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ORIGINAL STUDIES

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Clinical risk model for predicting 1-year mortality after transcatheter aortic valve replacement

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Abstract

Objectives: Estimating 1-year life expectancy is an essential factor when evaluating appropriate indicators for transcatheter aortic valve replacement (TAVR).

Background: It is clinically useful in developing a reliable risk model for predicting 1-year mortality after TAVR.

Funding information
Daicihi-Sankyo; Edwards Lifesciences; Medtronic

Methods: We evaluated 2,588 patients who underwent TAVR using data from the Optimized CathEter vAlvular iNtervention (OCEAN) Japanese multicenter registry from October 2013 to May 2017. The 1-year clinical follow-up was achieved by 99.5% of the entire population (n = 2,575). Patients were randomly divided into two cohorts: the derivation cohort (n = 1,931, 75% of the study population) and the validation cohort (n = 644). Considerable clinical variables including individual patient's comorbidities and frailty markers were used for predicting 1-year mortality following TAVR.

Results: In the derivation cohort, a multivariate logistic regression analysis demonstrated that sex, body mass index, Clinical Frailty Scale, atrial fibrillation, peripheral artery disease, prior cardiac surgery, serum albumin, renal function as estimated glomerular filtration rate, and presence of pulmonary disease were independent predictors of 1-year mortality after TAVR. Using these variables, a risk prediction model was constructed to estimate the 1-year risk of mortality after TAVR. In the validation cohort, the risk prediction model revealed high discrimination ability and acceptable calibration with area under the curve of 0.763 (95% confidence interval, 0.728–0.795, $p < .001$) in the receiver operating characteristics curve analysis and a Hosmer–Lemeshow χ^2 statistic of 5.96 ($p = .65$).

Conclusions: This risk prediction model for 1-year mortality may be a reliable tool for risk stratification and identification of adequate candidates in patients undergoing TAVR.

KEYWORDS
OCEAN, risk model, transcatheter aortic valve replacement

1 | INTRODUCTION

The indicators for transcatheter aortic valve replacement (TAVR) for aortic stenosis (AS) patients have been expanding globally in this decade.[1,2] The latest data revealed the potential advantage of TAVR compared with surgical aortic valve replacement (SAVR) in patients categorized into a low-risk subset.[3] With the development of less invasive catheter therapy, decision making for appropriate TAVR candidates should be clinically determined by balancing the risk–benefit and cost-effectiveness. A patient with a predicted life expectancy of less than 1 year is traditionally considered contraindicated for TAVR.[4] Patients who are very sick need to be identified before the procedure and are best treated with supportive care/noninvasive treatment. Otherwise, some patients classified into the low or intermediate risk category have a subsequent risk of not being included under previous traditional evaluations. Numerous clinical assessments including multiple comorbidities and clinical frailty status enabled us to identify the high-risk patients undergoing TAVR.[5-12] Physicians should pay attention to the entire risk and explain the therapeutic merits to patients and their family. A simple and reliable tool for risk stratification before TAVR is performed is needed in daily practice. Therefore, the current Japanese multicenter study aimed to establish a practical risk prediction model for estimating 1-year mortality according to the TAVR-specific clinical variables.

2 | MATERIALS AND METHODS

2.1 | Study population

Between October 2013 and May 2017, 2,588 patients were enrolled in the Optimized CathEter vAlvular iNtervention–transcatheter aortic valve implantation (OCEAN-TAVI) registry. The OCEAN-TAVI registry is an ongoing, multicenter effort with 14 relatively high-volume centers in Japan. All patients were diagnosed with severe AS as determined by echocardiography. The indicators for TAVR were decided on the basis of the local heart team's evaluation of the balance of the cardiac surgical risk. Traditional surgical risk score models were applied to the Society of Thoracic Surgeons (STS) predicted risk of mortality. Patient characteristics, comorbidities, frailty status, laboratory data, and echocardiographic parameters were obtained from the individual patient's chart in each center. Clinical follow-up was scheduled at 30 days, 3–6 months, 1 year, and every year after the procedure. Information regarding the occurrence and/or causes of death was obtained from the treating hospital or by contacting the patient and his or her family member(s). During the study period, the Edwards SAPIEN-XT and SAPIEN-3 (Edwards Lifesciences, Irvine, CA) balloon-expandable prostheses were used from October 2013. The Medtronic classical CoreValve and CoreValve Evolut-R (Medtronic, MN) self-expandable prostheses were also used from January 2016. The approach was chosen based on the multidetector computed

TABLE 1 Baseline patient characteristics

	Overall	Derivation	Validation	*p* value
Patients (*n*)	*n* = 2,575	*n* = 1931	*n* = 644	
Baseline clinical characteristics				
Age (years)	84.4 ± 5.2	84.4 ± 5.2	84.3 ± 5.2	.61
Male (*n*)	790 (30.7%)	591 (30.6%)	199 (30.9%)	.89
BMI (kg/m^2)	22.2 ± 3.6	22.2 ± 3.6	22.1 ± 3.6	.50
BMI <18 (*n*)	130 (5.0%)	102 (5.3%)	28 (4.3%)	.35
CFS 1–3	1,039 (40.3%)	775 (40.1%)	264 (25.4%)	
CFS 4–6	1,437 (55.8%)	1,079 (55.9%)	358 (24.9%)	.78
CFS ≥7	99 (3.8%)	77 (4.0)	22 (3.4%)	
NYHA 3/4 (*n*)	1,313 (51.0%)	974 (50.4%)	339 (52.6%)	.33
Dyslipidemia (*n*)	1,108 (43.0%)	816 (42.3%)	292 (45.3%)	.17
Diabetes (*n*)	552 (21.4%)	403 (20.9%)	149 (23.1%)	.23
Hypertension (*n*)	1979 (76.9%)	1,496 (77.5%)	483 (75.0%)	.20
AF (*n*)	546 (21.2%)	410 (21.2%)	136 (21.1%)	.95
PAD (*n*)	375 (14.6%)	299 (15.5%)	76 (11.8%)	.02
Stroke (*n*)	299 (11.6%)	227 (11.8%)	72 (11.2%)	.69
Coronary artery disease (*n*)	950 (36.9%)	724 (37.5%)	226 (35.1%)	.27
Chronic kidney disease (*n*)	1,542 (59.9%)	1,166 (60.4%)	376 (58.4%)	.37
Prior myocardial infarction (*n*)	167 (6.5%)	131 (6.8%)	36 (5.6%)	.29
Prior coronary artery bypass graft (*n*)	168 (6.5%)	133 (6.9%)	35 (5.4%)	.20
Prior cardiac surgery (*n*)	217 (8.4%)	168 (8.7%)	49 (7.6%)	.39
Pulmonary disease (*n*)	611 (23.7%)	440 (22.8%)	171 (26.6%)	.052
Liver disease (*n*)	75 (2.9%)	54 (2.8%)	21 (3.3%)	.54
Active cancer (*n*)	124 (4.8%)	97 (5.0%)	27 (4.2%)	.39
STS score (%)	6.5 (4.5–9.5)	6.5 (4.0–9.0)	6.6 (4.1–9.1)	.11
Transfemoral approach (*n*)	2,089 (81.1%)	1,549 (80.2%)	540 (83.9%)	.04
Nonelective (*n*)	150 (5.8%)	112 (5.8%)	38 (5.9%)	.93
Laboratory data				
Hemoglobin (g/dl)	11.3 ± 1.7	11.3 ± 1.7	11.3 ± 1.7	.53
Platelet (10^4/μl)	18.3 ± 6.8	18.4 ± 7.0	18.1 ± 6.0	.42
Albumin (g/dl)	3.7 ± 0.5	3.7 ± 0.5	3.8 ± 0.5	.41
Hypoalbuminemia (<3.5 g/dl), n	610 (23.7%)	467 (24.2%)	143 (22.2%)	.31
Natrium (mEq/L)	139.7 ± 4.5	139.8 ± 4.7	139.6 ± 3.9	.50
Kalium (mEq/L)	4.3 ± 0.5	4.3 ± 0.5	4.3 ± 0.5	.34
C-reactive protein (mg/dl)	0.1 (0.03–0.36)	0.1 (0.03–0.37)	0.1 (0.03–0.37)	>.99
Blood urea nitrogen (mg/dl)	23.5 ± 11.5	23.3 ± 11.1	23.9 ± 12.7	.23
Creatinine (mg/dl)	1.0 ± 0.5	1.0 ± 0.5	1.0 ± 0.6	.57
eGFR, ml/min/1.73 m^2	50.4 (38.0–63.0)	50.0 (37.5–62.5)	51.0 (37.6–64.4)	.60
Echocardiographic data				
Aortic valve area (cm^2)	0.6 ± 0.2	0.6 ± 0.2	0.6 ± 0.2	.32
Index aortic valve area (cm^2/m^2)	0.4 ± 0.1	0.4 ± 0.1	0.4 ± 0.1	.36
Peak velocity (m/s)	4.6 ± 0.8	4.6 ± 0.8	4.6 ± 0.8	.60
Mean gradient (mmHg)	50.5 ± 18.3	50.4 ± 18.0	51.0 ± 19.1	.52
Peak gradient (mmHg)	85.9 ± 29.5	85.7 ± 29.0	86.6 ± 31.1	.50
Stroke volume (ml)	60.4 ± 24.8	60.4 ± 24.8	60.4 ± 24.9	.98
Index stroke volume (ml/m^2)	41.3 ± 17.9	41.2 ± 18.0	41.6 ± 17.9	.64

TABLE 1 (Continued)

	Overall	Derivation	Validation	*p* value
Stroke volume index <35 ml/m^2 (*n*)	129 (5.0%)	97 (5.0%)	32 (5.0%)	.96
LVEF (%)	59.2 ± 12.7	59.2 ± 12.6	59.4 ± 13.0	.74
Pulmonary artery pressure (mmHg)	29.2 ± 15.1	29.0 ± 15.3	30.0 ± 14.8	.17
Enhanced computed tomography data				
Aortic valve annulus area (mm^2)	397.8 ± 73.0	397.8 ± 73.6	397.7 ± 71.1	.97
Aortic valve annulus perimeter (mm)	71.3 ± 9.5	71.3 ± 9.4	71.1 ± 10.0	.61

Note: Values are numbers (%), mean ± *SD*, or median (interquartile range).
Abbreviations: AF, atrial fibrillation; AVS, aortic valve stenosis; BMI, body mass index; CFS, clinical frailty scale; eGFR, estimated glomerular filtration rate; LVEF, left ventricle ejection fraction; NYHA, New York Heart Association; PAD, peripheral artery disease; STS score, Society of Thoracic Surgeons Predictive Risk of Mortality.

TABLE 2 Univariate and multivariate logistic regression analysis for the association with 1-year mortality after TAVR (standard model)

	Univariate model					Multivariate model				
Variables	Beta	*SE*	Odds ratio	95% CI	*p* value	Beta	*SE*	Odds ratio	95% CI	*p* value
Gender (male = 1)	0.343	0.154	1.41	1.04–1.91	.026	0.459	0.174	1.58	1.13–2.23	.008
BMI (per 1 kg/m^2 increase)	−0.103	0.022	0.90	0.86–0.94	<.001	−0.095	0.024	0.91	0.87–0.95	<.001
CFS (per 1-scale increase)	0.375	0.057	1.46	1.30–1.63	<.001	0.259	0.063	1.30	1.15–1.47	<.001
AF (yes = 1)	0.636	0.162	1.89	1.37–2.59	<.001	0.376	0.176	1.46	1.13–2.06	.033
Prior cardiac surgery (yes = 1)	0.546	0.225	1.73	1.11–2.68	.015	0.686	0.244	1.99	1.23–3.20	.005
Albumin (per 1 mg/dl increase)	−1.278	0.144	0.28	0.21–0.37	<.001	−0.947	0.159	0.39	0.28–0.53	<.001
eGFR (per 1 ml/min/1.73 m^2 increase)	−0.027	0.004	0.97	0.97–0.98	<.001	−0.022	0.005	0.98	0.97–0.99	<.001
Pulmonary disease (yes = 1)	0.478	0.163	1.61	1.17–2.22	.003	0.381	0.178	1.46	1.03–2.07	.032
PAD (yes = 1)	0.755	0.174	2.13	1.51–2.99	<.001	0.410	0.191	1.51	1.04–2.19	.032
Intercept						2.822				
Age (per 1-year increase)	−0.019	0.025	0.98	0.93–1.03	.45	Not selected				
NYHA 3/4 (for NYHA 1/2)	0.719	0.156	2.05	1.51–2.79	<.001	Not selected				
Coronary artery disease (yes = 1)	0.273	0.150	1.31	0.98–1.76	.069	Not selected				
Liver disease (yes = 1)	0.685	0.358	1.98	0.98–4.00	.056	Not selected				
Active cancer (yes = 1)	0.090	0.329	1.09	0.57–2.09	.79	Not selected				
STS score (per 1% increase)	0.059	0.009	1.06	1.04–1.08	<.001	Not selected				
Nonelective (yes = 1)	0.664	0.259	1.94	1.17–3.23	.010	Not selected				
Hemoglobin (per 1 g/dl increase)	−0.235	0.047	0.79	0.72–0.87	<.001	Not selected				
Natrium (per 1 mg/dl increase)	0.633	0.375	0.92	0.89–0.96	<.001	Not selected				
C-reactive protein (per 1 mg/dl increase)	0.134	0.033	1.14	1.07–1.22	<.001	Not selected				
LVEF (per 1% increase)	−0.005	0.006	0.99	0.98–1.01	.41	Not selected				
Stroke volume index <35 ml/m^2 (yes = 1)	0.646	0.169	1.91	1.37–2.66	<.001	Not selected				

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CFS, clinical frailty scale; CI, confidence interval; eGFR, estimated glomerular filtration rate; LVEF, left ventricle ejection fraction; NYHA, New York Heart Association; *SE*, standard error; STS score, Society of Thoracic Surgeons Predictive Risk of Mortality; TAVR, transcatheter aortic valve replacement.

tomography (MDCT) findings. The transfemoral (TF) approach was the main treatment option, and non-TF approaches, such as transapical, trans-subclavian, and direct aorta, were considered when the TF approach was not feasible. Procedural complications occurring during TAVR were evaluated according to the Valve Academic Research Consortium-2 (VARC-2) criteria.[13] This trial was registered with the University Hospital Medical Information Network (no.: UMIN000020423).

2.2 | Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics version 22 (IBM Corp., Tokyo, Japan) and Stata 14 (Stata Corp, College Station, TX). Categorical data are expressed as percentages of the total. Continuous variables are expressed as mean ± *SD* or median and interquartile range (IQR; 25–75%), depending on variable distribution. We initially excluded the 13 patient's data not obtained during the clinical

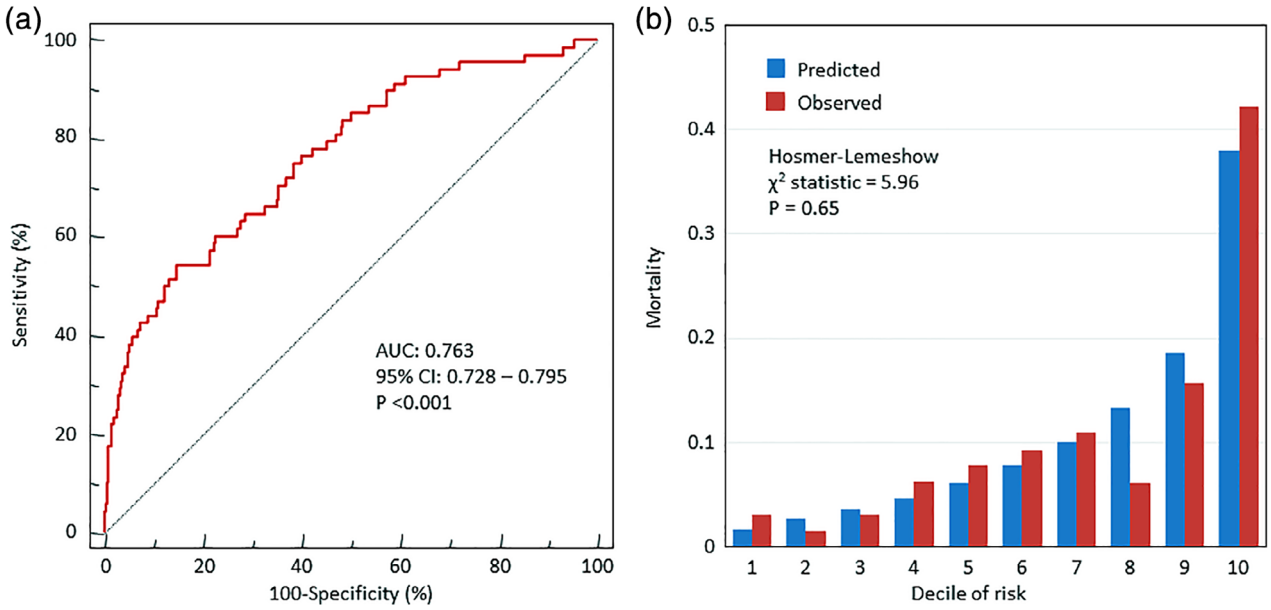

FIGURE 1 (a) Receiver operating characteristics curve analysis of the standard risk model for predicting 1-year mortality after transcatheter aortic valve replacement (TAVR) in the validation cohort. AUC, area under the curve. (b) Hosmer–Lemeshow χ^2 statistic of the standard risk model for 1-year mortality after TAVR in the validation cohort [Color figure can be viewed at wileyonlinelibrary.com]

follow-up at 1 year ± 1 month. To test the internal validity of the risk prediction model, the patients were randomly divided into two cohorts: the derivation cohort, which included 75% of the sample (n = 1931), and the validation cohort, which included the remaining 25% (n = 644). Comparisons of the baseline characteristics between the two cohorts were made using χ^2 tests for categorical variables and unpaired Student's t-test for continuous variables listed as mean values and Mann–Whitney U test for continuous variables listed as median values. We used the following variables as candidate predictors for incorporation into the risk prediction in conjunction with our previous reports[10-12,14-17]: sex, body mass index (BMI), Clinical Frailty Scale (CFS), New York Heart Association (NYHA) class, history of prior cardiac surgery, serum albumin concentration, estimated glomerular filtration rate (eGFR), presence of pulmonary disease, STS score, atrial fibrillation (AF), peripheral artery disease (PAD), liver disease, and active cancer. In addition, echocardiographic parameters such as left ventricle ejection fraction (LVEF) and stroke volume index were also considered. The CFS grading was recorded in our previous research.[11] All CFS stages were calculated by face-to-face assessments with patients and families to determine the baseline frailty status prior to TAVR. The CFS ranged from 1 (very fit) to 9 (terminally ill). The CFS results were categorized into five groups: nonfrail (CFS 1–3), vulnerable (CFS 4), mildly frail (CFS 5), moderately frail (CFS 6), and severely frail (CFS ≥7). The incidence of AF included both paroxysmal and persistent AF. In the derivation cohort, using these candidate predictors as explanatory variables, a multivariate logistic regression analysis with forward selection procedure was performed to select independent predictors of 1-year mortality after TAVR. Based on these results, the following general equation was used to calculate the absolute probability of 1-year mortality after TAVR:

$$\text{Probability} = 1/\left(1+\exp\left[-\sum_{i=1}^{p}\beta_i X_i\right]\right), \quad (1)$$

where X_i is the value of the ith selected predictor, β_i is the estimated regression coefficient of X_i, and p denotes the number of selected predictors. Using the validation cohort, the area under the curve (AUC) of the receiver operating characteristic (ROC) curve analysis of the resulting model was determined to estimate its discrimination ability. A Hosmer–Lemeshow χ^2 statistic with 8 degrees of freedom was also applied to evaluate the model's calibration. Category-free net reclassification improvement (cf-NRI) was performed to evaluate the incremental predictive ability of the new model for 1-year mortality after TAVR. The cf-NRI counts the direction of change in the calculated risk for each patient (i.e., either +1 or −1 is counted depending on whether the change is in the correct direction [higher for those with events, lower for those without events] or not, respectively). A risk score sheet was then constructed based on the method previously reported for facile calculation of the risk of 1-year mortality after TAVR.[18] All statistical tests were two-sided, and p <.05 was considered significant.

3 | RESULTS

3.1 | Patient demographics

The baseline characteristics of the study patients are presented in Table 1. The mean age was 84.4 years, and approximately 30% were men. The prevalence of PAD was significantly higher and TF approach was lower in the validation cohort than those in the derivation cohort. Prevalence of pulmonary disease showed trend toward higher incidence in the validation cohort, whereas other characteristics did not differ significantly between the cohorts.

3.2 | Risk prediction model for 1-year mortality after TAVR

The regression coefficient and odds ratio for 1-year mortality following TAVR are shown in Table 2. In the univariate model, all candidate variables for the model had significant odds ratio for 1-year mortality after TAVR. The multivariate model revealed that sex, BMI, CFS, AF, prior CS, serum albumin, eGFR, PAD, and presence of pulmonary disease were selected as independent predictors for 1-year mortality after TAVR.

3.3 | Model validation

In the validation cohort, the ROC curve analysis of the model showed good discrimination ability with an AUC of 0.763 (95% confidence interval [CI], 0.728–0.795, $p < .001$; Figure 1a). The results of the Hosmer–Lemeshow χ^2 statistic using the validation cohort indicated an acceptable calibration of the model, yielding a value of 5.96 ($p = .65$; Figure 1b).

3.4 | Risk score sheet

A practical risk score sheet was next developed to easily calculate the 1-year risk of mortality after TAVR (Figure 2). In this score sheet, 1 point was set as the risk associated with an increase in CFS category from 4 to 5. For scoring of continuous values, the range of possible values was divided into anywhere from 4 to 5 categories to enable the awarding of points depending on the category selected. For the scoring of binary questions, 0–3 points were assigned in accordance with the patient's answer. Although each point was originally computed as a decimal value, it was then rounded to the nearest integer for easy calculation. The approximate 1-year mortality risk after TAVR was then estimated via summation of the points awarded to each of the items.

3.5 | Development of simple office model

Among the nine variables in the aforementioned risk prediction model (standard model), information on the presence of pulmonary disease and PAD was not easily obtained by the general practitioner in the office. Therefore, we developed an alternative risk prediction model (simple office model) using seven variables that excluded the presence of pulmonary disease and PAD from the nine variables in the standard model. The regression coefficient and odds ratio of the simple model are shown in Supplemental Table S1. Although AF was not a significant predictor in the simple office model, we included AF in the model to maintain consistency with the standard model. As shown in Supplemental Figure S1, good discrimination ability and acceptable calibration were ascertained in the validation cohort.

When comparing discrimination ability between the standard and simple office models, there was no significant difference in the AUC of the ROC curve analysis ($p = .26$). However, a significant improvement in cf-NRI of the standard model was noted (0.297, 95% CI, 0.046–0.548, $p = .021$) as compared with the simple model.

Risk factor	Categories	Point
Gender	Female	0
	Male	2
BMI (kg/m^2)	≥ 25.0	0
	22.0 ~ < 25.0	2
	18.5 ~ < 22.0	3
	< 18.5	4
CFS category	1 ~ 3	-2
	4	0
	5	1
	6	2
	7 ~ 8	4
AF	No	0
	Yes	1
Prior cardiac surgery	No	0
	Yes	3
eGFR (ml/min/1.73m2)	≥ 60	0
	45 ~ < 60	2
	30 ~ < 45	4
	15 ~ < 30	5
	< 15	6
Albumin (mg/dl)	≥ 3.5	0
	3.0 ~ < 3.5	3
	2.5 ~ < 3.0	5
	< 2.5	6
Pulmonary disease	No	0
	Yes	1
PAD	No	0
	Yes	2
	Point total	

Point total	Estimated risk (%)
~ 5	~ 5
6 ~ 8	5 ~ 10
9 ~ 13	10 ~ 30
14 ~ 16	30 ~ 50
17 ~ 19	50 ~ 70
20 ~	70 ~

FIGURE 2 Risk score sheet based on the standard model for predicting the approximate 1-year mortality after transcatheter aortic valve replacement, which was estimated via summation of the points awarded to each of the items [Color figure can be viewed at wileyonlinelibrary.com]

A risk score sheet based on the simple model was finally developed for facile calculation of the 1-year risk of mortality after TAVR (Supplemental Figure S2). The steps for the risk calculation equation and the risk score sheet are described in the supplementary material.

4 | DISCUSSION

There is increasing evidence for the feasibility of the TAVR procedure that will therefore be expanding the indicators for this procedure

extensively. An appropriate use of this technique should be determined by balancing the risk–benefit, which means a well-estimated life expectancy for patients undergoing TAVR.[4] Our data were validated by the 99.5% 1-year follow-up achievement. The results enabled us to construct two types of risk prediction models: using seven (simple office model) and nine (standard model) principal clinical parameters, respectively, such as patient clinical status, comorbidities, frailty components, and procedural features. Importantly, both models showed good discrimination ability as indicated by AUC of the ROC curve and acceptable calibration by the Hosmer–Lemeshow χ^2 test, thus suggesting that we successfully developed reliable and practical risk prediction models for 1-year mortality after TAVR.

We constructed the standard risk model with nine variables including pulmonary disease and PAD as well as the simple risk model with seven variables that excluded pulmonary disease and PAD. Both the precise diagnosis of pulmonary disease and PAD are not easy to evaluate by the general practitioner in the office. Therefore, the simple office model is aimed to be mainly used in daily practice before consultation with the TAVR center. By contrast, in the TAVR center, pulmonary disease needs to be evaluated by respiratory test and abdominal-chest CT findings for periprocedural risk stratification of TAVR. The approach route is decided on the basis of TAVR-specific MDCT protocols and existence of PAD. This information is mandatory because the clinical course was significantly different between the TF and non-TF approaches after TAVR.[5,6,10,11] Therefore, the standard model is aimed at obtaining a more reliable risk estimation in the TAVR center, which enables us to establish appropriate decision making regarding the indication of TAVR. For example, as shown in supplementary case, the patient's estimated risk of 1-year mortality after TAVR is judged to be 40.0% using the simple risk model with seven variables. After adding his information of having both pulmonary disease and PAD, the estimated risk using the standard model increases to 55.6%. However, if he did not have pulmonary disease or PAD, the estimated risk decreases to 36.2%. Thus, the information of pulmonary disease and PAD sharpened the prognostic value of the current risk model.

Previous research and/or OCEAN-TAVI registry data demonstrated that clinical variables such as chronic kidney disease staging, AF, pulmonary disease, and PAD were found to be associated with significant increased risk of mortality after TAVR.[5-12,17] The survival advantage of women is also confirmed by previous data and meta-analysis.[6,19] Although the clinical impact of prior CS including coronary artery bypass grafting (CABG) is debatable, the rate of CABG in our cohort was significantly lower in comparison with the data from Western countries[14,20,21] Japanese patients with more complex coronary issues tend to undergo CABG reluctantly, and this fact was reflected by the advanced stage of systemic atherosclerosis in patients with CABG. These factors should be considered as race and regional differences.

The importance of frailty assessment is also highlighted when considering the clinical outcome after TAVR.[9-11] However, the approach for evaluating frailty status in geriatric participants is quite varied. The recent pivotal investigation suggested the simple frailty toolset comprised of five chair rises, cognitive function, hemoglobin, and albumin was paramount importance to predict the prognosis after TAVR.[9] Gait speed, grip strength, and cognitive function were important factors of frailty, whereas these parameters were difficult to evaluate for all patients before the procedure.[22,23] Some patients were unable to walk, grip, and complete the cognitive functional examination. Urgent or emergent patients were hardly able to undergo such kind of tests. These were regarded as important missing data. In this study, therefore, CFS, serum albumin value, and BMI without missing data were considered as important factors reflecting the individual patient's degree of frailty. The CFS is a simple scale not requiring specific geriatric evaluation and is broadly used as a useful tool for risk evaluation before TAVR.[11] The albumin value is also an established marker reflecting the nutritional status of each patient. Poor prognosis of hypoalbuminemia after TAVR is proven worldwide.[9,10,24] There were several discussions regarding the prognostic relevance of BMI in patients who undergo TAVR, which is known as the "obesity paradox." A recent investigation identified the paradoxical survival benefits of obesity in patients after TAVR.[25] Furthermore, low BMI (<20 kg/m^2) was one of the factors related to frailty according to the VARC-2 criteria.[13] We reported the poor prognosis of low, lean BMI using a previous formula.[15] Although the additional predictive value of lean BMI on BMI could be probably be derived, the complex calculation might be impractical in daily practice. The strong correlation between BMI and lean BMI was shown in our database; thus, the BMI was alternatively used as one of the risk prediction factors. For the same reason, albumin level was applied instead of the Geriatric Nutritional Risk Index calculated based on the albumin level, body weight, and ideal body weight. Geriatric Nutritional Risk Index was more sensitive than albumin alone for predicting mortality after TAVR.[16] However, a simple marker will be useful for validating the risk of each patient.

5 | LIMITATIONS

Several study limitations should be mentioned. The OCEAN-TAVI multicenter registry is from Japan, although numerous variables incorporated in this model are globally known for predicting increased risk of mortality after TAVR. Thus, the external validity of the current risk model should be evaluated in a Western cohort and then the model should be recalibrated if necessary. In general, advancing age increases the risk of mortality and other adverse events after undergoing a surgical or invasive procedure. However, previous reports from our registry (OCEAN-TAVI registry) did not significantly indicate that age was an independent predictor for 1-year mortality after TAVR.[10-12,14-17] This may be explained the majority of patients were elderly and the range of age distribution was not varied in our TAVR cohort. Further studies in various cohorts are needed to determine whether age is necessary for constructing risk prediction models after TAVR.

6 | CONCLUSIONS

This study established a reliable 1-year risk prediction-using standard (nine parameters) and simple (seven parameters) office models in patients who underwent TAVR. As the use of TAVR expands with low- to intermediate-risk patients, and considering the indication for highly inoperable patients, the risk–benefit balance should be an

important decision-making factor before the procedure. The current 1-year risk model is therefore practical and useful in determining an appropriate candidate for TAVR.

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CONFLICT OF INTEREST

M.Y., N.T., T.N., S.S., K.M., and Y.W. are clinical proctors for Edwards Lifesciences and Medtronic. M.A., M.T., K.T., A.H., and K.H. are clinical proctors of Edwards Lifesciences. H.U. is a clinical proctor for Medtronic. The remaining authors have nothing to disclose.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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