



Preoperative Instrumental Activities of Daily Living Predicts Survival After Transcatheter Aortic Valve Implantation

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Background: This aim of this study was to clarify prognosis after transcatheter aortic valve implantation (TAVI) in patients with aortic stenosis (AS) and to identify baseline factors associated with mortality.

Methods and Results: We prospectively enrolled 257 consecutive elderly persons with AS who were referred to Keio University Hospital and who underwent assessment of cardiac, physical (walking speed), cognitive, and renal functions, nutritional status, activities of daily living (ADL), instrumental ADL (IADL) assessed with the Frenchay activities index (FAI), and comorbidities. The primary outcome was postoperative death. Differences in basic characteristics were compared between a group that survived for a median of 661 days (IQR, 0–1,289 days) after TAVI and a group that did not. Multivariate hazard ratios (HR) were calculated for independent factors selected in Cox proportional hazard models. Thirty-one individuals died during follow-up. Walking speed was significantly faster (0.87 ± 0.25 vs. 0.70 ± 0.24 m/s, $P < 0.001$) and FAI was significantly higher (21.2 ± 8.0 vs. 15.7 ± 8.0 , $P = 0.026$) in the survival group compared with those who died. Multivariate HR for mortality according to walking speed was 0.05 (95% CI: 0.028–0.091) in model 1 and 0.04 (95% CI: 0.020–0.081) in model 2, and those for FAI were 0.94 (95% CI: 0.92–0.95) and 0.92 (95% CI: 0.90–0.92), respectively.

Conclusions: Preoperative walking speed and IADL are crucial factors associated with prognosis after TAVI even after adjustment.

Key Words: Elderly; Mortality; Transcatheter aortic valve implantation

Aortic stenosis (AS) is affected by aging, and the number of patients is increasing. Transcatheter aortic valve implantation (TAVI) is an option for individuals for whom surgical aortic valve replacement is unsuitable.¹ In the PARTNER trial, the CoreValve High Risk Study, and PREVAIL JAPAN, the mean age of individuals requiring TAVI was 83.6, 83.1, and 84.3 years, respectively.^{2–4} Thus, much older patients with AS are undergoing TAVI. Furthermore, the range of applications of TAVI is expanding, and it has recently been recommended for patients at moderate risk.⁵

Because TAVI is more frequently used in elderly patients, it is important to identify preoperative factors that could predict postoperative outcome. Frailty, activities of daily living (ADL), gait speed, and nutritional status are predictors of 30-day or 1-year mortality after TAVI.^{6–10} However, factors related to medium- and long-term mortality have not been documented in detail, and instrumental ADL (IADL) have not been investigated. A decline in

IADL in elderly persons is associated with sarcopenia¹¹ and mild cognitive dysfunction.¹²

Therefore, we investigated IADL and cardiac and motor functions to identify baseline factors associated with medium- and long-term mortality.

Methods

We prospectively enrolled 270 consecutive elderly persons with AS who were referred to the Department of Cardiology, Keio University Hospital between June 2014 and December 2017 for possible TAVI. All patients had cardiac symptoms of advanced aortic valve disease, were aged ≥ 75 years, and had severely calcified AS confirmed on echocardiography based on any 1 of the following criteria: mean gradient, >40 mmHg; jet velocity, >4.0 m/s, and initial aortic valve area, <1.0 cm². Patients who were unable to undergo evaluation because of unstable medical condition or severe disability (acute heart failure, severe cognitive impairment,

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Table 1. Patient Characteristics (n=257)	
Characteristics	
Age (years)	84.1±5.3
Sex (F/M)	87/170
BMI (kg/m ²)	21.8±3.6
Operation (TF/others)	236/21
NYHA class (I/II/III/IV)	13/126/119/5
LVEF (%)	63.9±12.7
BNP (pg/mL)	441.3±604.7
Aortic valve area (cm ²)	0.63±0.18
Aortic valve gradient (mmHg)	50.7±18.4
STS score (%)	7.0±4.4
Diabetes mellitus	63 (24.5)
Hypertension	202 (78.6)
Chronic kidney failure	142 (55.3)
Cerebrovascular disease	38 (14.8)
Coronary artery disease	85 (33.1)
Heart failure	79 (30.7)
Respiratory disease	94 (36.6)
Musculoskeletal disorder(s)	70 (27.2)
Family living together	199 (77.4)
Living environment (Home/Facility/Hospital)	237/6/14
Postoperative hospitalization (days)	9.5±12.6
Hand grip (kg) (n=255) [†]	17.6±6.1
Walking speed (m/s) (n=246) [†]	0.86±0.26
MMSE (n=247) [†]	26.1±3.5
FAI (n=226) [†]	20.7±8.4
MNA-SF (n=227) [†]	11.1±2.5

Data given as n (%) or mean±SD. [†]No. cases before multiple assignment. BMI, body mass index; BNP, brain natriuretic peptide; FAI, Frenchay activities index; LVEF, left ventricular ejection fraction; MMSE, Mini-Mental State Examination; MNA-SF, Mini Nutritional Assessment-Short Form; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; TF, Transfemoral.

motor paralysis, progressive neuromuscular disease), or whose death was associated with the operation (in-hospital death, or death at ≤30 days) were excluded from the analysis. There was no perioperative death that met the exclusion criteria. The Ethics Review Board at Keio University Hospital approved the study protocol, which was implemented according to the Declaration of Helsinki. All included patients provided written, informed consent to participate in the study.

As an assessment of cardiac status, New York Heart Association class,¹³ echocardiography findings, and plasma brain natriuretic peptide were analyzed. Echocardiography parameters consisted of left ventricular ejection fraction (LVEF), mean gradient of the aortic valve (mmHg), and aortic valve area (cm²). LVEF was measured on M-mode in accordance with the American Society of Echocardiography guidelines.¹⁴ We also obtained background Society of Thoracic Surgeons (STS) risk scores¹⁵ for the participants. As an assessment of physical function, grip strength of the left and right hands was measured to determine frailty¹⁶ using a Smedley-type hand dynamometer (T.K.K.5401, Takei Scientific Instruments, Tokyo, Japan), in seated patients with the elbow extended to the side of the body.¹⁷ The higher value was included in analyses. Walking speed was evaluated on 10-m walking test. The amount of time taken for the patients to walk a distance of 10m at their

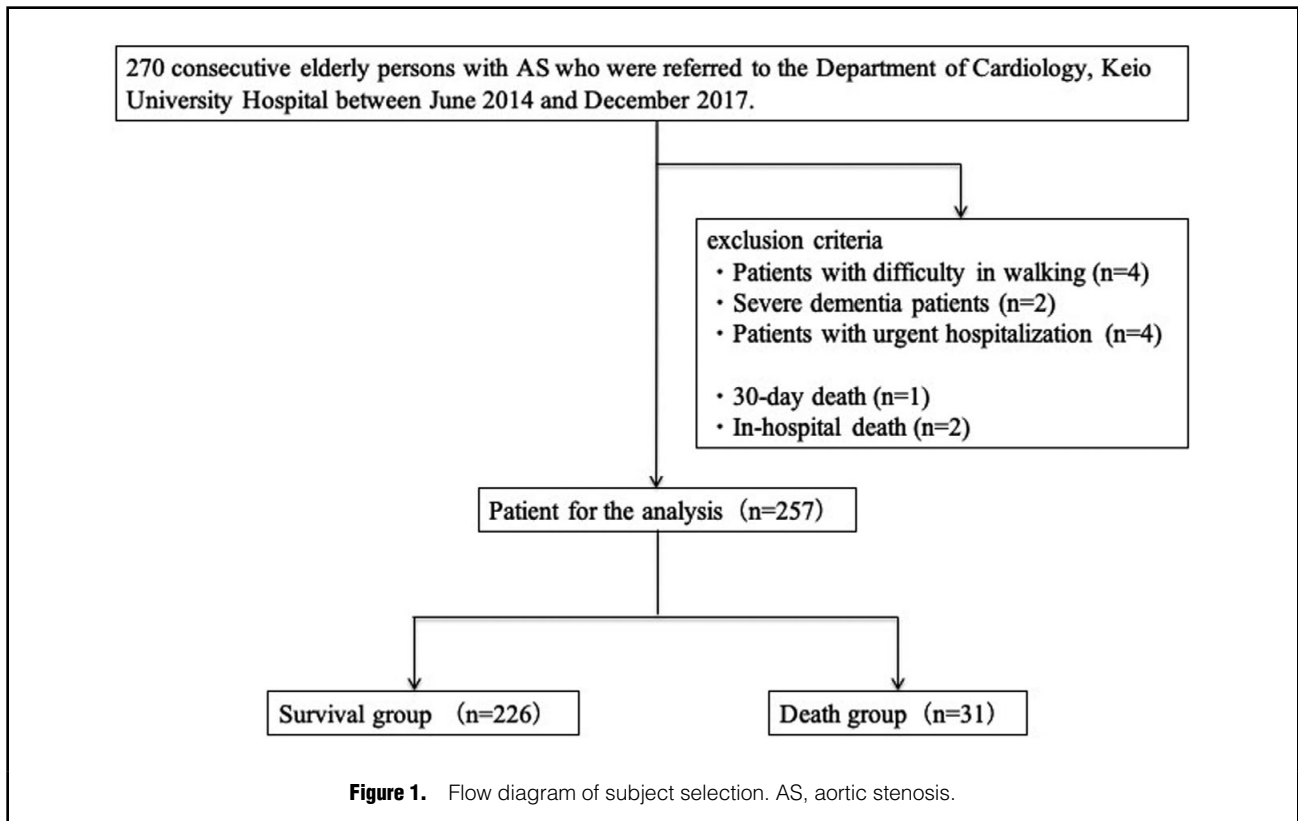
own pace with acceleration and deceleration phases of 2 m each was measured using a hand-held stopwatch. The shortest amount of time was included in analyses. As an assessment of nutritional status, we used the Mini Nutritional Assessment-Short Form (MNA-SF) to screen nutritional status during interview,¹⁸ and determined nutritional and metabolic status from blood tests. The MNA-SF evaluates dietary intake, weight loss, difficulties with walking, mental stress and/or acute disease, cognitive impairment, and body mass index (BMI). Each item is scored on scales of either 0–2 or 0–3. Total score ranges from 0 (worst) to 14 (best). Scores ≤11 and ≤7 indicate risk for malnutrition, and ≤6 indicates malnutrition. Total protein, serum albumin, hemoglobin, and C-reactive protein (CRP) were also measured. Cognitive function was evaluated using the Mini-Mental State Examination (MMSE),¹⁹ which tests orientation, memory, attention, calculation, language, and construction functions. Scores range from 0 to 30, with lower scores indicating worse cognitive function. We evaluated IADL using the Frenchay activities index (FAI),²⁰ which indicates the frequency with which the following tasks are undertaken within specific periods: preparing main meals, washing up after meals, washing clothes, light housework, heavy housework, local shopping, social occasions, walking outside for >15 min, actively pursuing a hobby, driving a car/travelling by bus, travel outings/car rides, gardening, household maintenance, reading books, and gainful work. Each item was scored on a scale of 0–3. Total scores ranged from 0 to 45, with higher scores indicating better IADL. A physical therapist who specializes in ADL assessment assessed these indexes.

As an assessment of background demographics, we collected information on age, sex, family living under one roof, living environment, postoperative hospitalization, medical history and/or comorbidities. Living environment was defined as home, facility or hospital. A history of coronary artery disease was defined as self-reported hospitalization for coronary artery disease. A history of hospitalization, treatment history and angiography either at the present hospital or elsewhere were confirmed from medical records. A history of heart failure was defined as self-reported hospitalization for heart failure, and/or descriptions of heart failure in the medical records based on the Framingham criteria.²¹ Cerebrovascular disease was defined as self-reported hospitalization, and/or neurology assessed by psychiatrists from medical records. Respiratory disease was defined as spirometric evidence of restrictive and/or obstructive ventilatory impairment or self-reported current respiratory medications. Musculoskeletal disorders were defined as self-reported spine, hip, knee or ankle diseases currently under treatment and/or left with impairment.

We obtained data regarding clinical follow-up at 1 month, 6 months, 1 year, and annually thereafter. Additional follow-up data, including data on death and incidental disease, were collected from the treating hospital or via telephone from the patient's family or from the patient's family physician.

Statistical Analysis

The primary outcome was postoperative death. Differences in basic characteristics between the group that survived and the group that died after TAVI were analyzed using t-test or chi-squared test. Thereafter, multivariate hazard ratios (HR) were calculated for meaningful independent factors identified from Cox proportion hazards models



adjusted for age, sex, BMI and STS risk score (model 1), and for the factors included in model 1 plus surgical procedure, comorbidity, family living under one roof and living environment (model 2).

Receiver operating characteristic (ROC) curve analysis was used for the variables that were significant in the Cox proportional hazard models. Area under the curve (AUC), sensitivity and specificity were calculated and the cut-off was determined using Youden index.

For missing values, we assumed that 50 was the maximum number of repetitions using multiplex substitution (Markov chain Monte Carlo).

All data were analyzed using IBM SPSS Statistics 24 (IBM, Armonk, NY, USA). Values with $P < 0.05$ were considered significantly different.

Results

Table 1 lists the participant characteristics and **Figure 1** shows the process of subject selection.

Thirteen of the 270 patients were excluded; thus, data from 257 patients were analyzed. The median duration of follow-up was 661 days (range, 33–1,289 days) and 31 (13.3%) died during this period. Pneumonia was the most frequent cause of death ($n=9$), followed by cardiac-related pathology (heart failure, arrhythmia and myocardial infarction; $n=6$; **Table 2**). Walking speed (mean \pm SD, 0.87 ± 0.25 vs. 0.70 ± 0.24 m/s, $P < 0.001$) and FAI (21.2 ± 8.0 vs. 15.7 ± 8.0 , $P = 0.026$) were significantly higher in the group that survived than in the group that died (**Table 3**).

The multivariate HR for mortality according to walking speed were 0.05 (95% CI: 0.028–0.091) in model 1 and 0.04 (95% CI: 0.02–0.08) in model 2. The multivariate HR for

Table 2. Causes of Death After TAVI	
	n
Pneumonia (aspiration, bacterial)	9
Cancer	4
Sudden death	3
Heart failure	3
Arrhythmia	2
Novel onset of cerebrovascular disease	2
Multiple organ dysfunction	1
Myocardial infarction	1
Esophageal bleeding	1
Multiple organ dysfunction	1
Cause unknown	4

TAVI, transcatheter aortic valve implantation.

FAI were 0.94 (95% CI: 0.92–0.95) and 0.92 (95% CI: 0.90–0.92; **Table 4**), respectively. On ROC analysis the cut-off for walking speed was 0.75 m/s (AUC, 0.663; sensitivity, 63.6%; specificity, 81.3%; $P = 0.033$; 95% CI: 0.500–0.825), and the cut-off for FAI was 20.5 (AUC, 0.702; sensitivity, 61.0%; specificity, 75.0%; $P = 0.008$; 95% CI: 0.578–0.826; **Figure 2, Supplementary Figure**).

Discussion

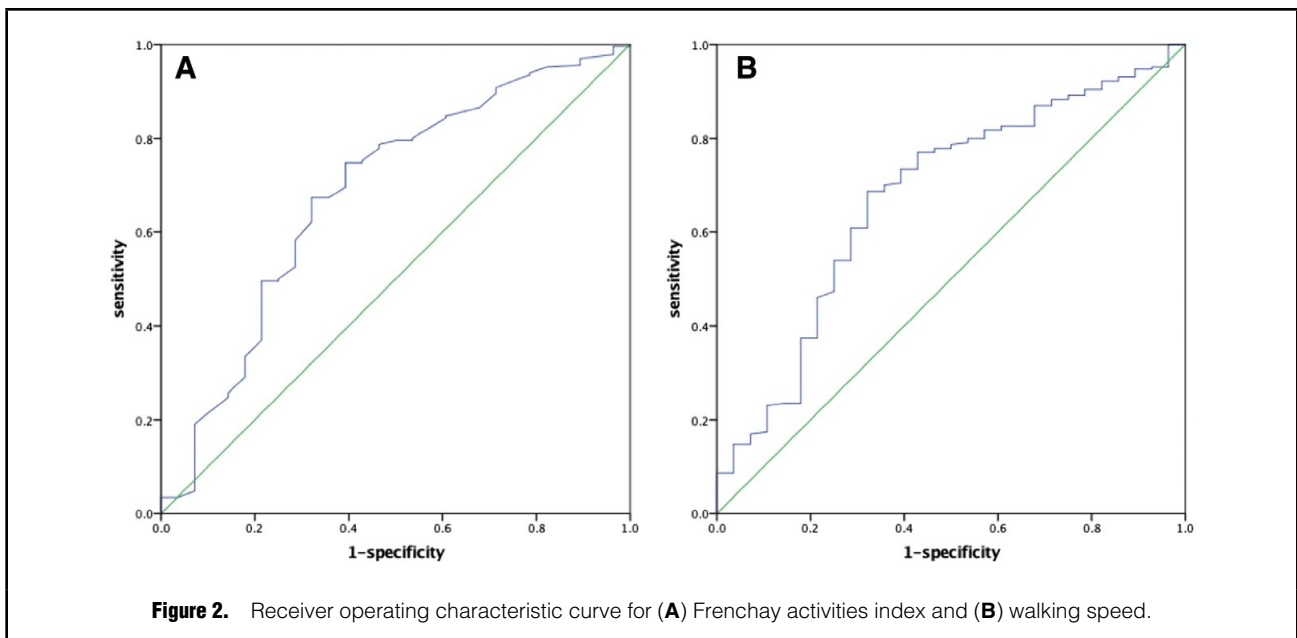
The aim of this study was to identify preoperative factors that might be associated with medium–long-term prognosis after TAVI at one of the leading facilities in Japan. The average age was 84.1 ± 5.3 years, and women comprised

Table 3. Univariate Indicators of Death After TAVI			
	Survival group (n=226)	Death group (n=31)	P-value
Age (years)	84.3±4.8	83.7±5.5	0.595
Sex (F/M)	72/154	16/15	0.068
BMI (kg/m ²)	21.9±3.5	21.3±4.0	0.082
Operation (TF/others)	203/23	26/5	0.319
NYHA class (I/II/III/IV)	12/110/102/2	1/12/15/2	0.093
LVEF (%)	64.4±12.3	60.6±16.1	0.139
STS score (%)	7.0±4.1	6.7±4.6	0.753
Diabetes mellitus	54 (23.9)	8 (25.8)	0.739
Hypertension	180 (79.6)	21 (67.7)	0.227
Chronic kidney failure	123 (54.4)	17 (54.8)	0.817
Cerebrovascular disease	30 (13.3)	7 (22.6)	0.144
Coronary artery disease	73 (32.3)	10 (32.3)	0.996
Heart failure	64 (28.3)	13 (41.9)	0.121
Respiratory disease	78 (34.5)	13 (41.9)	0.418
Musculoskeletal disorder(s)	63 (27.9)	6 (19.4)	0.315
Family living together	174 (77.0)	23 (80.6)	0.464
Living environment (Home/Facility/Hospital)	210/5/11	27/1/3	0.433
Hand grip (kg)	17.8±5.3	15.7±5.3	0.156
Walking speed (m/s)	0.87±0.25	0.70±0.24	<0.001
MMSE	26.1±3.5	26±3.3	0.55
FAI	21.1±8.0	17.1±8	0.026
MNA-SF	11.2±2.5	10.0±2.7	0.056

Data given as n (%) or mean±SD. Abbreviations as in Tables 1,2.

Table 4. Factors Associated With Mortality After TAVI									
Factors	Univariate model			Multivariate model					
	HR	95% CI	P-value	Model 1			Model 2		
	HR	95% CI	P-value	HR	95% CI	P-value	HR	95% CI	P-value
Walking speed	0.084	0.047–0.152	<0.001	0.05	0.028–0.091	<0.001	0.041	0.020–0.081	<0.001
FAI	0.935	0.919–0.951	<0.001	0.935	0.919–0.952	<0.001	0.919	0.900–0.938	<0.001

Multiple Cox proportional hazards models: model 1, adjusted for age, sex, BMI, STS score; model 2, model 1 plus operative procedure, comorbidities, family living together, living environment. Abbreviations as in Tables 1,2.



66.2%. The mortality rate was 13.3% during a 661-day follow-up. The reported 1- and 5-year mortality rates were 24.2% and 67.8% in 2011 (PARTNER trial cohort A)² and 30.7% and 71.8% in 2010 (PARTNER trial cohort B).²² The 1-year mortality rate in Japanese patients, however, has recently decreased to 11.3%.²³

A comfortable walking speed was selected as a preoperative indicator of prognosis, consistent with that of a study of mortality in the short term after TAVI.⁹ A comfortable walking speed is a representative index of motor function that is included in the diagnostic criteria for sarcopenia and frailty.^{24,25} In addition, a comfortable walking speed is a prognostic factor not only after TAVI but also after cardiovascular disease.²⁶ Therefore, walking speed should be routinely measured before surgery. Fukui et al reported that candidates for TAVI include those with physical frailty.²⁷

The cut-off for walking speed to distinguish all-cause mortality after TAVI was 0.75 m/s in the present study. Walking speed ≤ 0.8 m/s is generally regarded as a diagnostic criterion for sarcopenia,²⁴ and this speed affects the prognosis of patients with heart failure aged >65 years.²⁸ The present result was similar to these and thus is considered valid.

We also found that IADL was a prognostic indicator of post-TAVI outcome. IADL are essential to live independently in a community.²⁹ The relationship between IADL and prognosis has recently received attention. Factors of mortality including IADL were reported in a representative sample of elderly people.³⁰ A decline in IADL also affects the prognosis of patients with heart failure aged >65 years.²⁸ Although a decline in IADL might be difficult to discern during a clinical examination, the IADL of patients with severe AS in the clinical setting should nevertheless be considered.

The cut-off for FAI was 20.5. An FAI cut-off for patients with heart disease has not been defined, but FAI score ≥ 18 is a useful prognostic cut-off for patients with stroke.³¹ The total FAI score is 45 and an IADL score that falls to below half of this value might be associated with various risks for elderly persons. In contrast, STS score or logistic EuroSCORE is often used as a preoperative indicator of prognosis.^{15,32} These include assessments of comorbidity and general status. Walking speed and IADL were notably associated with prognosis after adjustment for STS in the present study. This indicates that a greater emphasis on IADL and physical frailty is required in the risk evaluation when assessing elderly people for surgery.

Study Limitations

The present study has several limitations. It was carried out at a single institution and involved a small patient cohort. Much of the past medical history was obtained by patient self-report and thus may be subject to recall bias. We did not consider types of preoperative risk assessment other than STS. STS score is commonly used, but if other scores were also adjusted, the study might have been more robust. Nevertheless, the present findings suggest that evaluation of comfortable walking speed and of IADL is important to estimate mid- and long-term prognoses after TAVI.

Conclusions

Preoperative walking speed and IADL are important factors associated with mid- and long-term mortality after TAVI.

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None.

Disclosures

The authors declare no conflicts of interest.

The Ethics Review Board at Keio University Hospital approved the study protocol, which was implemented according to the Declaration of Helsinki.

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Supplementary Files

Please find supplementary file(s);
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