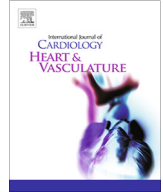




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## Short- and medium-term survival after TAVI: Clinical predictors and the role of the FRANCE-2 score



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### ABSTRACT

**Aim:** The aim of this study was to explore the value of the FRANCE-2 score in associating with clinical outcome in the medium and short-term after TAVI and to compare its relative merits with other risk score models.

**Methods:** 187 consecutive patients undergoing TAVI in a single UK centre were retrospectively studied. The FRANCE-2, logistic EuroSCORE, EuroSCORE II, German AV and STS/ACC TVT risk scores were calculated retrospectively and c-statistics associating with mortality were applied. Survival outcomes were compared between different risk groups according to the FRANCE-2 scores.

**Results:** Of the 187 patients, 57.2% were male and their mean age was  $80.9 \pm 6.9$  years. The c-index of FRANCE-2 score for predicting 30-day mortality was 0.793 ( $p = 0.009$ ), for 1-year mortality 0.679 ( $p = 0.016$ ) and for 2-year mortality was 0.613 ( $p = 0.088$ ). The mean survival time for patients with a high FRANCE-2 score (18.6 months) was significantly less than for patients with low and moderate scores ( $p = 0.0004$ ). The logistic EuroSCORE and EuroSCORE II were poorly associated with 30-day and 1-year mortality. STS/ACC TVT score was best predictive of 1-year mortality and German AV score was moderately predictive of 30-day mortality.

**Conclusions:** The FRANCE-2 risk score is associated with differential short- and medium-term survival in patients undergoing TAVI. The presence of a high FRANCE-2 score ( $>5$ ) is associated with poor survival. The FRANCE-2 scoring system could be considered as a useful additional tool by the Heart multidisciplinary team (MDT) in identifying patients who are likely to have limited survival benefit although this requires further prospective evaluation.

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## 1. Introduction

Aortic stenosis is the most prevalent valvular heart disease in the Western countries and is a common cause of mortality and morbidity in an aging population [1]. Transcatheter aortic valve implantation (TAVI) is now widely accepted as an alternative treatment option in patients with symptomatic and severe aortic stenosis who are at high-risk for conventional surgical aortic valve replacement (SAVR). Studies in surgically high-risk and even intermediate-risk patients have shown non-inferiority of short- and medium-term clinical outcomes with TAVI compared to SAVR

[2]. Most patient undergoing TAVI have good functional and survival outcomes but a small proportion of patients fail to derive benefit. Despite improving early outcomes with TAVI, national registry data have consistently reported that up to 25% of patients undergoing TAVI die within the first year [3], while a proportion of surviving patients do not obtain significant functional improvement [4]. A full understanding of the reasons for this mortality and disappointing functional outcome in the first year is important and studies have indicated that it usually associates with the presence of uncorrected cardiac and non-cardiac co-morbidities that are present at the time of the original procedure [5]. The important function of the Heart multidisciplinary team (MDT) is to ensure that patients are selected appropriately for TAVI and that the procedure is only undertaken in those that are likely to get significant functional and survival improvement. The input to the MDT discussions of clinical expertise from a variety of clinicians is essential

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but access to an objective and validated risk scoring system would be helpful to support the clinical decision-making process.

There is currently no consensus on the ideal clinical predictive models for TAVI. Conventional cardiac surgery risk models have been developed to support decision-making in patients being considered for possible coronary revascularisation including the Logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) [6]. The limitations of this and other scoring systems has, however, been recognised and their application to risk prediction in patients undergoing cardiac surgery for valvular heart disease has already been eluded to [7]. TAVI-focused risk score models have been developed from national registries, but they lack external validation and showed only moderate discrimination [8].

The FRANCE-2 multi-parametric risk score was previously developed to predict mortality after TAVI and comprises pre-procedural factors that are integrated into a 21-point scoring system [9]. It was originally validated against early (up to 30 days) or in-hospital mortality after TAVI but its association with longer term clinical outcome is uncertain. In this study, we aimed to investigate the possible association between the FRANCE-2 and medium as well as short term survival after TAVI and, in this regard, to consider its relative merits compared with other risk assessment scores in a single United Kingdom (UK) centre.

## 2. Methods

This retrospective audit and service evaluation was done in consecutive patients (n = 187) who had undergone TAVI between December 2010 to December 2017 at the University of Hospital Wales, Cardiff, United Kingdom. The baseline patient characteristics were collected from the UK Central Cardiac Audit Database (CCAD) and any missing data were acquired from the electronic health record or in-patient notes. Patients and public were not involved in this research study.

All procedures were undertaken in a tertiary University Centre with access to emergency cardiac surgery but that stand-by cardiopulmonary bypass was not considered to be needed. All patients were initially managed in either the Cardiac Intensive Care Unit or in the Coronary Care Unit during the early post-operative period and this was followed by a period of 'step-down' care on the general cardiology ward prior to discharge.

Survival status was established from patient records and also by independent mortality tracking from the Office of National Statistics (ONS). The survival status of all patients in May 2018 was achieved.

The demographic and clinical data, as well as the presence or absence of co-morbidities, was used to derive the FRANCE-2, logistical EuroSCORE, EuroSCORE II, German Aortic Valve (German AV) and Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) risk score in all patients at the time of undergoing TAVI. The risk scores were calculated by one investigator to maintain consistency and avoid inter-observer variability. To investigate the association between these scores and mortality, Receiver Operating Characteristic curves (ROC) were generated and the area under each curve was established. The c-index was also applied to further determine the association between the FRANCE-2 score or the alternative risk scores and subsequent mortality after TAVI. The author was blinded to the survival status of patients while doing this analysis, in order to minimise bias. Using the FRANCE-2 scores, patients were further divided into low risk (score 0), moderate risk (score 1–5) and high risk (score >5) groups and the survival outcome between these was compared.

Statistical analysis was undertaken in SPSS version 25.0 for Windows (IBM corporation). Continuous data were presented in

mean ± SD while discrete variables were reported in percentages and sample size. Kaplan-Meier curve was plotted for survival analysis and Breslow test was used to determine the statistical significance with p < 0.05 as significant. Univariate logistic regression analysis was performed to identify the relationship of co-morbidities with survival outcome. Log rank test was used to identify the significance of difference between each group with p < 0.05 being statistically significant. Calibration of the model was performed using the Hosmer-Lemeshow goodness-of-fit test.

This study involved the secondary use of data that was acquired primarily for clinical, departmental audit and non-research reasons. For this reason, ethical approval was not required or sought for the study and this was confirmed as appropriate by the Director of Research and Development at Cardiff and Vale University Health Board.

## 3. Results

### 3.1. Demographic data

The demographic data is presented in Table 1. Of the 187 patients studied, 80 were female and 107 were male with a mean age of 80.9 (SD 6.9). In the total cohort, 99% (n = 186) were white Caucasians and 1 patient was of Asian ethnicity. Patients who were offered TAVI were all symptomatic with breathlessness and 83.4% reported NYHA Class III symptoms. Mean aortic valve area was 0.71 cm<sup>2</sup>. Most patients underwent transfemoral TAVI while 12 patients (6.4%) underwent the procedure via the left subclavian approach with surgical cut-down. The Medtronic Corevalve system was used in all procedures.

Coronary artery disease was defined as more than 50% diameter stenosis in orthogonal views in one or more coronary arteries. Significant peripheral arterial disease was defined as the presence of reduced or absent peripheral pulse and/ or angiographic stenosis

**Table 1**  
Baseline demographic data of all patients included in the study.

Patient demographic	Values (N = 187)
Age	80.9 ± 6.9
Gender	
Male	57.2% (n = 107)
Female	42.8% (n = 80)
Coronary artery disease	39.6% (n = 74)
Peripheral arterial disease	40.1% (n = 75)
Previous cardiac surgery	34.2% (n = 64)
Atrial fibrillation	27.8% (n = 52)
Chronic pulmonary disease	43.9% (n = 82)
Previous neurological disease	28.9% (n = 54)
Diabetes mellitus	40.1% (n = 75)
Creatinine > 200 µg/ mmol	6.4% (n = 12)
New York Heart Association (NYHA)	
Class II	9.1% (n = 17)
Class III	83.4% (n = 156)
Class IV	7.5% (n = 14)
Left ventricular ejection function (LVEF)	
≥50%	30.5% (n = 57)
30%–49%	55.6% (n = 104)
<30%	13.9% (n = 26)
Aortic valve peak gradient (mmHg)	73.4 ± 20.8
Aortic valve area (cm <sup>2</sup> )	0.71 ± 0.15
Delivery approach	
Transfemoral	93.6% (n = 175)
Subclavian	6.4% (n = 12)
Types of anaesthesia	
General anaesthesia	58.3% (n = 109)
Regional anaesthesia	41.7% (n = 78)
Intraoperative echocardiography use	
Transoesophageal	58.3% (n = 109)
Transthoracic	41.7% (n = 78)

of more than 50%. Chronic pulmonary disease was noted in patients with a diagnosis of asthma, chronic obstructive pulmonary disease (COPD) or emphysema. Patients with previous TIA or stroke with or without full recovery were said to have previous neurological disease. Chronic kidney disease was defined as creatinine of more than 200  $\mu\text{g}/\text{mmol}$ .

### 3.2. Survival and association with comorbidities

Median follow up was 24 months (IQR 26 months) with no patients being lost to follow up. The independent clinical determinants that were associated with reduced survival were the presence of significant chronic obstructive pulmonary disease (COPD), pre-procedural New York Heart Association (NYHA) Class IV dyspnoea status, chronic kidney disease (CKD), peripheral arterial disease (PAD) and impaired left ventricular ejection fraction (LVEF < 30%). Other parameters that did not show significant association with reduced survival after TAVI were smoking status ( $p = 0.935$ ), previous myocardial infarction ( $p = 0.114$ ), previous stroke ( $p = 0.222$ ), previous cardiac surgery ( $p = 0.259$ ), pre-operative atrial fibrillation ( $p = 0.112$ ) and coronary artery disease ( $p = 0.443$ ). Fig. 1 shows the Kaplan Meier curves for each of the independent factor that were significantly associated with impaired survival.

### 3.3. Association between FRANCE-2 score and survival

The median FRANCE-2 score of the cohort was 2 and the maximum score was 9. The frequency of high-risk parameters in this cohort of patients that contributed to the FRANCE-2 scores are summarised in Table 2. The majority of the patients scored a point in regard to their body mass index (BMI) whilst almost half of the cohort was awarded 2 points for having respiratory insufficiency.

The survival rates of the total cohort were 95.7% ( $n = 179$ ) at 30 days, 88.2% ( $n = 165$ ) at 1 year and 77.5% ( $n = 145$ ) at 2 years, with a mean follow-up time of 28 months. The FRANCE-2 score was predictive of 30-day mortality with a c-index of 0.793 (95% CI 0.603–0.983,  $p = 0.009$ ) and was predictive of 1-year mortality with a c-index of 0.679 (95% CI 0.524–0.834,  $p = 0.016$ ) but not 2 year mortality with a c-index of 0.613 (95% CI 0.492–0.735,  $p = 0.088$ ). The Hosmer-Lemeshow test showed good calibration of the model with a chi-squared value of 0.70 ( $p = 0.87$ ) and 2.50 ( $p = 0.48$ ) in 30-day and 1-year mortality respectively.

Subgroup analysis was performed on 3 different risk groups according to the FRANCE-2 score. There were 15 patients (8%) defined as low risk, 161 patients (86%) as moderate risk and 11 patients (6%) as high risk using the FRANCE-2 scoring system. The mean survival time of these groups of patients were 53.8 (SD 7.5) months, 53.6 (SD 3.2) months and 18.6 (SD 4.7) months respectively, with a Breslow test of  $p < 0.005$ . Kaplan-Meier survival curves of the survival outcomes in each of the 3 risk groups is shown in Fig. 2.

### 3.4. Association between other risk scores and survival

Other established risk scores were also applied and the data is summarized in Table 3. The mean logistic EuroSCORE was 28.1 (SD 15.0). The logistic EuroSCORE was not predictive of 30-day mortality with a c-index of 0.605 (95% CI 0.299–0.912,  $p = 0.346$ ) and was not predictive of 1-year mortality with a c-index of 0.616 (95% CI 0.457–0.775,  $p = 0.11$ ). However, it demonstrated significant association to survival outcomes at 2-year follow up with a c-index of 0.67 (95% CI 0.552–0.788,  $p = 0.008$ ).

All patients were divided into three risk groups according to the logistic EuroSCORE. Low risk was defined as <14%, medium risk was between 14% and 24% while high risk was more than 24%

[8]. There was no significant difference in survival outcomes ( $p = 0.112$ ) between these three groups of patients. The Kaplan Meier curves of the three Logistic EuroSCORE derived risk groups is shown in Fig. 3.

EuroSCORE II was not predictive of 30-day mortality with a c-index of 0.638 (95% CI 0.348–0.929, 0.214) and was not predictive of 1-year mortality with a c-index of 0.646 (95% CI 0.497–0.795,  $p = 0.051$ ).

German AV risk score model demonstrated a c-index of 0.731 (95% CI 0.499–0.962,  $p = 0.039$ ) in 30-day mortality and c-index of 0.644 (95% CI 0.506–0.781,  $p = 0.054$ ) in 1-year mortality. On the other hand, STS/ACC TVT risk score model demonstrated a c-index of 0.751 (95% CI 0.575–0.927,  $p = 0.025$ ) in 30-day mortality and c-index of 0.707 (95% CI 0.590–0.824,  $p = 0.005$ ) in 1-year mortality.

## 4. Discussion

This study describes the factors that associate with poor outcome following TAVI in a single centre experience of consecutive patients. Furthermore, our results have demonstrated that the FRANCE-2 risk score is predictive of 30-day and 1-year mortality while the conventional use of logistic EuroSCORE and EuroSCORE II are not.

Since degenerative aortic stenosis is a disease of the elderly many of whom who had a variety of non-cardiac morbidities, the impact of these non-cardiac conditions on post-TAVI outcomes has been previously described. The data from the present study are consistent with the previously published literature which has described that COPD, NYHA Class IV, CKD, PAD and LVEF < 30% are associated with unfavourable outcomes after TAVI [10,11]. Meta-analysis has shown that COPD affects both short and long term outcomes after TAVI and a 6 min walk test (6MWT) of <170 m was found to be the best predictor of futility in these patients [12,13]. A subgroup analysis of the PARTNER trial showed that COPD patients requiring long term oxygen or with poor mobility had poorer outcomes [14]. In a different study, patients with CKD stage 3 or above were shown to have an increased risk of bleeding, in-hospital mortality and acute kidney injury (AKI) after TAVI [15]. This conclusion was further supported by a national database from France which described a higher mortality rate in patients with CKD 3b or above [16]. Unsurprisingly, PAD was commonly found in patients undergoing TAVI and a study from the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapy (TVT) database showed that PAD was associated with a high incidence of death, readmission and bleeding at 1 year follow up when TAVI was done from a transfemoral approach [17]. These findings are consistent with the data from the present study in which 94% of patients had transfemoral TAVI and in which survival outcome was worse in those with PAD as compared with those without.

The expansion in the use of TAVI to treat patients with aortic stenosis and an intermediate or even low risk of poor outcomes with conventional cardiac surgery means that it is even more important than previously to understand the circumstances at the higher end of the risk spectrum where TAVI is unlikely to be of benefit to patients or may be even futile [18,19]. The definition of futility in TAVI candidates is a matter of some debate but includes a high likelihood of death or life-threatening complications associated with the procedure or the lack of functional improvement during early to mid-term follow up (up to 1 year) despite a technically successful procedure [20]. The anticipation of futility, therefore, necessitates an assessment of risk associated with the procedure as well as an estimate of the likely symptomatic benefit a patient might receive from alleviating aortic

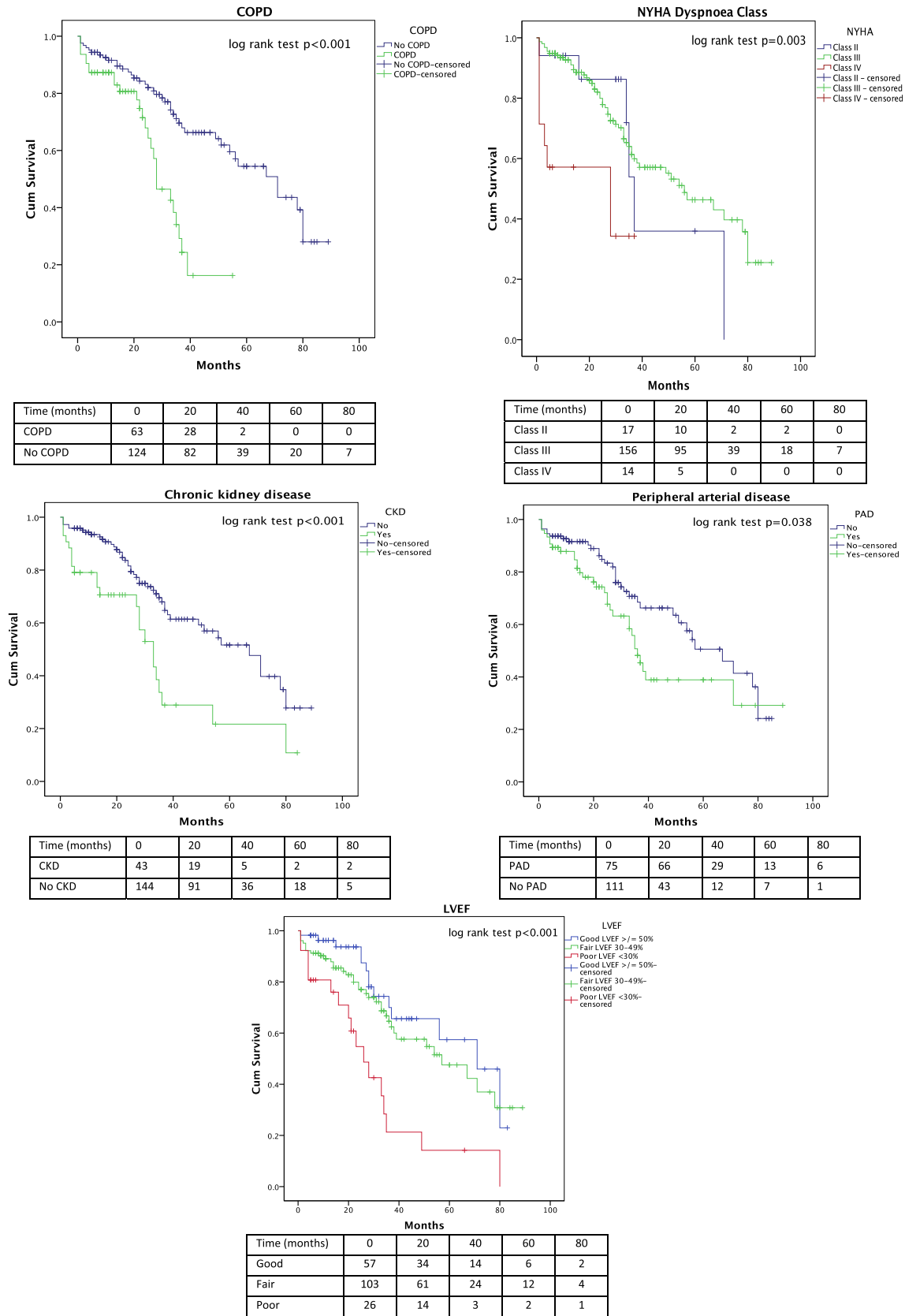


Fig. 1. Pre-procedural clinical determinants that showed significant association with survival outcome after TAVI.

stenosis alone. The EuroSCORE was initially developed to predict mortality risk in patients undergoing cardiac surgery for the treat-

ment of coronary artery disease and was subsequently refined to become the logistic EuroSCORE and later EuroSCORE II [21,22].

**Table 2**  
Patient parameters contributing to FRANCE-2 score.

Patient parameters (maximum points)	Incidence in the cohort
Age ≥ 90 years (1)	7.0% (n = 13)
BMI <18.5 (3)	1.6% (n = 3)
18.5–29.9 (1)	81.3% (n = 152)
NYHA Class IV (2)	7.5% (n = 14)
Acute pulmonary oedema ≥ 2 in past year (2)	6.4% (n = 12)
Systolic PAP ≥ 60 mmHg (1)	5.9% (n = 11)
Critical pre-operative state* (3)	4.3% (n = 8)
Respiratory insufficiency (2)	43.9% (n = 82)
Dialysis (4)	1.1% (n = 2)
Delivery approach	
Transapical (2)	0
Others excluding transfemoral or subclavian (3)	0

BMI: Body mass index; NYHA: New York Heart Association; PAP: Pulmonary artery pressure.

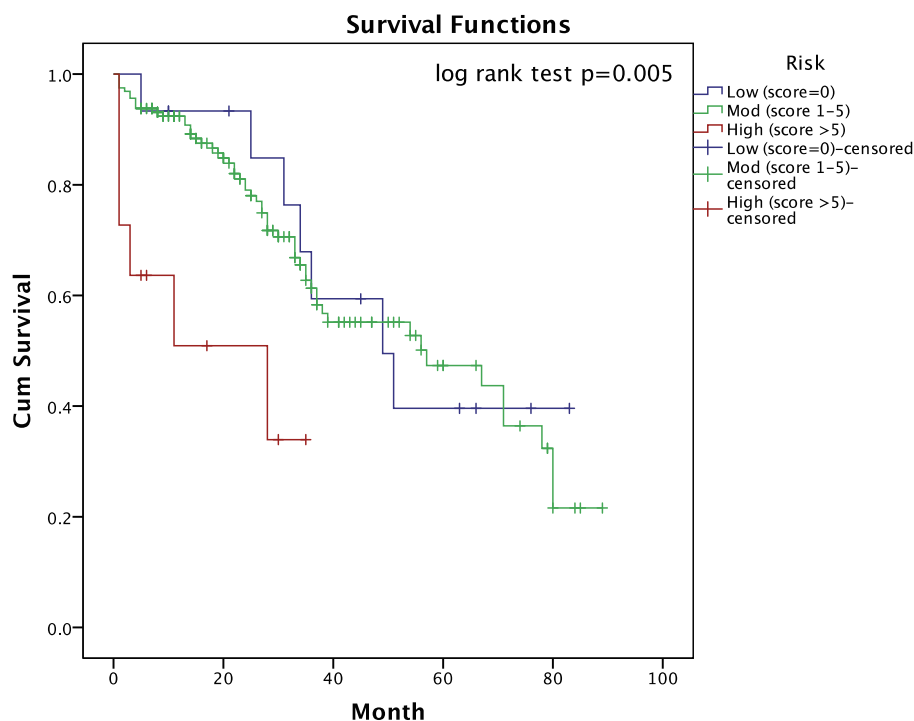
\* Critical pre-operative state includes any of the following options: ventricular tachycardia or ventricular fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before anaesthetic room, preoperative inotropes or IABP, preoperative acute renal failure (anuria or oliguria < 10 ml/hour).

Many of the pivotal randomised clinical trials that have demonstrated the clinical benefit of TAVI in the treatment of aortic stenosis have extrapolated the logistic EuroSCORE for use as a pre-operative risk assessment score [23]. The results of this study, however, are consistent with others in showing the inability of the logistic EuroSCORE and EuroSCORE II to predict 30-day mortality in patients undergoing TAVI [24,25]. National databases from several countries have been used to develop TAVI specific risk score models, including German AV, OBSERVANT, STS/ACC TVT, FRANCE-2 and UK-TAVI score [9,26–29]. Despite showing modest

value in determining the futility of TAVI, scant evidence exists to validate the use of these models in populations other than the development cohort.

The German AV risk score model was developed from the Germany national database to predict in-hospital mortality in patients who had SAVR and TAVI. The major disadvantage of the model is the extensive list of parameters (15 risk factors) included which can be time-consuming and impractical in routine clinical practice. Besides, application of the risk score model in our UK population proved to be inferior to the FRANCE-2 score. On the other hand, STS/ACC TVT score, developed from a US population, showed a better predictive ability of 1-year mortality than FRANCE-2 score but not in 30-day mortality. The risk score model is easily accessible with an automated risk calculator available online, however, acuity status which is commonly used in the US may not be applicable in the UK or other countries. This might hinder the wider uptake of the risk score internationally.

FRANCE-2 risk score was first developed by the national French registry to predict 30-day or in-hospital mortality after TAVI and included a combination of uncontrollable clinical risk factors. In the initial study that developed and validated this clinical risk score, a moderate discriminative power was described while in subsequent analyses comparing the FRANCE-2 score with other clinical prediction models developed from different national registries available at current time, the FRANCE-2 score was considered one of the most accurate tools in predicting mortality [8]. Our study retrospectively validated the FRANCE-2 risk score in a single centre UK population and showed acceptable predictive ability in risk stratification of TAVI patients in regard to both 30 day and 1 year mortality. The FRANCE-2 score uses simple parameters that can be easily derived during routine work-up of



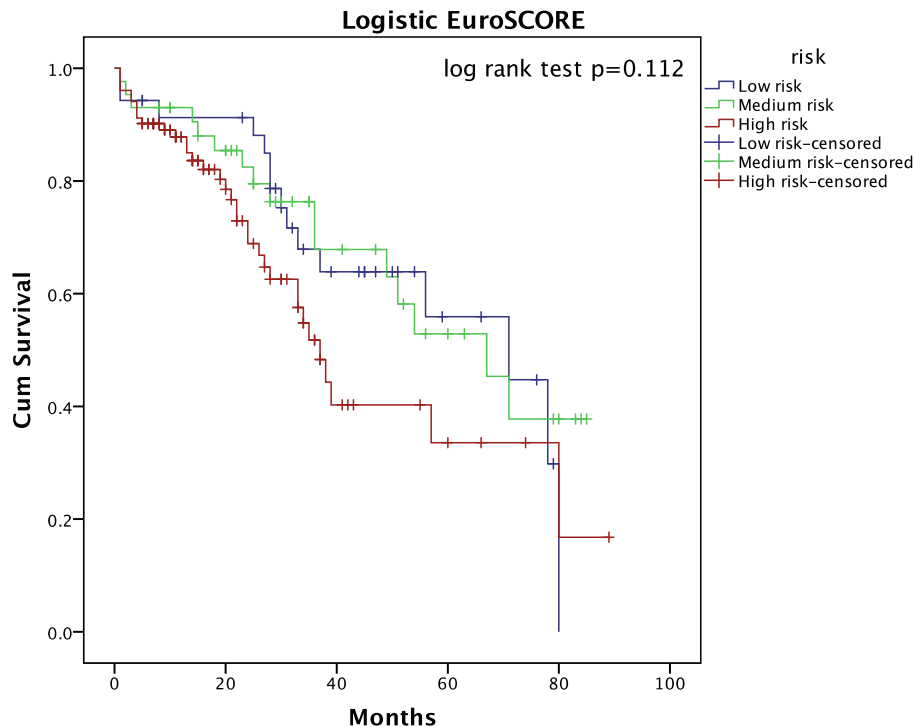
Time (months)	0	20	40	60	80
Low risk	15	12	7	4	1
Moderate risk	161	95	34	16	6
High risk	11	3	0	0	0

**Fig. 2.** Kaplan-Meier curve survival analysis of patients in three risks groups according to the FRANCE-2 score.

**Table 3**  
C-index of 30-day mortality and 1-year mortality of all risk score models.

Risk score models	30-day mortality			1-year mortality		
	C-index	95% CI	P-value	C-index	95% CI	P-value
FRANCE-2	0.793	0.603–0.983	0.009	0.679	0.524–0.834	0.016
Logistic EuroSCORE	0.605	0.299–0.912	0.346	0.616	0.457–0.775	0.11
EuroSCORE II	0.638	0.348–0.929	0.214	0.646	0.497–0.795	0.051
STS/ACC TAVR	0.751	0.575–0.927	0.025	0.707	0.590–0.824	0.005
German AV	0.731	0.499–0.962	0.039	0.644	0.506–0.781	0.054

CI: Confidence interval; German AV: German Aortic Valve; STS/ACC TAVR: Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy.



Time (months)	0	20	40	60	80
Low risk	35	30	15	6	1
Medium risk	43	33	16	9	4
High risk	102	45	10	5	2

**Fig. 3.** Kaplan-Meier curve survival analysis of patients in three risks groups according to the logistic EuroSCORE.

patients for TAVI and therefore has the potential to serve as an additional tool to support the decision-making process of the Heart MDT in planning treatment for patients at high risk in whom TAVI is being considered.

**5. Limitations**

We acknowledge that there are a few limitations in our study. Firstly, the number of patients included in this study are small and this is indicative of a relatively low volume of patients treated in this single centre. While this did not preclude the achievement of overall good clinical outcomes following TAVI in this study which are indicative of a good level of expertise in this centre, it may have contributed to the inadvertent introduction of bias. Secondly, the retrospective nature of the study may also have led to the introduction of bias although the methodology of the analysis was designed to eliminate this as best as possible. Our study

focused on the survival outcome after TAVI in defining futility but did not include an assessment of functional outcome after TAVI. Future studies should be done prospectively to analyse the up-front value of the FRANCE-2 score in predicting not just crude mortality but also the functional benefit that TAVI has to offer. We acknowledge that the assessment of frailty was not featured as a parameter in the FRANCE-2 score which is an important additional factor to consider in assessing the potential utility of TAVI.

**6. Conclusion**

In conclusion, this study has identified the value of the FRANCE-2 scoring system in predicting both short and medium time survival after TAVI. The FRANCE-2 score may be a useful additional clinical tool for use by the Heart MDT in identifying circumstances when TAVI is likely to be associated with reduced survival and may

even be futile, although this needs further evaluation in prospective clinical studies.

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#### Contributorship statement

**Zong Xuan Lee** contributed to the planning of this study, to the conduct of the study through data acquisition, analysis and interpretation and to the manuscript preparation.

**Senthil Elangovan** contributed to the conduct of the study through data acquisition, analysis and interpretation and to the manuscript preparation.

**Richard Anderson** contributed to the conduct of the study through managing included patients and undertaking TAVI procedures and through data acquisition and also contributed to the manuscript preparation.

**Peter Groves** contributed to the planning of this study, to the conduct of the study through managing included patients and undertaking TAVI procedures as well as data acquisition, analysis and interpretation and contributed to the manuscript preparation. Peter Groves takes responsibility for the overall content of this manuscript as guarantor.

#### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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