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Contemporary Short- and Mid-Term Outcomes of Transcatheter Aortic Valve Replacement for Nonagenarians in Japan

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Abstract

Purpose: Transcatheter Aortic Valve Implantation (TAVI) is increasingly being performed for elderly patients, although the clinical outcomes are unclear in Japan. This study evaluated real-world TAVI outcomes in Japanese nonagenarians with severe aortic stenosis.

Methods: This single-center study retrospectively assessed the short- and mid-term clinical outcomes of TAVI in nonagenarians (group N; n=23) and in younger patients (group Y; n=117).

Results: There were no postoperative deaths in either group and most short-term outcomes were comparable, although patients in group N required longer hospital stays (19 ± 32.1 days *vs.* 12.1 ± 9.3 days, p=0.04). The 5-year overall survival rate was non-significantly lower in group N (29.5% *vs.* 51.1%, p=0.26). The 5-year rates of freedom from cardiac events were equivalent in both groups (69.5% *vs.* 66.0%, p=0.68). There were no late cardiac deaths in group N, and the 5-year rates of freedom from late cardiac death were 100% in group N and 84.6% in group Y.

Conclusion: The short and midterm clinical outcomes of TAVI in Japanese nonagenarians were comparable to those in younger patients. Thus, TAVI appears to be effective for treating aortic stenosis in Japanese nonagenarians and may help prevent cardiac death.

Keywords: Nonagenarians; Elderly patients; Aortic valve stenosis; Transcatheter aortic valve implantation

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Introduction

According to the 2008 World Health Organization report, Japan has the longest life expectancy in the world [1]. The latest report from the Japanese Ministry of Health, Labor and Welfare stated that life expectancy has reached 81.2 years for men and 87.3 years for women, with the population including 438,000 people who are >90 years old [2]. Unfortunately, this aged group has an increased prevalence of aortic stenosis and is likely to have co-morbid conditions, which poses a dilemma to cardiologists and cardiac surgeons when selecting conservative or interventional treatment. Seven years ago, Surgical Aortic Valve Replacement (SAVR) was the only treatment for severe aortic stenosis in Japan, although Japanese national health insurance began covering Transcatheter Aortic Valve Implantation (TAVI) in 2013 as a less invasive alternative to SAVR [3,4]. Thus, TAVI was rapidly adopted, as previously seen in Europeans countries [5].

The widespread use of TAVI and the aging Japanese population have led to an increase in the number of TAVI procedures in elderly patients. Some Western studies have reported the outcomes of TAVI in nonagenarians [6-8], although few reports have evaluated TAVI for nonagenarians from Asian countries. This study aimed to clarify the outcomes of TAVI in Japanese nonagenarians with severe aortic stenosis.

Methods

This single-center retrospective study was approved by the Institutional Review Board of Yamaguchi University Hospital (Study ID: H2019-071). The center uses an opt-out consent process and all procedures complied with the Declaration of Helsinki.

The study included 140 patients who were treated at our institution for severe aortic stenosis

Table 1: Preoperative patient characteristics.

	Entire cohort (n=140)	N group (n=23)	Y group (n=117)	p-value
Age (years)	84.6 ± 5.4	92.1 ± 1.9	83.2 ± 4.7	<0.0001
[range]	[69-97]	[90-97]	[69-89]	
Male sex	47 (33.5%)	5 (21.7%)	42 (35.8%)	0.18
Hypertension	126 (90.0%)	22 (95.6%)	104 (88.8%)	0.32
Dyslipidemia	77 (55%)	12 (52.1%)	65 (55.5%)	0.76
DM	38 (27.1%)	4 (17.3%)	34 (29.0%)	0.25
IHD	55 (39.2%)	4 (17.3%)	51 (43.5%)	0.13
CVD	36 (25.7%)	4 (17.3%)	32 (27.3%)	0.3
COPD	6 (4.2%)	0	6 (5.1%)	0.58
Smoking	9 (6.4%)	0	9 (7.6%)	0.35
Chronic AF	21 (15.0%)	4 (17.3%)	17 (14.5%)	0.72
PMI	11 (7.8%)	4 (17.3%)	7 (5.9%)	0.09
Malignancy	7 (5.0%)	1 (4.3%)	6 (5.1%)	0.98
Previous cardiac surgery	11 (7.8%)	1 (4.3%)	10 (8.5%)	0.49
Serum creatinine (mg/dL)	1.01 ± 0.31	0.98 ± 0.29	1.02 ± 0.29	0.6
Serum albumin (g/dL)	3.66 ± 0.40	3.74 ± 0.38	3.64 ± 0.40	0.27
Hemoglobin (g/dL)	10.80 ± 1.68	10.34 ± 1.53	10.89 ± 1.70	0.15
Oral drug administration				
b-blocker	22 (15.7%)	5 (21.7%)	41 (35.0%)	0.26
Ca^{2+} blocker	67 (47.8%)	13 (56.5%)	54 (46.1%)	0.36
ACE-I	34 (24.2%)	5 (21.7%)	29 (24.7%)	0.75
ARB	57 (40.7%)	13 (56.5%)	44 (37.6%)	0.09
Statin	62 (44.2%)	10 (43.4%)	52 (44.4%)	0.93
Risk score				
STS risk score	7.9 ± 4.6	8.4 ± 4.6	7.7 ± 4.8	0.5
EuroSCORE II	5.1 ± 4.7	5.4 ± 3.3	5.0 ± 4.9	0.72
JapanSCORE	7.2 ± 6.2	5.1 ± 4.7	7.6 ± 6.8	0.09

ACE-I: Angiotensin Converting Enzyme Inhibitor; AF: Atrial Fibrillation; ARB: Angiotensin II Receptor Blocker; COPD: Chronic Obstructive Pulmonary Disease; CVD: Cerebral Vascular Disease; DM: Diabetes Mellitus; IHD: Ischemic Heart Disease; PMI: Pace Maker Implantation

between April 2014 and July 2019. All patients have been assessed by a multidisciplinary cardiac team that included cardiac surgeons, cardiologists, cardiac anesthesiologists, and physical therapists to determine the appropriate treatment strategy. We retrospectively assessed the short- and mid-term clinical outcomes after TAVI in nonagenarian patients (group N; n=23) and in younger patients (group Y; n=117).

Operative Procedure

The TAVI procedure was performed under general anesthesia with endotracheal intubation. A temporary right ventricle pacing lead wire was inserted though the right jugular vein and used when needed. The approach to deploy the transcatheter prosthetic valve was discussed by the cardiac team. The trans-femoral approach was considered the first choice, although other approaches were used if the femoral approach was not feasible. The type and size of the prosthetic valve were determined according to the findings regarding the aortic valve complex from preoperative enhanced cardiac computed tomography. The balloon-expandable valves were the Edwards Sapien XT and Sapien 3.

Devices (Edwards Life sciences, Irvine, CA) and the self-expandable valves were the Core Valve, Evolut R, and Evolut PRO devices (Medtronic Inc., Minneapolis, MN).

Statistical Analysis

Continuous data were expressed as mean ± standard deviation and evaluated using Student's t-test. Categorical data were evaluated using the χ^2 test or Fisher's exact test, as appropriate. Time-to-event analyses were performed using Kaplan-Meier estimates and the log-rank test. Independent predictors of overall survival were determined using Cox regression analysis. The multivariable models included covariates with a p-value of <0.1 in the univariate analyses. All statistical analyses were performed using StatView software (version 5.0; SAS Institute, Cary, NC) and differences were considered statistically significant at p-values of <0.05.

Results

Patient characteristics

Baseline patient characteristics are shown in Table 1. The mean ages were 83.2 ± 4.7 years in group Y and 92.1 ± 1.9 years in group N (p<0.0001). Preoperative pacemaker implantation was slightly more common in group N (17.3% *vs.* 5.9%). The Society of Thoracic

Table 2: Operative procedures and parameters.

	Entire cohort (n=140)	N group (n=23)	Y group (n=117)	p-value
Approach				
Femoral	105 (75.0%)	17 (73.9%)	88 (75.2%)	1
Apical	27 (19.3%)	4 (17.3%)	23 (19.7%)	1
Subclavian	5 (3.6%)	1 (4.4%)	4 (3.4%)	1
Aorta	3 (2.1%)	1 (4.4%)	2 (1.7%)	0.41
Prosthetic valves				
Balloon-expandable	101 (72.2%)	16 (69.6%)	85 (72.6%)	
Size (mm) 20/23/26/29	5/70/25/1	3/12/1/0	2/58/24/1	0.8
Self-expandable	39 (27.8%)	7 (30.4%)	32 (27.4%)	[Balloon- *vs.* self-expandable]
Size (mm) 23/26/29	2/23/2014	0/6/1	2/17/2013	
Operation time (min)	149 ± 40	159 ± 40	147 ± 40	0.2
Blood transfusion	47 (33.5%)	9 (39.1%)	38 (32.4%)	0.8

Table 3: Early clinical outcomes.

	Entire cohort (n=140)	N group (n=23)	Y group (n=117)	p-value
In-hospital death	0	0	0	1
ICU stay (days)	1.9 ± 1.1	2.0 ± 1.1	1.9 ± 1.1	0.76
Hospital stay (days)	13.3 ± 15.6	19.1 ± 15.6	12.1 ± 32.1	0.04
Newly required PMI	11 (7.8%)	3 (13.0%)	8 (8.5%)	0.34
PVL	14 (10.0%)	2 (8.6%)	12 (10.2%)	1
Cerebral infarction	5 (3.5%)	1 (4.3%)	4 (3.4%)	0.82
Disabling cerebral infarction	3 (2.1%)	1 (4.3%)	2 (1.7%)	0.41
Acute type B aortic dissection	2 (1.4%)	1 (4.3%)	1 (0.8%)	0.3
Annulus rupture	1 (0.7%)	1 (4.3%)	0	0.16
Coronary occlusion	1 (0.7%)	1 (4.3%)	0	0.16
Cardiac tamponade	1 (0.7%)	0	1 (0.8%)	1
Esophageal perforation	1 (0.7%)	0	1 (0.8%)	1

PMI: Pace Maker Implantation; PVL: Paravalvular Leakage

Surgery risk scores were 7.7% in group Y and 8.4% in group N. The other patient characteristics did not differ significantly between the two groups.

Operative parameters

Operative procedures and intraoperative findings are shown in Table 2. The approaches were trans- femoral (75%), trans-apical (19%), trans-subclavian (3%), and through the ascending aorta (2%). A balloon-expandable valve was implanted in 72% of patients and a self-expandable valve was implanted in 28% of patients. The approach, type of prosthetic valve, procedure time, and blood transfusion rates were not significantly different between the two groups.

Short-term outcomes

No in-hospital deaths occurred in either group. The hospital stay was significantly longer in group N (19 ± 32.1 days *vs.* 12.1 ± 9.3 days, p=0.04). However, the complication rates, including the need for pacemaker implantation, paravalvular leakage, cerebral infarction, and acute type B dissection, were not significantly different between the two groups (Table 3).

We assessed postoperative cardiac function using transthoracic echocardiography (Supplemental Figure 1), which revealed that the aortic valve area was significantly increased in both groups. In addition, the peak systolic velocity and mean pressure gradient were significantly decreased in both groups. There were no significant differences in the other echocardiographic findings between the two groups.

Mid-term outcomes

The overall 5-year survival rates were 35.1% in the entire cohort, 51.1% in group N, and 29.5% in group Y (group N *vs.* group Y: log-rank p=0.26; Figure 1A). The 5-year rates of freedom from cardiac events were 66.7% in the entire cohort, 69.5% in group N, and 66.0% in group Y (group N *vs.* group Y: log-rank p=0.68; Figure 1B). The 5-year rates of freedom from cardiac death were 88.7% in the entire cohort, 100% in group N, and 84.6% in group Y (Figure 1C).

A total of 36 late deaths were observed in the entire cohort, including 7 deaths in group N and 29 deaths in group Y. The causes of late death in group N were pneumonia in 3 patients, other infectious disease in 3 patients, and malignancy in 1 patient, with no cardiac deaths. The causes of late death in group Y were cardiac death in 8 patients, pneumonia in 8 patients, cerebrovascular disease in 3 patients, malignancy in 2 patients, and other causes in 8 patients.

Predictors of mortality after TAVI

We used Cox proportional hazard models to analyze the predictors of mortality after TAVI (Table 4). The univariate analysis revealed that preoperative serum albumin and hemoglobin concentrations

Table 4: Predictors of mortality after transcatheter aortic valve implantation.

		Univariate analysis			Multivariate analysis	
	Hazard ratio	(95% confidence interval)	p-value	Hazard ratio	(95% confidence interval)	p-value
Age	0.98	(0.93-1.04)	0.59			
Female sex	0.59	(0.30-1.14)	0.11			
STS risk score	0.96	(0.88-1.05)	0.45			
EuroSCORE II	0.92	(0.81-1.04)	0.2			
JapanSCORE	0.95	(0.87-1.03)	0.25			
Previous cardiac surgery	0.59	(0.14-2.49)	0.48			
Preoperative creatinine	1.31	(0.46-3.40)	0.6			
Preoperative albumin	0.37	(0.15-0.89)	0.02	0.54	(0.65-1.03)	0.08
Preoperative BNP	1	(1.00-1.01)	0.38			
Preoperative hemoglobin	0.77	(0.63-0.95)	0.01	0.83	(0.20-1.44)	0.22
Preoperative EF	1.02	(0.98-1.05)	0.14			
Blood transfusion	1.77	(0.89-9.49)	0.11			

BNP: Brain Natriuretic Peptide; EF: Ejection Fraction

Supplemental Table 1: Frailty assessment of nonagenarian patients (n=15).

	Preoperative state	At discharge †	Latest assessment†, ¶
5-meter walk test (s)	7.2 ± 2.4	8.2 ± 3.1 (p=0.24)	8.7 ± 5.2 (p=0.23)
% grip strength (%) ‡	74.0 ± 19.7	73.1 ± 19.6 (p=0.82)	74.2 ± 22.6 (p=0.94)
Knee extensor strength (N) §	145.8 ± 63.4	144.5 ± 61.9 (p=0.90)	127.8 ± 59.1 (p=0.21)

†P-values were determined by comparing the results to the preoperative state. ‡% grip strength was calculated using the frailty cut-off value for the dominant arm (male patients: 26 kg, female patients: 18 kg). §Knee extensor strength was calculated as the average of the values for the right and left knees. ¶The latest assessment was performed at 4.1 ± 2.6 months after TAVI

were associated with mortality. However, the multivariate analysis only revealed a non-significant relationship with preoperative serum albumin concentrations (hazard ratio: 0.54, 95% confidence interval: 0.65-1.03, p=0.08).

Discussion

Healthcare systems and life expectancy values vary from country to country. For example, Japan has a universal and compulsory health insurance system that creates a unique healthcare delivery environment, relative to in countries without compulsory health insurance systems. There are several reports regarding the outcomes of TAVI in nonagenarians from Western countries [6-8], although to the best of our knowledge, this is the first report to investigate outcomes in the Japanese population. Takeji et al. [3] reported that the current in-hospital mortality rate for TAVI is 1.3% in Japan, which suggests that it has a high success rate and is being performed safely with very low mortality. The present study also revealed that TAVI in Japanese nonagenarians provided excellent short- and mid-term outcomes. For example, the in-hospital mortality rates were identical for our nonagenarian patients and younger patients (0% *vs.* 0%). Although hospital stays were longer in group N, the other short-term outcomes were comparable, which indicates that TAVI can be safely performed even in very elderly patients. Studies from Western countries have also shown that TAVI can achieve acceptable in-hospital outcomes in nonagenarians, and that age alone should not exclude patients from this treatment [6-8], which agrees with our findings.

One decade ago, SAVR was the only effective therapy for aortic valve stenosis, although the development of TAVI has dramatically changed the surgical treatment of aortic valve stenosis. Previous studies with nonagenarian cohorts revealed early mortality rates of 11% to 17% after SAVR [9,10], while recent observational studies have revealed noticeably lower in-hospital or 30-day mortality rates after TAVI in nonagenarians (0% to 8.7%) [6,7]. Furthermore, we did not detect any cases of in-hospital or 30-day mortality among our nonagenarian patients. Thus, although the long-term outcomes of TAVI remain unclear, it appears to be a useful therapeutic option and a reasonable alternative to SAVR in nonagenarians, based on their relatively short life expectancy.

Our results revealed that nonagenarian patients required longer hospital stays, and prolonged hospitalization can cause postoperative muscle weakness and impair Activities of Daily Living (ADL). Stehli et al. [7] reported that impairment of ADL after TAVI was more common in older patients, and that 25% of nonagenarian patients transitioned to aged-care facilities within 1 year after TAVI. We believe that this points to a disadvantage of TAVI that is specific to very elderly patients. We evaluated frailty assessment data for 15 of 23 the nonagenarian patients, as these assessments were not routinely performed during the early study period, but failed to identify any deterioration in frailty status during the early phase after TAVI (Supplemental Table 1). However, these data are insufficient for assessing the possible changes in ADL and quality of life. Unconscious scaling back of physical activity is a well-characterized phenomenon in patients with cardiac disease, and gradual improvement in activity may be possible after recovery of cardiac function (Supplemental Figure 1). Further investigations are needed to understand the long-term ADL outcomes of TAVI.

The two groups had very similar rates of freedom from cardiac events, and it is interesting that no late cardiac deaths occurred in the nonagenarian cohort. In this context, the Japanese Ministry of Health, Labor and Welfare has reported that the top 5 causes of mortality in nonagenarians are cardiac disease, pneumonia, senility,

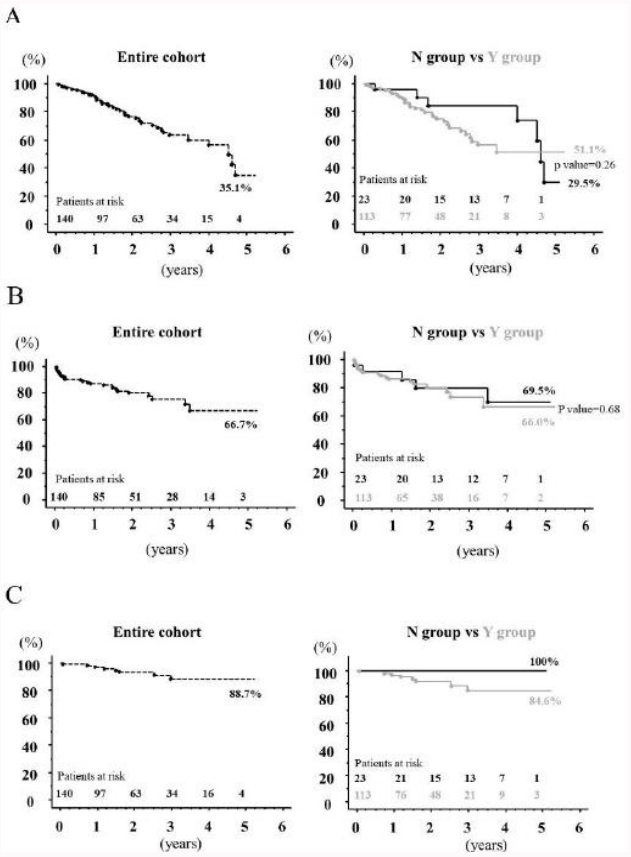
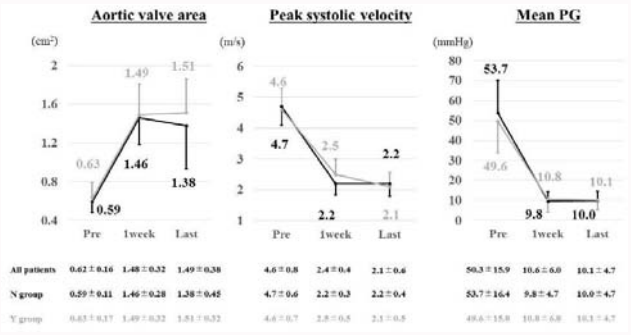


Figure 1: Mid-term outcomes: Curves for (A) cumulative survival, (B) freedom from cardiac events, (C) and freedom from cardiac death. The curves are indicated using a dashed black line for the overall cohort, a solid black line for the nonagenarian group (N), and a solid grey line for the younger group (Y).



Supplemental Figure 1: Preoperative and postoperative cardiac function evaluated using transthoracic echocardiography. The data of the nonagenarian (N) group are presented in black, and those of the younger (Y) group in gray. PG: pressure gradient.

cerebrovascular disease, and malignancy [11]. The causes of late death in our nonagenarian group were pneumonia in 3 patients, other infectious disease in 3 patients, and malignancy in 1 patient, but there were no cardiac deaths. Thus, TAVI may help prevent cardiac death in nonagenarian patients.

The wide-spread adoptions of TAVI and population aging have led to an increase in the number of TAVI procedures that are performed worldwide. Thus, it is essential to identify prognostic factors that can guide patient selection and stratification in the TAVI era. The reported predictors of post-procedural mortality after TAVI include anemia, intraoperative or postoperative blood transfusion, psoas muscle area, and appetite immediately before discharge [12-15]. The present study revealed that lower preoperative serum albumin concentrations might be associated with poor long-term outcomes, although this result was not statistically significant (p=0.08). However, serum albumin concentration is a known frailty marker and may be a potential predictor of TAVI outcomes. The present study also revealed that age did not predict prognosis, despite generally being a significant prognostic factor for other procedures. In this context, older patients have more co-morbidities and a higher operative risk, with older age considered an independent risk factor in major operative risk scores, including the Society of Thoracic Surgery, EuroSCORE, and JapanSCORE systems [16-18]. We believe that our finding regarding age might be explained by the equivalent risk scores in the nonagenarian and younger groups (Table 1). Thus, the nonagenarian patients might have been more carefully selected and in better condition, relative to the younger group, which would have affected the significance of age as a prognostic factor.

This study has several limitations. First, the retrospective observational study design is prone to selection bias. Second, the sample size was limited because our hospital is not a high-volume center. Third, data were not available regarding the outcomes of conservative medical therapy for nonagenarian patients with aortic stenosis.

Conclusion

The short- and mid-term clinical outcomes of TAVI in select Japanese nonagenarians were comparable to those in younger patients. Furthermore, TAVI may help prevent cardiac death in Japanese nonagenarian patients. Therefore, TAVI may be an effective treatment for aortic stenosis, even in nonagenarian patients.

Author Contributions

Hiroshi Kurazumi: data analysis and drafting the article. Akihito Mikamo, Takayuki Okamura: study conception and design. Ryo Suzuki, Bungo Shirasawa, Yosuke Miyazaki, Hiroki Tateishi, Tetsuro Oda: data collection. Masafumi Yano, Kimikazu Hamano: approval of the article.

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