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Long-term survival evaluation after transcatheter aortic valve implantation in patients with severe aortic valve stenosis: a retrospective cohort study

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Transcatheter aortic valve implantation (TAVI) in patients with severe aortic valve stenosis (AS) is becoming an established technique. However, data on long-term survival in Japan are limited and regional disparities remain. We aimed to evaluate long-term survival after TAVI using the Nara Kokuho Database (KDB). Patients who underwent TAVI between July 2014 and March 2023 were enrolled. The study outcomes were to evaluate survival rates after TAVI over 1–7 years and predict long-term prognostic factors using Kaplan–Meier analysis and Cox proportional hazards model. Of 446 consecutive patients, 284 were female participants (63.7%). The mean age was 84.1 ± 4.3 years. The overall survival rates were 95.1–54.4% over 1–7 years. Cox proportional hazards model analysis revealed that younger age (< 85 years, hazard ratio [HR], 0.38; 95% confidence interval [CI], 0.20–0.69; $p = 0.002$) and transfemoral approach (HR, 0.37; 95% CI 0.17–0.78; $p = 0.009$) were predictive factors. However, renal disease (HR, 2.02; 95% CI 1.08–3.77; $p = 0.03$), cerebrovascular disease (HR, 2.02; 95% CI 1.13–3.63; $p = 0.02$), and rheumatologic disease (HR, 2.71; 95% CI 1.19–6.18; $p = 0.02$) were poor long-term prognostic factors. This study measured the long-term survival after TAVI using Nara KDB data, identifying factors that might serve as predictive indicators.

Keywords Transcatheter aortic valve implantation, Aortic valve stenosis, Long-term survival, Prognostic factors, Nara prefecture, Kokuho database

Transcatheter aortic valve implantation (TAVI) has become an established alternative to surgical aortic valve replacement (SAVR) for severe aortic valve stenosis (AS)[1–5], with the number of TAVI procedures increasing exponentially over the past decades in Western countries. Furthermore, recent large trials comparing TAVI with SAVR in low-risk patients have revealed that TAVI yields more favorable clinical results in short-term follow-up[6,7]. However, data on the long-term outcomes of TAVI beyond 5 years are limited in Western countries[8–11]. The 7-year survival rates in cohort studies from Germany and the United Kingdom were 18.6%[10] and 23.2%[9], respectively. Since October 2013, insurance programs in Japan have considered TAVI as a therapeutic option in patients with severe AS. The numbers of treatment centers and treated patients are increasing rapidly. There is also a growing number of reports on the outcomes of TAVI in Japanese patients whose ethnic and anatomical characteristics are different from those of patients from other countries[12–14]. A multicenter registry of national data revealed significant improvements in clinical outcomes, including early mortality rates ranging from 2.0 to 5.0% following TAVI[15–19]. However, data on the clinical and long-term outcomes of TAVI in large Japanese cohorts are still limited compared with Western cohort studies[12,13]. In Japan, the long-term survival rates after

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TAVI have been reported to be 48.9–60.4% at 5 years and 35.8–45.3% at 7 years[20–23]. On the other hand, there are no reports evaluating long-term prognosis after TAVI with real-world data using Nara Kokuho Database (KDB) data or by prefecture or region in Japan. This study aimed to evaluate the long-term survival rate in patients after TAVI and predict long-term prognostic factors using Nara KDB data.

Results

In this study, 446 patient records were analyzed. The baseline characteristics of study patients are presented in Table 1; 284 (63.7%) of the patients were female individuals. The number of patients undergoing TAVI has increased annually (Fig. 1a). The age distribution of patients who underwent TAVI is shown in Fig. 1b. The mean age was 84.1 ± 4.3 years. The age data exhibited a normal distribution, and most of the patients were older than 75 years. Using the Kaplan–Meier analysis, the survival rates were 95.1% at 1 year, 90.5% at 2 years, 84.4% at 3 years, 79.2% at 4 years, 69.0% at 5 years, 63.8% at 6 years, and 54.4% at 7 years (Fig. 2a). A study was conducted to determine the cut-off value for the age of 85 years, in relation to 7-year long-term survival, using receiver operating characteristic (ROC) curve analysis. The area under the curve (AUC) was 0.63, with a sensitivity of 0.50 and specificity of 0.73. Based on the cut-off the value, the patients were allocated into two groups to compare long-term survival rates: those younger than 85 years (age < 85) and those aged 85 years or older (age ≥ 85). Kaplan–Meier analysis showed a statistically significant difference in survival rates in the < 85 age group (hazard ratio [HR], 0.40; 95% confidence interval [CI], 0.31–0.79; $p = 0.002$; Fig. 2b). We evaluated the differences in approach sites during procedures, i.e., transfemoral or transapical approaches. The transfemoral

	N = 446
Characteristics	
Female, n (%)	284 (63.7)
Age, years ± SD	84.1 ± 4.3
≤ 79	53 (11.9)
80–84	178 (39.9)
85–89	172 (38.6)
≥ 90	43 (9.6)
Past medical history	
Hypertension	428 (96.0)
Dyslipidemia	218 (48.9)
Diabetes mellitus with chronic complications	105 (23.5)
Chronic pulmonary disease	63 (14.1)
Coronary artery disease	304 (68.2)
Congestive heart failure	380 (85.2)
Atrial fibrillation	126 (28.3)
Peripheral arterial disease	50 (11.2)
Renal disease (moderate or severe renal disease)	68 (15.2)
Cerebrovascular disease	110 (24.7)
Dementia	37 (8.3)
Rheumatologic disease (including connective tissue disease)	33 (7.4)
Liver disease	20 (4.5)
Malignancy (including leukemia and lymphoma)	28 (6.3)
Peptic ulcer	36 (8.1)
Charlson Comorbidity Index, median IQR	2.0 (2.0–3.0)
Procedure approach	
Transfemoral approach	386 (86.5)
Transapical approach	25 (5.6)
*Undetected	35 (7.8)
Transcatheter heart valve	
Balloon-expandable valve	354 (78.4)
Self-expanding valve	92 (21.6)
Clinical intervention & outcomes	
Permanent pacemaker implantation	37 (8.3)
Transfusion	188 (42.2)
Length of hospital stays (days), median IQR	12 (10–16)

Table 1. Characteristics of the patients. SD = Standard deviation, IQR = Interquartile range. *Undetected: Transcatheter aortic valve replacement (150369950) medical practice code assigned but could not identify procedure approach.

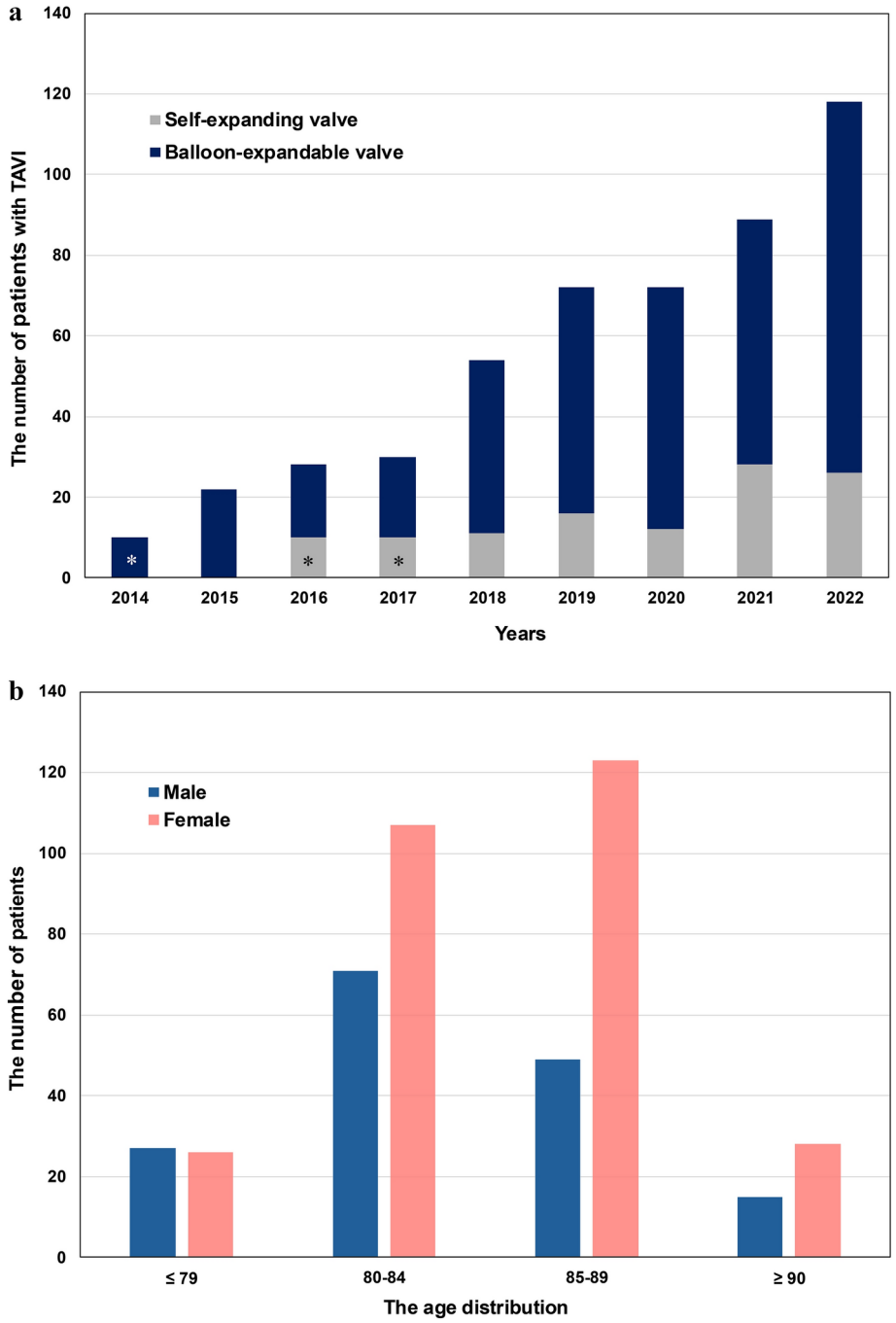

Fig. 1. The number and trend in transcatheter aortic valve implantation with a transcatheter heart valve (**a**) and the distribution of the age of patients (**b**). *When the number of patients was less than 10 (except 0), the value was not disclosed, according to the cell size suppression policy of the national health insurance data.

approach showed significantly better prognostic outcomes (HR, 0.29; 95% CI 0.15–0.57; $p = 0.0001$; Fig. 2c). In a comparison of the survival rates between the different types of transcatheter heart valves (self-expanding and balloon-expandable) performed with the transfemoral approach, which has been shown to have a favorable prognosis, there was no significant difference in the survival rate at 5 years among patients receiving self-expanding and balloon-expandable valve (HR, 0.53; 95% CI 0.22–1.25; $p = 0.14$; Fig. 2d).

The univariate and multivariate Cox proportional hazard model analyses were conducted to evaluate the prognostic factors for long-term survival. Among the several candidate predictors identified using the univariate analysis, multivariate Cox proportional hazard model analysis revealed favorable outcomes in the < 85-year-olds (HR, 0.37; 95% CI 0.20–0.69; $p = 0.002$) and transfemoral approach (HR, 0.37; 95% CI 0.17–0.78; $p = 0.009$) groups (Table 2). On the other hand, there was a significant difference in poor outcomes for renal disease (HR, 2.02; 95% CI 1.08–3.77; $p = 0.03$), cerebrovascular disease (HR, 2.02; 95% CI 1.13–2.89; $p = 0.02$), and rheumatologic

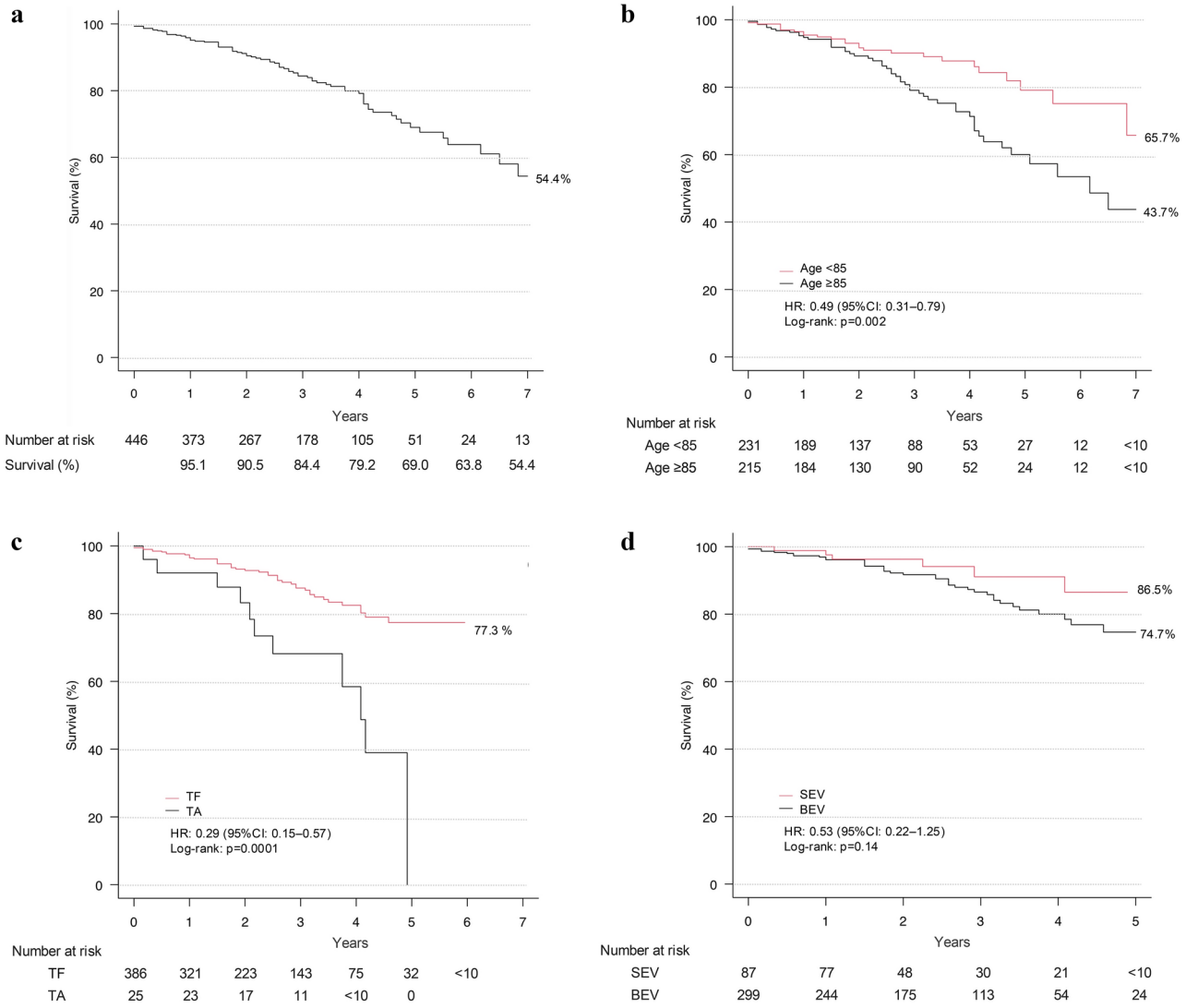

Fig. 2. The survival rate of all patients after TAVI (**a**). Comparison of the survival rate after TAVI in relation to age (over or under 85 years) (**b**), procedural approach (**c**), and transcatheter heart valve type (**d**). TAVI = Transcatheter aortic valve implantation, TF = Transfemoral approach, TA = Transapical approach, SEV = Self-expanding valve, BEV = Balloon-expandable valve. When the number of patients was less than 10 (except 0), the value was not disclosed, according to the cell size suppression policy of the national health insurance data.

disease (connective tissue disease) (HR, 2.71; 95% CI 1.19–6.18; $p = 0.02$) (Table 2). The Charlson Comorbidity Index (CCI) was significantly different using univariate Cox proportional hazard model analysis; however, no significant difference was found using multivariate analysis (HR, 1.14; 95% CI 0.99–1.31; $p = 0.08$) (Table 2).

Discussion

We evaluated survival rates after TAVI up to 7 years using Nara KDB data, and the overall survival rate was generally similar to that in several previous studies in Japan[20–23]. The results indicated that there were no significant differences for Nara KDB data, rural areas, and other regions, facilities, and registries in Japan. Due to the rapid aging of the population in Japan, comparing life expectancy after TAVI with that of the general population would be also important, which could not be assessed in this study. As for prognostic factors, we demonstrated that age (< 85) and a transfemoral approach were favorable factors for the long-term survival at 7 years after TAVI. Although age cut-off would be naturally biased toward older ages when the observation period for endpoints is shortened, this study evaluated the age cut-off at up to 7 years of survival. The fact that younger age and the transfemoral approach were associated with a better long-term prognosis of TAVI[24,25] and that the presence of renal disease and cerebrovascular disease were associated with poorer prognosis of AS is consistent with previous studies[24–26]. Renal disease including chronic kidney disease (CKD) has been shown to be associated with higher mortality and morbidity in patients undergoing TAVI, with advanced CKD (stages 4–5) correlating with increased 30-day and one-year mortality rates, particularly due to non-cardiovascular

	Univariate analysis			Multivariable analysis		
	HR	95% CI	p value	HR	95% CI	p value
Age < 85 years	0.49	0.31–0.79	0.003	0.37	0.20–0.69	0.002
Female	0.69	0.44–1.08	0.11	0.88	0.48–1.61	0.69
Hypertension	0.62	0.23–1.70	0.35	–	–	–
Dyslipidemia	0.86	0.55–1.35	0.52	–	–	–
Diabetes mellitus	2.07	1.29–3.31	0.02	1.58	0.86–2.90	0.14
Chronic pulmonary disease	1.28	0.74–2.21	0.37	–	–	–
Coronary artery disease	1.15	0.68–1.93	0.61	–	–	–
Congestive heart failure	1.69	0.73–3.89	0.22	–	–	–
Atrial fibrillation	1.49	0.93–2.39	0.10	–	–	–
Peripheral arterial disease	1.99	1.15–3.46	0.01	0.69	0.30–1.59	0.38
Renal disease (moderate or severe renal disease)	2.48	1.50–4.10	< 0.001	2.02	1.08–3.77	0.03
Cerebrovascular disease	1.90	1.20–3.00	0.006	2.02	1.13–3.63	0.02
Rheumatologic disease (connective tissue disease)	2.10	1.11–3.98	0.02	2.71	1.19–6.18	0.02
Liver disease	2.47	1.07–5.71	0.03	1.66	0.61–4.54	0.32
Dementia	0.85	0.40–1.77	0.65	–	–	–
Malignancy (including leukemia and lymphoma)	1.73	0.80–3.77	0.17	–	–	–
Charlson Comorbidity Index (continuous)	1.25	1.14–1.37	< 0.001	1.14	0.99–1.31	0.08
Transfemoral approach	0.29	0.15–0.57	< 0.001	0.37	0.17–0.78	0.009
Self–expanding valve	0.53	0.22–1.25	0.15	0.50	0.20–1.22	0.13
Permanent pacemaker implantation	0.38	0.12–1.21	0.10	–	–	–
Transfusion	2.07	1.27–3.37	0.01	1.13	0.61–2.10	0.70

Table 2. Cox proportional hazard ratio analysis for long-term survival. HR = Hazard ratio, CI = Confidence interval. Multivariate Cox proportional hazard models, adjusted for age < 85 years, sex, diabetes mellitus with chronic complications, peripheral arterial disease, renal disease (moderate or severe renal disease), cerebrovascular disease, rheumatologic disease (connective tissue disease), liver disease, Charlson Comorbidity Index scores (continuous variate), transfemoral approach, self–expanding valve, and transfusion as covariates.

events[27,28]. Cerebrovascular disease is one of the risks for cerebrovascular events after TAVI[29]. Moreover, a major stroke after TAVI not only affects survival but also significantly impacts patients' quality of life, with approximately 50% of patients with cerebrovascular events experiencing permanent disability (modified Rankin scale: 2–5) after 30 days[29–31]. Noteworthily, in this study, rheumatologic disease, including connective tissue disease, was a poor long-term prognostic factor. There are no reports from Japan evaluating the association between rheumatologic disease, including connective tissue disease, and AS or TAVI. Studies from the United States reported that the coexistence of rheumatoid arthritis is a risk factor for cardiovascular disease-related and AS-related death[32,33]. Our study suggests that rheumatologic disease, including connective tissue disease may be an important poor prognostic factor for the mortality after TAVI in the Japanese population. These factors, namely renal, cerebrovascular, and rheumatologic diseases including connective tissue disease, are important considerations for the management and prognosis of patients with AS after TAVI. Patients with these comorbidities might require careful individualized risk assessment and close follow-up to optimize long-term survival after TAVI.

Considering transcatheter heart valve types, the first balloon-expandable valve in Japan, which was approved in 2013, was SAPIEN XT, followed by SAPIEN 3; SAPIEN 3 ultra RESILIA is now mainstream. On the other hand, the use of self-expanding valves was first approved in 2016; the type of value use has changed from CoreValve to Evolut R, Evolut PRO, Evolut PRO+, and eventually Evolut FX. All patients who underwent procedures performed between 2013 and 2015 using transapical approaches received balloon-expandable valves, suggesting that this group included patients with poor prognoses. Therefore, when limiting the analysis to data of patients receiving the transfemoral approach after 2016, there was no significant difference in 5-year survival rates between patients receiving self-expandable and balloon-expandable valves. Caution should be exercised in interpreting these results because this study could not evaluate detailed baseline clinical characteristics of patients receiving self-expandable and balloon-expandable valves. Moreover, the study used a long-term observational period and did not consider procedures or the previously mentioned prosthetic valve modifications that might be time-dependent confounders. Though there are a few previous studies that have directly evaluated transcatheter heart valves for long-term survival, new valves are expected to have better durability and associated with fewer complications and longer life expectancy. A recent study has shown that self-expanding was non-inferior to balloon-expandable valve for clinical outcomes in patients with smaller aortic valve annulus and was superior to hemodynamic and bioprosthetic valve function for up to 12 months[34,35].

The majority of patients with AS undergoing TAVI are older adults, thus comorbidities are important factors to predict prognosis. The elderly population generally has a shorter life expectancy and a higher prevalence of comorbidities. Therefore, we evaluated CCI scores in this study. Few previous studies have assessed the

association between the CCI score and TAVI. CCI scores have been shown to have concurrent validity with many other prognostic scales or to result in concordant predictions[36,37]. The results of this study did not show significant differences using the multivariate COX proportional hazards model analysis, suggesting that CCI could be one of the assessments of comorbidity; however, it is not a sufficient indicator to predict prognosis. Thus, although comorbidity is an important factor, assessing severity and frailty, including using clinical data is also important.

Real-world long-term survival data after TAVI from the Nara KDB, regionally in prefectures, and in each facility setting in Japan, are helpful for treatment selection to achieve better life-long management in patients with AS. This is because these data allow for informed discussion and shared decision-making about both treatment options and advanced care planning in this patient population. In Japan, which has a population of extremely older people with an increasing number of facilities and patients undergoing TAVI, long-term survival rate and prognostic factors from the Nara KDB may serve as a predictive indicator.

This study has several limitations, including the fact that it was a retrospective cohort study. There may be inherent biases in patient selection, influenced by local practice, that could have influenced the generalizability of the results. Since this study was limited to Nara Prefecture, one should be cautious about interpreting the results of this study to be applicable to populations throughout Japan and around the world. Additionally, echocardiographic findings with aortic velocity, aortic valve pressure gradient, aortic valve area, and perivaluvular leak were lacking from the Nara KDB data. Moreover, information on the sizes of the transcatheter heart valves was also lacking. Moreover, the Society of Thoracic Surgeons (STS) risk model, Japan SCORE, EuroSCORE, and frailty scale, commonly evaluated in many TAVI studies, could not be assessed from the Nara KDB. The STS risk model, a traditional risk model designed and validated to predict operative mortality after adult cardiac surgery, has been reported to predict short- and mid-term prognosis after TAVI. Furthermore, complications associated with TAVI, such as arrhythmia, thrombosis, bleeding, and valve structure distraction/disorder, and laboratory findings were not investigated from the Nara KDB data. There was also a lack of data on pre- and postoperative drug therapy, including antithrombotic drugs after TAVI and therapeutic agents for chronic heart failure and complications other than TAVI. Since, in the past decade, significant changes in various treatments have been seen, including medication therapy for comorbidities as well as chronic heart failure with AS, these might have affected clinical outcomes.

Methods

Data source

We conducted a retrospective cohort study using the Nara KDB, which includes administrative claims data from the Nara Prefecture, Japan. Nara Prefecture is approximately located at the center of Japan and reflects the standard climate, demographics, and economic situation in Japan. The Nara KDB data includes approximately 0.6 million people from Nara Prefecture. There are three main types of public health insurance in Japan, covering almost the entire Japanese population: employees' health insurance (EHI), national health insurance (NHI), and late elders' health insurance (LEHI). Those aged over 75 years old are enrolled in the LEHI and under insurance by the prefecture. The Nara KDB includes data on the NHI and LEHI but not on the EHI. Therefore, almost all residents aged 65 years old or older in Nara Prefecture were included in the database. We merged these medical and long-term care administrative claims databases using a unique identifier for each individual. We used a patient-matching technique, and the database was available for longitudinal patient follow-up[38].

In this study, we analyzed data from April 1, 2014 to March 31, 2023. The washout observation period was at least 6 months from September 2022. As the first patient underwent TAVI in July 2014, the patients who underwent TAVI from July 2014 to September 30, 2022 were included (Fig. 3). The data included registrant information: sex; age; observation period; withdrawal of NHI or LEHI; and death dates. These data also comprised insurance claim data: prescribed medicines, procedures, and 10th Revision of the International Classification of Diseases (ICD-10) codes and long-term care insurance data: support and care level, as well as information on the care services provided for insured individuals. The claims data are updated monthly. The ICD-10 diagnostic

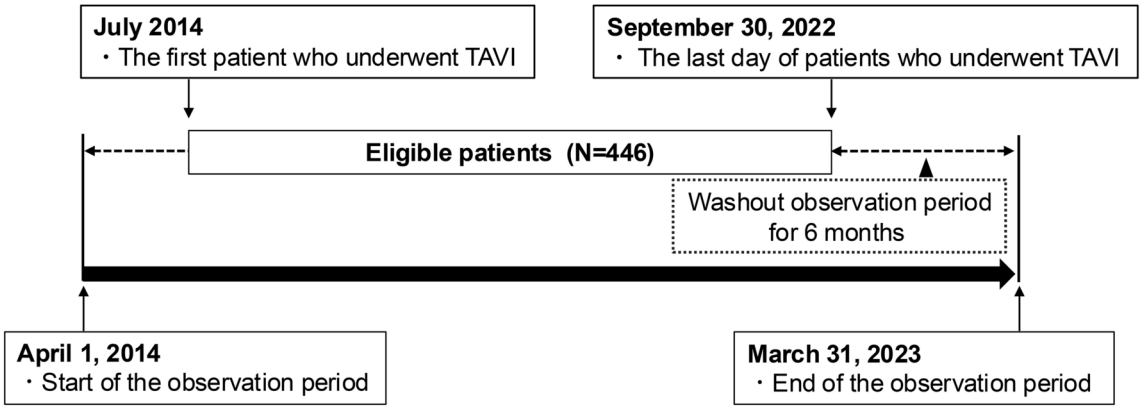

Fig. 3. Schematic diagram of the study design. TAVI = Transcatheter aortic valve implantation.

Comorbidities/underlying diseases	ICD-10	Score
Chronic pulmonary disease	I278; I279; J40-J47; J60–J67; J684; J701; J703	1
Rheumatologic disease (connective tissue disease)	M05; M06; M315; M32; M33; M34; M351; M353; M360	1
Diabetes with chronic complications (diabetes with end-organ damage)	E102–E105; E107; E112–E115; E117; E122–E125; E127; E132–E135; E137; E142–E145; E147	1
Renal disease (moderate or severe renal disease)	I120; I131; N032–N037; N052–N057; N18; N19; N250; Z490; Z491; Z492; Z940; Z992	1
Congestive heart failure	I110; I130; I132; I255; I420; I425–I429; I43; I50; P290	2
Dementia	F00–F03; F051; G30; G311	2
Mild liver disease	B18; K700–K703; K709; K713–K715; K717; K73; K74; K760; K762–K764; K768; K769; Z944	2
Hemiplegia or paraplegia	G041; G114; G801; G802; G81; G82; G830–G834; G839	2
Any malignancy including leukemia and lymphoma	C00–C26; C30–C34; C37–C41; C43; C45–C58; C60–C76;C81–C85; C88; C90–C97	2
Moderate or severe liver disease	I850; I859; I864; I982; K704; K711; K721; K729; K765; K766; K767	4
AIDS/HIV	B20–B22; B24; Z21	4
Metastatic solid tumor	C77–C80	6

Table 3. ICD-10 coding and scoring algorithms for the Charlson Comorbidity Index. ICD = International Classification of Diseases, AIDS = Acquired immune deficiency syndrome, HIV = Human immunodeficiency virus. Comorbidities for the Charlson Comorbidity Index were extracted from the disease information from the in- and out-of-hospital claims within 1 year before transcatheter aortic valve implantation.

codes are updated for the duration of the treatment of specific diseases. The data were linked with patients using anonymized individual identifiers for research purposes.

Study population and eligibility patients

Patient eligibility was defined as patients with AS who aged ≥ 50 years and have undergone TAVI. Patients with AS who did not undergo TAVI were excluded. A confirmed diagnosis of AS (name of disease including AS) was determined via the presence of the ICD-10 codes for aortic valve stenosis (I350), aortic insufficiency with stenosis (I352), aortic valve disease (I358), non-rheumatic aortic stenosis (I359), rheumatic aortic stenosis (I060), rheumatic aortic insufficiency with stenosis (I062), mitral insufficiency with aortic valve disease (I080), tricuspid insufficiency with aortic disease (I082), tricuspid stenosis with aortic disease (I082), tricuspid insufficiency with stenosis and aortic disease (I082), congenital aortic valve stenosis (Q230), bicuspid aortic valve (Q231), subaortic stenosis (Q244), and supravalvular aortic stenosis (Q253). The comorbidities were also categorized by ICD-10 codes for the CCI[34–37]. Table 3 presents the ICD-10 coding and scoring algorithms for the CCI scores and major underlying diseases. Total CCI scores were calculated using the updated CCI scores in 2011[33]. Cerebrovascular diseases, myocardial infarction, peripheral vascular disease, peptic ulcers, and diabetes without chronic complications were excluded from the original version of the CCI score[34–37,39]. TAVI was detected using the medical practice codes, i.e., the transapical approach with transcatheter aortic valve replacement (150387210), transfemoral approach with transcatheter aortic valve replacement (150387310), and transcatheter aortic valve replacement (150369950). The transcatheter heart valve types were detected using specific material codes, i.e., balloon-expandable valve (710010745) and self-expanding valve (710010893). Death was defined as the loss of NHI or LEHI codes.

The endpoint of outcome

The primary outcome of this study was the survival rates from 1 to 7 years after TAVI. The survival rate was investigated in the context of age distribution, type of procedural approach, and transcatheter heart valve type. We evaluated the predictive long-term prognostic factors.

Statistical analyses

Data regarding patient characteristics are expressed as n (%) for categorical variables and as median (interquartile range, IQR) for continuous parameters as appropriate. Kaplan–Meier analysis and the Cox proportional hazards model were used to determine the long-term prognostic factors. ROC curves were used to determine the age cut-off values for the long-term survival up to 7 years after TAVI in all patients. From previous studies, a younger age, being female, and undergoing a transfemoral approach for TAVI were considered medically significant and with better predictive functions[24–26]. Univariate and multivariate Cox proportional hazards model analyses were added to these factors to identify independent prognostic factors. Variables with $p < 0.10$ from univariate Cox proportional hazards model analysis identified the individual factors related to long-term survival. Multivariate Cox proportional hazards model analysis was conducted with age < 85, sex, diabetes mellitus with chronic complications (diabetes with end-organ damage), peripheral arterial disease, renal disease (moderate or severe renal disease), cerebrovascular disease, rheumatologic disease (connective tissue disease), liver disease, transfemoral approach, transcatheter valves, and CCI scores, or with the potential associations with long-term survival from previous studies mentioned above[24–26]. All p values were two-sided, and $p < 0.05$ was considered statistically significant. All statistical analyses were conducted using IBM Statistical Product and Service Solutions (SPSS) version 27.

Ethics declarations

This study was approved by the Ethics Committee of the Nara University School of Medicine (approval number: 1123). The requirement for informed consent was waived because of the anonymized nature of the claim datasets. The datasets generated during the current study complied with of the Declaration of Helsinki.

Data availability

Data cannot be shared publicly because local governments own medical insurance claims data. Data are available from corresponding author for researchers who meet the criteria for access to confidential data.

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Declarations

Competing interests
The authors declare no competing interests.

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