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Frailty as a predictor of delayed discharge and 12-month mortality following transcatheter aortic valve implantation

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ABSTRACT

Background Transcatheter aortic valve implantation (TAVI) is the principal treatment for aortic stenosis in older and high-risk patients. Whilst important in holistic decision making, frailty indices vary in ease of use, objectivity, and accuracy. We assess prognostic ability of the Clinical Frailty Scale (CFS) and Essential Frailty Toolset (EFT) in predicting delayed discharge and 1-year mortality following TAVI.

Methods Prospective, single centre, observational cohort study of patients undergoing TAVI at a tertiary centre in the UK from 2020-2022. Clinical characteristics, CFS, and EFT were collected pre-procedurally. Primary outcomes were length of hospital stay following TAVI and mortality at 1- year post-procedure. Generalized regression with elastic net is used to assess the additive discriminative ability of frailty scores to predict outcomes. Stepwise regression is used to identify informative outcome predictors.

Results One hundred and four patients were included with mean age 81.3 ± 5.9 years, 47% female. Median post-procedural stay length was 2 days (IQR 2.75). Use of EFT and CFS resulted in a statistically significant prediction of survival at 1 year post TAVI (EFT: ΔLogL of 2.68, ChiSq P = 0.021; RCFS ΔLogL: 1.42, ChiSq P = 0.092) compared to predictive model using conventional clinical characteristics. EuroSCORE II and TAVI2SCORe were poor predictors of outcomes. CFS and access site (femoral *vs.* non-femoral) significantly improved prediction of delayed discharge.

Conclusions EFT informs decision making on survival 1-year post-TAVI, beyond conventional measures. Use of non-femoral access site and high CFS are the best predictors of delayed discharge. Surgical risk stratification scores poorly predict medium-term TAVI survival and delayed discharge.

Transcatheter Aortic Valve Implantation (TAVI) has revolutionized the treatment of aortic valve disease in older adults. It is now the most commonly performed valvular intervention for adults, and is effective with respect to improving quality of life and reducing major adverse cardiovascular events.[1] The appropriate selection of patients for TAVI has profound importance at both a patient and population level.[2] Physicians and healthcare systems endeavor to identify patients most likely to benefit from intervention, whilst making informed decisions to avoid procedures which may have limited utility.

Historically, TAVI was reserved for patients excluded from Surgical Aortic Valve Replacement (SAVR) due to inoperability.[3] However safety and efficacy has been progressively demonstrated in patients at high, intermediate and low surgical risk.[4,5] Multidisciplinary heart teams now evaluate patients for consideration of SAVR, TAVI, or palliative treatment options depending on multiple factors, with current international guidelines placing primary importance on age and life expectancy, left ventricular ejection fraction, presence of symptoms, and intervention risk using STS-PROM or EuroSCORE II, to aid with the decision.[3,4]

Both ESC and AHA/ACC guidelines advise the consideration of other factors in decision making, including anatomy relevant to intervention, frailty, malnutrition, cognitive dysfunction, and other cardiac and non-cardiac organ failures.[3,4] Frailty is defined as decreased physiological capacity for recovery and accumulating health deficits. It is a patient-focused metric and incorporation into decision making seeks maximize quality of life and independence and minimize avoidable harm.[5] In patients undergoing TAVI, frailty assessment predicts morbidity and mortality alongside traditional risk scoring.[6,7,8,9,10]

Despite the links between frailty indices and morbidity and mortality outcomes, uncertainty remains as to how this should be implemented in clinical practice. Current risk-scoring tools, generally calibrated for 30-day mortality, do not account for frailty.[11] The number and choice of measures varies significantly between frailty indices, but generally encompass proxy markers for physical and cognitive robustness.[12] Frailty indices are generally developed to assist with prognostication in specific situations and environments (e.g. admission to hospital, community assessment, or pre-procedural), yet the ideal frailty index is generalizable. In the context of cardiovascular MDT decisions, this may assist in assessment of peri/post- procedural morbidity and mortality, as well as outcomes.

Successful integration of frailty assessment must use a tool which is time-efficient to implement, while remaining objective and minimizing interobserver subjectivity. The Rockwood Clinical Frailty Scale (CFS) is the most widely adopted frailty assessment tool in general and emergency medicine departments. Its use is advocated by national societies as part of a Comprehensive Geriatric Assessment. The CFS classes patients on a scale of 1-8 with increasing number illustrating increased level of frailty (with a ninth level indicating an individual at the end of life, but not necessarily frail). The score is inherently subjective, leaving it open to bias, although most studies report moderate to good inter-rater concordance.[13] However, proper implementation of the CFS for accurate scoring is a time-intensive process.[14] There has been limited use of the CFS within interventional cardiology settings, but a retrospective database analysis relating dichotomized CFS to 1- year mortality reported mortality rates of 19.1% for the frail cohort versus 9.8% for the non-frail cohort.[15] Consensus statements report limited use of the CFS for mortality outcomes after TAVI.[14]

As such, there has been a recent shift in trend towards composite frailty indices as a form of assessment. Various methods of frailty assessment have been proposed in the TAVI work-up phase, including the Fried frailty phenotype, CFS, Short Physical Performance Battery, Columbia Scale, and the Essential Frailty Toolset (EFT).[10] The EFT is a -four-parameter index comprising objective scores from measures of 5-chair rise time, cognitive impairment, serum albumin and haemoglobin, summed to produce a scale from 0 to 5 points. The scale was derived in the planning of, and then demonstrated in, the FRAILTY-AVR study in a large cohort of older adults undergoing valve replacement.[7] It aims to provide a balanced assessment metric for physical robustness, nutritional status and cognitive status and showed good predictive power for prediction of post-TAVI short-medium term mortality.

This study aims to establish the utility of frailty measures in predicting 1-year mortality and post-procedural length of stay in TAVI patients when compared to traditional metrics. Specifically, the EFT is compared to the CFS to establish their predictive value in this cohort.

METHODS

Study Design

A single centre, prospective, cohort study design was used. The approval was provided by the Local Research Ethics Committee REC C-CA-376.

Setting and Participants

One hundred and nine patients with aortic stenosis who were referred and planned for TAVI following multidisciplinary heart team discussion at a tertiary cardiothoracic centre in the United Kingdom were approached for recruitment to the study between 2021 and 2022.

Variables

The following characteristics were collected: age, sex, height, weight, creatinine, haemoglobin, albumin, comorbidities including chronic obstructive pulmonary disease (COPD), atrial fibrillation, hypertension, hypercholesterolemia, peripheral vascular disease, liver disease, polymyalgia rheumatica, diabetes, history of stroke, transient ischemic attack, and myocardial infarction. NYHA heart failure class and Canadian Cardiovascular Society (CCS) Angina Grade were collected before and after intervention.

Prior procedural history data was collected including percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), and other cardiac surgery. Medication use prior to intervention, including insulin use, antiplatelet and anticoagulation use, and type was collected from electronic records. Left ventricular ejection fraction and pulmonary artery systolic pressure (PASP) measured by transthoracic echocardiogram (TTE) were collected before and after intervention.

Outcomes

Primary outcomes were defined as survival at 1-year post procedure, and length of hospitalization after the procedure, in which discharge two days or fewer following procedure was used as a dichotomization threshold.

Data Sources

Frailty assessment

EFT and CFS were calculated for each patient prior to TAVI. The EFT score consisted of four key measures: (1) time to rise from a chair 5 times without the use of arms (patients scored 0 if completed in under 15 s, 1 if completed in 15 s or more, or 2 if unable to complete task); (2) Presence of cognitive impairment (patients scored 1 if screened to be cognitively impaired); (3) serum albumin (patients scored 1 if serum albumin was less than 35 g/L); and (4) serum haemoglobin (patients scored 1 if serum haemoglobin was less than 130 g/L in men or 120 g/L in women).

This was summed to give a total EFT score from 0-5. The most recent blood test prior to intervention was used. Cognitive impairment was assessed using the Mini-Cog assessment, with threshold for impairment defined by Mini-Cog score ≤ 2.[16–23] Five-chair rise time is the time taken to stand from a chair and return to sitting five times consecutively without the aid of the arms.

CFS was determined as per the original scale developed by Rockwood and colleagues.[24] Where a binary classification of frailty was required, we used an EFT score of ≥3 and CFS score ≥5 to define frailty.[25,26]

Outcome data

Outcome data was collected using the hospital electronic health and primary care records. Post-procedural stay duration was defined as zero days for discharge on the same day procedure, 1 day for discharge the next day, and so on.

Bias and Study Size

Data was collected and cross checked by two independent researchers. Target recruitment was 100 patients. Patients were screened between February 2021 and July 2022.

Statistical Methods

Demographic and baseline data were described with descriptive statistics. Discriminative performance was used to assess prognostic models (EuroSCORE II and TAVI2SCORe). Discrimination of a model is its ability to distinguish those who experienced the outcome from those who did not and was estimated with the area under (AU) the receiver operating characteristic (ROC) curve. To assess the prognostic performance of the frailty measures over and above conventional clinical characteristics for prediction of 1 year mortality, clinical variables were calibrated for this cohort using a generalized regression model. This comprised continuous variables age, sex, Body Mass Index (BMI), Creatinine Clearance (CrCl) and LVEF; and nominal variables procedural urgency, non-femoral route, atrial fibrillation, hypercholesterolemia, liver disease, polymyalgia rheumatica, COPD, hypertension, previous coronary procedure or event, peripheral or neurovascular disease, and pulmonary arterial hypertension. Generalized regression was performed with adaptive elastic net estimation (α = 0.5). Model validation was performed using the leave-one-out method. The generalized regression model was then used to generate a risk score for each subject. The subsequent performance of EFT or CFS, in addition to the risk score was evaluated.

Model predictive performance was evaluated graphically using the receiver operating characteristic curves with discriminative performance quantified by the AUROC, for which 1 describes perfect discrimination and 0.5 no better than chance; and Loglikelihood, Bayesian information criterion (BIC) and Akaike information criterion (AICc) parameters, in which lower values indicate better predictive performance. Statistical testing between loglikelihood values was performed using Chi-squared distribution.

Stepwise regression analysis was used to screen and select informative predictor variables for delayed discharge and 1-year mortality. This method evaluates all variables to assess which are non-informative for prediction based upon whether their removal (if performed in a backward fashion) improves the AICc of the model (AICc penalizes too many predictors). Whole effects of categorized variables respected heredity (relevant to grouped LVEF, smoking status, NYHA). Data analysis was performed using JMP Pro 18.0.2 (NC, USA).

RESULTS

Participants

One hundred and nine patients were screened for enrolment. Five patients were excluded for the following reasons: lack of appropriate access (two), procedure cancellation (two), or change to surgical valve replacement as opposed to TAVI (one). One hundred and four patients were included in the study. All patients were followed up at 12 months following index procedure. No patients were lost to follow up.

Descriptive Data

Summary statistics for baseline characteristics for patients and procedures are shown in Table S.1. Distribution of frailty as per the EFT and CFS are shown in Figure S. 1. CFS and EFT are poorly correlated ($P = 0.25$), as shown in Figure 1. EFT and chronological age are also poorly correlated ($P = 0.079$).

Outcome Sources

Median post-procedural stay length was 2 days, as shown in Figure S1, interquartile range was 2.75 days. Survival at 1 year was 82.7% ($n = 86$).

Main Results

Procedural risk was calculated for each patient using the EuroSCORE II. Logistic regression showed no statistically significant relationship between EuroSCORE II and either delayed discharge (ChiSquare = 0.012, DF = 1, Prob > ChiSq 0.91) or mortality (ChiSquare = 0.023, DF = 1, Prob > ChiSq = 0.87).

The EuroSCORE II model performed poorly in this cohort of TAVI patients, as reported elsewhere.[27] The

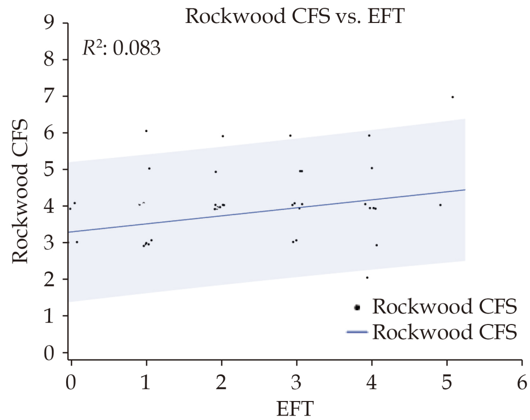

Figure 1 Correlation between Rockwood CFS and EFT. CFS: Clinical Frailty Scale; EFT: Essential Frailty Toolset.

TAVI2SCORe was also calculated for this cohort, with minimal improvement over the EuroSCORE II, AUROC 0.5255 *vs.* 0.5123, as show in Table S2. Given the poor calibration of the TAVI2SCORe and EuroSCORE II models for 1-year mortality in this cohort, a new clinical variable model was calibrated on this cohort using generalized regression. The variable coefficients for the clinical variable model are shown in the supplementary materials (Table S3).

ROC curves were generated comparing the performance of the EuroSCORE II, TAVI2SCORe and the selected clinical variable model, with the addition of either CFS or EFT frailty measures, as shown in Figure 2.

The use of ordinal EFT improved 1-year mortality prediction with an AICc change from 78.5 to 72.6 and loglikelihood difference of 4.02 (ChiSq $P = 0.0046$), as shown in Table S.2. Dichotomization of the EFT also led to a statistically significant improvement in predictive ability (loglikelihood difference to baseline model of 2.68, $P = 0.021$). The CFS also resulted in an improvement with AICc change from 78.5 to 77.76 (loglikelihood difference 1.42 ChiSq $P = 0.092$). The benefit of using ordinal frailty measures, over dichotomizing at a cut off value significantly improves performance. Addition of either EFT or CFS frailty measure showed improvement in predictive performance for 1-year mortality, with EFT superior to CFS (ChiSq $P = 0.023$ when used in addition to the clinical variable model).

As a hypothesis generating step, stepwise regression analysis was performed for the 1-year mortality in this cohort to identify the informative variables for prediction. The AICc curve is shown in Figure S2, demonstrating that EFT, pre-procedural antiplatelet use, age, CrCl, hypertension and sex are the most informative predict-

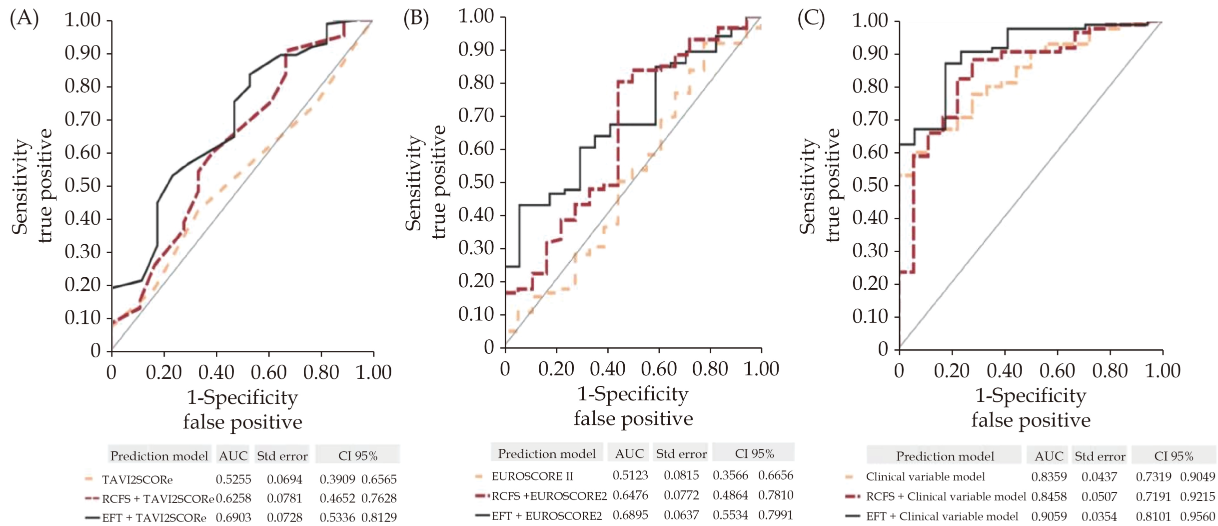

Figure 2 ROC curves comparing (A) TAVI2SCORe, (B) EUROSCORE II, (C) our clinical variable model, and the addition of EFT or CFS to model for prediction of mortality at 1 year. CFS: Clinical Frailty Scale; EFT: Essential Frailty Toolset.

ors for 1-year survival in this cohort. The nominal logistic fit based on these parameters alone produces a AUROC of 0.852, with ROC shown in Figure S3. The parameter estimates shown in Table S4 provide valuable insight into the predictive utility of EFT. Given that there is minimal interaction between age and EFT ($P = 0.079$), a unit increase in EFT is approximately equivalent to a 4-year increase in age, when used to predict 1-year mortality after TAVI.

The individual components of the EFT were assessed for the contribution to predicting 1- year mortality. The most significant predictor of mortality is a chair rise score of 2 (*vs.* 0), as shown in Table 1, where OR for survival at 1 year was 0.08 (Chisq $P = 0.007$).

No validated models within the literature were found to guide delayed discharge following TAVI, so stepwise regression was used to identify informative predictors. For the prediction of delayed discharge, the combination of access site and CFS provided optimal information, with all other variables being minimally informative, as shown by Figure S4. Binomial generalized regression was then performed using these two variables, to demonstrate their ability to discriminate delayed discharge within this cohort. The resultant confusion matrix (Table S5) and ROC curve (Figure S5), generate an AUROC of 0.716. Using Youden's J statistic to optimize the CFS cut-off suggested that if a femoral route is used, CFS ≥ 5 (95% CI: 4.3–7.4 CFS) predicts delayed discharge, and if a non-femoral route is used, CFS ≥ 3 (95% CI: 0.8–4.8 CFS).

DISCUSSION

Key Results

The cohort assessed in this study is representative of typical patients undergoing TAVI in the UK, predominantly represented by older patients at moderate surgical

Table 1 Odds ratios for survival at 1 year for components of the EFT.

Parameter	One year survival with clinical variable model + EFT		1 year survival with EuroSCORE II + EFT		1 year with TAVI2SCORe + EFT	
	OR (per unit)	95% CI (*P* > ChiSq)	OR (per unit)	95% CI (*P* > ChiSq)	OR (per unit)	95% CI (*P* > ChiSq)
Hb (EFT score)	0.406	0.085-1.673 (0.216)	0.540	0.134-1.982 (0.356)	0.338	0.062-1.543 (0.165)
Albumin (EFT score)	1.386	0.331-6.418 (0.658)	1.130	0.325-4.129 (0.849)	1.164	0.325-4.415 (0.816)
Chair rise (EFT score 1 *vs.* 0)	0.323	0..015-2.419 (0.297)	0.235	0.012-1.455 (0.131)	0.215	0.011-1.325 (0.105)
Chair rise (EFT score 2 *vs.* 0)	0.094	0.004-0.766 (0.025)	0.086	0.007 (0.004-0.548)	0.083	0.004-0.540 (0.007)
Mini-cog (EFT score)	1.080	0.229-6.424 (0.926)	0.789	0.211-3.416 (0.736)	0.881	0.241-3.736 (0.854)

EFT: Essential Frailty Toolset; Hb: haemoglobin.

risk. Outcomes are similar to those described elsewhere.[10] As noted previously, surgical risk scores, such as EuroSCORE II have poor predictive ability when applied to TAVI.[11] Models used and developed during the early phases of TAVI adoption, for example the EuroSCORE II and TAVI2SCORe respectively, did not provide any further predictive power, supporting the lack of widespread adoption and need for better risk prediction. Notably, neither contain any recognized measure of frailty. Models for 30-day mortality have been described in large cohorts, though have not yet been integrated into international guidelines or been widely adopted.[28] These clinical prediction models use subjective measures of frailty (KATZ Index and CSHA frailty scale), and so in this study we sought to test the benefit of using the EFT, a fast and objective measure of frailty, for use in TAVI procedural planning.

In this study, generalized regression was performed with recognized physiological and co-morbidity factors on the cohort of patients, to produce a risk model. Frailty scores are independent predictors of 1-year mortality. The significance of frailty scores is illustrated by examination of the variable coefficients, showing that a unit increase in EFT score approximately equates to an increase in age by four years, in the context of 1-year mortality. The use of ordinal EFT resulted in a statistically significant improvement in discriminative ability, as did CFS, though to a lesser extent. EFT has minimal interobserver variability, particularly when compared to the CFS, making it an attractive measure to integrate into treatment pathways and use as a decision-assisting tool.

The prediction of delayed discharge is important for patient consent and system planning. CFS and knowledge of the access site provides an acceptable model (AUROC 0.72) for prediction of delayed discharge. This information is particularly important for service planning from a capacity and financial perspective, in particular noting that the cost of delayed discharge has been estimated at over £3,000 per patient post-TAVI.[29]

Frailty factors and composite indices have also previously demonstrated good predictive value in other peri-procedural outcome measures. Fried criteria, for example, has been shown to be predictors for non-home discharge destination post-TAVI.[18] Further work is required to assess the full utility of the EFT in predicting post-procedural outcomes, including discharge destination to a location other than home, requirement for early re-admission and quality of life indices.

Limitations

This study is limited in its restriction to a single centre, and a relatively small number of patients. While EFT was collected for the purpose of the study, other clinical characteristics were determined by retrospective assessment of the electronic patient record, documentation of which may have varied between referring clinicians.

The findings of this study should be primarily viewed as hypothesis generating. The use of generalized regression can lead to model over-calibration; however, the use of leave-one-out validation reduces this risk. Stepwise regression modelling of this cohort is primarily a hypothesis generating technique to identify key predictors, and these variables should not be used alone to guide decision-making.

EFT scores were also collected during the patient's admission for TAVI as opposed to at time of referral. The interval between referral and procedure can be significant, median intervals between referral and procedure in the UK was 20 weeks.[30] Application of the EFT to referrals, procedural assessment, and decision making should acknowledge this difference.

This study was not powered to detect peri-procedural or in-hospital mortality, which has been widely reported by others, nor other outcomes such as disability at 1 year, stroke or prosthetic valve dysfunction.[28,31] Few emergent TAVI procedures are performed in this centre, and these are not well represented in this dataset.

The EFT used in this study differs slightly to previous studies used in the pre-procedural assessment for TAVI.[7] This study used the slightly shorter and more easily administered Mini-Cog assessment as opposed to the mini-mental state exam (MMSE), due to recent studies showing either non-inferiority or superiority for abbreviated cognitive assessment.[32-34] TAVI2SCORe was evaluated using peripheral vascular disease in place of porcelain aorta.

Interpretation

This study shows that a thorough understanding of frailty is essential to patient-centered care throughout the TAVI planning process. EFT is an objective measure that can improve prediction of 1-year survival. CFS is inherently more nuanced and subjective and hence benefits from staff training and/or geriatrician input for accurate assessment, yet it plays a beneficial role in mortality prediction at 1 year and is an excellent predictor of delays to discharge post-procedurally.

The identification of EFT as an excellent predictor of 1-year mortality following TAVI supports the findings of Afilalo, *et al*.[7] in the multi-centre FRAILTY-AVR study, where 7 frailty indices were compared, with EFT proving to be the best predictor of mortality and disability 1 year after TAVI. This study is the first to apply EFT to a UK cohort, supporting the external validity of North American findings.

Importantly, the lack of correlation between EFT and either CFS or chronological age, combined with the greater weighting of EFT in predicting 1-year mortality (Figure S.2), underscores the need for the use of objective measures for informed decision-making.

Frailty is a transitive concept, with modifiable aspects, which may allow a degree of optimization during the pre-procedural phase. For example, adaptation of living environment and the provision of appropriate adjuncts can increase patient independence (reflected in the CFS) and may reduce the likelihood of a delayed discharge in the post-procedural setting. Equally, optimization of nutritional status, that may be reflected in the EFT, may contribute to improved post-procedural results. This is supported by Yu, *et al*.[35] who performed CGA-based cardiac rehab prior to TAVI with positive results. The PERFORM-TAVR is an ongoing trial (NCT03522454) aiming to establish the impact of pre-procedure interventions on potentially modifiable frailty factors including protein supplementation and exercise regimes, on outcomes following TAVI.[25] Existing studies have demonstrated the benefit of post-procedural rehabilitation after TAVI, associated with increased mobility and performance in activities of daily living.[36] Being able to pre-emptively identify and target frail patients undergoing procedure enables us to better plan interventions aimed at optimizing post-procedural quality of life.

Generalizability

The study provides evidence to support the routine inclusion of frailty assessments in the workup for TAVI, and to help inform benefit/futility decisions. Furthermore, the use of objective assessment using the EFT is shown to be an important predictor of 1-year mortality. This data supports efforts to integrate frailty calculators into clinical practice, for example through use of the calculator available at frailtytool.com.

To support generalization of these results, multi-centre observational data should be assessed with frailty data at the time of referral. Furthermore, the assessment of all patients considered or referred for valve replacement should be performed, as opposed to solely those selected by the heart team MDT. The addition of co-morbidity, quality of life and disability metrics at 1 year, and beyond, should be included in further studies to aid decision making.

Conclusions

In a cohort of older individuals planned to undergo TAVI, standard surgical and conventional TAVI risk scores have limited predictive accuracy for 1-year mortality or delayed discharge. Integrating frailty indices into risk scores results in a statistically significant improvement in the ability to predict 1-year mortality following TAVI, particularly when the ordinal EFT score is used. Two predictors: use of non-femoral access sites, and the pre-procedural Clinical Frailty Scale, are good predictors of delayed discharge following procedure.

DECLARATIONS

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Conflict of Interests

None.

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