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RAPID COMMUNICATION

Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement for Aortic Stenosis in Japan

— Analysis of a Nationwide Inpatient Database —

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Background: Nationwide data on transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in Japan are scarce.

Methods and Results: Using a nationwide inpatient database, we analyzed patients undergoing TAVI (n=8,338) or SAVR (n=16,298) due to aortic stenosis between 2014 and 2017. The annual number of TAVI increased rapidly from 2014 to 2017, particularly in older patients. In-hospital deaths were lower and the length of hospital stay was shorter for patients undergoing TAVI than SAVR.

Conclusions: TAVI has been penetrating in Japan as an alternative therapeutic option for aortic stenosis and is associated with acceptable clinical outcomes.

Key Words: Epidemiology; Surgical aortic valve replacement; Transcatheter aortic valve implantation

Transcatheter aortic valve implantation (TAVI) has rapidly become an alternative option for the treatment of aortic stenosis (AS) worldwide. TAVI has been available in Japan since October 2013. The latest guideline on the management of valvular heart disease of the Japanese Circulation Society (JCS) generally recommends surgical aortic valve replacement (SAVR) for patients aged <75 years but TAVI for patients aged ≥80 years, regardless of surgical risk.[1] However, the penetration rate of TAVI in real-world clinical practice in Japan was unknown, and real-world data comparing TAVI and SAVR in Japan that could validate the most recent JCS guidelines are scarce. In the present study, using a nationwide inpatient database, we sought to clarify the current status of TAVI and SAVR as a therapeutic option for AS and to compare the short-term clinical outcomes of TAVI and SAVR in Japan.

Methods

Data Source and Study Design

We undertook a retrospective cohort study using the Diagnosis Procedure Combination database, a nationwide inpatient database in Japan.[2,3] This database includes administrative claims data and clinical data for approximately 8 million hospitalized patients per year from participating hospitals, including all 82 academic hospitals. The main diagnosis, comorbidities on admission, and complications during hospitalization are recorded using the International Classification of Disease and Related Health Problems, 10th Revision (ICD-10) codes. Data for patients undergoing TAVI (n=8,338) and SAVR (n=21,812) for the

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Table 1. Clinical Characteristics and Outcomes of the Study Population

	Overall (n=24,636)	SAVR (n=16,298)	TAVI (n=8,338)	P value
Age (years)	79 [73–84]	76 [70–81]	85 [82–88]	<0.001
Age groups				
20–69 years	3,684 (15.0)	3,608 (22.1)	76 (0.9)	–
70–74 years	3,348 (13.6)	3,109 (19.1)	239 (2.9)	–
75–79 years	5,335 (21.7)	4,525 (27.8)	810 (9.7)	–
80–84 years	6,474 (26.3)	3,796 (23.3)	2,678 (32.1)	–
85–89 years	4,426 (18.0)	1,131 (6.9)	3,295 (39.5)	–
≥90 years	1,369 (5.6)	129 (0.8)	1,240 (14.9)	–
Male sex	9,871 (40.1)	7,245 (44.5)	2,626 (31.5)	<0.001
BMI (kg/m²)	22.7 [20.3–25.3]	23.0 [20.6–25.5]	22.1 [19.8–24.6]	<0.001
BSA (m²)	1.5 [1.4–1.6]	1.5 [1.4–1.7]	1.4 [1.3–1.5]	<0.001
Hypertension	13,710 (55.7)	9,325 (57.2)	4,385 (52.6)	<0.001
Diabetes	6,527 (26.5)	4,785 (29.4)	1,742 (20.9)	<0.001
Chronic renal disease	2,905 (11.8)	2,370 (14.5)	535 (6.4)	<0.001
Chronic liver disease	877 (3.6)	586 (3.6)	291 (3.5)	0.672
Chronic respiratory disease	1,397 (5.7)	895 (5.5)	502 (6.0)	0.089
Ischemic heart disease	6,663 (27.0)	3,870 (23.7)	2,793 (33.5)	<0.001
Myocardial infarction	104 (0.4)	73 (0.4)	31 (0.4)	0.383
Stroke	536 (2.2)	380 (2.3)	156 (1.9)	0.019
AF/atrial flutter	3,451 (14.0)	2,264 (13.9)	1,187 (14.2)	0.461
Clinical outcomes				
PCI	150 (0.6)	6 (0.0)	144 (1.7)	<0.001
Blood transfusion	18,546 (75.3)	14,043 (86.2)	4,503 (54.0)	<0.001
Pacemaker implantation	1,002 (4.1)	280 (1.7)	722 (8.7)	<0.001
Myocardial infarction	60 (0.2)	37 (0.2)	23 (0.3)	0.462
Stroke	526 (2.1)	379 (2.3)	147 (1.8)	0.004
Aortic dissection	23 (0.1)	5 (0.0)	18 (0.2)	<0.001
LOS (days)	21 [15–31]	23 [18–33]	16 [11–25]	<0.001
Length of ICU stay (days)	1 [0–3]	1 [0–3]	0 [0–1]	<0.001
LOS after main procedure (days)	16 [11–22]	18 [14–25]	10 [8–15]	<0.001
Medical costs (JPY)	5,157,965 [4,343,095–6,011,960]	4,576,445 [4,138,465–5,301,308]	5,943,945 [5,570,903–6,679,485]	<0.001
In-hospital death	558 (2.3)	421 (2.6)	137 (1.6)	<0.001
30-Day readmission rate	1,294 (5.4)	807 (5.1)	487 (5.9)	0.005

Data are presented as the median [interquartile range] or n (%). AF, atrial fibrillation; BMI, body mass index; BSA, body surface area; ICU, intensive care unit; LOS, length of hospital stay; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

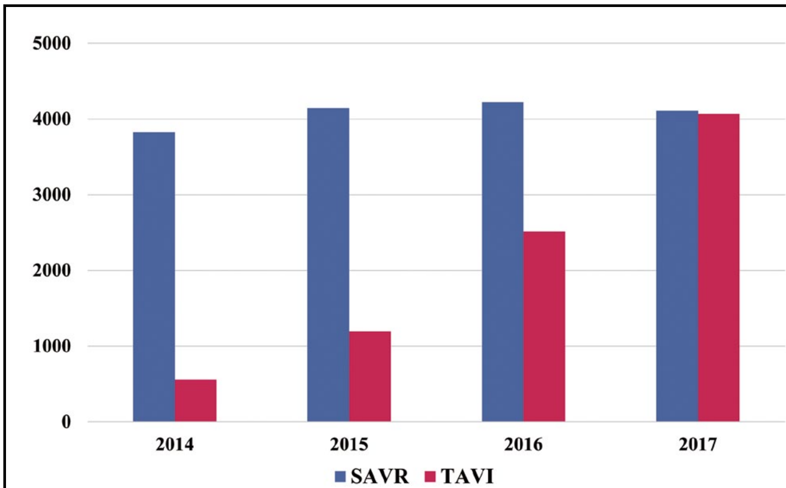

Figure 1. Serial changes in the annual number of surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI) procedures between 2014 and 2017.

Table 2. Comparison of SAVR and TAVI by Age and Year of Procedure

	SAVR	TAVI	P value
In-hospital mortality			
<70 years	1.7 (63/3,608)	2.6 (2/76)	0.562
70–74 years	2.2 (69/3,109)	3.3 (8/239)	0.262
75–79 years	2.7 (120/4,525)	1.7 (14/810)	0.122
80–84 years	3.2 (120/3,796)	1.3 (34/2,678)	<0.001
85–89 years	3.7 (42/1,131)	1.6 (53/3,295)	<0.001
≥90 years	5.4 (7/129)	2.1 (26/1,240)	0.019
LOS after main procedure (days)			
<70 years	16 [13–22]	11 [8–18]	0.486
70–74 years	17 [14–23]	12 [8–19]	<0.001
75–79 years	18 [14–25]	10 [7–15]	<0.001
80–84 years	19 [15–27]	10 [7–14]	<0.001
85–89 years	20 [16–29]	11 [8–16]	<0.001
≥90 years	21 [15–29]	11 [8–17]	<0.001
Medical costs (JPY)			
<70 years	4,444,630 [4,010,313–5,143,133]	6,038,855 [5,595,208–7,048,298]	<0.001
70–74 years	4,511,540 [4,108,205–5,203,270]	6,142,040 [5,550,870–7,074,290]	<0.001
75–79 years	4,606,300 [4,177,330–5,293,720]	5,941,760 [5,592,983–6,582,138]	<0.001
80–84 years	4,647,795 [4,215,373–5,408,115]	5,869,765 [5,532,495–6,542,023]	<0.001
85–89 years	4,807,190 [4,322,950–5,660,470]	5,954,200 [5,574,510–6,715,220]	<0.001
≥90 years	5,192,340 [4,551,765–6,021,320]	6,070,120 [5,644,175–6,891,508]	<0.001
In-hospital mortality			
2014	2.7 (103/3,825)	2.5 (14/559)	0.796
2015	2.6 (108/4,146)	1.5 (18/1,197)	0.027
2016	2.7 (112/4,220)	1.6 (40/2,515)	0.004
2017	2.4 (98/4,107)	1.6 (65/4,067)	0.011
LOS after main procedure (days)			
2014	18 [14–25]	10 [8–16]	<0.001
2015	18 [14–25]	11 [8–16]	<0.001
2016	18 [14–25]	11 [8–16]	<0.001
2017	17 [14–24]	10 [7–14]	<0.001
Medical costs (JPY)			
2014	4,554,060 [4,109,925–5,264,235]	6,210,960 [5,952,550–6,973,150]	<0.001
2015	4,579,170 [4,144,098–5,327,608]	6,219,850 [5,894,310–6,995,625]	<0.001
2016	4,579,285 [4,144,700–5,306,113]	5,946,910 [5,567,490–6,693,220]	<0.001
2017	4,591,450 [4,152,760–5,299,180]	5,775,740 [5,476,960–6,512,690]	<0.001

Data are presented as the median [interquartile range] or as the percentage (n/N). LOS, length of hospital stay; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

treatment of AS between 2014 and 2017 were extracted from the database. Patients who underwent SAVR and other cardiac surgeries, such as coronary artery bypass graft, and other valve surgeries simultaneously (n=5,514) were excluded from the study, with only patients undergoing isolated SAVR (n=16,298) included.

Ethics

This study was approved by the Institutional Review Board of The University of Tokyo [Reference no. 3501-(3)]. This study was conducted in accordance with the Declaration of Helsinki. Because of the anonymous nature of the database, the requirement for informed consent was waived.

Statistical Analysis

Continuous and categorical data are presented as the median with interquartile range and as numbers with percentages, respectively. Unpaired t-tests were used to compare continuous data between TAVI and SAVR, whereas categorical variables were compared using the Chi-squared test. P value <0.05 was considered significant. Statistical analyses were performed using SPSS version 25 and STATA version 16.

Results

Characteristics of the Study Population

Overall, patients undergoing TAVI were older than those undergoing SAVR and more likely to be female. Body mass index and body surface area were both lower in patients undergoing TAVI. The annual number of TAVI increased from 559 in 2014 to 4,067 in 2017 (**Table 1**). The annual case numbers of SAVR and TAVI are summarized in **Figure 1**. The ratio of TAVI to patients undergoing TAVI or SAVR increased from 12.8% in 2014 to 49.8% in 2017.

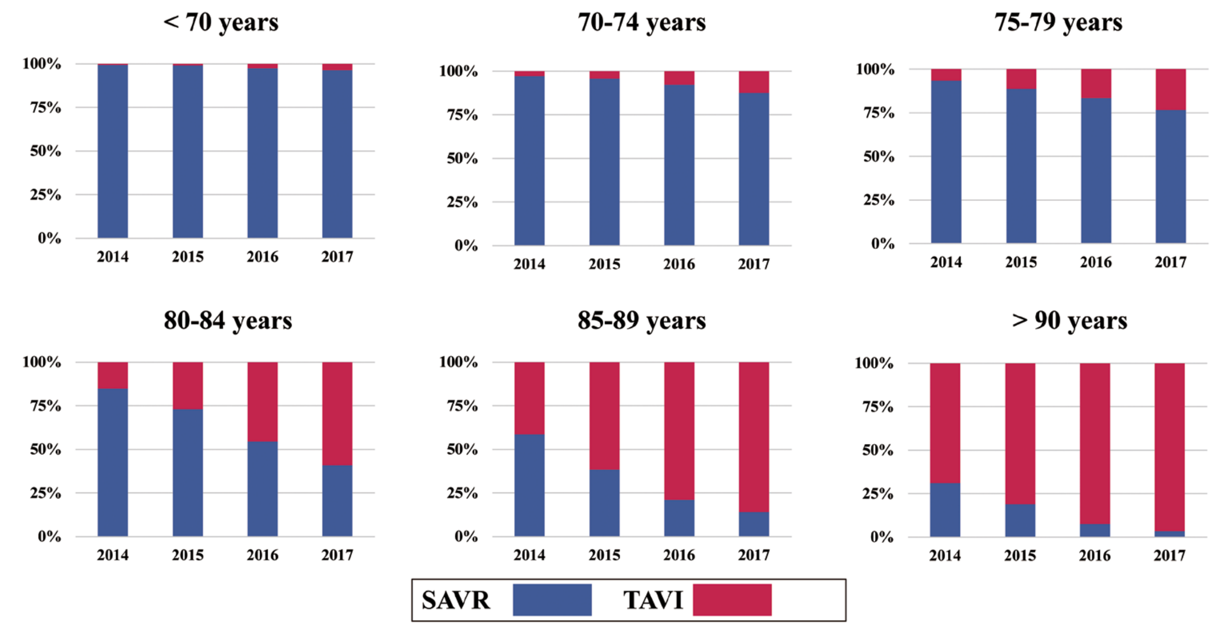

Figure 2. Serial changes in the ratio of surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI) procedures according to age.

Comparison of Clinical Outcomes Between TAVI and SAVR

Stroke was less common, whereas percutaneous coronary intervention and pacemaker implantation were more common in patients undergoing TAVI than SAVR. In-hospital mortality was higher and the length of hospital stay was longer in patients undergoing SAVR. Conversely, medical costs were higher for patients undergoing TAVI than for those undergoing SAVR (**Table 1**).

Comparison of SAVR and TAVI by Age Category

Among patients aged <80 years, there was no significant difference in-hospital mortality between patients undergoing SAVR and TAVI; however, for patients aged ≥80 years, in-hospital mortality was significantly lower in patients undergoing TAVI. Length of hospital stay was comparable between the 2 groups among patients aged <75 years, but was shorter for patients treated with TAVI for those aged ≥75 years. Medical costs were higher for patients undergoing TAVI than for those undergoing SAVR in all age categories (**Table 2**).

Comparison of SAVR and TAVI by Year of Procedure

In-hospital mortality was not significantly different between the SAVR and TAVI groups in 2014, but was significantly lower in patients undergoing TAVI in 2015, 2016, and 2017. The length of hospital stay was longer for patients undergoing SAVR than TAVI during 2014 and 2017. Medical costs were higher for patients treated with TAVI than SAVR every year. However, the medical cost for patients undergoing TAVI declined gradually between 2015 and 2017 (**Table 2**).

Serial Changes in the Ratio of SAVR and TAVI by Age

In all age categories, the ratio of TAVI to SAVR cases increased between 2014 and 2017. However, SAVR was performed in most patients aged <80 years, even in 2017. Conversely, TAVI was the treatment of choice in most patients aged ≥80 years in 2017 (**Figure 2**).

Discussion

SAVR has been the only therapeutic option for patients with AS for decades. However, TAVI has emerged as a novel alternative treatment strategy for AS patients who were considered inoperable or at high conventional surgical risk.[4–6] TAVI obtained a CE mark in 2007. Since then, the number of TAVI procedures has been increasing rapidly, primarily in Western countries. German nationwide data demonstrated that the number of SAVR declined slightly between 2008 and 2014, whereas there was a 20-fold increase in the number of TAVI during the same period, with the number of TAVI surpassing the annual number of isolated SAVR in 2013.[7]

In the early days, TAVI was primarily performed in patients with AS who were considered inoperable or at high surgical risk. However, advances in treatment techniques and devices have reduced in-hospital mortality and life-threatening complications of TAVI,[8] and recent randomized controlled trials demonstrated that TAVI was non-inferior or even superior to SAVR in patients with AS at intermediate or low surgical risk.[9,10] This striking clinical evidence also supports the penetration of TAVI.

In Japan, the number of elderly patients with heart failure is increasing,[2] and nationwide actions are required for the upcoming era of the "heart failure pandemic".[11,12] From this point of view, TAVI has been thought to have great potential in Japan because valvular heart disease, particularly AS, is a major cause of heart failure in the elderly.

Six years after the introduction of TAVI in Europe, TAVI became eligible for reimbursement in Japan in October

2013; thereafter, TAVI has become a novel therapeutic option for AS in Japan as well. Recently, the JCS updated the guidelines for the management of valvular heart disease.[1] This updated JCS guideline generally recommends SAVR for patients aged <75 years and TAVI for those aged ≥80 years, regardless of surgical risk. Although a report from combined registries is available,[13] so far there are no nationwide large-scale data available comparing TAVI and SAVR in Japan. Therefore, there has been scarce real-world clinical data supporting this updated guideline. According to the statistics of the Japanese Association for Thoracic Surgery, the database we used in the present study includes more than 80% of TAVI and SAVR cases. Therefore, we believe that our study is suitable for overviewing the current status of TAVI and SAVR for the treatment of AS in Japan, and for validating the updated JCS guideline regarding the management of valvular heart disease.

As expected, the number of TAVI procedures increased over time in all age categories (**Figures 1**,**2**). However, it should be noted that the number of SAVR cases did not decrease after the introduction of TAVI, which may imply that TAVI has been used as a novel therapeutic option for patients who would not have been treated with surgery before the introduction of TAVI. Accordingly, TAVI has already been performed in most patients aged ≥80 years, suggesting that TAVI has become the mainstream treatment for AS in elderly patients in Japan. Conversely, SAVR was predominantly performed in patients aged <75 years, even in 2017. SAVR is still a standard treatment for younger patients. From this perspective, the recommendation in the updated JCS guideline is concordant with the real-world clinical practice for the treatment of patients with AS in Japan.

Notably, analysis of the overall population showed that TAVI had better short-term clinical outcomes, including in-hospital mortality and length of hospital stay, than SAVR, despite the fact that patients treated with TAVI were approximately 10 years older than those undergoing SAVR. Taking this into consideration, the widespread use of TAVI in Japan is generally acceptable and reasonable. However, the 30-day readmission rate was unexpectedly higher in patients undergoing TAVI. Because the reasons for the hospital readmission were not available, detailed evaluation of this phenomenon is unfortunately difficult. Further studies are required to investigate this finding.

The next issue is whether TAVI could be a standard treatment for AS among patients in their late 70s. In the latest JCS guideline, the indications for patients aged 75–79 years are positioned as a "grey area".[1] Our analysis showed that the short-term clinical outcomes of TAVI were favorable in this category. In the latest European Society of Cardiology guideline, TAVI is recommended for patients aged ≥75 years.[14] However, considering the difference in life expectancy between Japanese and European patients and the unknown long-term durability of TAVI, more detailed clinical data with a longer follow-up (particularly deterioration of biological valves), including in Japanese patients, are needed.

Although the medical costs were significantly higher for patients undergoing TAVI than SAVR, the medical costs of TAVI have declined gradually. Factors contributing to the reduction in medical costs for patients treated with TAVI include the use of local anesthesia and shorter hospital stays. The spread of minimally invasive TAVI procedures may lead to a further decline in medical costs. From the perspective of healthcare economics, medical costs are quite important. More data on medical costs are also needed.

As reported previously,[15–17] there are still several unresolved issues associated with TAVI, such as paravalvular regurgitation, conduction disturbance requiring pacemaker implantation, postprocedural heart failure, coronary occlusion, and the indication for bicuspid AS, among other. Although our analysis of a nationwide epidemiological database showed favorable outcomes of TAVI, a thorough evaluation of and detailed discussion for individual cases by a multidisciplinary heart team are always indispensable for determining the optimal management and treatment strategies. Because detailed data assessing specific conditions and complications are unfortunately lacking in the Diagnosis Procedure Combination database, data from on-going registries focusing on TAVI, such as the OCEAN registry, the K-TAVI registry, and our IMPACT-TAVI registry, are also essential as informative data sources of Japanese patients treated with TAVI.

Study Limitations

We acknowledge several limitations in this study. Unfortunately the Diagnosis Procedure Combination database lacked data on several factors that could have affected outcomes, including the severity of heart failure, renal function, left ventricular ejection fraction, anatomical features, and surgical risk scores (e.g., Society of Thoracic Surgeons score and Logistic EuroSCORE). Therefore, we could not conduct adjusted analyses and present unadjusted data. In addition, we had no information on mortality after hospital discharge. Although the validity of diagnoses and procedures in the Diagnosis Procedure Combination database was reported to be high,[18] recorded diagnoses are generally considered less well validated because of the nature of administrative data and retrospective studies.

Conclusions

Our analysis of a nationwide inpatient database showed a rapid increase in the number of TAVI procedures in all generations in Japan, in association with acceptable short-term clinical outcomes of TAVI. We believe that our results provided an informative overview of the current status of TAVI and SAVR in Japanese patients with AS. Further continuous research is essential for the development of this novel field.

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Disclosures

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IRB Information

This study was approved by the Clinical Research Review Board of The University of Tokyo [Reference no. 3501-(3)].

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