ORIGINAL ARTICLE

New risk factors in determining long-term mortality in patients undergoing TAVI: can the conventional risk scores be used as a long-term mortality predictor?

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KEY WORDS
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ABSTRACT

BACKGROUND Surgical risk in patients after transcatheter aortic valve implantation (TAVI) is determined by conventional scoring systems. However, these risk scores were developed to predict surgical mortality. Due to their insufficient predictive ability in patients after TAVI, novel risk scores are needed to predict long-term mortality in this population.

AIMS The study aimed to investigate the value of conventional risk scores in predicting long-term mortality. Additionally, the impact of laboratory parameters on long-term mortality was evaluated.

METHODS Our study included 121 patients who underwent transfemoral TAVI.

RESULTS The mean (SD) logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE), EuroSCORE II, and the Society of Thoracic Surgeons (STS) risk score were 27.4 (9.7), 7.9 (4.6), and 4.6 (2.4), respectively. In-hospital mortality rate was 1.7%. None of the risk scoring systems predicted in-hospital mortality correctly. The STS score corresponded with the mortality rate of approximately 2 months, EuroSCORE II, with 6 months, and logistic EuroSCORE, with 30 months. Male gender (odds ratio [OR], 5.668; 95% CI, 1.055–30.446; $P = 0.04$) and low albumin levels before TAVI (OR, 0.109; 95% CI, 0.018–0.654; $P = 0.02$) were found to be the independent predictors of long-term mortality.

CONCLUSIONS Although all conventional risk scores overestimated in-hospital mortality, the STS risk score predicted 2-month, EuroSCORE II, 6-month, and logistic EuroSCORE, 30-month mortality. The independent predictors of long-term mortality were male gender and low blood albumin levels before the TAVI procedure.

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INTRODUCTION Aortic stenosis (AS) is the most frequently diagnosed valvular disease worldwide.[1,2] Severe symptomatic AS has a poor prognosis with conservative treatment.[3] Leaving patients untreated results in the manifestation of symptoms and a high mortality rate: approximately 30% to 50% of the patients die in the first 2 years after symptom occurrence.[4-6] Because AS is a disease of old age, comorbidities are usually more frequent in this group of patients, which makes surgery difficult. It has been reported that 30% of severely symptomatic patients cannot be operated on due to multiple clinical comorbidities.[7,8]

Transcatheter aortic valve implantation (TAVI) is a well-established alternative to surgical valve replacement in patients at high surgical risk.[9] Surgical risk is determined by conventional scoring systems. These risk scores, including the logistic European System for Cardiac

WHAT'S NEW?

Conventional scoring systems including logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE), EuroSCORE II, and the Society of Thoracic Surgeons risk score are used to determine the surgical risk in patients undergoing transcatheter aortic valve implantation (TAVI). However, these risk scores were developed to predict perioperative surgical mortality and we need a specific tool to determine periprocedural and long-term mortality in patients undergoing TAVI. In this study, we found that all conventional risk scoring systems overestimated in-hospital mortality. Furthermore, we demonstrated that male gender and low albumin levels before the procedure were independent predictors of long-term mortality in this population.

Operative Risk Evaluation (EuroSCORE), EuroSCORE II, and the Society of Thoracic Surgeons (STS) risk score, were developed to predict perioperative mortality and morbidity in patients undergoing cardiac surgery.[10-12] Therefore, it is unclear whether these surgical risk scores can be used for predicting early and late mortality in patients undergoing TAVI. In addition, risk factors related with late mortality in this population have not been completely elucidated yet. As the abovementioned risk scores were considered to have the insufficient predictive ability, the Valve Academic Research Consortium (VARC)-2 consensus document advocated for other anatomical and biological tools for the evaluation of risk and outcome in patients undergoing TAVI.[13] Since then, new predictors and risk scores were developed to prognosticate the risk associated with TAVI. Recent studies demonstrated that male gender and hypoalbuminemia, as a predictor of frailty, are independent predictors of mortality in patients undergoing TAVI.[14,15]

The aim of our study was to evaluate the predictive value of conventional risk scores regarding long-term mortality in patients undergoing TAVI. Apart from that, we assessed risk factors that are not included in the scoring systems yet might prove effective as predictors of long-term mortality.

METHODS

Patient selection A total of 121 patients who underwent transfemoral TAVI between June 2012 and March 2016 were included in this study. Among them, 119 had severe calcific AS and 2 had severe symptomatic aortic regurgitation. All procedures were conducted by the same experienced team. The Heart Team evaluated all the patients, and the decision on TAVI was made based on the current guidelines.[10] The echocardiographic criteria of severe AS were determined as follows: aortic valve area (AVA) <1 cm^2 and/or mean transvalvular gradient >40 mm Hg, and/or maximal transvalvular blood flow velocity >4 m/s. Low-flow, low-gradient aortic stenosis was defined as AVA <1 cm^2, mean transvalvular gradient <40 mm Hg, ejection fraction (EF) <50%, and stroke volume index ≤35 ml/m^2; paradoxical low-flow, low-gradient aortic stenosis, as AVA <1 cm^2, mean transvalvular gradient <40 mm Hg, EF ≥50%, stroke volume index ≤35 ml/m^2.[16]

The study was approved by the ethics committee of Dokuz Eylül University and informed consent was obtained from the patients.

Imaging procedures All patients were evaluated using transthoracic echocardiography (Philips HD11XE, SONOS 4500, Andover, Massachusetts, United States). Echocardiographic measurements were performed according to the Journal of the American Society of Echocardiography guidelines.[17] We used transesophageal echocardiography and/or computed tomography to evaluate the aortic valve structure, degree of calcification and stenosis, AVA, annulus, and ascending aorta. The aortic annulus was measured between its hinge points. Coronary angiography was performed in all patients before the TAVI procedure. Patients requiring revascularization were treated prior to TAVI.

Study design The baseline clinical characteristics of all patients, the mortality and morbidity rates during the procedure, and the long-term follow-up were reviewed retrospectively. Complications were evaluated according to the VARC-2 criteria. All patients underwent echocardiography and laboratory tests before the procedure, 24 hours after that, and before the hospital discharge. All of them were evaluated at the outpatient clinic in the 1st, 3rd, 6th, 12th, 24th, and 36th month of follow-up after the procedure.

Transcatheter aortic valve implantation procedure The TAVI procedures were performed in the catheter laboratory under general or local anesthesia along with deep sedation. In all patients, the implantation was performed via the transfemoral approach. The surgical cut-down was utilized in 77.7% of the patients, and the percutaneous access, in the remaining 22.3% (with the ProStar XL10Fr or Perclose Proglide [Abbott Vascular Devices, Redwood City, California, United States] vascular closure devices).

We used the balloon-expandable Edwards SAPIEN XT valve (Edwards Lifesciences, Irvine, California, United States), the self-expandable CoreValve Revalving System (Medtronic CoreValve, Minneapolis, Minnesota, United States), the reclaimable Evolut R valve (Medtronic CoreValve, Minneapolis, Minnesota, United States), and the Direct Flow Medical valve systems (Direct Flow Medical Inc., Santa Rosa, California, United States). Using angiography, we attempted to implant the Edwards SAPIEN XT valve in the middle, according to the annular line. The Medtronic CoreValve System was inserted

using high implantation technique with a target depth of ≤6 mm below the aortic annulus so as to prevent the deformation of the leaflets. After the procedure, we evaluated aortic insufficiency, valve position, and blood flow in coronary arteries using aortic root angiography. The peripheral entry site was then closed and follow-up angiography was performed.

Postprocedural follow-up The patient was put on 6-month dual antiplatelet therapy with aspirin and clopidogrel. Single or dual (based on the bleeding risk) antiplatelet therapy in combination with oral anticoagulants for at least 3 months was applied in patients who had to receive oral anticoagulants due to any reason. After their general condition became stable, patients were discharged from the hospital and scheduled for follow-up visits after 1 month, 3 months, 6 months, and 1 year. During follow-up visits, patients' functional capacities, results of routine physical examinations, echocardiograms, and laboratory tests were evaluated. Their survival data were obtained from our hospital records, the ministry of health, and/or by contacting the patients by phone.

TABLE 1 Baseline clinical characteristics of the study population

Parameter	TAVI patients (n = 121)
Age, y	78 (7.7)
Sex, male/female	46/75
BMI, kg/m^2	26.4 (3.8)
Logistic EuroSCORE	27.4 (9.7)
EuroSCORE II	7.9 (4.6)
STS score	4.6 (2.4)
Comorbidities, n (%)	
Hypertension	79 (65.3)
Diabetes mellitus	30 (24.8)
Atrial fibrillation	39 (32.2)
COPD	33 (27.3)
History of CABG	27 (22.3)
History of valve surgery	10 (8.3)
Coronary artery disease	42 (35)
Laboratory variables	
Hemoglobin, g/dl	11 (1.5)
Leukocytes, × 10^3/μl	8.4 (9.8)
Platelets, × 10^3/μl	220 (87)
Urea, mg/dl	25.7 (10.7)
Creatinine, mg/dl	1.1 (0.3)
Albumin, g/dl	3.6 (0.4)
Echocardiographic variables	
LVEF, %	49.5 (14.7)
Maximum gradient, mm Hg	74 (20.6)
Mean gradient, mm Hg	45.2 (14)
AVA, cm^2	0.57 (0.14)
sPAP, mm Hg	48.4 (14.2)
LVMI, g/m^2	153.8 (33.9)

Data are presented as mean (SD) unless otherwise indicated.

Abbreviations: AVA, aortic valve area; BMI, body mass index; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; EuroSCORE, European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction; LVMI, left ventricular mass index; sPAP, systolic pulmonary artery pressure; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation

Statistical analysis Statistical analyses were performed with the Statistical Package for Social Sciences 15.0 software (SPSS, Chicago, Illinois, United States). The Kolmogorov–Smirnov test was performed to assess whether the data had normal distribution. Continuous variables were presented as mean (SD) and/or median (interquartile range, Q1–Q3) and compared with the *t* test and/or Mann–Whitney test depending on the type of data distribution. Categorical variables were presented as number and percentage. The χ^2 test and the Fisher exact test were performed to compare categorical variables. Preprocedural and postprocedural variables were compared with the paired *t* test. The Kaplan–Meier survival curve was used to determine survival rates and estimated life expectancy; the log-rank test was applied for the comparison. The independent predictors of long-term mortality were identified based on multivariate logistic regression analysis. Receiver operating characteristic curve analysis was performed to find the best predictive value regarding mortality. A *P* value less than 0.05 was considered significant.

RESULTS A total of 121 patients were included in this study. The mean (SD) age of patients was 78 (7.7) years. The baseline clinical characteristics of the patients are presented in TABLE 1. A surgical cut-down was used in 94 patients (77.7%), while percutaneous closure, in 27 patients (22.3%). Also, 30 implanted valves (24.8%) were Edwards SAPIEN, 88 Core Valve Medtronic (72.7%), and 3 Direct Flow Medical (2.5%) (TABLE 2).

Maximum ($P = 0.01$) and mean ($P = 0.02$) transaortic gradients decreased, while AVA ($P < 0.001$) and EF ($P < 0.001$) increased after the procedure. In addition, creatine levels increased on the first day after the procedure compared with the preprocedural value ($P < 0.001$). Assuming that an increase in postprocedural creatine values higher than 25% was considered a significant creatinine increase, it was observed in 29 patients (24.2%) (TABLE 3).

Complication rates are listed in TABLE 4. There was no case of periprocedural death, while

TABLE 2 Procedural characteristics of the study patients

Parameter		TAVI patients (n = 121)
Access route	Surgical cut-down	94 (77.7)
	Percutaneous closure	27 (22.3)
Valve type and valve size	ESV 23 mm	7 (5.8)
	ESV 26 mm	21 (17.4)
	ESV 29 mm	2 (1.7)
	MCV 23 mm	5 (4.1)
	MCV 26 mm	28 (23.1)
	MCV 29 mm	42 (34.7)
	MCV 31 mm	13 (6.2)
	DFM 23 mm	0
	DFM 25 mm	1 (0.8)
	DFM 27 mm	2 (1.7)
	DFM 29 mm	0
Predilatation		113 (93.4)
Postdilatation		6 (5)
Second valve implantation		4 (3.3)

Data are presented as number (percentage) of patients.

Abbreviations: DFM, Direct Flow Medical; ESV, Edwards SAPIEN valve; MCV, Medtronic CoreValve; others, see TABLE 1

TABLE 3 Echocardiographic and laboratory variables before and after transcatheter aortic valve implantation

Parameter	Before TAVI	After TAVI	*P* value
LVEF, %	50.3 (15.2)	54 (13.8)	<0.001
Maximum gradient, mm Hg	75.1 (22.5)	16.7 (7.8)	0.01
Mean gradient, mm Hg	45.3 (15.1)	8.3 (4.3)	0.02
AVA, cm^2	0.6 (0.1)	1.9 (0.4)	<0.001
sPAP, mm Hg	49.5 (13.5)	42.3 (16.1)	<0.001
Leukocytes, $\times 10^3/\mu l$	8.5 (9.9)	11.2 (9.2)	0.68
Hemoglobin, g/dl	10.9 (1.5)	9.8 (1.2)	<0.001
Platelets, $\times 10^3/\mu l$	219 (87)	189 (88)	<0.001
Creatinine, mg/dl	1.0 (0.4)	1.1 (0.4)	<0.001
Albumin, g/dl	3.57 (0.4)	3.04 (0.3)	<0.001

Data are presented as mean (SD).

Abbreviations: see TABLE 1

in-hospital death occurred in 2 patients (1.7%). Mean follow-up was 23.2 months. One patient was lost to follow-up. All-cause mortality was observed in 26 patients during the follow-up. Ten cases of death were associated with non-pneumonic sepsis, 5 with pneumonia, 3 with renal failure, 1 with trauma-related hemorrhagic cerebrovascular event, 2 with cancer, and 5 with progressing heart failure. According to the data obtained in the Kaplan–Meier analysis, the survival rates were as follows: 3 months—93.3%, 6 months—91.6%, 1 year—85.9%, 2 years—78.3%, and 3 years—71.3% (FIGURE 1A).

The mean (SD) results of the logistic EuroSCORE, EuroSCORE II, and the STS risk score were 27.4 (9.7), 7.9 (4.6), and 4.6 (2.4), respectively. All of these scores overestimated the in-hospital mortality and, therefore, could not predict it (1.7%) accurately. However, when we reviewed the mortality rates related with these scores, the mortality risk estimation provided by the STS score corresponded with the mortality rate of approximately 2 months, the EuroSCORE II with that of 6 months, and the logistic EuroSCORE—of 30 months (TABLE 5).

Gender and death The survival data obtained in the Kaplan–Meier analysis showing gender differences are presented in FIGURE 1B: the survival rate was higher in women compared with men ($P = 0.008$).

Age and death The patients were divided into 3 groups to study the effect of age on mortality in the following intervals: ≤75, 76–84, and ≥85 years. No significant difference was detected among groups in terms of survival ($P = 0.99$, FIGURE 1C).

Predictors of long-term mortality Multivariate logistic regression analysis demonstrated that male gender (odds ratio, 5.668; 95% CI, 1.055–30.446; $P = 0.04$) and preprocedural albumin levels (odds ratio, 0.109; 95% CI, 0.018–0.654; $P = 0.02$) were independent predictors of long-term mortality (TABLE 6). The analysis of the receiver operating characteristic curve showed that the cutoff value of 3.4 for albumin predicted mortality with a sensitivity of 73% and specificity of 65% (FIGURE 2).

DISCUSSION

In this study, we aimed to determine whether the traditional risk scores had, indeed, an effect on short-term and long-term survival in patients after TAVI. We also investigated other potential factors associated with mortality in this population, which were not included in the risk scoring systems previously. The main finding of our study was that any traditional risk scoring system did not accurately predict short-term mortality in patients after TAVI and that these risk scores overestimated in-hospital and short-term mortality. In addition, we found that male gender and low albumin levels before the TAVI procedure were independent predictors of mortality.

Several large-scale studies examined the early and long-term mortality rates in patients after TAVI. The in-hospital and long-term mortality rates obtained in our study were lower

TABLE 4 Complication rates according to the Valve Academic Research Consortium-2 criteria

Complication	TAVI patients (n = 121)
Vascular complication	14 (11.6)
Coronary obstruction	1 (0.8)
Annular rupture	0
New left bundle branch block	17 (14)
≥2 events of paravalvular aortic regurgitation	8 (6.6)
Permanent pacemaker implantation	38 (31.4)
Stroke	1 (0.8)
Ventricular septal defect	1 (0.8)
Periprocedural death	0
In-hospital mortality	2 (1.7)

Data are presented as number (percentage) of patients.

Abbreviations: others, see TABLE 1

TABLE 5 Mortality rates by follow-up

Follow-up, mo	Mortality rate, %
1	0
2	4.3
6	8.4
12	14.1
24	21.7
30	26.4
36	28.7

TABLE 6 Independent predictors of mortality according to multivariate regression analysis

Parameter	β	SE	Wald	OR (95% CI)	*P* value
Male sex	1.735	0.858	4.091	5.668 (1.055–30.446)	0.04
Pre-TAVI albumin level	–2.217	0.914	5.880	0.109 (0.018–0.654)	0.02

Analyzed variables: age, gender, STS risk score, preprocedural left ventricular ejection fraction, postprocedural mean gradient, vascular complication, postprocedural aortic regurgitation of a degree ≥2, postprocedural creatine levels, preprocedural albumin levels

Abbreviations: OR, odds ratio; others, see TABLE 1

compared with the data presented in those large-scale studies. The 30-day mortality rates were 5% in the PARTNER (Placement of Aortic Transcatheter Valve Trial) cohort B, 3.9% in the PARTNER 2 study, and 9.2% in the recently published FRANCE 2 (The French Aortic National CoreValve and Edwards) study.[15,16,18,19] However, the 30-day mortality rate according to the VARC-2 criteria occurred only in 1.7% of our study population. Regarding late mortality, the 1-year mortality rate was 30.7% in the TAVI group of the PARTNER cohort B, 24.3% in the PARTNER cohort A, and 23.2% in the FRANCE 2 study, yet 14.1% in our study.[15,16,18,19] The 2-year mortality rate was 33.9% in the PARTNER cohort A and 32.9% in the FRANCE 2 study, yet 21.7% in our study.[19,20] The low mortality rates in our study may be explained, firstly, by the fact that the intervention was conducted by the same experienced Heart Team. Secondly, the patients in our study underwent TAVI in the years 2012–2016 when the advanced technologies and new-generation valves were introduced.

The logistic EuroSCORE, EuroSCORE II, and the STS risk score are the 3 scoring systems used for predicting perioperative mortality and determining the risk of cardiac surgery.[10-12] These scoring systems have recently been introduced to decide whether the aortic valve intervention should be surgical or percutaneous. In high-risk patients, TAVI is applied based on these scoring systems. Although higher risk scores are associated with poor outcomes,[21] it is also known that these risk scores overestimate the procedural risk in patients undergoing TAVI.[22] The mean (SD) STS risk score and the logistic EuroSCORE were 11.2 (5.8) and 26.4 (17.2), respectively, in the PARTNER study cohort B, but the 30-day mortality rate was only 5%.[15] The mean (SD) STS risk score was 5.8 (2.1) in the PARTNER 2 study, but 30-day mortality rate was only 3.9%.[18] In the FRENCH 2 registry, the mean (SD) logistic EuroSCORE was 21.8 (14.1) in the balloon-expandable valve group and 21.5 (14.5) in the self-expandable valve group; however, 30-day mortality rate was 9.2%.[19] Similarly, in our study, none of the scores predicted in-hospital mortality accurately in patients after TAVI. We demonstrated that the STS risk score and EuroSCORE II had similar and realistic predictive power; however, the mortality predictions provided by the logistic EuroSCORE were exaggerated. The STS risk score showed the closest to precise predictability for the actual short-term mortality. The overestimated predictions obtained by these scoring systems in patients undergoing TAVI are not surprising since TAVI is an easier procedure than a surgery. In our study, we investigated the use of these scoring systems in a different field, in patients after TAVI, and asked which risk score estimated mortality at which month. Our analyses revealed that the STS risk score corresponded with the mortality rate of 2 months, EuroSCORE II with that of 6 months, and logistic EuroSCORE—of 30 months. We suggest that the current scoring systems can be used for a purpose other than predicting surgical risk in patients after TAVI.

The overestimation of mortality by classical risk scoring systems has led to the development of new risk scores and predictive parameters regarding mortality in patients after TAVI.[23-25] We found that male gender and preprocedural low albumin levels were independent predictors of long-term mortality after TAVI. Similar to our

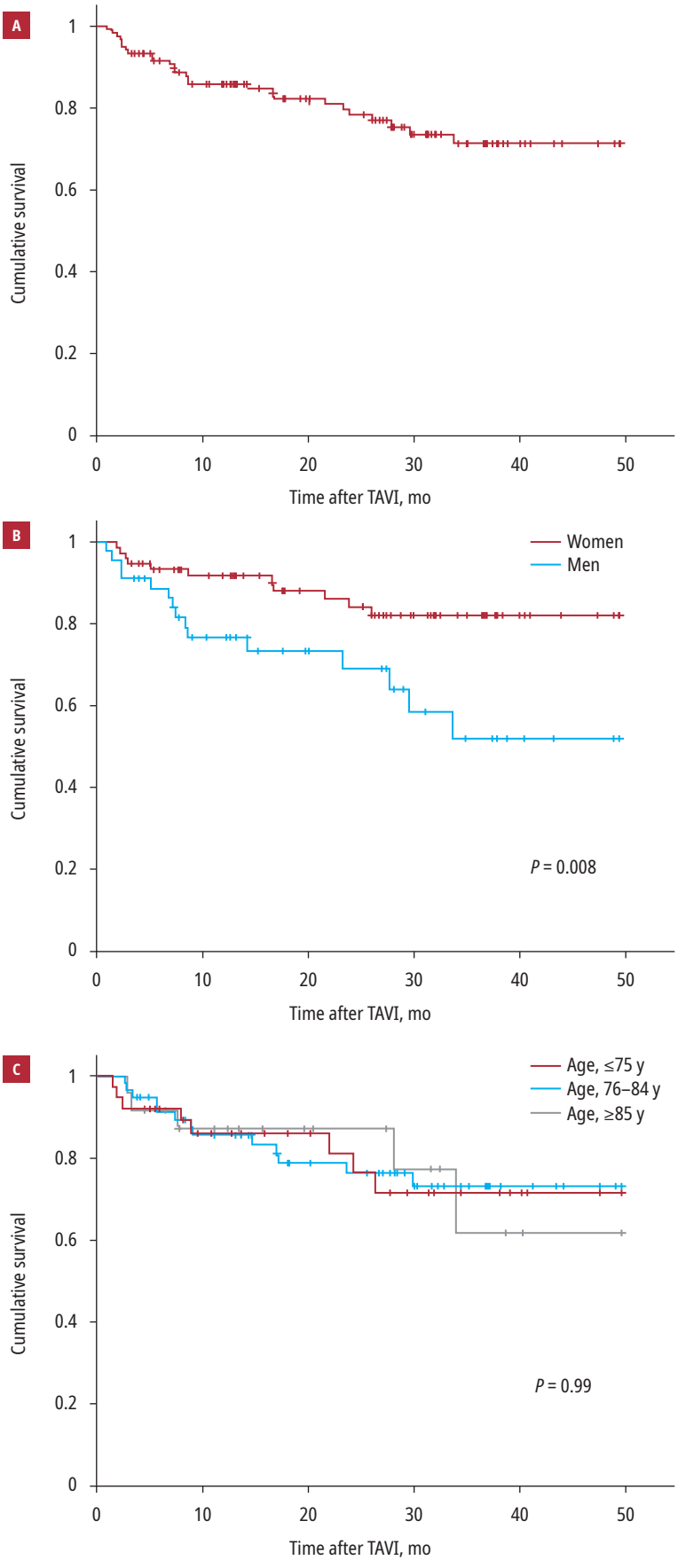

FIGURE 1 **A** – Kaplan–Meier survival curve of all patients; **B** – Kaplan–Meier survival curve according to gender difference; **C** – Kaplan–Meier survival curve according to age groups

study, Sannino et al[26] reported that the 1-year mortality rate after TAVI in men was higher compared with women. Moreover, the data from large studies also reported that higher mortality was found in men after TAVI.[26-28] The higher frequency of history of myocardial infarction and lower left ventricular EF in this subgroup in our study may explain this result.

Frailty, which is not included in the risk scoring systems, is one of the most significant risk factors in determining the surgical risk according to the VARC-2 criteria.[29,30] However, objective parameters of frailty are limited. One of the important parameters used in this field is the albumin level. It is expected to be low in frail patients due to a potential risk for irregular eating and/or malnutrition. Some studies investigated the prognostic value of frailty in the risk assessment before TAVI.[31] However, little is known about the prognostic value of albumin levels as a marker of frailty. In our study, we demonstrated that low preprocedural albumin levels independently predicted post-TAVI long-term mortality. Furthermore, each unit decrease in the preprocedural albumin level increased the long-term all-cause mortality by 11%. This finding is similar to the recently published data.[14] It can be concluded that mortality is higher in patients undergoing TAVI who have low albumin levels. Even though our study is important for demonstrating the clinical significance of preprocedural albumin levels, further large-scale studies are needed to confirm these results because our study included a small sample.

The TAVI procedure is commonly performed under general anesthesia with endotracheal intubation. However, advances in transcatheter valve technology have made it feasible with local anesthesia. Although general anesthesia has some advantages such as providing a safe environment for the operator and facilitating the use of devices during the procedure, recent studies have demonstrated that it is associated with a higher 30-day mortality, longer procedure time, and prolonged hospitalization.[32] In our study, the majority of patients underwent TAVI under general anesthesia. Unfortunately, we did not record the type of anesthesia, and long-term mortality was assessed without taking into account such subgroups of patients. Nevertheless, the 30-day mortality rate was relatively lower (1.7%) in our study. In addition, the type of anesthesia may have no influence on the long-term mortality in patients undergoing TAVI. It could be valuable to determine the effect of anesthesia type on short- and long-term mortality in our study.

Study limitations The most important limitations of our study were a relatively small number of patients included and its single-center design. The heterogeneity that resulted

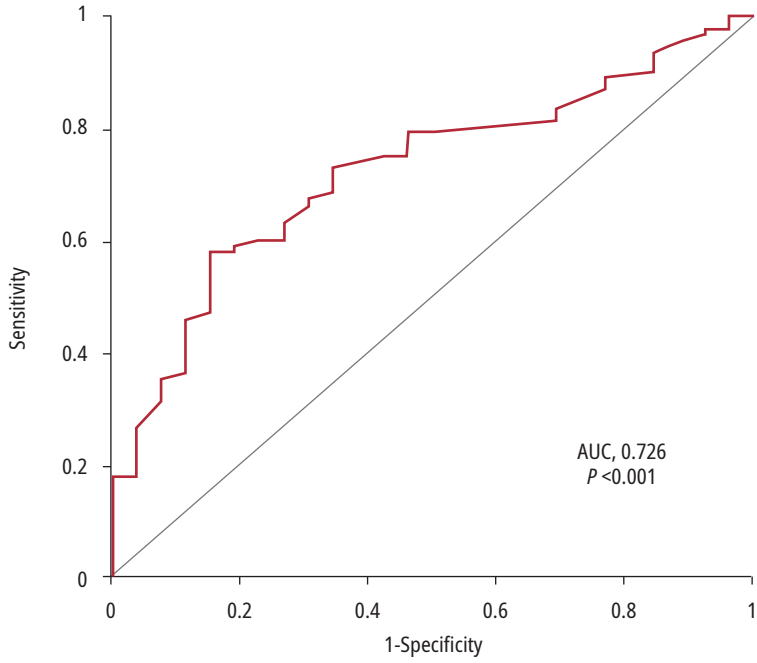

FIGURE 2 Receiver operating characteristic curve of preprocedural albumin levels for predicting mortality
Abbreviations: AUC, area under the receiver operating characteristic curve

from using valves of different generations and brands constitutes another limitation of our study. Moreover, recent studies confirmed that TAVI is superior to surgical aortic valve implantation in low-risk patients.[33] Therefore, our results cannot be generalized to the total population of patients who are currently eligible for TAVI.

Conclusions Although all conventional risk scoring systems overestimated in-hospital mortality, we found that the STS risk score predicted the 2-month mortality, EuroSCORE II, the 6-month mortality, and logistic EuroSCORE, the 30-month mortality. To our knowledge, this is the first study regarding this issue. In addition, preprocedural low blood albumin levels were found to be an independent predictor of long-term mortality in patients undergoing TAVI. This shows that malnutrition and frailty are parameters worth considering in this group of patients. Therefore, we suggest that TAVI should be performed before clinical deterioration and increased frailty are observed.

ARTICLE INFORMATION

NOTE This study was presented as a poster at the 2018 European Society of Cardiology Congress on August 28, 2018 in Munich, Germany (https://doi.org/10.1093/eurheartj/ehy565.P2653).

CONFLICT OF INTEREST None declared.

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