ORIGINAL ARTICLE

Elderly aortic stenosis patients' perspectives on treatment goals in transcatheter aortic valvular replacement

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Abstract

Aims   Transcatheter aortic valvular replacement (TAVR) is increasingly being performed for elderly patients with aortic stenosis (AS), and current guidelines acknowledge the importance of shared decision-making in their management. This study aimed to evaluate elderly symptomatic severe AS patients' perspectives on their treatment goals and identify factors that influence their treatment choice.

Methods and Results   We performed a pre-procedural cross-sectional survey using a questionnaire at a single university hospital. The questionnaire included three primary domains: (i) symptom burden, (ii) goals and important factors related to treatment, and (iii) preferred place of residence after treatment. We investigated 98 symptomatic severe AS patients who underwent TAVR (median age 86 years, 26% men). None of the patients died during hospitalization, and most of them (94%) were discharged home. Prior to TAVR, the three most common symptom burdens were poor mobility (52%), shortness of breath (52%), and weakness (44%). The reported preferred treatment goals were symptom burden reduction (78%), independence maintenance (68%), ability to perform a specific activity/hobby (62%), and improvement in prognosis (58%). In total, 54% of the patients rated 'in alignment with my values' as the factor that affected their decision to undergo TAVR. Nearly all patients (95%) stated that they preferred to live at home after TAVR.

Conclusions   Among elderly AS patients with varying symptoms who underwent TAVR, symptom burden reduction was the most cited patient-reported goal. Nearly all the patients preferred to live at home after the procedure. Encouraging patients to define their specific goals may improve the quality of shared decision-making in such settings.

Introduction

Aortic stenosis (AS), the most observed valvular heart disease in developed countries, is associated with a high symptom burden, functional limitations, and high mortality.[1] In the treatment of elderly AS patients, appropriate individualized decision-making is complex due to the multiple treatment options available (i.e. medical therapy, transcatheter aortic valve replacement [TAVR], and surgical aortic valve replacement),[2] as well as the heterogeneity in patients' clinical backgrounds (including multimorbidity, frailty, disability, and impaired cognition) and their treatment preferences.[3] These challenges can potentially be overcome through the use of a patient-centred approach by the heart team. Current international guidelines for AS treatment recommends the employment of shared decision-making (SDM),[1,4,5] the

well-defined process in which medical providers and patients discuss treatment options based on the best available evidence (e.g. risks and benefits) as well as patients' treatment goals/preferences.[6] However, SDM is still not commonly used in the treatment of elderly AS patients,[7] owing to a paternalistic view that places the conventional preference of medical professionals over that of individual patients.[8]

Discussion of treatment goals along with an understanding of a patient's values is paramount for SDM. Elderly heart failure (HF) patients with multi-morbidity may have various treatment-related goals and expectations.[9,10] For instance, although a large proportion of HF patients aged ≥60 years would not trade their years of life for a better quality of life, this preference was reversed with increasing age and functional status reductions.[11] In a large ambulatory HF population, less than half of all patients rated HF as the greatest limitation to their quality of life; this was particularly evident among those with co-morbidities.[12] Owing to the heterogeneity in elderly AS patients' treatment goals, gaining a clear understanding of each patient's treatment goals is integral to the achievement of an improved treatment quality. However, to date, no studies have investigated the treatment goal-related perspectives of elderly AS patients referred for TAVR. Accordingly, this study aimed to evaluate elderly symptomatic severe AS patients' perspectives on their treatment goals and identify the factors that strongly influence their treatment choice.

Methods

Study population

This cross-sectional observational study employed a self-administered questionnaire. We evaluated 98 patients with symptomatic severe AS who underwent TAVR with SAPIEN 3 prosthesis (Edwards Lifesciences, Irvine, California) or Evolut R prosthesis (Medtronic, Minneapolis, Minnesota) from July 2018 to March 2020 at Keio University Hospital, a tertiary university hospital in Tokyo. The inclusion criteria were the presence of symptomatic degenerative AS with a New York Heart Association Class ≥II, a mean gradient >40 mmHg or jet velocity >4.0 m/s, or an aortic valve area <1.0 cm^2 (or an effective orifice area index <0.6 cm^2/m^2). TAVR was performed by members of the multidisciplinary Heart Team of the Heart and Vascular Center. A Heart Team, defined broadly, may include interventional cardiologists, cardiac surgeons, echocardiographers, HF clinicians, anaesthesiologists, and nurses, among other administrative and clinical support staff. To be eligible for this study, patients were required to complete a self-reported questionnaire. Out of 163 patients who were approached to complete our questionnaire survey, 49 refused to participate and/or

had significant cognitive, motor, or sensory disabilities or other conditions that made it difficult for them to complete a self-reported questionnaire. Furthermore, 16 patients who did not respond to the question pertaining to the three primary outcomes (symptom burden, goals and important factors related to treatment, and preferred place of residence after treatment) were also excluded. Finally, 98 patients were included in this analysis. This study protocol was approved by the Keio University School of Medicine Ethics Committee, and informed consent was obtained from all patients.

Clinical variables

Clinical data, including those on age, sex, body mass index, cardiovascular risk factors and co-morbidities, laboratory data, transthoracic echocardiogram, frailty factors (Clinical Frailty Scale and hand grip strength), and cognitive function (Mini-Mental State Examination), were obtained from patients' clinical electronic medical charts. The degree of operative risk was calculated using the Society of Thoracic Surgeons Predictive Risk of Mortality (STS) score. All variables were defined according to the Optimized Transcatheter Valvular Intervention-Transcatheter Aortic Valve Implantation Registry, an ongoing, prospective, multicentre TAVR registry in Japan.[13,14] Procedural complications during TAVR, including myocardial infarction, stroke, acute kidney disease, and bleeding, were evaluated according to Valve Academic Research Consortium-2 criteria.[15]

Procedures

Before the initial evaluation by the Heart Team, at the time of the outpatient clinic visit, our nurse team conducted a patient educational programme using written material for guidance on AS treatment. The investigator (N.N.), a certified nurse specialized in chronic HF and a member of the Heart Team, distributed the questionnaire to all patients and obtained completed questionnaires. This was followed by face-to-face counselling for the facilitation of discussions with the patient and his/her family regarding the processes of care. Patients were provided assistance, if necessary, when filling out the questionnaire.

Questionnaire

The questionnaire included questions across a wide range of variables (*Table S1*), comprising three domains: (i) symptom burden during the last month; (ii) patient-defined treatment goals and factors considered important in the choice of treatment; and (iii) patients' preferred places of residence after treatment.

As there was no validated template, the questions were originally developed through in-depth discussions among investigators, including a board-certified cardiologist (T.K.), a certified nurse specialized in chronic HF nursing (N.N.), and a board-certified psychiatrist (D.F.) who had expertise in SDM. We first generated two major domains: (a) patient-defined treatment goals and factors considered important in the choice of treatment and (b) patients' preferred places of residence after treatment, which was largely based on previous studies and international scientific statements for older patients.[16,17] The items were initially chosen based on existing literature[9,18,19] and investigator (T.K., N.N., and D.F.)-hypothesized patient preferences. To evaluate and validate the preliminary questionnaire, we conducted a pilot study with 39 patients (not included in the final study). On reviewing the responses, we attempted to identify which symptoms affected each patient. Therefore, we adjusted the questionnaire with the addition of questions related to symptom burden. In the 'symptom burden and preferred place of residence after treatment' domain, patients had the option to list an 'other' as an open response item. Open responses were also invited for the 'patient goal of treatment' domain. Responses were reviewed, and no further adjustments to the questionnaire were necessary.

Domain 1, the symptom burden domain, consisted of 14 symptoms, 10 symptoms derived from the literature (shortness of breath, weakness or lack of energy, nausea, vomiting, poor appetite, constipation, sore or dry mouth, drowsiness, poor mobility, other),[20] and four other well-known symptoms of AS or cardiovascular disease (chest pain, syncope, oedema, palpitation). Patients were asked to rate their symptom burden level during the last month on a 5-point Likert scale ('how has each symptom affected you over the past month?'; 1 = *not at all*, 2 = *slightly*, 3 = *moderately*, 4 = *severely*, 5 = *overwhelmingly*). The questions in Domain 2 pertained to four patient-defined goals of treatment ('what do you hope to accomplish by your treatment?'; improved prognosis, symptom reduction, independence maintenance, ability to perform a specific activity/hobby) and four factors considered important in the choice of treatment ('How important are the following items in terms of your treatment?'; lower financial burden, not being a burden to the family, not being a burden to society, in alignment with my values), based on previous literature.[9,18,19,21] Patients were asked to rate these factors using a 7-point Likert-scale (1 = *absolutely disagree*, 2 = *disagree*, 3 = *somewhat disagree*, 4 = *unsure*, 5 = *somewhat agree*, 6 = *agree*, or 7 = *absolutely agree*). For the final domain (Domain 3), patients were asked to state their preference in terms of their place of residence after treatment ('where do you hope to live after the treatment?'). Patients were given the following options to choose from: their own home (independently, or with family); nursing-care facility; hospital; or other.

Statistical analysis

Simple descriptive statistics were used to describe the enrolled patients' characteristics. Normally distributed data are presented as mean ± standard deviations, and non-normally distributed data as medians (interquartile range). Kolmogorov–Smirnov-tests were used to assess the presence of a normal distribution. Categorical variables are expressed as absolute values and percentages. According to the Likert-type response for each item in Domain 1, the enrolled patients were divided into the symptomatic (score of 3 or higher) and less symptomatic (score of 1 or 2) groups. They were also divided into the agreement (score of 6 or 7) and disagreement groups (score of 5 or less), based on the Likert-type response to each item in Domain 2. Owing to the exploratory nature of this study, we did not perform any statistical hypothesis tests. All statistical analyses were performed using SPSS software Version 25 (IBM Corp., Armonk, NY, USA).

Results

Patient characteristics

Table 1 presents the characteristics of the 98 participants. The majority (96.9%) of patients were aged 75 years or older (median age 86 years), and 25.5% of the patients were men. The median pre-procedural left ventricular ejection fraction and STS score were 65 [60–70]% and 4.5 [3.5–6.4]%, respectively. Trans-femoral TAVR was used in all the patients. None of the patients died in the hospital, and most of those who underwent TAVR were discharged home: independently (24.5%), with family (69.4%), or to a nursing care facility (4.1%) (*Figure 1A*).

Patients' symptom burden and perspectives towards treatment

Before TAVR, 52.0% of the patients reported having poor mobility, 52.0% had shortness of breath, and 43.9% had weakness. Less than 30% of the patients reported having chest pain (23.5%), and syncope (7.1%) during the last month (*Figure 2*).

Overall, in 77.6% of the patients, the preferred treatment goal was symptom burden reduction; in 68.4%, it was independence maintenance; in 62.2%, it was the ability to perform a specific activity/hobby; and in 58.2%, it was improvement in prognosis (*Figure 3A*). With regard to factors that affected patients' decision to undergo AS treatment, approximately 54.1% of the patients chose the option 'in alignment with my values', 52.0% chose 'not being a burden to the family', 34.7% chose 'not being a burden to society', and 30.6% chose 'lower financial burden' (*Figure 3B*). Nearly all

Table 1 Patient background and in-hospital clinical outcomes

	Overall *n* = 98
Clinical characteristics	
Age, years	86 [82–89]
Male	25 (25.5%)
BMI, kg/m^2	22.8 [21.0–24.7]
STS-PROM	4.5 [3.5–6.4]
NYHA Class III–IV	24 (24.5%)
Smoker (current/past)	0 (0.0%), 13 (13.3%)
Co-morbidity	
Hypertension	56 (57.1%)
Diabetes mellitus	24 (24.5%)
Dyslipidaemia	40 (40.8%)
Chronic kidney disease	66 (67.3%)
Coronary artery disease	28 (28.6%)
Stroke	5 (5.1%)
Peripheral vascular disease	7 (7.1%)
Chronic obstructive pulmonary disease	4 (4.1%)
Frailty assessment	
MMSE score	28 [25–29]
Clinical frailty scale	3 [3–4]
Gait speed (m/s)	0.8 [0.7–1.0]
Grip strength (kg)	17 [13–21]
Medication	
Calcium channel blocker	49 (50.0%)
ACE-I/ARB	52 (53.1%)
Beta blocker	22 (22.4%)
Statin	51 (52.0%)
Diuretics	42 (42.9%)
Echocardiographic variables	
Left ventricular ejection fraction, %	65 [60–70]
Mean aortic gradient, mmHg	51 [41–66]
Aortic valve area index, cm^2/m^2	0.4 [0.3–0.5]
Stroke volume, mL	64 [48–79]
Laboratory data	
B-type natriuretic peptide, pg/mL	163 [83–288]
Haemoglobin, g/dL	11.4 [10.5–12.5]
eGFR, mL/min/1.73 m^2	48 [36–61]
C-reactive protein, mg/dL	0.06 [0.03–0.16]
In-hospital outcomes	
All cause death	0 (0%)
Peri-procedural myocardial infarction	1 (1.0%)
Stroke	4 (4.1%)
Major bleeding	2 (2.0%)
Acute kidney injury	0 (0%)
Permanent pacemaker implantation	11 (11.2%)

Values are medians [25th to 75th percentiles] or no. (%).
ACE-I, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; BMI, body mass index; eGFR, estimated glomerular filtration rate; MMSE, Mini-Mental State Examination; NYHA, New York Heart Association; STS-PROM, Society of Thoracic Surgery predicted risk of mortality.

the patients (94.9%) stated that they preferred to continue to live at home after treatment (28.6% living alone, 66.3% living with family) (*Figure 1B*). Among 93 patients who preferred to continue to live at home after treatment, 90 (96.8%) were discharged home.
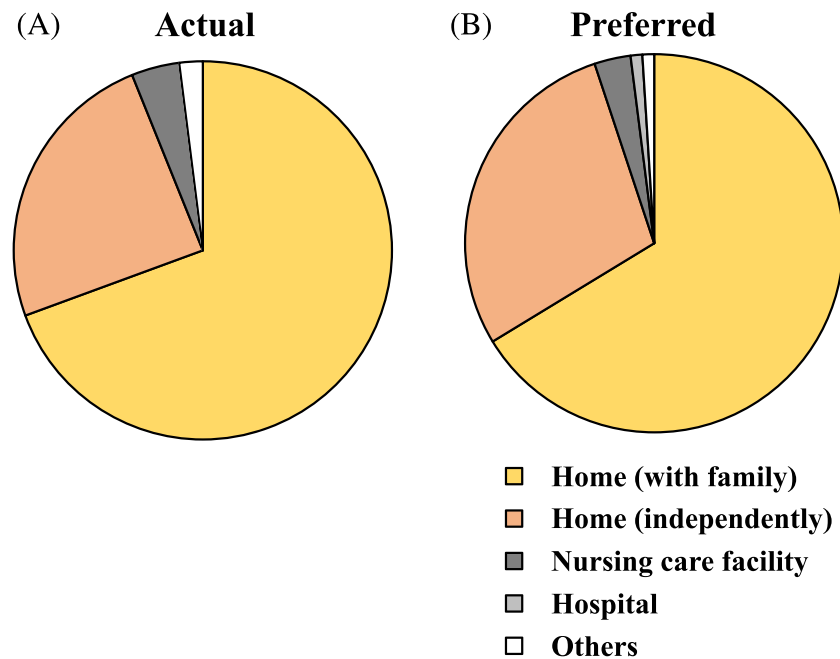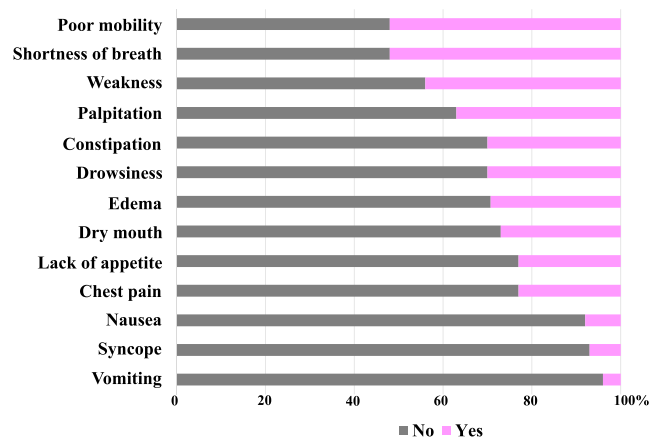
Discussion

In this cross-sectional study, (i) the three most cited symptoms were poor mobility, shortness of breath, and weakness; (ii) the two most important patient-reported goals were symp-

tom burden reduction and independence maintenance, with approximately 50% of the patients reporting that the treatment chosen should be in alignment with their values; and (iii) most of the patients were discharged home after TAVR, the option that was preferred by nearly all the patients.

Although it has been established that gaining an understanding of patient-defined treatment goals is of great importance in the use of TAVR, few studies have examined how patients themselves define their treatment goals. Previous studies focusing on treatment goal setting in other clinical contexts demonstrated the presence of discrepancies between patient- and clinician-defined treatment goals.[22,23] Our findings are consistent with the American Heart Association, American College of Cardiology, and American Geriatrics Society Scientific Statement, which revealed that the key outcomes that are particularly important to elderly patients are patient-centred outcomes (e.g. quality of life, physical function, and maintenance of independence), in addition to conventional clinical outcomes (e.g. mortality and re-admission).[17] It must be taken into account that cardiologists may make inaccurate assumptions about patients' treatment goals, particularly in a medical culture that is focused on a 'disease outcome-based' paradigm.

The concept of 'home-time', defined as the duration in which a patient is alive and out of a healthcare institution, has been investigated in various populations and shown to be a robust and an easily measured patient-centred outcome.[24,25] In our study, nearly all the patients preferred to live at home after TAVR; from a patient's perspective, home-time may be a feasible and objective outcome. Most of the patients in this study cohort were discharged home. Among those with a high frailty score, in addition to the success of TAVR, the reception of support from a multidisciplinary HF team in collaboration with specialist rehabilitation teams and medical social workers, as well as the involvement of family and caregivers, are necessary for the accomplishment of their treatment goals.

The strength of our study is that we evaluated the perspectives of symptomatic severe AS patients referred for TAVR on their treatment goals, which are infrequently assessed in routine clinical care and clinical research. HF patients with multi-morbidity often experience symptom burdens of varying degrees due to cardiac and non-cardiac causes, associated with a decline in their functional status, an increased degree of frailty, and a reduced quality of life.[9,26] We believe that efforts aimed at improving the quality of care provided to patients with several co-morbidities should focus on the placement of patients at the centre of the healthcare value chain; clinicians need to shift their focus from the treatment of individual diseases in insolation to the achievement of patients' specific health priorities, that is, transition from disease-centred to patient-centred healthcare values.[27] Notably, in our cohort, a relatively lower proportion of patients had symptoms typical of AS (i.e. chest pain or syncope) than

Figure 1 The proportion of patients' actual (A) and preferred place of living after treatment (B).

(A) **Actual**   (B) **Preferred**

- ☐ **Home (with family)**
- ☐ **Home (independently)**
- ☐ **Nursing care facility**
- ☐ **Hospital**
- ☐ **Others**

Figure 2 Patients' symptom burden during the last month.

those with non-specific symptoms (poor mobility or weakness), suggesting that the alleviation of several symptoms may be difficult with the use of AS-targeted therapies alone. Furthermore, our study demonstrated that elderly AS patients could express their treatment goals through a simple questionnaire. Although patients often do not feel empowered to express their preferences and values in the consideration of treatment options, this type of patient-reported data must be measured and assessed with the same consistency in daily practice, in an uncomplicated manner. The next step important for the successful implementation of SDM is the provision of training to medical pro-

viders on how to incorporate these data into patient–clinician conversations about the treatment options available as well as the associated risks and benefits.

This study had several limitations that should be considered in the interpretation of its results. First, this small-scale study was conducted in a single centre; consequently, the statistical power may not have been sufficient for the detection of reliable outcomes. Additionally, there could be a possible bias since the investigator who developed the questionnaire completed the questionnaires with patients. Using a multicentre registry, further investigation with larger scale studies is warranted to confirm the external consistency

Figure 3 Patients' perspectives towards treatment. Patient-defined treatment goals (A) and factors considered important in the choice of the treatment (B).
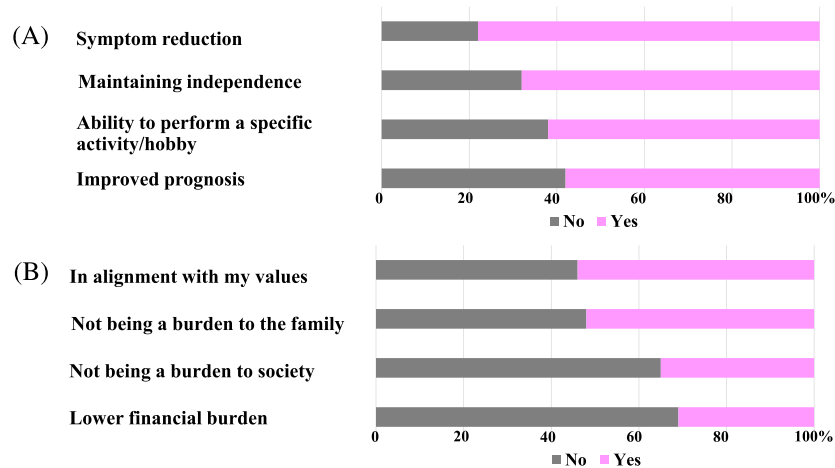
of our results. Second, our findings may be unique in that our study cohort included predominantly female and elderly Japanese patients. In Japan, the attitudes towards SDM could be different from that in Western countries. According to data obtained from a single academic medical institution in the USA, many AS patients communicate their preferred treatment goals that are based on their ability to perform a specific activity rather than on reducing specific symptomatology,[18] which is inconsistent with our findings. Further studies with international collaboration are needed to assess our findings across different cultural contexts. Third, we only included symptomatic severe AS patients who were treated with TAVR, limiting the generalizability of our findings, which does not include severe AS patients treated with other methods (surgical aortic valvular replacement and medical therapy). *Furthermore, we only analysed the patients who completed our survey, which limits the generalizability of our study finding, and may have resulted in a substantial selection bias. Because of these limitations, our study may be considered as hypothesis-generating.* Fourth, because of the nature of the cross-sectional design of this study, we could not clarify how TAVR would affect patient-reported treatment goals (e.g. 'home-time'). Post-operative assessment of how patients' expectation meets the actual results after TAVR will add value to our study. Further longitudinal studies should investigate the achievement of patients' treatment goals (e.g. living at home independently) following TAVR. Currently, general methods that assess patients' perceptions regarding achievement of their goals after TAVR are lacking, in order to assess whether TAVR contributes to the achievement of patient-defined treatment goals; validated methods are required to ascertain whether medical providers provide patient-centric care. Recently, the Toronto Aortic Stenosis Quality of Life Questionnaire (TASQ) was developed as an AS-specific quality of life measurement tool that can evaluate

physical symptoms and limitations.[28] For comparative purposes, we did not collect corresponding data on this validated questionnaire. Whether there is a good alignment of our questionnaire with other validated questionnaires in terms of symptom burden will be elucidated in the future. Serial evaluation of symptom burden (e.g., TASQ) could be a generalizable method for patients with a positive attitude towards symptom reduction as their treatment goal. Fifth, our study elucidated the patients' perspectives only through the current form of our questionnaire. Further studies using a qualitative study design and in-depth semi-structured interviews will be required to obtain a comprehensive understanding of patients' perspectives regarding their treatment goals.

Conclusions

Among severe AS patients with varying symptom burden levels who underwent TAVR, symptom burden reduction and independence maintenance were the two most important patient-reported treatment goals. Nearly all the patients preferred to live at home after TAVR. Based on the emphasis of patient-centred management, physicians should encourage patients to define their goals and prioritize patients' treatment goals in disease management.

Acknowledgement

Conflict of interest

Dr. Hayashida is a clinical proctor for Edwards Lifesciences and Medtronic. All the other authors declare there are no

conflicts of interest, including those pertaining to related consultancies, shareholdings, and funding grants.

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Supporting information

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

Table S1. Questionnaire for patients treated with transcatheter aortic valve replacement.

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