# ORIGINAL ARTICLE





# Changes in the nutritional and activity status of elderly patients within 6 months of transcatheter aortic valve replacement: A mixed methods approach

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#### **Abstract**

**Aim:** Our aim was to explore changes in nutritional and activity status of patients within 6 months after transcatheter aortic valve replacement (TAVR) and factors affecting malnutrition post-TAVR in this cohort, and to gain understanding of their lifestyle considerations.

Methods: Using a mixed methods approach, we conducted a prospective, longitudinal survey, consisting of interviews and a questionnaire, of 50 participants aged ≥70 years (mean age, 83 years; 58.0% female) undergoing TAVR. Mini Nutritional Assessment (MNA) and albumin level (to measure nutritional status) and Physical Component Summary (PCS) scores from the 36-item Short Form Health Survey (to measure activity status) were collected at pre-TAVR and 1 month and 6 months post-TAVR. Laboratory data and some index scores (e.g., the Clinical Frailty Scale [CFS] and the Mini-Mental State Examination [MMSE]) assessed before TAVR were collected from medical records as related factors.

**Results:** Significant change was observed only in the MNA scores of participants who were assessed as malnourished at pre-TAVR, which improved, but did not reach normal nutritional status. Low-flow low-gradient aortic stenosis (odds ratio [OR]: 166.39, 95% confidence interval [CI]: 5.43–5094.43), higher CFS scores (OR: 2.58, 95% CI: 1.01–6.54), and lower MMSE scores (OR: 0.65, 95% CI: 0.43–0.99) were related to malnutrition post-TAVR. From interviews, three themes emerged: "balancing heart-healthy lifestyle and longstanding habits," "living with aging and disease" and "prospects for the rest of life."

**Conclusions:** Our results could be utilized to identify patients at risk of malnutrition post-TAVR, and to provide support with consideration of their lifestyle concerns.

#### KEYWORDS

elderly, frailty, nutritional status, physical activity, transcatheter aortic valve replacement

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# 1 | INTRODUCTION

Worldwide, aortic stenosis (AS) incidence has been steadily rising along with the aging population. Transcatheter aortic valve replacement (TAVR), a less invasive modality than surgery, is the preferred treatment method for severe AS among older adults. TAVR reduces mortality and improves health-related quality of life (QOL) compared with medical treatment alone (Leon, 2010; Reynolds, 2011). However, in a previous study, approximately 20% of patients who had undergone TAVR had poor outcomes at 6 months post-TAVR in terms of mortality or reduced OOL (Arnold et al., 2014). Some predictors of poor outcomes after treatment include decreased cognitive function, low-flow low-gradient AS (LF-LG AS), frailty syndrome, and malnutrition (Arnold et al., 2014; Green et al., 2015; Shimura, 2017; Stortecky et al., 2012). In particular, some studies have reported that 44%-53% of patients were malnourished prior to TAVR, which increased the risk of mortality, major adverse cardiovascular and cerebral events, and decline in physical ability (Schoenenberger et al., 2013; Stortecky et al., 2012).

Nutritional status affects not only treatment outcomes but also a healthy aging process. Nevertheless, few studies have focused on changes in nutritional status during the recovery period post-TAVR. Furthermore, although early intervention for patients at risk of malnutrition post-TAVR is essential in the limited window of the perioperative period, preoperative factors affecting post-TAVR nutritional status have not been well studied.

The effects of cardiac rehabilitation including nutrition and exercise therapy post-TAVR have been elucidated (Eichler et al., 2017; Zanettini et al., 2014). In Japan, there are far fewer outpatient cardiac rehabilitation facilities than in Western countries (Goto, 2014), and many post-TAVR patients do not receive therapy under the direction of professionals after discharge. Although lifestyle counseling, including dietary and exercise guidance, are provided during the perioperative period, evaluation of nutritional and activity status and further support are required for this high-risk population. Previous studies of post-TAVR patients after discharge have shown that they slowly recovered from weakness and got back to living their lives with hope for the future (Astin et al., 2017; Olsson, Näslund, Nilsson, & Hörnsten, 2018). However, the focus of previous studies was not on the change in patients' dietary habits or physical activities after treatment and counseling, their thoughts on the treatment effects and health management, or problems affecting their health care. A better understanding of patients' experiences along with exploring changes in diet and physical activity status and pre-TAVR factors affecting post-TAVR malnutrition may have the potential to improve support strategies in post-TAVR patients.

Therefore, we aimed to explore changes in the nutrition and activity status of elderly patients within 6 months post-TAVR,

as well as factors affecting postoperative malnutrition in this cohort. We also described their diet and activity levels as well as integrated and interpreted the results using a mixed methods approach.

# 2 | METHODS

We adopted a convergence model with a triangulated mixed methods approach to gain in-depth comprehension of nutritional and activity status and lifestyle in post-TAVR participants. This methodology allowed us to compare, corroborate, or relate quantitative data (from questionnaires pertaining to nutrition and activity) and qualitative data (from lifestyle-related interviews) (Creswell & Plano Clark, 2007). Quantitative and qualitative data were collected concurrently and analyzed separately, followed by an integrated interpretation of the results.

# 2.1 | Participants and study setting

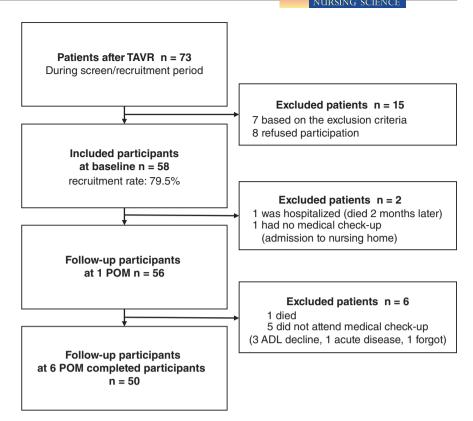
This study was undertaken in a cardiovascular ward and an outpatient clinic of a university hospital in Japan. Patients aged ≥70 years, without diagnosed cognitive dysfunction, and undergoing TAVR between February and July 2017 were consecutively recruited. Patients diagnosed with advanced cancers before TAVR and/or who were diagnosed with swallowing dysfunction and could not consume a meal by mouth in hospital were excluded, due to the suspected significant influence of such conditions on nutritional status or dietary management. A flow chart illustrates the recruitment of participants (Figure 1).

# 2.2 | Definition of terms

Heart-healthy diet/lifestyle

We defined "heart-healthy diet/lifestyle" as the lifestyle, including diet and physical activities, counseled by health professionals and based on the guidelines for heart failure management in elderly people (The Japanese Circulation Society, 2010). We considered that the recommendations provided during the counseling before and after TAVR could be reflected in participants' lifestyle or views post-TAVR, and needed to be clarified in our qualitative research. In the interview, we ascertained how the recommendations had influenced their lifestyle post-TAVR. The goals and methods of diet and exercise therapy in elderly people differ among individuals, depending on their comorbidities or physical abilities. Regarding the specifics of the recommended lifestyle, because >50% of the participants in this study had hypertension or kidney disease, most participants were given pre- and post-TAVR dietary recommendations to avoid high salt or excessive water intake in order to prevent heart failure. Daily moderate exercise and

**FIGURE 1** Flow chart of the participants' recruitment. ADL, activities of daily living; TAVR, transcatheter aortic valve replacement; POM, postoperative months



maintaining a well-balanced diet including various nutrients were also recommended.

# 2.3 | Data collection and procedure

The data were collected through medical records review, questionnaires, and interviews. We approached the candidates during their hospitalization, through an introduction by the cardiovascular ward's manager who had been informed of the patient recruitment criteria. We collected medical record data pre-TAVR (baseline). Questionnaires, including nutritional and activity status assessment tools, were administered at baseline during hospitalization, at 1 month postoperatively (1 POM) as an early time-point, and at 6 months postoperatively (6 POM) as an intermediate time-point (Kappetein *et al.*, 2012). Interviews were conducted at two time-points (1 POM and 6 POM) to assess changes over time. Data were collected during the waiting time for routine medical checkups to minimize the burden imposed on elderly participants post-TAVR.

# 2.4 | Measurements

#### **2.4.1** | Nutrition

Nutritional status was evaluated by the Mini Nutritional Assessment<sup>®</sup> (MNA) tool and by serum albumin (Alb) values. The MNA was developed and validated as a nutritional screening and assessment tool for people aged ≥65 years, and includes 18 items such as appetite, weight

loss, mobility, dietary intake, mid-arm and calf circumferences (Guigoz, Vellas, & Garry, 1996). The maximum possible total score is 30 points. Total scores of <17, 17.5–23.5, and ≥24 points indicate malnutrition, malnutrition risk, and normal nutritional status, respectively (Vellas *et al.*, 2006). We used height and weight to calculate body mass index (BMI) for assessing one item in the MNA. Alb values were followed up from clinical records at all time-points.

# 2.4.2 | Activity level

The Physical Component Summary (PCS) scores calculated from the 36-item Short Form Health Survey version 2 (SF-36v2<sup>®</sup>) (Fukuhara & Suzukamo, 2004) were used to evaluate activity levels. The reliability and validity of the SF-36 has been extensively confirmed in various countries. The PCS score comprises subscales that provide information on physical function, vitality, and the influence of any physical limitations on activity levels to summarize one's physical condition. It is standardized to reflect a general population mean of 50 and a standard deviation (SD) of 10, with higher scores meaning better physical health.

### 2.4.3 | Clinical data as related factors

The following pre-TAVR data were collected from medical records as factors related to nutritional and activity status (Hickson, 2006; Wernio *et al.*, 2018): demographic data (age and sex), family background, comorbidities, service

(elderly daycare services and meal delivery services) use, oral status (denture use and teeth extraction pre-TAVR for infective endocarditis prevention).

Since malnutrition is associated with poor outcomes (Barr & Schumacher, 2003), and malnutrition might consequently relate to decreased QOL or mortality because of frailty syndrome, we also collected the following data on known predictors of poor outcomes in QOL and mortality post-TAVR (Arnold et al., 2014; Carreras et al., 2018; Hermiller, 2016; Kataoka, 2018; Puls et al., 2014; Reynolds, 2011; Schoenenberger et al., 2013; Shimura, 2017; Tribouilloy et al., 2015): disease information (classification of the New York Heart Association; left ventricular ejection fraction, %; mean pressure gradient [mean PG]:  $\leq$ 40.0 mm Hg, severe; aortic valve area [AVA]:  $\leq$ 1.0 cm<sup>2</sup>, severe; peak flow velocity [V<sub>max</sub>]: ≤4.0 m/s, severe), diagnosed LF-LG AS (Hachicha, Dumesnil, Bogaty, & Pibarot, 2007), mortality risk score using the Society of Thoracic Surgeons score (high risk:  $\leq 10\%$ ), physical function status (5-m gait speed, sec/5 m), basic activities of daily living (ADL) and the Katz Index of Independence in ADL (Shelkey & Wallace, 2000). frailty status (Clinical Frailty Scale [CFS]; frailty: >5) (Rockwood et al., 2005), and cognitive functional status (Mini-Mental State Examination [MMSE]; normal, ≥24) (Mitchell, 2009). These assessment tools have widely confirmed reliability and validity. These data had been recorded by an attending doctor pre-TAVR, and were collected from the medical records. Baseline laboratory data of Alb, total protein, creatinine, and hemoglobin, height, and weight were also collected and used.

#### 2.4.4 | Interviews

The first author conducted semi-structured interviews following the question topic guide (Table 1) and recorded the responses with the participants' consent. The details of dietary

and activity habits before and after TAVR were gathered via open questions; participants were allowed to speak freely, and further questions were asked according to the flow of their narration. To enhance data analysis reliability, accuracy of our interpretation of the participants' narration was confirmed through re-interviews, as required.

# 2.5 | Data analysis

# 2.5.1 | Quantitative data

Clinical record data, including participant characteristics at baseline, were summarized using mean  $\pm$  SD for continuous data, and frequency and percentage for categorical data.

Changes in all participants' MNA and PCS scores and Alb levels were analyzed using one-way repeated measures analysis of variance (ANOVA). Moreover, we divided all participants into two groups based on the MNA classification at baseline: a baseline-malnourished group (score ≤17) and a baseline-acceptable group (i.e., an acceptable nutritional status; score >17). To identify changes in MNA and PCS scores and Alb levels in both groups, these values were compared between groups at three given time-points, using two-way repeated measures ANOVA. For multiple comparisons, the Bonferroni correction was used.

To explore factors causing deterioration in nutritional status, we divided participants into two groups based on the MNA results at 6 months: 6 POM-malnourished group (score  $\leq$ 17) and 6 POM-acceptable group (score >17), using the 6 POM-acceptable group as the reference group. Independent t test and Chi-squared tests were conducted to compare between the two groups. Baseline predictors of malnutrition post-TAVR were selected by considering previous studies, a correlation between independent variables, the sample size,

TABLE 1 The interview outline

Interview question headings		
Current symptoms and recovery status	Have you had any symptoms recently?	
	What do you think about your condition following the TAVR?	
Experiences of daily life post-TAVR	Has anything in your daily life changed since hospital discharge / your previous medical check?	
	Has your daily life changed (or not changed)?	
Self-management	Please tell me about your heart health management.	
Adjusting to diet and activities	How is your appetite / what is your way of preparing a meal / do you have a change of intake?	
	Please tell me your thoughts on daily diet / physical activity.	
	Please tell me if you usually perform some physical activity.	
	Please tell me about the kind of physical activity you undertake, the frequency, your walking distance (if you walk), and the type of strength training machine you use, for example.	
Feelings with regard to the disease,	What do you think about the disease / the treatment?	
treatment, and daily life	How do you want to spend your daily life?	

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and referring to *P*-values <.2 in bivariate analysis (Altman, 1991; Kanda, 2015). The following independent variables were included in multivariate logistic regression analysis: sex, meal delivery service, MMSE score, Alb, CFS score, and

diagnosed LF-LG AS.

Stepwise forward selection was used to adapt the predictive variables automatically. SPSS version 25.0 (IBM Corp., Armonk, NY, USA) was used for all data analyses. The sig-

nificance level for all statistical tests was set at P < .05.

# 2.5.2 | Qualitative data

A qualitative inductive content analysis method was used to gain insight into what affected participants' diet and activity during the recovery process (Elo & Kyngäs, 2008; Schreier, 2012). The first and fourth authors conducted the analysis collaboratively; the first author transcribed all the interview data at 1 POM and 6 POM verbatim, confirmed the content, and coded it openly (i.e., all sentences considered relevant to diet and activity were headlined and coded once). The data were re-coded after 6 months; the percentage of agreement in the double-coding was calculated to assess the reliability (Schreier, 2012). Codes with similar concepts were grouped into subcategories and further integrated into categories, and finally summarized into themes. The fourth author read all transcripts and supervised and checked the coding and categorizing processes. Discussions occurred until a final agreement was reached. We used concise and clear descriptions for transferability; all stages of the research process were recorded for auditing.

# 2.6 | Ethics approval

The ethics committees of Tokyo Medical and Dental University (no. M2016-165) and Keio University School of Medicine (no. 2016-0331) approved this study. We obtained written informed consent after providing participants with a written and an oral explanation of the study objectives, assurance of voluntary participation, and guarantee of anonymity.

# 3 | RESULTS

During the registration period, 58 participants were included at baseline. Finally, the study population comprised 50 participants (Figure 1).

# 3.1 | Medical record data and questionnaires

Table 2 shows baseline characteristics. The mean age was 83 years and 58.0% of participants were female. Hypertension occurred in 74% of all participants, and the average Alb level

was near the low end of the normal range. There were nine (18%) patients with malnutrition at 6 months post-TAVR.

Table 3 shows the changes in participants' MNA and PCS scores and Alb levels within 6 months post-TAVR at each time-point. There were no significant differences in these three indicators between time-points. Next, for changes in MNA and PCS scores and Alb levels in the two groups based on the MNA classification at baseline, Table 4 shows the results of each main effect of the group or time factor and two-factor interaction. Changes in MNA scores revealed a statistical significance in the main effect of the group and time factor, and also two-factor interaction. Due to the observed statistical significance in the interaction, a simple effects test of the group factor at each level of the time factor was conducted. Significant simple effects were observed at all levels (baseline: F [1, 48] = 55.6, P = .00; 1 POM: F [1, 48] = 8.87, P = .005; 6 POMs: F [1, 48] = 5.94,P = .019). A simple effects test of the time factor at each level of the group factor was conducted. Significant simple effects were shown at the level of the baselinemalnourished group (F [2, 96] = 5.41, P = .006). Through Bonferroni correction, MNA scores in the baselinemalnourished group at 1 POM were higher than at baseline. MNA scores at all time-points in the baseline-malnourished group were lower than those of the baseline-acceptable group, whereas changes in PCS scores and Alb levels of both groups did not have statistical significance. PCS scores in the baseline-malnourished group seemed to decrease at 6 months post-TAVR less than at baseline. A decline in the scores at 6 months to less than the baseline scores was found in 20 participants.

Baseline data of individuals in the 6 POM-malnourished and 6 POM-acceptable groups are also shown in Table 2. There were significant differences between the two groups in terms of meal delivery service use, CFS scores, indicators of severe AS, including peak flow velocity ( $V_{max}$ ), mean PG, and AVA; and LF-LG AS diagnosis. Table 5 shows the results for the factors associated with malnutrition assessed using the MNA 6 months post-TAVR. The presence of LF-LG AS, lower MMSE scores, and higher CFS scores were associated with malnutrition.

# 3.2 | Interview results and further relevant data

The total interview time amounted to 1668.4 min (average 17.2 min per interview session). The double-coding concordance rate was 85.1%. All codes were summarized into three themes, namely, balancing heart-healthy lifestyle and longstanding habits, living with aging and disease, and prospects for the rest of life, and were composed of 26 categories (Table 6).

**TABLE 2** Baseline characteristics and acceptable nutritional status group versus malnutrition group results, assessed using MNA scores 6 months post-TAVR

	All participants $(N = 50)$	Acceptable group (n = 41)	Malnutrition group (n = 9)	P value
Age, year	$83.6 \pm 5.5$	$83.8 \pm 5.5$	$82.9 \pm 5.7$	.657
Female, n (%)	29 (58.0)	22 (53.7)	7 (77.8)	.171
Living alone, n (%)	13 (26.0)	12 (29.3)	1 (11.1)	.25
Meal delivery services, n (%)	7(14.0)	3 (7.3)	4 (44.4)	.015*
Tooth extraction for TAVR treatment, n (%)	11 (22.0)	8 (19.5)	3 (33.3)	.308
Hypertension, n (%)	37 (74.0)	32 (78.0)	5 (55.6)	.164
Hypercholesterolemia, n (%)	28 (56.0)	21 (51.2)	7 (77.8)	.139
Diabetes, n (%)	15 (30.0)	13 (31.7)	2 (22.2)	.451
Coronary artery disease, n (%)	13 (26.0)	9 (22.0)	4 (44.4)	.164
Chronic kidney disease, n (%)	19 (38.0)	17 (41.5)	2 (22.2)	.247
Chronic pulmonary disease, n (%)	15(30.0)	11(26.8)	4 (44.4)	.254
NYHA III or IV, n (%)	23(46.0)	19 (46.3)	4 (44.4)	.606
Diagnosed LF-LG AS, n (%)	4 (8.0)	1 (2.4)	3 (33.3)	.016*
Vmax, m/s	$4.54 \pm 0.81$	$4.7 \pm 0.7$	$3.9 \pm 0.8$	.004*
Aortic valve area, cm <sup>2</sup>	$0.62 \pm 0.2$	$0.60 \pm 0.21$	$0.72 \pm 0.10$	.018*
Mean PG, mm Hg	$50.3 \pm 19.5$	$53.2 \pm 19.0$	$36.9 \pm 16.1$	.021*
Left ventricular ejection fraction, %	$61.8 \pm 11.4$	$61.7 \pm 10.7$	$62.2 \pm 12.7$	.905
Society of Thoracic Surgery score, %	$7.2 \pm 4.6$	$7.4 \pm 4.9$	$6.4 \pm 3.0$	.505
5 m gait speed, sec,	$7.2 \pm 2.5$	$7.1 \pm 2.7$	$7.2 \pm 2.0$	.959
MMSE, score	$26.7 \pm 3.2$	$27. \pm 2.5$	$24.4 \pm 5.0$	.14
Clinical frailty scale, score	$3.94 \pm 1.1$	$3.7 \pm 0.1$	$4.9 \pm 1.4$	.004*
Katz index, score	$5.88 \pm 0.6$	$6.0 \pm 0.2$	$5.4 \pm 1.3$	.267
Body mass index, kg/m,	$21.7 \pm 3.4$	$21.9 \pm 3.2$	$20.6 \pm 3.7$	.291
Total protein, g/dL	$6.7 \pm 0.6$	$6.7 \pm 0.5$	$6.6 \pm 0.8$	.8
Serum albumin, g/dL	$3.7 \pm 0.4$	$3.7 \pm 0.4$	$3.5 \pm 0.4$	.147
Hemoglobin, g/dL	$11.2 \pm 1.3$	11.2 ± 1.2	11.2 ± 1.9	.903
Creatinine, mg/dL	$2.1 \pm 2.7$	$2.2 \pm 2.7$	$1.7 \pm 2.3$	.629

*Note*: Values are mean  $\pm$  SD or n (%).

Abbreviations: Acceptable group, acceptable nutritional status group; Katz index, Katz index of independence in activities of daily living; LF-LG AS, low-flow low-gradient aortic stenosis; Mean PG, mean pressure gradient aortic valve; MMSE, Mini-Mental Status Examination score; NYHA, New York Heart Association; MNA, Mini Nutritional Assessment; TAVR, transcatheter aortic valve replacement; Vmax, peak aortic jet velocity.

Note: Compared between two groups by using t test for continuous variables and Chi-square test for categorical variables. \*P value <.05.

	Baseline	1 POM	6 POM		
Variable	Mean $\pm$ SD			F value (DF)	P value
MNA score	$21.7 \pm 3.26$	$22.6 \pm 3.15$	$22.6 \pm 4.18$	2.35 (2, 86.6)	.108
PCS score	$28.1 \pm 16.12$	$30.3 \pm 16.74$	$27.8 \pm 15.87$	1.11 (2, 98)	.333
Alb levels	$3.65 \pm 0.39$	$3.74 \pm 0.33$	$3.75 \pm 0.37$	2.49 (2,82.8)	.231

**TABLE 3** Changes in MNA and PCS scores and Alb levels in all participants within 6 months post-TAVR using repeated analysis of variance measures

*Note*: N= 50.

Abbreviations: Alb, serum albumin; DF, degree of freedom; MNA, Mini Nutritional Assessment; PCS, Physical Component Summary; TAVR, transcatheter aortic valve replacement; 1 POM, 1 month postoperatively; 6 POM, 6 months postoperatively.

TABLE 4 Changes in the nutritional and physical activity statuses between two groups based on the MNA classification using two-way analysis of variance measures

	Baseline-malnourished group (n = 8)	Baseline-acceptable group (n = 42)	Group effect	Time effect	Group × time interaction effect
Variable	Mean ± SD		F value (DF) P value	F value (DF) P value	F value (DF) P value
MNA score			22.5 (1, 48)	5.8 (1.7,82.5)	3.5 (1.7,82.5)
Baseline	$16.3 \pm 0.6$	$22.7 \pm 2.4$	<.001**	.006**	.04*
1 POM	$19.8 \pm 2.6$	$23.1 \pm 3.0$			
6 POM	$19.4 \pm 3.2$	$23.2 \pm 4.1$			
PCS score			.84 (1, 48)	1.60 (2,94)	1.11 (2, 94)
Baseline	$26.2 \pm 13.6$	$28.4 \pm 16.7$	.37	.21	.33
1 POM	$27.3 \pm 6.6$	$30.9 \pm 18.0$			
6 POM	$19.9 \pm 9.8$	$29.3 \pm 16.4$			
Alb levels (g/o	dL)		1.75 (1, 48)	1.98 (1.6, 78.6)	1.12 (1.6, 78.6)
Baseline	$3.51 \pm 0.41$	$3.68 \pm 0.39$	.19	.15	.32
1 POM	$3.70 \pm 0.33$	$3.75 \pm 0.33$			
6 POM	$3.54 \pm 0.42$	$3.78 \pm 0.35$			

*Note*: N = 50.

Abbreviations: Alb, serum albumin; Baseline-acceptable group, baseline-acceptable nutritional status group; DF, degree of freedom; MNA, Mini Nutritional Assessment; PCS, Physical Component Summary; TAVR, transcatheter aortic valve replacement; 1 POM, 1 month postoperatively; 6 POM, 6 months postoperatively. \*P value <.05.

**TABLE 5** Factors relating to the development of malnutrition 6 months post-TAVR using multivariate analysis

Dependent variable: Independent	Malnour by using	ed	
variables	OR	CI 95%	P value
Diagnosed LF-LG AS	166.39	5.43-5,094.43	.003
MMSE	0.65	0.43-0.99	.048
CFS	2.58	1.01-6.54	.047

Abbreviations: CFS, clinical frailty scale, continuous value; CI, confidence interval; LF-LG AS, low-flow low-gradient aortic stenosis, discrete value; MMSE, Mini-Mental Status Examination, continuous value; MNA, Mini Nutritional Assessment; OR, odds ratio; TAVR, transcatheter aortic valve replacement.

*Note*: MMSE and CFS were used as continuous variables in this analysis model. Stepwise forward selection was the adopted probability for entry  $\leq$ .05 and probability for removal  $\geq$ .10. The Hosmer-Lemeshow test showed a P value = .747.

# 3.2.1 | Balancing heart-healthy lifestyle and longstanding habits

Some participants willingly adopted the heart-healthy diet independently or with support from family or meal delivery services. They enjoyed eating and noticed that their appetites had increased slightly over the 6-month period. Several participants were unhappy about a heart-healthy diet, but made

efforts to maintain it, whereas some gradually paid less attention to following the recommended heart-healthy diet and continued to eat what they liked. A few became aware of their malnourished condition and put more priority into maintaining food consumption rather than following a heart-healthy diet.

Some refrained from participating in intense physical activities until the medical checkup at 1 month due to recovery concerns post-TAVR. However, to improve their muscle weakness, physical activities were started, leading to an increase in the number of participants attending rehabilitation facilities before 6 months. Several participants were not interested in performing physical activities, retained the same lifestyle as previously, and reported being satisfied with pursuing a leisurely life with fewer physical pursuits.

# 3.2.2 | Living with aging and disease

Although many participants had improvements in their conditions post-TAVR with few particular problems in their eating patterns and maintained or increased their appetite and intake, some participants, including those who ate little, did not improve. A decreased sense of taste, a decrease in salt intake, or a gradual decline in intake associated with aging, contributed to a decrease in appetite in some participants. Teeth extraction pre-TAVR, undertaken to prevent infective endocarditis, contributed to chewing problems in some who

<sup>\*\*</sup>P value <.01.

**TABLE 6** Themes and sample quotes

Themes	Categories	Sample quotes
Balancing heart-healthy lifestyle and longstanding habits	Maintaining heart-healthy diet	I usually season a meal recalling low-salt hospital food. (ID27, 1 POM)
	Struggling to manage a low-salt diet	The low-salt meal from home delivery was not tasty. So, I changed the company and the content containing 3.5 g salt. (ID18, 6 POM)
	Enjoying being able to eat independently	Eating is enjoyable when reaching my age. Being able to eat shows that my health is in good condition, and I have gained 2 kg. (ID28, 6 POM)
	Putting more priority on intake than on a heart-healthy diet	I'll lose my appetite more if all side dishes tasted too plain. So, for keeping up my intake, now I do not care much about low-salt and I sometimes eat somewhat salty foods. (ID31, 6 POM)
	Paying less attention to consuming a heart-healthy diet	I often eat cook-chill foods. I do not feel like making meals only for me and my husband. But you know, those meals taste a bit salty. (ID13, 6 POM)
	Unwilling to change dietary habits	I tried not to eat salty foods too much, but then, I often felt I wanted to eat some salty foods like rice crackers. So now, I eat what I like and actually I'm getting fat. (ID42, 6 POM)
	Confirming health conditions through checking weight and blood pressure regularly	I am worried that some problems might happen in the heart after surgery. So, I regularly check blood pressure and weight. (ID44, 6 POM)
	Refraining from intense activities	I have not resumed walking or exercise yet in earnest. Today I'll confirm with the doctor whether my recovery allows me to do them or not. (ID58, 6 POM)
	Striving to maintain muscle strength	There are many slopes and steps around my home. I make it a habit to take a walk. (ID6, 1 POM)
	Performing housework or work	I am living alone, so preparing a meal, cleaning up rooms and the bathroom, also farm work, are tasks I do myself. I am active. (ID34, 1 POM)
	Spending my time leisurely	Normally, watching the TV, reading newspapers, taking a nap I spend my time leisurely. (ID49, 6 POM)
	Hesitating to perform physical activities	Well, I know I had better do some exercise, but my feet aren't in great condition. I think I do not need to force myself to do that. (ID10 at 6 POM)
Living with aging and disease	Various risks of loss of intake or weight due to aging	Hmm meal Of course, I try to eat as possible But the amount has a limit, and it's decreasing gradually, because I'm old enough. (ID17, 6 POM)
	Loss of appetite and intake due to a low-salt diet	I became sensitive to eating. I was anxious whether I was taking too much salt or not. (ID30, 1 POM)
	Chewing problems due to teeth extraction pre-treatment	I cannot eat all solid foods because my teeth were extracted 4 weeks ago. Since then, I consume only water and liquid food. (ID53, 1 POM)
	Improvement in cardiac symptoms	My body without those symptoms allows me to move. (ID12, 6 POM)
	Ongoing cardiac symptoms	You see, breathing difficulty and palpitation have still not gotten betterWhen I just walk a little, I breathe with difficulty, so I need to move with frequent rests. I cannot do anything without resting. (ID56, 1 POM)
	Poor feeling of improvement in cardiac symptoms	I no longer go upstairs or hardly walk outside. I have been leading such an inactive life from before surgery. So, I have no feeling of improvement in my heart disease symptoms. (ID5, 1 POM)
	Presence of comorbidities or aging	Sometimes I take a walk, because I am afraid of becoming unable to walk, but just 500–600 steps. I could do more if my backache was better. (ID50, 6 POM)
	Cognitive decline and lack of social support	During summer, I sweat very much during work. I heard that losing salt with sweat makes heatstroke worse. So, I ate salty food and drank about 2 L of water after work. I've already got the treatment. I thought a strict diet was not necessary. (ID11, 6 POM)
	Decreased muscle strength and weakness	Through several admissions to the hospital for my heart, my muscle strength has weakened. It's awful to realize this. (ID6, 1 POM)
	Disappointed as recovery was slower than expected	Like "An old car with a new motor in"my body does not run as I expected, though the symptoms disappeared. (ID39, 6 POM)

TABLE 6 (Continued)

Themes	Categories	Sample quotes
Prospects for the rest of life	Trade-off between benefit from treatment and efforts to maintain health	Fortunately, I could have the operation though I also have dialysis. At least I should try to keep my health. It is like a "trade-off". (ID8, 1 POM)
	Motivated to live through interaction with people	Going to karaoke with friends or joining a lunch meeting for elderly people it seems that I can get energy by interacting with someone. (ID52, 6 POM)
	Wishing to "live as I like in the remaining days of my life"	Since I've recovered from heart disease and I can really take care of my health, I want to do everything. (ID4, 1 POM)
	Wishing to continue independent living	Being able to walk and go to the bathroom by myself I never want to lose these abilities, because I am living alone. (ID56, 6 POMs)

Abbreviations: ID, identification; 1 POM, 1 month postoperatively; 6 POM, 6 months postoperatively.

already had buccal issues and challenges with eating, leading to reductions in intake throughout the 6-month post-TAVR period. These factors were observed in seven of nine participants in the 6 POM-malnourished group. Furthermore, these were also found in six of eight participants in the baseline-malnourished group, involving BMI <19 kg/m<sup>2</sup> from pre-TAVR to 6 POM.

Participants who experienced improvements in cardiac symptoms reported feeling more mobile. While this positively influenced maintenance of healthy diets and physical activity levels, it led to excessive food, salt, or fluid intake and excessive physical activity among some participants. Misunderstandings due to hearing impairment or declining memory, and the lack of social support discouraged them from maintaining the recommended lifestyle and their health. Participants experienced impaired muscle strength post-TAVR due to activity restrictions to decrease the pre-interventional cardiac burden pre-TAVR. While this influenced their motivation to maintain healthy diets and physical activity levels or to change their inactive lifestyle, a limited feeling of improvement in their symptoms due to the restriction and a continuously inactive life led to impaired physical activity and motivation levels. Factors limiting physical activity during the recovery period also included ongoing cardiac symptoms, falls, fractures, injury, and an increase in pain that may itself be affected by deterioration in physical activity and comorbidities. These restricting complications occurred in 14 of 20 participants whose PCS scores were lower at 6 POM than at baseline. Participants who had undergone TAVR to address their health problems but whose actual conditions did not improve drastically raised concerns about their future. Some of them tried to reconcile their expectations with their actual condition; however, their motivation levels did not increase.

# 3.2.3 | Prospects for the rest of life

Some participants maintaining a heart-healthy lifestyle were careful about their lifestyle as a trade-off to experiencing treatment benefits, because they either were taking care of their families or they lived alone and felt the need to protect their livelihood. These participants proactively managed their health using available social resources. Their desire to maintain an independent life boosted their motivation to follow a heart-healthy lifestyle, but the desire to live the rest of their life to their liking occasionally prevented some participants from adopting the recommended lifestyle.

# 4 | DISCUSSION

We explored changes in nutrition and activity levels in elderly participants within 6 months after TAVR and the factors affecting malnutrition, as well as their views about lifestyle. Some cross-sectional quantitative studies have evaluated pre-TAVR nutritional status using the MNA tool to show the association between frailty in patients before TAVR and outcomes after treatment. However, to our knowledge, no reports have prospectively described the changes in nutritional or activity status or have explored the factors affecting malnutrition post-TAVR together with participants' experiences. Our study adds a qualitative dimension to the evidence regarding elderly post-TAVR patients.

The participants in the baseline-acceptable group maintained their nutritional status. Integrating the results of the interview, we found that most participants had remarkably few problems in relation to eating or their nutritional status pre- and post-TAVR, and had adopted a heart-healthy diet. This finding, that many elderly participants reassessed their dietary habits post-TAVR, was welcome and underlines the importance of lifestyle guidance. Our results also demonstrate that while MNA scores in the baseline-malnourished group showed improvement post-TAVR, the scores in this group did not reach normal nutritional status within 6 months post-TAVR. Based on our interviews, these scores could indicate that many participants in this group could be at a risk of malnutrition in the future due to ongoing factors affecting their appetite and intake, and the improvement in MNA scores might not be sustained or advanced. While the

fact that many participants were maintaining adequate nutritional status could support the value of providing TAVR for elderly AS patients, the current brief nutritional interventions pre- and post-TAVR may not be sufficient to ensure an appropriate diet for patients with nutritional problems. A systematic review has found that elderly patients with heart failure should not have their sodium intake severely restricted, because that can cause loss of appetite and reduced intake (Abshire et al., 2015). Some participants in our study tried to adhere to a lowsalt diet, as recommended in the lifestyle guidance, and consequently struggled with these problems. Moreover, we showed that the participants' lifestyles were affected by "prospects for the rest of life." Previous qualitative studies have also emphasized the importance of patients having hope for their lives post-TAVR (Astin et al., 2017; Olsson et al., 2018). We suggest that lifestyle counseling for elderly patients post-TAVR should be developed further to include assessing their comorbidities and their nutritional status, and discovering each patient's goals for a healthy life. Nurses with good understanding of a patient's disease, general condition, treatment, and lifestyle should follow up the evaluations of the individual's nutritional status after TAVR, especially in cases where an unfavorable recovery process is predicted, and coordinate with home doctors, dietitians, physical therapists, homevisiting nurses or care workers, and dentists.

One previous study showed improvements in patients' physical health status and QOL post-TAVR (Reynolds, 2011). In our study, the PCS scores did not change significantly within 6 months for all the nutritional status groups, whereas the scores in the baseline-malnourished group appeared to be lower at 6 months post-TAVR than at baseline. Interpreting this result through interviews, we found that acute events, such as falls and fractures that directly affect physical function, could have caused the decline in PCS scores through impairing patient activity and motivation levels. This is known as a cycle of frailty, where the occurrence of such events induces sarcopenia, subsequently causing a decline in strength and activity, and leading to malnutrition with further worsening sarcopenia (Xue, Bandeen-Roche, Varadhan, Zhou, & Fried, 2008). Considering the situations in such elderly participants, we suspect that, in the future, the nutritional and activity statuses of these participants could be affected because of the mechanism of frailty. Moreover, we consider that elderly patients undergoing TAVR who have complicated medical backgrounds or reduced physiological reserves associated with aging and disease could be categorized as being unable to perform physical activity independently, even following definitive cardiac treatment. Although the effects of resistance exercise and aerobic exercise in elderly chronic heart failure or frail patients are well known, there is limited information on exercise safety for these patients (Abete et al., 2013). Safe exercise therapy at home is essential. Further expansion of cardiac rehabilitation for patients post-TAVR is required to improve QOL and physical ability (Eichler *et al.*, 2017; Zanettini *et al.*, 2014). In addition, nurses should also instruct patients to pay sufficient attention to prevent accidents that affect physical function, such as falls.

We suggest some probable factors affecting malnutrition 6 months post-TAVR. LF-LG AS, known as a state of progressed severe AS, is associated with higher mortality post-TAVR (Carreras et al., 2018; Kataoka, 2018; Tribouilloy et al., 2015). The results of this study may not be robust considering the OR estimates and the CIs because of the small sample size and the low prevalence rate. However, the results show the possibility of a positive association with malnutrition post-TAVR, and appear to support previous studies that have shown poor LF-LG AS outcomes. Frailty is known to be associated with higher 1-year mortality in patients post-TAVR (Shimura, 2017). The CFS is a simple frailty assessment tool, but it does not include an evaluation of nutritional status (Rockwood et al., 2005). We suggest an association between this scale and malnutrition in post-TAVR participants based on MNA results. Regarding MMSE, MNA includes a question item regarding cognitive status; therefore, our results may be self-evident. However, previous findings regarding the association between malnutrition and cognitive function decline in elderly people could be supported by our results (Ogawa, 2014). Also, our interviews showed that a lack of knowledge regarding the hearthealthy diet affected participants' lifestyle and health, so we believe that this could also be associated with malnutrition. Although the analysis of factors associated with malnutrition post-TAVR did not indicate the influence of teeth extraction pre-TAVR, on the basis of the interview results, we cannot ignore the possibility that teeth extraction contributed to decline in dietary intake throughout the 6-month post-TAVR period. It is important to provide prompt care and continuous support for patients who need to renew their dentures, to prevent decline in appetite and intake in the postoperative period. We believe that noting these probable factors may prompt clinical staff to follow up patients' changes in nutritional status from before treatment more attentively and continuously. Further, for the patients at risk of malnutrition before or/and after TAVR, we suppose that it should be required to evaluate and reconsider of their dietary management from before the treatment, and introduce some social supports or discuss with their carers to ensure appropriate diet after discharge.

# 4.1 | Limitations

This study has some limitations. First, both the sample size and the malnourished group size were small. Additionally,

the study was conducted at one institution. Increasing the number of participants and facilities is required for more generalizable results. Second, the participants in this study were all Japanese, and the experiences narrated in the interviews could have been influenced through lifestyle habits peculiar to Japanese culture or Japanese elderly care systems. However, the results of our study provide new insight into lifestyle changes post-TAVR, and may help in developing future lifestyle guidance. Third, we selected the PCS score on the SF-36 as an indicator of participants' activity status. Although there are alternative scales for the measurement of activity in elderly people (Sabia et al., 2015; Yasunaga et al., 2007), we were concerned that undertaking numerous investigations concurrently may have resulted in an added burden for the participants. Future studies should evaluate patients' activity status from multiple perspectives. Fourth, participants' insights regarding their pre-TAVR lifestyle were given looking back after treatment, because we limited our interviews to the postoperative period. We did this for a similar reason of not wishing to potentially increase their physical and/or mental burden. Finally, we collected clinical data only at baseline, and could not use some data from echocardiography, which was not conducted in all participants. Nonetheless, postoperative clinical data may be associated with post-TAVR malnutrition.

# 4.2 | Implications for practice

Our results suggest the following implications for practice.

- Screen patients at risk for serious nutritional and/or dietary problems after TAVR and regularly evaluate their nutritional status.
- Instruct patients in the necessity of prevention for problems affecting physical functions that can occur post-TAVR, as well as recommending exercise.
- Follow up more attentively the change in nutritional status from before treatment in patients who have the risk factors of LF-LG AS, frailty progression, cognitive function decline, and teeth extraction pre-TAVR.

# 5 | CONCLUSIONS

In summary, approximately 20% of patients had poor nutritional status 6 months post-TAVR. The only significant change was observed in the improved MNA scores of participants who had been assessed as malnourished pre-TAVR; however, these participants did not attain normal nutritional status. The presence of LF-LG AS, frailty progression, and cognitive function decline appear likely to be associated with malnutrition in participants 6 months post-TAVR. Lifestyle factors such as diet and physical activity post-TAVR can be summarized into three

linked themes: "balancing heart-healthy lifestyle and longstanding habits," "living with aging and disease" and "prospects for the rest of life." The complexity and irreversibility of issues associated with aging or diseases and preinterventional malnutrition affect changes in postoperative nutritional and activity status. Nurses should focus on the patients at risk of post-TAVR malnutrition and offer early and continuous support starting pre-TAVR, in collaboration with other medical professionals. Individual differences in nutritional and activity status, comorbidities, treatment effects, and goals for a healthy life also need to be taken into account.

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#### CONFLICT OF INTEREST

Coauthors Drs. H.S. and K.H. are clinical proctors for Edwards Lifesciences. This study has no relevant financial relationships to disclose or any conflicts of interest.

#### **AUTHOR CONTRIBUTIONS**

S.O. contributed to the conception and design of this study, performed all data collections and analyses, and wrote the manuscript; H.S. and K.H. contributed to the conception of this study and coordinated with research facilities or participants; Y.K. mainly contributed to performing the qualitative analysis with S.O.; and M.T. critically reviewed the manuscript and supervised the whole study process. All authors revised the manuscript and approved the final version.

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