0.982 to 1.017)	0.965
Mean AV gradient (mm Hg)	0.983 (0.974 to 0.993)	<0.001	0.994 (0.969 to 1.021)	0.676

*Adjusted for all other variables.

†Not including percutaneous coronary intervention.

AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; TA, transapical; TF, transfemoral.

Considering only patients with a logEuroSCORE of <20%, CAD was the only variable that remained a significant baseline predictor of 1-year mortality (OR 2.408; 95% CI 1.361 to 4.262; $p=0.003$) (table 4). AF also showed potential clinical, if not statistical, relevance (OR 1.620; 95% CI 0.947 to 2.770; $p=0.078$).

Calculated risk versus logEuroSCORE

In total, 1132 patients had both a calculated risk value for mortality at 1 year and a baseline logEuroSCORE available. The calculated risk fell within 2% of the logEuroSCORE-predicted risk in just 12.9% of cases, being comparatively lower in 62.5% of patients (figure 3).

DISCUSSION

The present real-world analysis suggests that there is little clinical value in the 20% logEuroSCORE cut-off. Indeed, despite obvious differences in baseline characteristics, patients both above and below the 20% threshold had excellent clinical outcomes, with low rates of peri-procedural complications and high survival rates at 1 year. Furthermore, the actual calculated risk of mortality following TAVI was below that predicted by the logEuroSCORE in over 60% of cases, demonstrating the score's inaccuracy in this indication. Among other variables, CAD was

associated with a greater risk of mortality in the year after TAVI, remaining the only independent predictor in patients with a logEuroSCORE <20%. Raising awareness of this association among physicians may result in more appropriate treatment decisions.

Peri-procedural outcomes

Regardless of logEuroSCORE, the peri-procedural outcomes observed in the present study were highly satisfactory, with complications being extremely rare and largely comparable between the higher-risk and lower-risk groups. This is in agreement with prior studies in low-risk/intermediate-risk patients undergoing TAVI, which have also reported low rates of AKI, new arrhythmia and re-intervention.⁸⁻¹⁰ Importantly, such studies have found the risk of these events to be significantly reduced with TAVI compared with SAVR.⁸⁻¹¹ This was recently reinforced by the publication of two major randomised trials, showing that the procedure is at least as safe or even superior in low-risk patients.¹²⁻¹³ Furthermore, PPI was required by <9% of patients in each of the present logEuroSCORE groups. This value is at the lower end of the rates reported by prior TAVI studies (range: 6.5%–33.7%¹⁴⁻¹⁸) and only slightly higher than those reported for low-risk/intermediate-risk patients undergoing

Table 4 Predictors of mortality at 1 year post-TAVI in patients with a logEuroSCORE <20%

	Univariate OR (95% CI)	P value	Multivariate OR (95% CI)*	P value
Age (years)	1.001 (0.965 to 1.038)	0.947	0.996 (0.950 to 1.044)	0.868
Female gender	1.176 (0.726 to 1.905)	0.509	1.482 (0.842 to 2.609)	0.172
Cardiac history				
Prior MI	1.028 (0.488 to 2.165)	0.942	0.854 (0.360 to 2.024)	0.720
Prior cardiac surgery†	0.802 (0.397 to 1.620)	0.539	0.772 (0.337 to 1.771)	0.542
Prior stroke	0.814 (0.312 to 2.123)	0.674	0.745 (0.248 to 2.236)	0.600
Comorbidities				
AF	1.716 (1.065 to 2.766)	0.027	1.620 (0.947 to 2.770)	0.078
Hypertension	1.991 (0.601 to 6.595)	0.260	1.360 (0.389 to 4.761)	0.630
CAD	1.815 (1.112 to 2.961)	0.017	2.408 (1.361 to 4.262)	0.003
Mitral valve insufficiency (>II°)	1.757 (0.485 to 6.367)	0.391	1.636 (0.403 to 6.638)	0.491
Porcelain aorta	1.263 (0.752 to 2.121)	0.377	1.115 (0.638 to 1.950)	0.702
Pulmonary hypertension	1.628 (0.905 to 2.928)	0.104	1.527 (0.797 to 2.926)	0.202
COPD	1.169 (0.648 to 2.110)	0.605	1.154 (0.605 to 2.202)	0.664
Diabetes mellitus	1.166 (0.692 to 1.964)	0.564	0.966 (0.539 to 1.733)	0.908
Kidney insufficiency	1.156 (0.721 to 1.854)	0.546	0.983 (0.580 to 1.667)	0.949
NYHA class III or IV	1.716 (0.853 to 3.453)	0.130	1.519 (0.732 to 3.152)	0.262
LVEF (%)	0.990 (0.969 to 1.011)	0.346	0.988 (0.964 to 1.013)	0.352
Peak AV gradient (mm Hg)	1.002 (0.992 to 1.012)	0.747	0.999 (0.978 to 1.021)	0.931
Mean AV gradient (mm Hg)	1.003 (0.988 to 1.018)	0.668	1.012 (0.981 to 1.045)	0.446

*Adjusted for all other variables.

†Not including percutaneous coronary intervention.

AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; TA, transapical; TF, transfemoral.

SAVR (range: 6.6%–7.3%^{8 9 19}). While vascular complications were more common in the logEuroSCORE <20% compared with the logEuroSCORE ≥20% group, this is likely a result of TAVI being more commonly performed via the TF route in the former patients. Indeed, the greater risk of major vascular complications in TF-TAVI compared with TA-TAVI is well recognised.²⁰ Nevertheless, the rate of 3.4% observed in the logEuroSCORE <20% group is strikingly lower than the values reported by the majority of studies in low-risk/intermediate-risk patients undergoing TAVI or SAVR.^{8 19} This may be partly attributable to the ‘best for TF’ approach employed at our institution, given that only patients with the most compatible access vasculature undergo TF-TAVI. Overall, our data demonstrate that patients selected for TAVI by an expert Heart Team at our site have excellent periprocedural outcomes, regardless of whether or not they have a logEuroSCORE above or below the 20% cut-off. As such, this threshold appears to have little clinical value for discerning between good and poor candidates for TAVI.

Mortality at 1 year

The increased risk of mortality in elderly, multimorbid individuals undergoing open heart surgery is well recognised. Such characteristics feature heavily in surgical

risk-stratification tools,²¹ the logEuroSCORE being no exception.¹ Accordingly, it is appropriate for SAVR to be avoided in patients with a logEuroSCORE of ≥20% and for the minimally invasive alternative, TAVI, to be used. However, it does not necessarily follow that patients with a logEuroSCORE below this 20% threshold fail to benefit from TAVI. In the present study, 1-year survival rates were extremely high in the logEuroSCORE <20% group, being similar to those previously reported for low-risk/intermediate-risk patients undergoing SAVR.^{8 19} While such comparisons are hindered by between-study heterogeneity, several important clinical trials have demonstrated a lower rate of all-cause mortality after TAVI compared with SAVR in patients at intermediate surgical risk.^{8 9} This trend was also reiterated by a recent, high-profile propensity score-matched analysis.¹⁹

Furthermore, our in-hospital mortality rates were low (logEuroSCORE ≥20%: 3.0% and logEuroSCORE <20%: 2.7%) compared with a large-scale, real-world German study.²² This study found TF-TAVI to result in similar or lower in-hospital mortality rates compared with SAVR across all surgical-risk groups (logEuroSCORE <10%: 2.4% vs 2.0%, $p=0.302$; logEuroSCORE 10%–20%: 3.5% vs 5.3%, $p=0.025$; logEuroSCORE 20%–30%: 5.5% vs

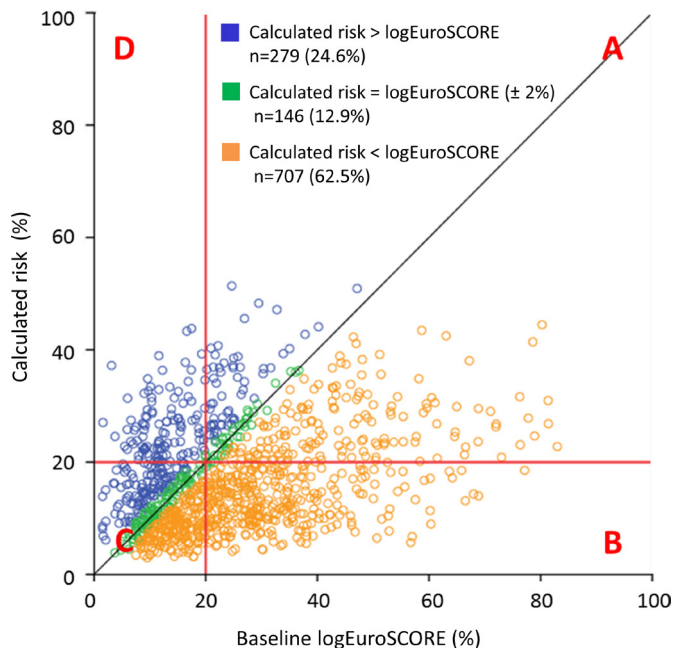


Figure 3 Calculated risk of mortality at 1 year compared with logEuroSCORE-predicted risk. N=1132; calculated risk could not be generated for 547/1679 patients due to missing data for ≥ 1 baseline variables. (A) Both logEuroSCORE and actual risk $\geq 20\%$ (n=256; 22.6%); (B) logEuroSCORE $\geq 20\%$ and calculated risk $< 20\%$ (n=334; 29.5%); (C) both logEuroSCORE and calculated risk $< 20\%$ (n=432; 38.2%); (D) logEuroSCORE $< 20\%$ and calculated risk $\geq 20\%$ (n=110; 9.7%). logEuroSCORE, logistic European System for Cardiac Operative Risk Evaluation.

12.2%, $p < 0.001$; logEuroSCORE $> 30\%$: 6.5% vs 12.9%, $p = 0.008$).²² As such, it appears that informed selection of patients with a logEuroSCORE $< 20\%$ for TAVI can result in at least comparable survival compared with SAVR. As such, the use of a 20% logEuroSCORE cut-off to denote automatic ineligibility for TAVI reimbursement may require revision.

Predicting TAVI-related risk

The fact that survival was greater in the logEuroSCORE $< 20\%$ group compared with the logEuroSCORE $\geq 20\%$ group is unsurprising considering the differences in age and comorbidities at baseline. Indeed, all of the four variables identified as independent predictors of all-cause death within the overall population (AF, CAD, kidney insufficiency and NYHA class III/IV) were more prevalent in the logEuroSCORE $< 20\%$ group. However, of these, only renal insufficiency features in the logEuroSCORE algorithm. This may explain why the score was able to predict approximate trends in post-TAVI mortality but had limited accuracy for identifying actual risk, with $< 13\%$ of calculated risk values falling within 2% of the logEuroSCORE. As such, the present study adds to the considerable pool of evidence demonstrating the inappropriacy of the logEuroSCORE for predicting outcomes after TAVI.^{4 23–27} A number of TAVI-specific risk-assessment scores have been developed, including

SURTAVI, TARIS, FRANCE-2, TAVI2-SCORE, STT and OBSERVANT (contributory variables outlined in online supplementary table 2)^{28–33}; however, while several of these have shown promise, none has yet been extensively validated, adopted or endorsed by expert consensus. In Germany specifically, the re-calibrated German AV score (GAVS) II has been presented, although still offers only modest predictive ability (C-statistic: 0.74) and has only been validated in terms of in-hospital mortality.³⁴ Consequently, the urgent need for a TAVI-specific, accurate risk-stratification system remains.

Besides being one of several variables associated with death in the overall study population, CAD was the only independent predictor of 1-year mortality in patients with a logEuroSCORE $< 20\%$, increasing the risk more than twofold. This likely reflects the reduced capacity of patients with CAD to tolerate the ischaemic and haemodynamic burden of the procedure, which includes rapid ventricular pacing, balloon inflation and periods of hypotension. CAD does not specifically feature in the logEuroSCORE; however, it has been previously recognised as a key risk factor in TAVI patients and is included in both the SURTAVI and GAVS II TAVI-specific risk-assessment tools.^{33 34} CAD and AS commonly coexist due to shared risk factors and mechanisms of pathogenesis.^{35 36} Fortunately, the former condition may be treated through coronary artery bypass grafting or percutaneous coronary intervention (PCI).^{37 38} Several studies have shown that such revascularisation prior to treatment of the AS results in improved long-term outcomes³⁹; however, these studies have mainly been performed in SAVR patients and few data exist in the context of TAVI. Nevertheless, ESC guidelines contain a class IIa recommendation for PCI to be considered in patients with a primary indication for TAVI and coronary artery diameter stenosis $> 70\%$ in proximal segments.⁴ Our data suggest that the resolution of CAD prior to TAVI may allow better outcomes, especially in patients with a logEuroSCORE $< 20\%$, and this merits further investigation. The incorporation of CAD into future TAVI-specific risk scores should also be considered.

Interestingly, a clinically (if not statistically) significant association between AF and post-TAVI mortality risk was observed in patients with a logEuroSCORE of $< 20\%$. AF has been widely associated with poorer long-term survival and stroke in patients with AS, regardless of treatment approach or classically assessed procedural risk⁴⁰; however, this effect appears to be largely related to a lack of guidelines for optimum antithrombotic therapy regimens during AVR. Development of such standardised recommendations would likely reduce the risk of thromboembolic events and bleeding complications in patients with AF undergoing TAVI, translating into a lower mortality risk and enabling more low-risk patients to safely undergo the procedure.

Limitations

Given that the present study was based on TAVI-specific data from a quality assurance initiative, SAVR data were

unavailable for comparison. This limits the conclusions we are able to draw regarding the choice between TAVI and SAVR in low-risk patients. Nevertheless, our data suggest the inappropriacy of using a finite logEuroSCORE <20% cut-off to indicate that TAVI would not be beneficial. A second limitation is the proportional difference in TAVI access routes between low-risk and high-risk groups, which may have influenced outcomes. Nevertheless, route selection was based on comprehensive patient assessment by an expert Heart Team and is representative of real-world practice, with other registries also reporting a higher frequency of TF-TAVI in low-risk patients.⁴¹ Third, some patients in the present study underwent TAVI a considerable number of years ago, with the procedure's rapid evolution in recent years having resulted in contemporary improvements in valve technology and operator experience.⁴¹ Furthermore, BAV predilation, which at the beginning of the study was a mandatory step in the TAVI procedure and is thus highly prevalent in the present dataset, is now considered largely unnecessary in the majority of patients and may even be harmful.⁴² As such, our data may underestimate the up-to-date safety/efficacy of the TAVI procedure. Finally, the study was confined to a single German site that adopts the 'best for TF' method for access route selection. As such, our findings may not be generalisable to centres in other countries or that employ alternative approaches to access decision.

CONCLUSIONS

At our institution, the outcomes of patients with a logEuroSCORE <20% selected for TAVI by our multidisciplinary Heart Team were excellent, with good periprocedural safety and high rates of medium-term survival. Given the overwhelming evidence that the logEuroSCORE is inaccurate for identifying TAVI-associated mortality risk, we suggest that such non-specific scores should be given less importance when evaluating an individual's suitability for TAVI, with additional risk factors and the expert opinion of the Heart Team given greater weight. From a clinical perspective, CAD may deserve particular attention in patients with a logEuroSCORE <20% being considered for TAVI.

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