

# Prevalence, Predictors, and Mid-Term Outcomes of Non-Home Discharge After Transcatheter Aortic Valve Implantation

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**Background:** Transcatheter aortic valve implantation (TAVI) has been widely used as a valued alternative to surgical aortic valve replacement. In cardiovascular surgeries, discharge disposition has been widely investigated. We examined the prevalence and predictors of non-home discharge after TAVI, and the prognosis based on discharge destination.

**Methods and Results:** We retrospectively analyzed 732 consecutive patients undergoing TAVI, and divided them into 2 groups: the home group (discharged directly home; n=678 [92.6%]) and the non-home group (n=54 [7.4%]). From baseline and procedural characteristics, peripheral artery disease (PAD; odds ratio [OR] 2.73; 95% confidence interval [CI] 1.25–5.97; P=0.012), previous stroke (OR 2.57; 95% CI 1.03–6.45; P=0.045), albumin level (OR 0.16 per 1-g/dL increase; 95% CI 0.07–0.39; P<0.001), and procedural stroke (OR 31.6; 95% CI 10.9–91.7; P<0.001) were independently associated with non-home discharge. In Kaplan-Meier analysis, the non-home group had worse survival than the home group (log-rank, P=0.001). In multivariate analysis, male sex, atrial fibrillation or atrial flutter, and low albumin concentrations were associated with all-cause mortality, but non-home discharge was not (P=0.18).

**Conclusions:** Non-home discharge was recorded for 7.4% of patients undergoing TAVI, and was associated with PAD, nutritional status, and previous and procedural stroke. Non-home discharge reflects worse baseline characteristics, and may be a marker of mid-term outcome after TAVI.

Key Words: Discharge location; Home discharge; Transcatheter aortic valve implantation

ranscatheter aortic valve implantation (TAVI) has emerged as a viable alternative to surgical aortic valve replacement in high-surgical-risk and inoperable patients with significant symptomatic aortic stenosis (AS).<sup>1,2</sup> The evolution of the transcatheter heart valve (THV) system and accumulated experience have improved the outcomes of TAVI. The indication for TAVI has been expanded to intermediate- and low-surgical-risk populations.<sup>3,4</sup> The efficacy and safety endpoints of TAVI include the rate of device success, procedural complications, mortality, and readmission.

The long-term prognosis after TAVI may differ according to different discharge destinations. Non-home discharge after cardiac and orthopedic surgeries has been reported to be associated with postoperative prognosis.<sup>5–7</sup> The prediction of discharge destination would be useful for patient screening, informed consent, and postprocedural care. However, limited data are available regarding the status, predictors of, and outcomes for different discharge destinations (e.g., home, rehabilitation facility, nursing home, or other acute hospital) in patients undergoing TAVI.

The aims of the present study were to evaluate: (1) the prevalence and predictors of non-home discharge in patients who underwent TAVI; and (2) the prognosis based on discharge destination (home or non-home discharge).

# Methods

# Subjects and Study Protocol

We retrospectively enrolled 737 consecutive patients with

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symptomatic severe AS who underwent TAVI between October 2013 and June 2019 at Sakakibara Heart Institute. Clinical data, including patient characteristics, laboratory and echocardiographic data, procedural variables, postdischarge survival, and discharge location, were recorded prospectively and analyzed retrospectively. Comorbidities were defined based on a previous report (**Supplementary Table**).<sup>8</sup> Our database did not contain information of the patients' location before hospitalization.

Patients were divided into 2 groups based on discharge destination: a home group (discharged to their own residence) and a non-home group (discharged to a rehabilitation facility, nursing home, or other acute hospital). Patients were followed up until August 2019. The status of all patients was obtained from medical records, attending physicians at the patients' referring hospital, or by contacting the patients or their relatives by telephone. Survival time was calculated from the date of TAVI to the time of death or last follow-up. Sudden death was regarded as cardiovascular death.

The study protocol was approved by the Ethics Committee of Sakakibara Heart Institute, and the study was conducted in accordance with the principles outlined in the Declaration of Helsinki. Reporting of the study conformed to STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) along with references to STROBE and the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) guidelines.<sup>9</sup>

#### **TAVI Procedure and Post-TAVI Management**

Severe AS was defined as aortic valve area <1.0 cm<sup>2</sup> and mean pressure gradient >40 mmHg or peak jet velocity >4.0 m/s on transthoracic echocardiography.<sup>10</sup> The decision to perform TAVI was made by the multidisciplinary Heart Team at Sakakibara Heart Institute, which consisted of cardiologists, cardiac surgeons, radiologists, anesthesiologists, and other medical professionals related to the field. The heart team preferred TAVI in high-surgical-risk or inoperable patients. In low- or intermediate-surgical-risk patients, TAVI or surgical aortic valve replacement was selected after considering patient age, frailty, and compatibility with TAVI. The preferred approach for TAVI was transfemoral, and alternative approaches, including transapical, trans-subclavian, and direct aortic, were considered if aorto-ilio-femoral access was not suitable. The firstgeneration THVs used were the SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA) and CoreValve (Medtronic, Minneapolis, MN, USA); the second-generation THVs used were the SAPIEN3 (Edwards Lifesciences), Evolut R (Medtronic), Evolut PRO (Medtronic), Lotus (Boston Scientific, Marlborough, MA, USA), and Acurate (Boston Scientific). TAVI was performed under general or local anesthesia with sedation at the hybrid catheterization laboratory. Antithrombotic therapy following TAVI consisted of a single antiplatelet or anticoagulant agent.

After the procedure, patients were monitored in the cardiac care unit for a few hours. In the general ward, patients underwent comprehensive cardiac rehabilitation and guideline-directed medical therapy. In addition, social resources were put in place to achieve home discharge.

## **Definition of Outcome and Study Endpoint**

Clinical events were defined according to Valve Academic Research Consortium-2 criteria.<sup>11</sup> The combined endpoint included all-cause mortality, all stroke, life-threatening bleeding, acute kidney injury Stage 2 or 3, coronary artery obstruction, major vascular complication, and valve-related dysfunction requiring repeat procedure. Device success was defined as the absence of procedural mortality, correct positioning of a single prosthetic heart valve, and intended performance of the prosthetic heart valve. The primary endpoint of the study was all-cause mortality after TAVI.

# **Statistical Analysis**

Categorical variables are expressed as numbers and percentages. The Chi-squared test was used for comparisons of categorical variables, followed by Fisher's exact test if appropriate. Normality was confirmed using the Shapiro-

	Total	Home group	Non-home group	<b>D</b> . 1
	(n=732)	(n=678)	(n=54)	P value
Demographic data				
Age (years)	84.4±5.1	84.3±5.1 85.7±5.3		0.056
Female sex	512 (69.9)	473 (69.8)	39 (72.2)	0.71
BMI (kg/m²)	22.4±3.8	22.5±3.8	21.7±4.2	0.17
NYHA class III or IV	374 (51.1)	333 (49.1)	41 (75.9)	<0.001
5-m walking time (s)	7.4±3.8	7.4±3.7	8.0±4.7	0.26
Hand-grip strength (kg)	17.4±6.5	17.5±6.5	16.2±5.5	0.15
HDS-R (points)	24.4±4.6	24.5±4.4	23.3±5.9	0.047
EuroSCORE II (%)	6.4±6.9	5.9±6.1	12.5±12.3	<0.001
STS score (%)	6.7±4.6	6.3±4.1	10.9±7.9	<0.001
Past medical history				
Hypertension	548 (74.9)	515 (76.0)	33 (61.1)	0.015
Diabetes	153 (20.9)	141 (20.8)	12 (22.2)	0.80
Peripheral artery disease	108 (14.8)	91 (13.4)	17 (29.8)	0.001
Previous stroke	79 (10.8)	65 (9.6)	14 (25.9)	0.001
AF/AFL	170 (23.2)	151 (22.2)	19 (35.2)	0.031
COPD	26 (3.6)	23 (3.4)	3 (5.6)	0.30
OMI	42 (5.7)	40 (5.9)	2 (3.7)	0.50
Previous CABG	47 (6.4)	43 (6.3)	4 (7.4)	0.76
Laboratory data				
Log NT-proBNP (pg/mL)	3.1±0.6	3.1±0.6	3.5±0.6	<0.001
eGFR (mL/min/1.73m²)	52.1±16.9	52.1±16.5	52.8±20.9	0.76
Hemoglobin (g/dL)	11.7±1.5	11.7±1.5	11.3±1.7	0.092
Albumin (g/dL)	3.8±0.4	3.8±0.4	3.4±0.5	<0.001
Echocardiographic data (before TAVI)				
LVEF (%)	59.4±9.3	59.8±9.2	54.4±10.1	<0.001
Aortic valve area (cm <sup>2</sup> )	0.67±0.16	0.67±0.16	0.58±0.15	< 0.001
AV mean pressure gradient (mmHg)	53.9±18.9	53.9±18.6	53.9±22.3	0.99
MR of moderate or greater severity	26 (3.6)	21 (3.1)	5 (9.3)	0.019
Procedural characteristics				
THV				
First-generation	182 (24.9)	168 (24.8)	14 (25.9)	0.85
Second-generation	550 (75.1)	510 (75.2)	40 (74.1)	5.00
General anesthesia	249 (34.0)	222 (32.7)	27 (50.0)	0.010
Transfemoral approach	670 (91.5)	624 (92.0)	46 (85.2)	0.082
Device success	709 (96.9)	659 (97.2)	50 (92.3)	0.062
Procedural complications				
Combined endpoint	60 (8.2)	45 (6.6)	15 (27.8)	<0.001
Procedural stroke	25 (3.4)	12 (1.8)	13 (24.1)	<0.001
Life-threatening bleeding	14 (1.9)	12 (1.8)	2 (3.7)	0.30
Acute kidney injury stage 2 or 3	8 (1.1)	7 (1.0)	1 (1.9)	0.55
Major vascular complication	19 (2.6)	17 (2.5)	2 (3.7)	0.56
Pacemaker implantation	65 (8.9)	63 (9.3)	2 (3.7)	0.16
Postprocedural AR of moderate or greater severity	20 (2.7)	15 (2.2)	5 (9.3)	0.002
Thirty-day readmission	6 (0.8)	6 (0.9)	0 (0.0)	0.49

Unless indicated otherwise, data are given as n (%) or the mean±SD. AF, atrial fibrillation; AFL, atrial flutter; AR, aortic regurgitation; AV, aortic valve; BMI, body mass index; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; EuroSCORE, European system for cardiac operative risk evaluation; HDS-R, revised Hasegawa's dementia scale; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; NT-proBNP, N-terminal pro B-type natriuretic peptide; NYHA, New York Heart Association; OMI, old myocardial infarction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve.

Table 2. Logistic Regression Analysis: Associations Between Clinical Profiles and Non-Home Discharge						
		Univariable		Multivariable		
	OR	95% CI	P value	OR	95% Cl	P value
Demographic data						
Age (per 1-year increase)	1.06	1.00-1.12	0.055			
Female sex	1.13	0.61-2.09	0.71			
BMI (per 1-kg/m <sup>2</sup> increase)	0.95	0.88-1.02	0.17			
NYHA III or IV	3.25	1.71–6.17	<0.001			
5-m walking time (per 1-s increase)	1.03	0.98-1.10	0.26			
Hand-grip strength (per 1-kg increase)	0.97	0.92-1.01	0.15			
HDS-R (per 1-point increase)	0.95	0.90-1.00	0.049	0.98	0.92-1.06	0.63
Past medical history						
Hypertension	0.50	0.28-0.88	0.017	0.59	0.27-1.30	0.19
Diabetes	1.09	0.56-2.12	0.80			
Peripheral artery disease	2.96	1.60-5.48	0.001	2.73	1.25–5.97	0.012
Previous stroke	3.30	1.71–6.39	<0.001	2.57	1.03-6.45	0.044
AF/AFL	1.86	1.05-3.41	0.033	1.18	0.56-2.49	0.67
COPD	1.68	0.49–5.77	0.41			
OMI	0.61	0.14-2.61	0.51			
Previous CABG	1.18	0.41-3.42	0.76			
Laboratory data						
Log NT-proBNP (per 1-unit increase)	3.96	2.39-6.57	<0.001	1.61	0.69-3.72	0.27
eGFR (per 1-mL/min/1.73 m <sup>2</sup> increase)	1.00	0.99–1.11	0.76			
Hemoglobin (per 1-g/dL increase)	0.85	0.70-1.03	0.092			
Albumin (per 1-g/dL increase)	0.14	0.08-0.26	<0.001	0.16	0.07-0.39	<0.001
Echocardiographic data						
LVEF (per 1% increase)	0.95	0.93-0.98	<0.001	1.01	0.97-1.04	0.80
Aortic valve area (per 1-cm <sup>2</sup> increase)	0.02	0.003-0.13	< 0.001	0.10	0.007-1.35	0.083
AV mean pressure gradient (per 1-mmHg increase)	1.00	0.99–1.02	0.99	0110	0.007 1.00	0.000
Moderate or greater MR	3.19	0.15-8.83	0.025	1.19	0.30-4.74	0.81
Procedural characteristics	0.110		0.020		0.00	0.01
First-generation THV	1.06	0.54-2.00	0.85			
General anesthesia	2.05	1.18-3.59	0.0011	1.79	0.86-3.74	0.12
Transfemoral approach	0.50	0.22-1.11	0.088	1.70	0.00 0.71	0.12
Device success	0.36	0.12-1.10	0.073			
Procedural complications	0.00	0.12 1.10	0.070			
Combined endpoint	5.77	2.92-11.2	<0.001			
Procedural stroke	18.6	7.93-43.4	<0.001	31.6	10.9–91.7	<0.001
Life-threatening bleeding	2.21	0.48–10.2	0.31	01.0	10.0-01.7	<b>NO.001</b>
Acute kidney injury Stage 2 or 3	1.87	0.40-10.2	0.56			
Major vascular complication	1.55	0.25-15.5	0.57			
Pacemaker implantation	0.38	0.09-1.58	0.57			
				2.16	071 14 0	0.12
Moderate or greater postprocedural AR	4.50	1.58–12.9	0.005	3.16	0.71–14.0	0.13

CI, confidence interval; OR, odds ratio. Other abbreviations as in Table 1.

Wilk test in each group. Normally distributed variables are presented as the mean $\pm$ SD, and non-normally distributed variables (e.g., N-terminal pro-B-type natriuretic peptide [NT-proBNP]) were log transformed. Missing data for 5-m walking time (26.6% of all), hand-grip strength (26.1%), and revised Hasegawa's dementia scale (12.7%) were handled using a mean imputation method. Normally distributed variables were compared using Student's t-test, whereas non-normally distributed variables were compared using the Mann-Whitney U-test. Logistic regression analysis was used to determine factors related to non-home discharge. In multivariate analysis, variables were selected considering multicollinearity, clinical plausibility, and significance in univariate analysis. The Kaplan-Meier method was used to evaluate postprocedural survival using the log-rank test. The prognostic value of clinical variables was tested by Cox proportional hazard analysis. Two-sided P<0.05 was considered significant in all analyses. Analyses were performed using SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA).

# Results

#### **Baseline and Procedural Characteristics**

The patient flow chart is shown in **Figure 1**. Patients who died in hospital after TAVI (n=5) were excluded from the



		Univariable			Multivariable			
	HR	95% CI	P value	HR	95% CI	P value		
Age	1.03	0.99-1.07	0.20					
Female sex	0.43	0.28-0.64	<0.001	0.51	0.34-0.79	0.002		
BMI	1.86	0.57-6.04	0.30					
NYHA III or IV	1.81	1.19–2.74	0.005	1.18	0.73–1.91	0.50		
Hypertension	0.69	0.44-1.08	0.10					
Diabetes	1.23	0.78–1.95	0.38					
Peripheral artery disease	1.60	0.99–2.58	0.055					
Stroke	1.90	1.12–3.21	0.017	1.71	0.97–3.03	0.065		
AF/AFL	2.42	1.60-3.65	<0.001	2.30	1.48–3.58	<0.001		
COPD	2.33	1.12–4.82	0.023	2.01	0.87–4.63	0.10		
OMI	1.13	0.52-2.45	0.75					
eGFR	0.99	0.98-1.00	0.16					
Hemoglobin	0.89	0.77-1.03	0.11					
Albumin	0.26	0.16-0.40	<0.001	0.30	0.19-0.49	<0.001		
Aortic valve area	0.62	0.16-2.44	0.49					
MR ≥ moderate	1.74	0.64-4.75	0.28					
General anesthesia	1.50	0.92-2.48	0.10					
Transfemoral approach	0.67	0.40-1.13	0.14					
Device success	0.38	0.18-0.78	0.009	0.49	0.20-1.20	0.12		
Procedural stroke	1.09	0.35-3.46	0.88					
Life-threatening bleeding	2.19	0.89-5.42	0.090					
Acute kidney injury Stage 2 or 3	3.54	1.30–9.68	0.014	1.52	0.49–4.70	0.47		
Major vascular complication	0.87	0.28-2.75	0.81					
Pacemaker implantation	1.15	0.53–2.22	0.68					
AR ≥ moderate	3.60	1.30-9.97	0.014	1.42	0.37-5.52	0.61		
Non-home vs. home discharge	3.11	1.79–5.43	<0.001	1.54	0.82-2.91	0.18		

HR, hazard ratio. Other abbreviations as in Tables 1,2.

analysis. Of 732 patients included in the study, 678 (92.6%) were assigned to the home group, and 54 (7.4%) were assigned to the non-home group. The clinical characteristics for the 2 groups are given in Table 1. Compared with the home group, the non-home group had a significantly higher New York Heart Association class, European system for cardiac operative risk evaluation (EuroSCORE) II and Society of Thoracic Surgeons (STS) scores, and lower values on the revised Hasegawa's dementia scale. The non-home group had a higher prevalence of hypertension, peripheral artery disease (PAD), previous stroke, and atrial fibrillation. Although NT-proBNP concentrations were higher and albumin concentrations were lower in the non-home than home group, estimated glomerular filtration rate did not differ between the 2 groups. Echocardiography before TAVI revealed that the non-home group had a lower left ventricular ejection fraction, smaller aortic valve area, and more frequent prevalence of moderate or greater mitral regurgitation. During TAVI, a greater proportion of procedures were performed under general anesthesia in the non-home than home group, but there was no significant difference in the type of THV or approach site between the 2 groups. The incidence of procedural stroke and residual aortic regurgitation was higher in the non-home group, whereas the incidence of life-threatening bleeding, acute kidney injury, pacemaker implantation, and major vascular complications was equivalent between the 2 groups.

#### Predictors of Non-Home Discharge

As indicated in **Table 2**, we focused on possible factors associated with non-home discharge. All factors presented in **Table 1** were analyzed, except for complex indices such as the EuroSCORE II and STS scores. In multivariate regression analysis, PAD, previous stroke, albumin concentrations, and procedural stroke were significantly associated with non-home discharge.

#### **Post-Discharge Prognosis**

During the follow-up period (mean 696 days), there were 94 all-cause deaths: 19 deaths from cardiovascular causes (20.2%; heart failure, 10; sudden death, 9) and 75 deaths from non-cardiovascular causes (79.8%; pneumonia, 22; malignancy, 12; stroke, 9; gastrointestinal disease, 9; sepsis, 8; natural death, 7; multiple organ failure, 3; unknown, 5). Kaplan-Meier analysis (**Figure 2**) revealed that the non-home group had worse survival than the home group (P<0.001). Multivariable Cox proportional hazard analysis (**Table 3**) revealed that male sex, atrial fibrillation or atrial flutter, and hypoalbuminemia were associated with a higher post-discharge all-cause mortality, but non-home discharge was not (P=0.18).

# Discussion

In the present study we evaluated the prevalence, predictors, and mid-term outcomes of discharge location in patients who underwent TAVI. We found that: (1) the prevalence of non-home discharge after TAVI was 7.4% (54 of 732 patients); (2) a past history of PAD and stroke, preprocedural albumin concentrations, and procedural stroke were significantly associated with non-home discharge; and (3) the non-home group (vs. the home group) had higher post-discharge all-cause mortality, but non-home discharge was not associated with worse survival after TAVI in itself.

#### **Postoperative Non-Home Discharge**

There are several reports on discharge environment in the field of orthopedics.<sup>5,6</sup> In patients with a fractured femur neck, advanced age, male sex, cerebrovascular disease, chronic obstructive pulmonary disease, renal disease, anemia, the use of walking aids, and requiring assistance with basic activities of daily living (ADL) are predictors for discharge destination.<sup>5</sup> The predictors for discharge location in patients undergoing lumbar laminectomy are age, mobility, marital status, and prior ADL level.6 Conversely, there are only a few reports regarding discharge destination after TAVI.<sup>12-14</sup> Because most candidates for TAVI are elderly with some level of frailty, studies focusing on discharge location are essential in patients undergoing TAVI. Although TAVI has been recently applied to selected intermediate- and low-surgical-risk patients, predictions of discharge location and post-discharge care are important for a better prognosis.

## Prevalence of Non-Home Discharge and Its Prognostic Impact

In the present study (in Japan), the non-home group accounted for 7.4% of all patients, which is lower than that in previous studies from Europe (24.8%12) and the US (27.8%<sup>13</sup> and 46.8%<sup>14</sup>), and had higher mid-term mortality compared with the home group. There are 3 possible reasons for the higher rate of direct home discharge in the present study. First, the prevalence of comorbidities, including diabetes, PAD, previous stroke, atrial fibrillation, and chronic obstructive pulmonary disease, was lower than in previous studies.<sup>12-14</sup> In particular, the prevalence of PAD and previous stroke was significantly lower in the present than previous studies, and both PAD and previous stroke were found to be associated with non-home discharge in the present study. Second, the rates of local anesthesia (66.4%), transfemoral approach (91.7%), and the use of second-generation devices (75.1%) were higher than in previous studies.<sup>12-14</sup> Third, differences in the healthcare insurance system may have resulted in significant differences in the proportion of patients in the non-home group. With regard to prognosis, Mehilli et al<sup>12</sup> reported that non-home discharge after TAVI was associated with a higher 1-year risk of the safety endpoint, death, and stroke. However, another 2 studies did not reported the prognosis of nonhome discharge because of the nature of the large-scale registry.<sup>13,14</sup> In the present study, non-home discharge was not a significant predictor in multivariate analysis. The true prognosis of non-home discharge requires further investigation.

## Predictors of Non-Home Discharge, Procedural Complications, and Future Approach

In the present study, PAD, preprocedural albumin concentrations, and previous and procedural stroke were significantly associated with non-home discharge. PAD is related to non-transfemoral access routes, and non-transfemoral TAVI is associated with a greater risk of death at 1 year,<sup>15</sup> and a >50% increase in vascular complications.<sup>16</sup> In addition, the presence of PAD indicates underlying polyvascular disease, relevant risk factors, systemic inflammation, myocardial damage, and impaired exercise capacity. PAD is associated with poor prognosis in patients with heart failure.<sup>17</sup>

Serum albumin concentrations <3.5 g/dL are considered a marker of frailty.<sup>18</sup> Shimura et al<sup>19</sup> reported that

hypoalbuminemia was associated with poor prognosis, and Afilalo et al<sup>20</sup> reported that albumin concentrations were strong predictors of 1-year disability after TAVI. Hypoalbuminemia was associated with non-home discharge, and so evaluation of patients' nutritional status and nutrition therapy before TAVI are important. Serum albumin concentrations were not considered in previous studies,<sup>12–14</sup> but we should pay attention to nutritional status or frailty in patients with hypoalbuminemia.<sup>8</sup>

Finally, stroke is a major complication that results in worse morbidity and mortality among patients who undergo TAVI.<sup>21</sup> Mehilli et al<sup>12</sup> reported that the rate of procedural stroke was higher in a non-home discharge group, and Shah et al<sup>14</sup> reported that paralysis was a predictor for discharge to rehabilitative facilities after TAVI. In the present study, procedural stroke was a strong predictor of non-home discharge; thus, the prevention of procedural stroke is important for home discharge after TAVI. Procedural stroke following TAVI is multifactorial, with possible reasons including: (1) thromboembolus, calcium emboli, and/or embolism of any tissue; (2) periprocedural hemodynamic instability; and (3) procedure-related systemic inflammation.<sup>21–23</sup> Although there is no definite way, careful attention should be paid to periprocedural antithrombotic agents, assessment of the aortic valve and access root, careful catheter manipulation, minimum rapid ventricular pacing, and the use of less invasive strategies. The results of ongoing clinical trials into antithrombotic agents are awaited (e.g., NCT02943785, NCT02664649). There are embolic protection devices being developed; however, no significant differences were seen between patients undergoing TAVI with or without such devices with regard to clinically evident stroke and mortality.<sup>24</sup>

#### Study Limitations

Because of the retrospective nature of this study, we did not have sufficient information regarding patients' locations before the index hospitalization, social background, and reasons and detailed locations of non-home discharge in our database. There is a likelihood that many social factors have an effect on non-home discharge (e.g., healthcare system, national or ethnic customs, family support, physicians' discretion and patients' will). The results of this study should be carefully interpreted in different settings. Because each attending physician decided to measure 5-m walking time, hand-grip strength, and revised Hasegawa's dementia scale, there may be potential selection bias in these measurements. To adjust for missing data as much as possible, we complemented missing data using a mean imputation method.

## Conclusions

Non-home discharge was documented for 7.4% of patients undergoing TAVI, and was associated with PAD, nutritional status, and previous and procedural stroke. Patients in the non-home discharge group had higher all-cause mortality following TAVI.

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#### Disclosures

I.T. and T.T. are clinical proctors for Edwards Lifesciences and Medtronic. The remaining authors have no conflicts of interest to declare.

#### **IRB** Information

This study was approved by the Ethics Committee of Sakakibara Heart Institute (Reference no. 17-005).

#### Data Availability

Data will not be shared.

#### References

- Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011; 364: 2187– 2198.
- Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363: 1597–1607.
- Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2017; 376: 1321–1331.
- Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019; **380**: 1695–1705.
- Salar O, Baker PN, Forward DP, Ollivere BJ, Weerasuriya N, Moppett IK, et al. Predictors of direct home discharge following fractured neck of femur. *Ann R Coll Surg Engl* 2017; 99: 444– 451.
- Kanaan SF, Yeh HW, Waitman RL, Burton DC, Arnold PM, Sharma NK. Predicting discharge placement and health care needs after lumbar spine laminectomy. *J Allied Health* 2014; 43: 88–97.
- Stuebe J, Rydingsward J, Lander H, Ng J, Xu X, Kaneko T, et al. A Pragmatic preoperative prediction score for nonhome discharge after cardiac operations. *Ann Thorac Surg* 2018; 105: 1384–1391.
- Yoshihisa A, Kanno Y, Watanabe S, Yokokawa T, Abe S, Miyata M, et al. Impact of nutritional indices on mortality in patients with heart failure. *Open Heart* 2018; 5: e000730.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. *BMJ* 2007; 335: 806–808.
- 10. Bonow RO, Carabello BA, Chatterjee K, deLeon AC Jr, Faxon DP, Freed MD, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 guidelines for the management of patients with valvular heart disease) developed in collaboration with the Society of Cardiovascular Anesthesiologists endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. Am J Coll Cardiol 2006; 48: e1-e148.
- Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document. *J Thorac Cardiovasc Surg* 2013; 145: 6–23.
- Mehilli J, Chandrasekhar J, Sartori S, Chieffo A, Petronio AS, Lefèvre T, et al. Impact of discharge location after transcatheter aortic valve replacement on 1-year outcomes in women: Results From the WIN-TAVI Registry. *Can J Cardiol* 2019; 35: 199–207.
- Dodson JA, Williams MR, Cohen DJ, Manandhar P, Vemulapalli S, Blaum C, et al. Hospital practice of direct-home discharge and 30-day readmission after transcatheter aortic valve replacement in the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry. J Am Heart Assoc 2017; 6: e006127.
- Shah RM, Hirji SA, Jolissaint JS, Lander HL, Shah PB, Pelletier MP, et al. Comparison of sex-based differences in home or

nonhome discharge utilization of rehabilitative services and outcomes following transcatheter aortic valve implantation in the United States. *Am J Cardiol* 2019; **123**: 1983–1991.

- Chandrasekhar J, Hibbert B, Ruel M, Lam BK, Labinaz M, Glover C. Transfemoral vs non-transfemoral access for transcatheter aortic valve implantation: A systematic review and meta-analysis. *Can J Cardiol* 2015; **31:** 1427–1438.
- Mehilli J, Jochheim D, Abdel-Wahab M, Rizas KD, Theiss H, Spenkuch N, et al. One-year outcomes with two suture-mediated closure devices to achieve access-site haemostasis following transfemoral transcatheter aortic valve implantation. *EuroIntervention* 2016; 12: 1298–1304.
- Nakamura Y, Kunii H, Yoshihisa A, Takiguchi M, Shimizu T, Yamauchi H, et al. Impact of peripheral artery disease on prognosis in hospitalized heart failure patients. *Circ J* 2015; **79**: 785–793.
- Koifman E, Magalhaes MA, Ben-Dor I, Kiramijyan S, Escarcega RO, Fang C, et al. Impact of pre-procedural serum albumin levels on outcome of patients undergoing transcatheter aortic valve replacement. *Am J Cardiol* 2015; 115: 1260–1264.
- Shimura T, Yamamoto M, Kano S, Kagase A, Kodama A, Koyama Y, et al. Impact of the clinical frailty scale on outcomes after transcatheter aortic valve replacement. *Circulation* 2017; 135: 2013–2024.
- Afilalo J, Lauck S, Kim DH, Lefèvre T, Piazza N, Lachapelle K, et al. Frailty in older adults undergoing aortic valve replacement:

The FRAILTY-AVR Study. Am J Coll Cardiol 2017; 70: 689–700.

- Nombela-Franco L, Webb JG, de Jaegere PP, Toggweiler S, Nuis RJ, Dager AE, et al. Timing, predictive factors, and prognostic value of cerebrovascular events in a large cohort of patients undergoing transcatheter aortic valve implantation. *Circulation* 2012; **126**: 3041–3053.
- Auffret V, Regueiro A, Del Trigo M, Abdul-Jawad Altisent O, Campelo-Parada F, Chiche O, et al. Predictors of early cerebrovascular events in patients with aortic stenosis undergoing transcatheter aortic valve replacement. *Am J Coll Cardiol* 2016; 68: 673–684.
- Van Mieghem NM, El Faquir N, Rahhab Z, Rodríguez-Olivares R, Wilschut J, Ouhlous M, et al. Incidence and predictors of debris embolizing to the brain during transcatheter aortic valve implantation. *JACC Cardiovasc Interv* 2015; 8: 718–724.
- Bagur R, Solo K, Alghofaili S, Nombela-Franco L, Kwok CS, Hayman S, et al. Cerebral embolic protection devices during transcatheter aortic valve implantation: Systematic review and meta-analysis. *Stroke* 2017; 48: 1306–1315.

#### **Supplementary Files**

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