Assessment of Commonly Used Frailty Markers for High- and Extreme-Risk Patients Undergoing Transcatheter Aortic Valve Replacement

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Background. **The effect of frailty on outcomes after transcatheter aortic valve replacement (TAVR) remains incompletely understood. The objective of this study was to evaluate the performance of four commonly used frailty markers as predictors of early and late outcomes among patients undergoing TAVR.**

Methods. **A review was performed of 361 high- and extreme-risk patients undergoing TAVR from 2011 to 2015. Four frailty variables were assessed: serum albumin (g/dL), 5-m walk (seconds), grip strength (kg), and Katz index of independence in activities of daily living. Logistic regression was used to examine the association between the frailty indicators and 30-day composite of mortality, stroke, new heart block requiring permanent pacemaker, major or life-threatening bleeding, acute renal failure, major vascular complication, and 30-day readmission rate. Minimum distance to the perfect point (0, 1) was performed to delineate a cutoff point for each frailty indicator, and risk models were compared using receiver-operating characteristics curves.**

Results. **The composite of outcomes occurred in 28% of patients. Serum albumin, activities of daily living, and 5-m walk were independent predictors for 30-day composite outcomes, but only albumin was predictive of 30-day mortality. A new frailty model (four frailty indicators, age, and sex) to predict 30-day mortality was created and compared with The Society of Thoracic Surgeons predicted risk of mortality. Better discrimination was found with the new frailty model (area under the curve 0.74 versus 0.58). New individual frailty variable cutoff values were found to predict our composite of events.**

Conclusions. **Among high- and extreme-risk patients undergoing TAVR, our new frailty model was more discriminative of 30-day mortality than The Society of Thoracic Surgeons predicted risk of mortality. New cutoff values for frailty indicators were identified and will require further validation.**

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Frailty has been defined as a geriatric biologic syndrome of increased vulnerability to environmental factors. This syndrome is characterized by reduced physiologic reserves, affecting multiple organ systems, and has been related to increased in morbidity and mortality as well as falls and hospitalization [1, 2]. There is a growing consensus that variables associated with the frailty syndrome includes age-associated declines in lean body mass, strength, endurance, balance, walking performance, and low activity [3, 4].

In open cardiac surgery, the most common assessment tool for predicting early outcomes has been The Society of Thoracic Surgeons (STS) predicted risk of mortality (PROM) score [5]. Prediction of transcatheter aortic valve replacement (TAVR) short-term outcomes has also

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utilized the STS score, although most frailty variables are not captured in the STS score. To date, the most commonly used frailty indicators in the assessment of the TAVR patients include albumin, Katz activities of daily living (ADL), grip strength, and 5-m walk test. Whereas some studies have found no association between frailty status and procedural outcomes [6, 7], others have reported an association between variables associated with frailty and postoperative outcomes [8, 9]. Furthermore, there remains conflicting data because the cutoff values currently used were validated with cohorts of younger patients living in the community [10] and not with high- and extreme-risk patients who comprise the majority of the TAVR cohort.

The objective of the current study was to evaluate the effect of commonly used predictors of frailty and their cutoff values to assess early and 1-year outcomes. Secondarily, we chose to examine new frailty cutoff values for these high- and extreme risk TAVR patients. The final objective was to create a model that includes the different weight of the frailty indicators to predict 30-day mortality and to compare the discrimination of 30-day mortality, and to compare its discriminative ability with STS PROM.

Patients and Methods

This is a retrospective study using data collected prospectively from 2011 to 2015 on 361 patients who had comprehensive frailty measures assessed before undergoing TAVR at Emory University Hospitals. This study was approved by the Emory University Institutional Review Board.

Frailty Assessment

All patients who underwent TAVR had a frailty assessment between 1 and 30 days before the procedure including serum albumin (g/dL), the 5-m walk test, grip strength, and the Katz activities of daily livings (ADL) questionnaire. A serum albumin level of 3.4 g/dL or less was considered frail. For the 5-m walk test, participants were told to stand with their feet touching the starting line, to walk at their regular speed, and then to begin walking when receiving the simple order to start walking. Three attempts were made, allowing 15 seconds between each attempt, and the average was recorded. The frailty cutoff times to walk 5 m are between 6 and 7 seconds, depending on height. The handgrip test is a physical performance test that required three attempts. Patients were asked to squeeze a handgrip dynamometer as hard as possible (all attempts made with the dominant hand). The frailty cutoff values for grip strength are between 29 kg and 32 kg for men and 17 kg and 21 kg for women, depending of their body mass index. The Katz questionnaire is an instrument that assesses functional status as a measure of the patient's ability to perform ADL. It assesses bathing, dressing, toileting, transferring, continence, and feeding. Patients provide binary responses (yes/no) to each of these six components; a score of less than 4 is considered indicative of frailty [11].

TAVR and Outcomes of Interest

The preferred access was transfemoral, either using standard or minimalist approaches [12]. If needed, alternative access was at the discretion of the heart team and included transapical, transaortic, transcarotid, or transcaval approaches. All procedural outcomes were defined using STS and Valve Academic Research Consortium-2 (VARC-2) criteria [13].

Statistical Analysis

The composite outcome was defined as having any of the following within 30 days after the procedure: all-cause mortality, stroke, new-onset heart block requiring pacemaker implantation, major or life-threatening bleeding, acute renal failure, major vascular complication, and 30-day readmission. Logistic regression analyses were used to examine the associations between the selected frailty markers, and the 30-day composite outcomes as well as 30-day and 1-year mortality. Access approaches (transfemoral versus nontransfemoral) and 30-day perivalvular leak variables were also added to the logistic regression model to investigate their effect on the composite of adverse events and on mortality. While identifying an optimal cutoff point for each frailty marker, we used the minimum distance to the perfect point (0, 1) where sensitivity and specificity are equal to 1. We estimated the predicted probability of 30-day mortality for each individual patient $(\widehat{p}/1+\widehat{p})$ based on the logistic regression model that included age, sex, and the four frailty variables. The area under the receiver-operating characteristics curve (AUC) was also used to evaluate the performance of prediction models. The two-tailed significance level was set at 0.05. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

Demographics

Median age was 82 years (interquartile range [IQR]: 76 to 86), and 46.3% (167 of 361) were female. The majority of TAVR procedures, namely, 57.6% (208 of 361), were performed using the transfemoral route. Median STS PROM was 9.2% (IQR: 6.5 to 12.1), and the majority of patients (83.1%) had New York Heart Association functional class IV symptoms. Thirty-five percent of patients had previous bypass surgery (Table 1). Mean preprocedural albumin level was 3.53 ± 0.47 g/dL. Mean grip strength was 21.90 ± 11.84 kg. Median ADL score was 6 (IQR: 5 to 6), and median 5-m walk test was 6 seconds (IQR: 4.7 to 8.7).

Perioperative Data

The majority of valves implanted were using the Sapien XT (Edwards Lifesciences, Irvine, CA) valves (67.6%) by means of transfemoral access (57.6%). The minimalist approach was used in 49.6% of patients. Sixty-four percent of patients did not have any paravalvular leak at 30 days. Other periprocedural values are included in Table 2.

Table 1. Demographics

Demographics	(n = 361)
Age, years	82 (76–86)
Female	167 (46.3)
White	317 (87.8)
STS score	9.2 (6.5–12.1)
Body mass index, kg/m^2	26.5 (22.7–30.4)
Diabetes mellitus	162 (44.9)
Hypertension	351 (97.2)
COPD	
None	170 (47.1)
Mild	90 (24.9)
Moderate	47 (13.0)
Severe	54 (15.0)
NYHA functional class	
III	55 (15.2)
IV	300 (83.1)
Coronary artery disease	227 (62.9)
Prior CABG	127 (35.2)
Prior PCI	144 (39.9)
Prior cerebrovascular disease	127 (35.2)
Peripheral artery disease	123 (34.1)
Liver disease	8 (2.2)
ESRD on hemodialysis	11 (3.0)
Left ventricular ejection fraction	55 (43–60)

Values are median (interquartile range) or n (%).

CABG = coronary artery bypass graft surgery; COPD = chronic obstructive pulmonary disease; ESRD = end-stage renal disease; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS = The Society of Thoracic Surgeons.

Table 2. Procedure-Specific Details

Procedural Variables	(n = 361)
Valve type	
Sapien	117 (32.4)
Sapien XT	244 (67.6)
Valve size	
23	134 (37.1)
26	140 (38.8)
29	87 (24.1)
Valve-in-valve TAVR	27 (7.5)
Access	
Transfemoral	208 (57.6)
Transapical	90 (24.9)
Transaortic	48 (13.3)
Other	15 (4.2)
Minimalist TAVR	179 (49.6)
Need second valve	29 (8.0)
Need for postdilation	143 (39.7)
Thirty-day PVL	
None	216 (63.7)
Mild	101 (29.8)
Moderate/severe	22 (6.5)

Values are n (%).

PVL = perivalvular leak; TAVR = transcatheter aortic valve replacement.

Postoperative Outcomes

The 30-day mortality for the entire cohort was 5.8%, stroke rate was 1.4%, and readmission rate was 3.9%. The composite of outcome (30-day mortality, stroke, new-onset heart block requiring pacemaker, major or life-threatening bleeding, acute renal failure, major vascular complication, and 30-day readmission) occurred in 28% of patients. New-onset heart block requiring pacemaker implantation occurred in 3.9% of patients, and major vascular complications in 5% (Table 3). We also investigated the associations between six complications (stroke, new heart block requiring pacemaker, major or life-threatening bleeding, acute renal failure, major vascular complication, and 30-day readmission) and 30-day mortality using Fisher's exact tests. Table 4 displays the frequency counts, the corresponding percentages, and the test results. Among the adverse events considered, vascular complications seemed to most influence 30-day mortality based on our data (Table 4).

Univariable and Multivariable Analyses

In the univariable analyses, preprocedural albumin (odds ratio [OR] 0.32 per g/dL, $p < 0.0001$), grip strength (OR 0.97, $p = 0.02$), ability to perform walk test (OR 0.39, $p = 0.003$), and ADL score (OR 0.82, $p = 0.01$) were significantly associated with the probability of 30-day composite of outcomes. Only a high albumin level was predictive of decreased mortality (OR 0.27 per g/dL, $p = 0.009$). At 1 year, only poor grip strength was associated with increased mortality ($p = 0.04$). The odds of dying at 1 year was estimated to decrease by 3% per 1-kg increase in grip strength.

In the multivariable analysis of one frailty marker at a time, serum albumin was a significant predictor for 30-day composite outcomes and mortality. For a 1-g/dL increase in the preprocedural albumin level, the odds of having a 30-day composite event outcomes and 30-day mortality were estimated to decrease by 68% (OR 0.32, $p = 0.0002$) and 74% (OR 0.26, $p = 0.02$), respectively. It was marginally significantly associated with 1-year mortality (OR 0.53, $p = 0.07$). The ADL score was significantly associated with 30-day composite outcomes (OR 0.83, $p = 0.03$) and 1-year mortality (OR 0.80, $p = 0.04$).

Table 3. Postprocedural Outcomes

Major Procedural Complications	(n = 361)
Thirty-day mortality	21 (5.82)
Any stroke	5 (1.39)
New heart block requiring pacemaker	14 (3.88)
Major or life-threatening bleeding	56 (15.51)
Acute renal failure	7 (1.94)
Major vascular complication	18 (4.99)
Thirty-day readmission	14 (3.88)
One-year mortality	45 (12.5)

Values are n (%).

Table 4. Associations Between Adverse Events and 30-Day Mortality

	30-Day Mortality		
Adverse Event	No (n = 340)	Yes (n = 21)	*p* Value
Pacemaker			1.00
No	326 (95.88)	21 (100)	
Yes	14 (4.12)	0 (0)	
Major bleeding			0.11
No	290 (85.29)	15 (71.43)	
Yes	50 (14.71)	6 (28.57)	
Vascular complications			<0.001
No	328 (96.47)	15 (71.43)	
Yes	12 (3.53)	6 (28.57)	
Acute renal failure			0.06
No	335 (98.53)	19 (90.48)	
Yes	5 (1.47)	2 (9.52)	
Stroke			1.00
No	335 (98.53)	21 (100)	
Yes	5 (1.47)	0 (0)	
Readmission, 30 days			1.00
No	326 (95.88)	21 (100)	
Yes	14 (4.12)	0 (0)	

Values are n (%).

The ability to perform the walk test was also significantly associated with 30-day composite outcomes (OR 0.36, $p = 0.003$), and was marginally associated with 1-year mortality (OR 0.45, $p = 0.06$). Among the 313 patients who completed the walk test, increased walking time was predictive of 1-year mortality (OR 1.10 per 1-second increase in walk time, $p = 0.03$).

For the investigation of the access approaches, we did not find a significant association between access and the 30-day composite of outcomes nor between 30-day or 1-year mortality. We also compared four frailty markers between transfemoral and nontransfemoral groups and found significant differences in their ADL scores ($p = 0.03$) and albumin levels ($p < 0.01$). To further assess the confounding effect of access, access (transfemoral versus nontransfemoral) was added to the multivariable logistic regression model. The changes in the coefficient estimates corresponding to frailty variables were less than 5%, indicating limited and ignorable confounding. Also, perivalvular leak was included in the multivariable logistic model, and was not significantly associated with 30-day composite ($p = 0.74$) or 1-year mortality ($p = 0.37$). We further examined the confounding effect of perivalvular leak by comparing the coefficient estimates for each frailty marker between the models with and without perivalvular leak. We did not find any appreciable differences in the coefficient estimates.

New Cutoff Values

Based on our data, the optimal cutoff points for albumin, grip strength, 5-m walk test, and ADL for the 30-day

Table 5. Optimal Cutoff Point for 30-Day Composite Outcomes Identified by Minimum Distance to Perfect Point (0, 1) Where Sensitivity = Specificity = 1

Frailty Markers	New Cutoff Values Values Used	Actual Cutoff
Preprocedure albumin levels, g/dL	≤3.5	≤3.4
Male grip strength, kg	24.7	29–32[c]
Female grip strength, kg	14.7	17–21[c]
Activities of daily living	≤6	≤3
Male 5-m walk test, seconds (n = 176)[a]	6.1	6–7[d]
Female 5-m walk test, seconds (n = 137)[a]	9.3	6–7[d]
Male 5-m walk test, seconds (n = 194)[b]	6.1	…
Female 5-m walk test, seconds (n = 167)[b]	9.3	…

[a] Patients who completed test. [b] Maximum value (25.5 seconds) was assigned to 18 male and 30 female patients who were unable to perform the walk test; assigning values greater than 25.5 did not change the cutoff points. [c] Range depends on body mass index. [d] Range depends on height.

composite outcomes using both minimal distance to the perfect point (0, 1) are displayed in Table 5. The actual commonly used cutoff values were also included in Table 5.

Prediction Model

To determine whether multiple predictors of frailty outperformed single ones, we compared the values of AUC for models with different combinations of frailty markers for the prediction of the 30-day composite outcomes. The full model with four frailty markers was our reference model, and models with one, two, and three frailty markers were compared with this reference model. The AUC and the associated *p* value for each model are displayed in Table 6. The reference model produced the highest AUC as expected, and its prediction performance was significantly better than other models with grip strength, ADL, or walk test (Table 6).

Model to Predict 30-Day Mortality

Based on the logistic regression results, we obtained the predicted probability of 30-day mortality for each individual patient. First, we computed the estimated odds with this formula:

$$\hat{p} = \exp(-7.4261 + 0.0843\text{ age} - 0.1776\text{ male} - 1.2574\text{ albumin (g/dL)} - 0.022\text{ grip strength (kg)} + 0.4584\text{ ADL score} + 0.013\text{ walk test (seconds)}),\ \text{if the patient was capable of walking; or}$$

$$\hat{p} = \exp(-6.5562 + 0.0843\text{ age} - 0.1776\text{ male} - 1.2574\text{ albumin (g/dL)} - 0.022\text{ grip strength (kg)} + 0.4584\text{ ADL score}),\ \text{if the patient was unable to walk.}$$

Then, the predicted probability for 30-day mortality = $([\hat{p}]/[1+\hat{p}])$ was multiplied by 100 to obtain the percentage of risk. The result of the Hosmer-Lemeshow test indicated no evidence for lack of fit ($p = 0.85$). The AUC

Table 6. Area Under Receiver-Operating Characteristics Curve for Different Combinations of Frailty Markers for Prediction of 30-Day Composite Outcome

Model	Area Under ROC Curve	95% CL Lower	95% CL Upper	*p* Value[a]
Four frailty markers	70.2%	63.5%	76.9%	…
One frailty marker				
Albumin	66.1%	58.8%	73.3%	0.08
Grip strength	58.4%	51.6%	65.2%	0.001
ADL	58.1%	51.3%	65.0%	0.002
Walk test	63.4%	56.5%	70.3%	0.03
Two frailty markers	68.2%	61.3%	75.1%	0.18
Albumin + grip strength	66.9%	59.8%	74.1%	0.13
Albumin + ADL	68.9%	62.0%	75.7%	0.31
Albumin + walk test	61.2%	54.6%	67.9%	0.01
Grip strength + ADL	64.5%	57.6%	71.3%	0.03
Grip strength + walk test	63.0%	55.9%	70.0%	0.03
ADL + walk test	68.6%	61.7%	75.4%	0.25
Three frailty markers	70.2%	63.5%	76.9%	0.83
Albumin + grip strength + ADL	68.8%	62.0%	75.7%	0.27
Albumin + grip strength + walk test	64.7%	57.9%	71.5%	0.04
Albumin + ADL + walk test	66.1%	58.8%	73.3%	0.08
Grip strength + ADL + walk test	58.4%	51.6%	65.2%	0.001

[a] Area under the receiver-operating characteristics (ROC) curve compared with the four frailty markers model.

ADL = activities of daily living; CL = confidence limits.

of this model was compared with the other three models, including the frailty marker model without age and sex, a model with the STS score alone, and the model with both STS score and frailty markers (Fig 1). The models with only four frailty markers produced almost identical AUC values compared with the model with frailty markers plus STS score (71.9% versus 71.9%, $p = 0.91$), suggesting that the STS score does not provide independent predictive value for 30-day mortality above and beyond the four frailty markers in terms of predicting 30-day mortality. Moreover, compared with the model with the STS score alone (AUC = 57.7%), the new model with age, sex, and four frailty markers significantly improved the prediction of 30-day mortality (AUC = 73.6%, $p = 0.04$; Fig 1).

Comment

In this study, we found that albumin, ADL, and 5-m walk test were predictive of our composite of 30-day outcome, and that albumin was the only independent predictor of 30-day mortality. We also identified new cutoff values that provide better discrimination for the frailty variables assessed in this high-risk and extreme-risk cohort of patients undergoing TAVR. A performance model was used to determine the best combination of frailty markers to predict of the composite outcome. The four-variable model was the most predictive, but was predominantly driven by albumin. Lastly, we confirmed our hypothesis that individual frailty indicators should have different weights, and we developed equations with a fair discrimination to predict 30-day mortality. We also showed that compared with the most commonly used scoring system, the STS PROM, our model that includes age, sex, and the four frailty markers provided superior discrimination for 30-day mortality.

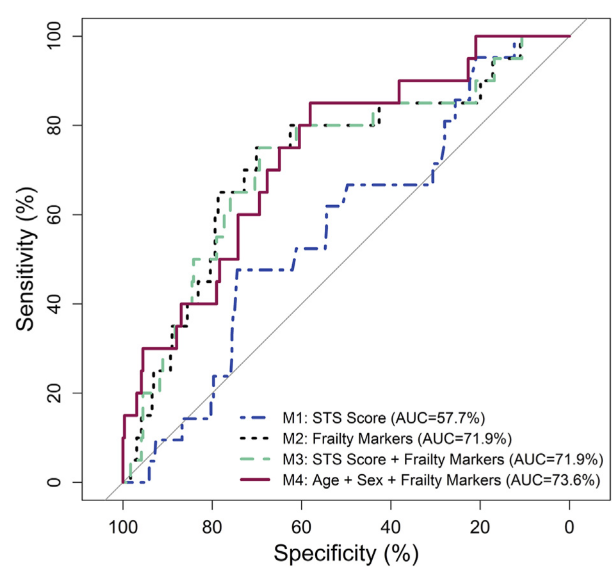

Fig 1. Receiver-operating characteristics curves for 30-day mortality (M): M1 (blue line) The Society of Thoracic Surgeons (STS) score (area under the curve [AUC] = 57.7%; M2 (black line) frailty markers (AUC = 71.9%); M3 (green line) STS score plus frailty makers (AUC = 71.9%); and M4 (purple line) age plus sex plus frailty markers (AUC = 73.6%).

Origin of Frailty

The popularization of the use of frailty originated from the Cardiovascular Health Study, which proposed these main characteristics to assess frailty: shrinking, weakness, poor endurance, exhaustion, slowness, and low activity [14]. They classified patients as frail if three criteria or more were present, as intermediate or "prefrail" if one or two criteria were present, and as not frail if none of the criteria was found. After adjustment, frail and prefrail categories independently predicted adverse outcomes and death versus the not frail group. This work proposed a standardized phenotype of frailty for older adults and demonstrated predictive validity for the adverse outcomes that geriatricians rely on to identify frail older adults as being at risk for falls, hospitalizations, disability, and death. The approach used in this study indicated that frailty is not rare in a community-dwelling population and is a meaningful predictor of adverse outcomes and death when people are relatively functional [14]. In the current study, we reassessed the original cutoff values for frailty indicators in higher risk patients undergoing TAVR who differ substantially from a community-dwelling population.

Frailty and Composite Outcome

We evaluated four variables related to frailty under the domains of physical performance and nutritional status that were predictive of the 30-day composite outcome. We hypothesize that the fair discrimination of our model and others in the literature reflects missing elements from other domains of frailty such as cognition, mental health, and biomarkers. In the performance model that we built to predict of the 30-day composite outcome, we showed that the four-variable model was not statistically different from the single albumin model. However, this analysis was not designed to assess equivalency among models. We can only conclude that both are fair models to predict the 30-day composite outcome. However, an additional complexity is that frailty is a dynamic variable, and it remains unclear to what extent the level of frailty can be influenced by interventions such as TAVR [15]. That adds to the difficulty of the true assessment and predictive nature of frailty among patients undergoing TAVR.

STS PROM Scoring Tool

The STS PROM is a well-validated predictor of 30-day mortality after open cardiac surgical procedures [16]. We have recently shown for more that 140,000 low-, intermediate-, and high-risk patients undergoing isolated surgical aortic valve replacement in the United States that the STS PROM was predictive of early mortality [17]. However, others have shown that the STS PROM may underestimate or overestimate [5] perioperative risk during a cardiac procedure. The disadvantages in exclusively relying f on STS PROM in the assessment of patients undergoing TAVR is based on the consistent overestimation of early mortality in these patients and the lack of frailty variables within the STS PROM modeling. An example of this discrepancy includes the recent data from the PARTNER 2 (Placement of AoRTic TraNscathetER) Sapien 3 study which showed an observed to expected ratio of 0.2 with third-generation TAVR valves [18, 19]. In the current study, we have provided a novel approach in which we have added four frailty variables to the modeling to potentially increase the accuracy of the STS PROM in this population of TAVR patients. Interestingly, we found that the frailty model alone (AUC = 0.727) was better at predicting 30-day mortality than the STS PROM score model alone (AUC = 0.579) or combined with the frailty model (AUC = 0.699) in this specific high- and extreme-risk cohort of TAVR patients (Fig 1).

Frailty and TAVR

There is a growing interest in the predictive nature of frailty for patients undergoing TAVR. Green and colleagues [8] evaluated the impact of frailty on procedural outcomes in 159 TAVR patients using the same frailty markers as in the current study. They dichotomized patients on the basis of median frailty scores between "frail" and "not frail" and found no association between frailty status and procedural outcomes [8]. Investigators from the Medtronic CoreValve US Pivotal Trial evaluated the impact of a new model of frailty on early and late mortality in 1,205 patients undergoing TAVR [6]. They found that home oxygen use, assisted living, albumin level less than 3.3 g/dL, falls in the last 6 months, and an age more than 85 years predicted death at 30 days. Other variables such as grip strength, gait speed, and Katz index were not found to be predictors of 30-day mortality [6]. Of the traditional frailty variables, only albumin was found to be a strong predictor of 30-day mortality. Similarly, in the current study, we noted that a preoperative albumin level was the strongest predictor of early all-cause mortality. The AUC obtained for our model and the CoreValve prediction model [6] are similar and showed fair discrimination (AUC = 0.74 and AUC = 0.79, respectively).

Future Directions

Future studies should consider a more comprehensive definition of frailty that should include assessment of physical performance, including gait speed and mobility, nutritional status, mental health, and cognition, as well as biomarkers, which are important and require further assessment. These additional variables will need to be tested for patients undergoing transfemoral TAVR, which is the least invasive procedure for the elderly patient and now comprises more than 90% of procedural access. The cutoff values for the frailty variables defined in this study should be validated prospectively in a larger patient cohort and should also be assessed in a lower risk cohort of patients. It may be feasible to incorporate these variables in the STS/American College of Cardiology Transcatheter Valve Therapy database to facilitate a larger, more comprehensive future analysis. Another important area of investigation includes the reassessment of frailty after TAVR, considering that frailty may have a reversible component.

Study Limitations

This study was performed in an experienced TAVR center, resulting in a low number of adverse events, which has a limiting effect on study power. That was overcome, in part, by defining a composite outcome to capture various adverse events. Also, generalizability is limited by patient selection, which was based in part on perceived procedural risks so that the heart team deliberately chose not to perform TAVR in patients at excessive risk of poor outcomes.

Conclusion

For high- and extreme-risk patients undergoing TAVR, serum albumin, ADL, and 5-m walk test were associated with increased risk of adverse outcomes. However, only albumin was predictive of 30-day all-cause mortality. The new frailty model provides greater discrimination for 30-day mortality than the STS PROM. New cutoff values for frailty indicators and models to predict 30-day mortality were proposed and will require further validation.

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DISCUSSION

DR DAVID R. JONES (New York, NY): Do you foresee doing an actual clinical trial in this and are you going to go with the composite index, because, again, in your center at least, the events are pretty low and you have made the composite. Is that your plan moving forward?

DR FORCILLO: Yes, exactly. We will validate our data on another cohort of 600 patients shortly. Also, because of the few number of events, we did not have the choice to use a composite of events.

DR JONES: Are you going to have another center perhaps or other centers for more of an external validation as opposed to it only works at your institution?

DR FORCILLO: It would be very interesting if other centers would be interested in collaborating with us.

DR KEVIN D. ACCOLA (Orlando, FL): Jessica, a very nice presentation. It is interesting, as many of these patients who are frail have a normal creatinine before transcatheter aortic valve replacement (TAVR), although after the procedure end up with creatinine elevation or worse, renal failure requiring dialysis, which is a huge morbidity. Have you looked at these patients more discriminately in regard to glomerular filtration rate? Are there other laboratory tests that we could do that might delineate the high-risk patients, and in addition to frailty.

DR FORCILLO: Exactly, that is a good point and that was proven in other papers that glomerular filtration rate was predictive of increased adverse events. In the next work that we will be doing we want to include biomarkers, and we probably will include also glomular filtration rate and look at some other biochemical variables.

DR ACCOLA: In any of these people who are deemed frail, do you ever do a balloon valvuloplasty initially, give them 3 to 6 months to see if they can improve on their frailty assessment before proceeding with TAVR?

DR FORCILLO: Yes, we do that, but it was basically based on a subjective evaluation. It was not objectively based on frailty.

DR ACCOLA: Nice presentation again. Thank you.

DR FORCILLO: Thank you.

DR FREDERICK GROVER (Aurora, CO): Thanks for bringing frailty to our attention. Frailty, as you well know, is quite important, particularly in the elderly population. We have added the 6-minute walk test, as a test for frailty, to the STS database, but have poor compliance with data entry. This is important to us as a specialty because if frailty is not captured, it can result in a lower expected mortality or morbidity in a patient, which in turn can have a negative effect on a hospital or groups performance report. Also, in the ASCERT (American College of Cardiology [ACC] Foundation/STS Collaboration on the Comparative Effectiveness of Revascularization Strategies Trial), frailty was noted to be a potential missing confounding variable, resulting in criticism of the study. I think further studies should hopefully define and continue to emphasize this point. We appreciate your work and hope that you will continue it.

DR FORCILLO: Thank you. Just to add to your comment, I think that frailty is also multidimensional and reversible. So it has never been evaluated in the literature whether you can reverse frailty by doing a procedure. That would be interesting to see, probably using biomarkers, whether frailty could be reversible. That explains why frailty is so difficult to evaluate and define.

ABTS Announcement for Maintenance of Certification

The American Board of Thoracic Surgery's Maintenance of Certification program was adopted 9 years ago. Since that time, there has been a continuous evaluation in the Board's thinking about the overall process, based upon internal discussions and input from our diplomates.

These inputs resulted in our decision to migrate from a purely knowledge-based multiple choice exam, utilizing a Pearson Testing Center to a Mastery Learning Process, using a SESATS format. Diplomates, enrolled in this year's (2017) 10-year MOC process, will fulfill their Part III requirement by completion of a home or office-based secure learning exam, following the instructions on the ABTS website.

In brief, you will be directed to a secure website. The only special computer hardware needed will be a camera for your home or office computer (most laptops now come with a built-in camera). Once logged in, you will be asked to verify your identity by holding up your driver's license with your picture next to your face. You will be visually monitored for the time you are logged onto the website.

There are 100 SESATS-based questions that focus on your specialty designation (Adult Cardiac, General Thoracic, Cardiothoracic, and Congenital), that you will need to work through as instructed. The exam will now be modular and tailored to your practice – for example, if your practice is 100% adult cardiac, you will only have adult cardiac and critical care questions. You will have 15 hours with as many as 10 logins to complete the 100 questions during the months of September and October 2017. For those diplomates who have used SESATS in the past, the process of working through the questions is the same. For those who are not familiar with SESATS, it might be beneficial to purchase and download SESATS and work through the specialty specific module. This preparation will give you familiarity with the process. While SESATS may be helpful preparation, it is not required.

The goal of this exam is to provide a learning opportunity using judgement and decision making as well as knowledge.

The Board and MOC Committee believe that reading the critique is key to the learning process using SESATS. The remote proctoring system will allow us to verify the pace of completion and thus limit the passing grades to those who earnestly participate in the process.

The Board sincerely hopes that this focus on life-long learning is viewed favorably by our diplomates. The Board will continue with this new strategy and refine SESATS as we go forward to assure that new standards of care are communicated to members of the ABTS community as part of the MOC process. There will be a brief survey following the last SESATS question which needs to be completed to officially finish the process.

Everyone at the ABTS thanks you for embracing the primary principle of MOC—life-long learning, which is consistent with our obligation to the public trust.

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