Use of the reported Edmonton frail scale in the assessment of patients for transcatheter aortic valve replacement: a possible selection tool in very high-risk patients?

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Transcatheter aortic valve replacement (TAVR) has revolutionised the treatment of patients with aortic stenosis (AS) over the last 15 years.[1] TAVR is a well-established procedure for the treatment of patients considered high risk for open surgery.[2] Results from the PARTNER (Placement of AoRTic traNscathetER) trial showed that inoperable patients randomly assigned to TAVR, had a 20% reduction in all-cause mortality, as well as hospitalisation, at one year compared to best medical management.[3]

The European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) 2017 guidelines for AS management recommend consideration for TAVR in patients with severe symptomatic AS who are not suitable or deemed to be of high risk for cardiac surgery.[4] The guidelines recommend that TAVR decisions are taken by the 'Heart Team', including cardiologists, cardiothoracic surgeons and anaesthetists. To aid decision making multidisciplinary teams (MDTs) can make use of risk scores. Commonly used risk scores including Society of Thoracic Surgeons (STS) and EuroSCORE II have been found to be inaccurate at predicting mortality and morbidity in TAVR patients.[5,6] This is felt to be related to the complexity of this subgroup of patients, with multiple co-morbidities and frailty.[7]

Frailty is a recognised clinical entity, independent of age, co-morbidity and disability. It is a defined as a state of reduced physiological reserve, and associated with an increased susceptibility to poor healthcare outcomes.[8] Frailty has been shown to result in worse post-operative recovery across surgical specialties.[9] Green, *et al.*[10] identified in-

creased mortality and higher rates of poor outcomes at one year following a TAVR, in frail patients. However, such studies use complex frailty scores, which are difficult and time consuming in real life situations. For example, Huded, *et al.*[11] used a modified Fried frailty assessment that comprised of four domains and required specialist equipment.

The Edmonton Frail Scale (EFS) is a simple to perform frailty assessment that comprises of 10 questions and one physical assessment ('timed up and go'). The EFS has been validated against Comprehensive Geriatric Assessment (CGA), the current gold-standard for frailty assessment, and shown to be reliable and feasible for routine use by non-geriatricians.[12] Scores range from 0 (not frail) to 18 (very frail), with scores of 8 or above being defined as frail. Dasgupta, *et al.*[13] described use of Edmonton Frail Scale (EFS) on patients pre-operatively, in advance of elective orthopaedic operations. The study found individuals with a score of 7 or more were likely to have increased post-operative complications and less likely to be discharged home.[13] REFS is an adaptation of EFS, that can be performed in less than 10 min by any healthcare professional.[14] REFS substitutes the last domain on EFS, the physical performance measure, with three self-assessed physical performance questions (Table 1). This is ideal for use in busy cardiology clinics when patients are being assessed for suitability for intervention. In addition, it is common for patients exercise ability to be affected by worsening AS, and thus not perform as well in the physical assessment part of the EFS.[15]

Some clinicians might argue that frailty is something that can be diagnosed 'from the end of the bed' or a quick glance. However, Hii, *et al.*[16] showed that there was limited corre-

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Table 1. Reported Edmonton frail scale, adapted from Hilmer, *et al*.[14]

Domain	Item	0 point	1 point	2 points
Cognition	Pre-drawn circle. Add the numbers in the correct positions to make a clock then place the hands to indicate a time of ten after eleven	No errors	Minor errors	Major errors
General health	In the past year, how many times have you been admitted to a hospital?	0	1–2	> 2
	In general, how would you describe your health?	Good/Excellent	Fair	Poor
Functional independence	With how many of the following activities do you require help? Meal preparation Shopping Transportation Telephone Housekeeping Laundry Managing money Taking medications	0–1	2–4	> 4
Social support	When you need help, can you count on someone who is willing and able to meet your needs?	Always	Sometimes	Never
Medication use	Are you on five or more different prescription medications on a regular basis?	No	Yes	
	At times, do you forget to take your prescription medications?	No	Yes	
Nutrition	Have you recently lost weight such that your clothing has become looser?	No	Yes	
Mood	Do you often feel sad or depressed?	No	Yes	
Continence	Do you have a problem with losing control of urine when you do not want to?	No	Yes	
Functional performance	Two weeks ago, were you able to: Do heavy work around the house like washing windows, walls, or floors without help?	Yes	No	
	Walk up and down stairs to the second floor without help?	Yes	No	
	Walk 1 km without help?	Yes	No	

lation between cardiologists attempting to diagnose frailty from 'the end of the bed', and that such an assessment was not a reliable way to determine frailty.[16] To be able to use an objective and scored measure of frailty to aid the TAVR assessment process and MDT discussions would be invaluable.

To date, there is currently no literature on the application of REFS to predict outcomes of TAVR patients. Therefore, the purpose of this study was to evaluate the correlation between frailty score using REFS and outcomes following TAVR, specifically mortality, length of hospital stay and discharge destination.

Consecutive patients with severe symptomatic aortic stenosis referred for evaluation at Imperial College NHS Trust, considered high risk for surgical aortic valve replacement (SAVR), but eligible for TAVR were included. This group of high risk patients were assessed in the TAVR clinic between March 2014 to July 2016. Following clinic each patient was discussed in a MDT that consisted of interventional cardiologists, cardiothoracic surgeons, anaesthetist, radiologists and a geriatrician. A consensus was reached amongst the MDT about offering a TAVR. Patients were excluded if they had TAVR as an emergency or they were not reviewed by the geriatrician undertaking the REFS prior to their procedure. The REFS was performed with the patients and/or caregiver.

All patients had extensive cardiac baseline examinations including echocardiography to evaluate left ventricular ejection fraction, aortic valve orifice area and mean gradient, in addition to coronary angiography, CT angiography and lung function tests. Symptomatic history was elicited including allocation to NYHA classification.

A Medtronic CoreValve or an Edwards Sapien XT bio-prosthesis was implanted. The transcatheter aortic valve was introduced transfemorally whenever feasible, otherwise transapical or subclavian routes were adopted.

The primary outcomes measured were length of hospital stay, 30-day mortality, 12-month mortality, 18-month mortality and destination on discharge.

To analyse data, we used Chi-Square test for assessment of two categorical variables and Mann-Whitney test for nonparametric variables. For all statistical analyses, we used commercially available software (GraphPad Software).

Frailty assessment was performed on 62 patients with severe symptomatic aortic stenosis between March 2014 and July 2016 who subsequently underwent TAVR. Mean age was 84 years (range 68 to 95) with 26 being females (42%). REFS ranged from 1 to 12, with mean score of 6, mode 5, median 5 (Figure 1). Forty seven (76%) patients were deemed not frail (score of 7 or less) and 15 (24%) frail (score of 8 or above). Demographics and clinical character-
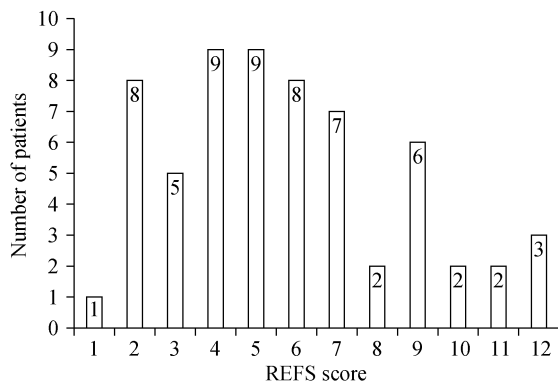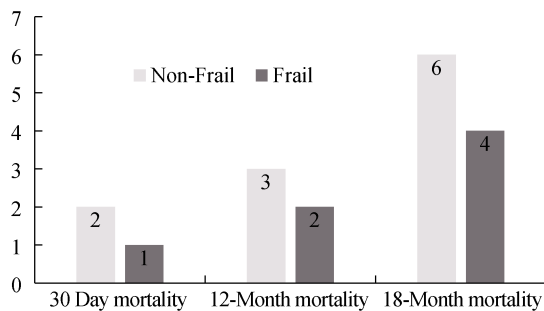
Figure 1.   Distribution of REFS scores.

Figure 2.   Mortality of non-frail and frail patients at 30-day, 12-months and 18-months.

Table 2.   Patient characteristics.

	Non-frail, *n* = 47	Frail, *n* = 15
Male	27 (57%)	9 (60%)
Female	20 (43%)	6 (40%)
Age	85 ± 6	81 ± 4
Smoker/Ex-Smoker	19 (40%)	6 (40%)
Diabetes	9 (19%)	3 (20%)

Data are presented as mean ± SD or *n* (%).

istics were very similar between the frail and non-frail groups (Table 2).

Three (5%) patients died within 30 days of undergoing TAVR. Of these, two were non-frail (4% of non-frail group) and one was frail (6% of frail group). Over the following 11 months, a further two patients died (one non-frail and one frail). After 18-months, 10 patients had not survived. Of these six were non-frail (13% of non-frail group) and 4 frail (27% of frail group); chi-square 1.62, *P*-value 0.20 (Figure 2).

Mean length of stay (LOS) of the surviving to discharge patients (58 patients) was 8 days; range 1 to 22 days post procedure. Non-frail mean length of stay was 7 days and frail group was 10; Mann Whitney *U* test with LOS: *Z*-score = −1.7444 (*P* = 0.04).

Fifty four of the surviving to discharge patients were discharged directly back to their original place of residence,

the other four were sent to rehabilitation either at a local hospital or community facility. Of which, three were non-frail patients.

Whilst the concept of frailty and poor health outcome is well documented in the literature, limited information is available relating to the practicability of frailty to predict outcomes following TAVR.[8] This study identifies a statistically significant correlation between REFS and LOS in patients who underwent TAVR. It did not confirm an association with in-hospital, 12-month or 18-month mortality. Despite the patients being classified as 'high risk' the vast majority (95%) survived to discharge, and were discharged to their original place of residence. In particular, 52 (84%) patients were still alive at 18 months post TAVR, despite being deemed too high risk for SAVR. This compares favourably to outcomes observed in the original TAVR trials. Incorporating REFS into the pre-operative assessment could be pivotal in helping run an efficient service within the constraints of healthcare finance. Knowing that frailer patients are able to undergo the operation with similar mortality but require longer hospital stay, is important for patient choice, resource management and planning. The more intensive use of therapists and specialist geriatricians may be able to help the discharge of frailer patients, particularly when identified prior to admission.

On the basis of our observations described, our unit now routinely uses REFS as part of the overall assessment of patients referred for TAVR, in conjunction with current risk stratification scores and MDT assessment. The Montreal Cognitive Assessment, anatomical considerations on the ease of performing TAVR versus SAVR, and patient choice are all used in the final assessment to determine a definitive management plan.

This is a small sample from a single centre, but the data highlights a link between length of stay following TAVR and frailty using REFS. In keeping with other studies, there was an increase in longer term mortality in the frail group (13 *vs*. 27%, *P* = 0.2). However, this was not statistically significant, again, probably a reflection of study size. The study did not follow up or further assess patients that did not undergo intervention and received medical management alone. It is likely that this group would have the highest mortality.

In conclusion, REFS demonstrates a simple, quick and free-to-use frailty score that can be completed in less than a few minutes by any member of the team. A REFS score of greater than seven identifies patients that are likely to experience longer hospital stays. However, frailty should not be an obstacle to TAVR as their long-term survival is better than those treated with medications alone. This score provides a

quantifiable measure of frailty to inform the MDT discussion when determining optimal management strategies in the complex high-risk patient group.

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