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ORIGINAL ARTICLE

Hemodynamic comparison of CoreValve and SAPIEN-XT TAVI valves in Japanese patients

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Abstract

Transcatheter aortic valve implantation (TAVI) is a viable treatment option for high-risk patients with severe aortic stenosis. In Japan, TAVI can be performed using first-generation self-expandable Medtronic CoreValve or balloon-expandable Edwards SAPIEN-XT from 2012. Since the durability and hemodynamic outcomes after transcatheter heart valve (THV) implantation in Japanese patients have not been clearly elucidated, we assessed serial changes in post-TAVI THV performances over a-3-year period by transthoracic echocardiography (TTE). From January 2012 to September 2014, among 83 patients with severe aortic stenosis, 26 underwent TAVI with CoreValve and 57 underwent TAVI with SAPIEN-XT. We assessed the serial changes in first post-implant (FPI) and 3-year post procedure THV hemodynamics by TTE. Valve performance was evaluated by serial assessment of aortic valve mean pressure gradient (PG) and aortic valve area (AVA) assessments. Three-year clinical outcomes were compared between the patients with CoreValve and those with SAPIEN-XT. Seventeen patients with CoreValve and 34 patients with SAPIEN-XT had FPI and 3-year TTEs. The AVA decreased significantly from FPI to 3-year follow-up among patients with SAPIEN-XT, but not among patients with CoreValve. The mean aortic PG decreased significantly from FPI to the 3-year follow-up point among patients with CoreValve; however, it was not significantly different from those with SAPIEN-XT. The absolute change in mean PG from FPI to the 3-year follow-up point decreased significantly among those with CoreValve compared to those with SAPIEN-XT. Clinical outcomes after TAVI were similar for both devices at 3-years after TAVI. In this study, long-term clinical outcomes for CoreValve and SAPIEN XT were similar. The 3-year THV performance of both devices was maintained after TAVI. Serial change in mean aortic PGs for CoreValve decreases significantly from FPI to the 3-year follow-up point compared to that for SAPIEN-XT.

Keywords Transcatheter aortic valve implantation · Aortic stenosis · Durability · Transcatheter heart valve performance

Introduction

Transcatheter aortic valve implantation (TAVI) has emerged as a viable treatment option for patients with severe aortic stenosis (AS) who are considered poor surgical candidates [1, 2]. Two types of devices, self-expandable and balloon-expandable, have been developed for use in TAVI. Numerous studies have been published on the safety and efficacy of both devices, and both valves have been associated with favorable short- and long-term outcomes [3, 4].

The first clinical trials on TAVI were conducted in Japan. The results showed that both the balloon-expandable and self-expandable valves were functionally and anatomically effective when used in high surgical risk patients with severe symptomatic AS [5, 6]. Moreover, mid-term and long-term results demonstrated that TAVI was associated with sustained clinical and functional cardiac improvement in Japanese patients [7, 8]. Based on these results, TAVI, using the balloon expandable device, became a feasible option for treating AS, and has been covered by Japanese insurance policies since October 2013. However, there is limited

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evidence regarding the long-term valve hemodynamic performance following TAVI with the balloon-expandable or self-expandable devices are used in Japanese patients who have smaller body sizes than Western people [9, 10]. These differences could influence the hemodynamic performance after TAVI. Moreover, long-term maintenance of transcatheter heart valve (THV) performance is an important factor if TAVI is to be considered acceptable for use in a larger number of patients, including those younger patients with a lower surgical risk.

Herein, we assessed that the serial change in the post-TAVI THV hemodynamic performance of the CoreValve and SAPIEN-XT over a 3-year period by transthoracic echocardiography (TTE) in high-risk Japanese patients treated for severe AS.

Methods

Patient selection

The study population included patients with severe symptomatic aortic stenosis who were candidates for TAVI from January 2012 to July 2013. Of those patients, 26 were treated using the CoreValve (Medtronic CoreValve LLC, Irvine, CA USA), which included 20 patients who participated in clinical trial MDT-2111 at our institution to get official approval from Japanese Ministry of Health and Welfare. The primary MDT-2111 analysis was reported previously [5]. In brief, the key inclusion criteria were: severe symptomatic AS, with a mean gradient > 40 mmHg and an aortic valve area < 0.8 cm^2. Clinical exclusion criteria were: recent myocardial infarction (MI) (≤ 30 days prior to the procedure); percutaneous vascular procedure (≤ 30 days prior to the procedure); untreated, clinically significant coronary artery disease; left ventricular ejection fraction < 20%; cerebrovascular incident within the previous 6 months; and end-stage renal disease requiring chronic replacement therapy. Anatomical exclusion criteria were: a native aortic annulus size < 20 mm or > 27 mm; a preexisting prosthetic heart valve in any location; mixed aortic valvular disease with predominant aortic regurgitation; moderate to severe mitral or tricuspid valve regurgitation; an ascending aortic diameter > 40 mm; bicuspid or unicuspid valve; femoral or iliac arterial diameter < 6 mm (unable to accommodate an 18F sheath).

From October 2013 to September 2014, 57 patients were treated using the SAPIEN-XT (Edwards Lifesciences, Irvine, CA, USA) in routine medical practice. All patients were evaluated in a multidisciplinary review conference by a heart team that included 2 interventional cardiologists, a cardiac surgeon, and an anesthesiologist. All patients provided written informed consent for the procedures. The study protocol was approved by the Institutional Review Board (Approval Number: TGE01069-024) at Tokushukai Group Ethical Committee and conformed to the Declaration of Helsinki.

Antiplatelet and anticoagulation therapies including daily aspirin 81–325 mg and ticlopidine were recommended for at least 3 months following the procedure. Continuation beyond 3 months was left to the discretion of the treating physicians.

Echocardiography

All patients underwent serial echocardiograms performed at baseline (before valve replacement), post-TAVI (first post-implant (FPI) at 24–48 h after the procedure), and at 7 days, 30 days, 6 months, 1 year, 2 years, and 3 years after the procedure.

Study endpoints

The primary endpoint of this study is the serial change in THV hemodynamics including the parameters of aortic valve area (AVA), peak velocity, and mean aortic pressure gradient (PG) for the CoreValve and SAPIEN-XT at FPI and 3-year post-procedure on TTE. All TTE measurements were performed in accordance with the recommendation of the American Society of Echocardiography [11].

We compared the 3-year clinical outcomes between the patients of CoreValve implantation and those of SAPIEN-XT. Furthermore, we investigated clinical events according to Valve Academic Research Consortium (VARC)-2 criteria [12]. These data were retrospectively analyzed.

Statistical analysis

Quantitative variables are expressed as means ± standard deviations or medians and interquartile ranges (IQRs), as appropriate. Quantitative variables were compared using the Student's *t* test or Wilcoxon rank-sum test. Variables were compared between the FPI and 3-year time points using the paired *t* tests or McNemar tests for continuous and categorical variables, respectively. Survival curves regarding for all-cause mortality were estimated using the Kaplan–Meier method, and survival estimates were compared using the log-rank test. For all analyses, statistical significance was defined as $p < 0.05$. All statistical calculations were carried out using SPSS statistics version 19.0 (SPSS, Chicago, IL, USA).

Results

Baseline characteristics

From January 2012 to September 2014, 26 patients with severe aortic stenosis were treated using self-expandable

CoreValves. Of these, 20 patients were treated with CoreValves during the clinical trial (MDT-2111) in our hospital. Fifty-seven patients were treated with balloon-expandable valves (Edwards SAPIEN-XT) as part of routine medical practice (Fig. 1). Baseline characteristics among patients with CoreValve and SAPIEN-XT are presented in Table 1. The mean age was 86 ± 3.6 years among patients that received CoreValve and 84 ± 5.1 among those that received SAPIEN-XT ($p = 0.10$). The baseline risk factors were comparable between the 2 devices except for the Logistic Euroscore (24.6 ± 8.6 for CoreValve and 17.1 ± 10.6 for SAPIEN-XT, $p < 0.05$). On baseline echocardiography, the two devices were similar with respect to the AVAs, AVA indices, in-stent peak velocities, aortic valve mean PGs, stroke volume indices, and ejection fractions (Table 2). Left ventricular diastolic dimensions (LVDd), left ventricular end diastolic volumes (LVEDV) and left ventricular end systolic volumes (LVESV) were greater in patients with the SAPIEN-XT compared to those with the CoreValve. The procedure characteristics showed that transfemoral access was the most common access route for both devices (Table 3).

Clinical outcomes

All-cause mortality rate at 30 days was 3.8% in patients of CoreValve and 1.8% in SAPIEN-XT ($p = 0.454$). Rates of VARC-2 defined neurologic events, myocardial infarction, vascular complications and life-threatening bleeding at 30 days are listed in the Table 4. Three-year long-term mortality was 30.8% in CoreValve and 21.0% in SAPIEN-XT. The Kaplan–Meier survival curve is illustrated in Fig. 2, and shows no significant difference between the two devices (log-rank $p = 0.400$).

One patient with CoreValve underwent TAVI in TAVI (CoreValve in CoreValve) after 2 months because of valve migration to the ascending aorta. Two patients with SAPIEN-XT underwent surgical aortic valve replacement due to valve migration to the left ventricule.

Long-term valve performance

As shown in the Fig. 1, 3-year's echocardiographic follow-up results were available for 17 patients of 26 patients in CoreValve (65.4%) and 34 patients of 57 patients in SAPIEN-XT (69.2%). Mean pressure gradients decreased from 57.8 mmHg (pre-TAVI) to 13.0 mmHg (FPI); AVAs increased from 0.53 (pre-TAVI) to 1.84 (FPI) for the CoreValve. Likewise, mean pressure gradients decreased from 52.4 (pre-TAVI) to 11.6 (FPI); AVAs increased from 0.58 to (pre-TAVI) to 1.88 (FPI) for the SAPIEN-XT. After the TAVI procedure, the AVA and AVA index were not significantly different between the FPI and 3-year measurements for the CoreValve (FPI: 1.84 cm^2/1.31 cm^2/m^2, 3-year: 1.85 cm^2/1.37 cm^2/m^2, $p = 0.28/0.18$). For the SAPIEN-XT, the AVA was significantly smaller, but the AVA index was not significantly different between the FPI and 3-year time points (FPI: 1.88 cm^2/1.33 cm^2/m^2, 3-year: 1.86 cm^2/1.29 cm^2/m^2, $p = 0.025$ /0.10). The mean PG significantly decreased from FPI to the 3-year point in MCV (FPI 13.0 mmHg, 3-year 8.1 mmHg, $p < 0.001$). On the other hand, there was no significant difference from FPI to

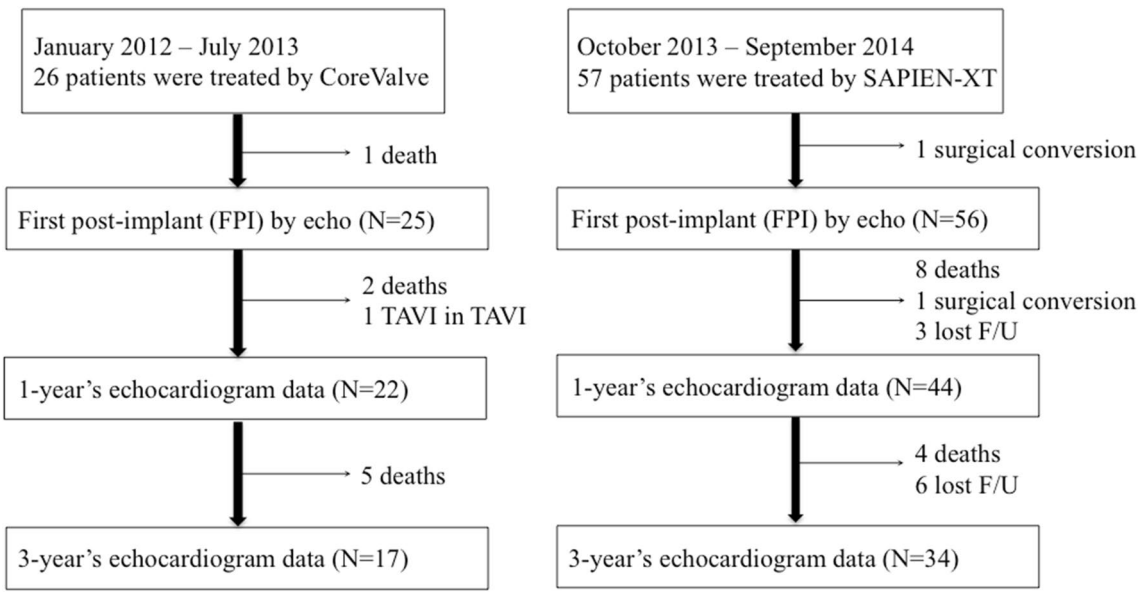

Fig. 1 Study flow chart. Among patients with the SAPIEN-XT, 34 (59.6%) were examined by echocardiography at 3 years. Seventeen patients (65.4%) with CoreValves were examined

Table 1 Baseline characteristics

	CoreValve, $n=26$	SAPIEN-XT, $n=57$	p value
Baseline clinical characteristics			
Age, years	85.9 ± 3.6	84.0 ± 5.1	0.086
Male	7 (26.9)	19 (33.3)	0.618
Height, cm	150.0 ± 10.0	152.6 ± 9.1	0.235
Body weight, kg	47.9 ± 10.1	50.2 ± 10.8	0.371
BMI, kg/m^2	21.2 ± 2.9	21.5 ± 3.5	0.716
BSA, m^2	1.40 ± 0.18	1.45 ± 0.18	0.297
Peripheral artery disease, *n*	3 (11.5)	3 (5.3)	0.371
Coronary artery disease, *n*	11 (42.3)	21 (37.5)	0.808
Previous MI, *n*	3 (11.5)	5 (8.8)	0.701
Previous PCI, *n*	14 (53.8)	20 (35.1)	0.149
Previous CABG, *n*	3 (11.5)	2 (3.5)	0.175
Previous pacemaker implantation, *n*	0	4 (7.0)	0.304
Atrial fibrillation, *n*	2 (7.7)	13 (22.8)	0.129
Diabetes mellitus, *n*	5 (19.2)	18 (32.1)	0.295
Hypertension, *n*	20 (76.9)	38 (67.9)	0.447
Chronic obstructive pulmonary disease, *n*	1 (3.8)	10 (17.5)	0.160
eGFR, ml/min	63.1 ± 17.9	72.8 ± 26.5	0.092
CKD (eGFR < 60), *n*	13 (50.0)	23 (40.4)	0.478
STS score, %	6.6 ± 2.5	7.2 ± 5.3	0.589

BMI body mass index, *BSA* body surface area, *MI* myocardial infarction, *PCI* percutaneous coronary intervention, *CABG* coronary artery bypass grafting, *eGFR* estimated glomerular filtration rate, *CKD* chronic kidney disease, *STS* Society of Thoracic Surgeons

Table 2 Baseline echocardiographic characteristics

	CoreValve, $n=26$	SAPIEN-XT, $n=57$	p value
Aortic valve area, cm^2	0.54 ± 0.15	0.57 ± 0.17	0.387
Indexed aortic valve area, cm^2/m^2	0.39 ± 0.10	0.41 ± 0.11	0.493
Peak velocity, m/s	4.95 ± 0.54	4.64 ± 0.65	0.055
Mean pressure gradient, mmHg	57.8 ± 14.0	53.1 ± 16.9	0.267
Peak pressure gradient, mmHg	96.0 ± 19.0	86.4 ± 25.0	0.114
Heart rate, beats/min	70.0 ± 12.8	68.4 ± 12.7	0.710
LVEF, %	58.5 ± 14.5	59.9 ± 8.8	0.659
LV mass	182.9 ± 44.8	197.7 ± 44.1	0.217
LVMI	130.4 ± 27.3	137.9 ± 26.5	0.296
LVDd, mm	40.5 ± 6.1	44.0 ± 5.1	0.021
LVDs, mm	27.6 ± 4.5	29.7 ± 4.2	0.067
IVSth, mm	12.7 ± 1.4	12.2 ± 1.4	0.164
PWd, mm	12.2 ± 2.7	12.1 ± 1.0	0.867
LVEDV	59.5 ± 21.4	76.1 ± 30.4	0.023
LVESV	22.9 ± 9.8	32.5 ± 17.8	0.017
MR ≥ moderate	0	3 (5.3)	0.242
AR ≥ moderate	0	2 (3.5)	0.495

LVEF left ventricular ejection fraction, *LV* left ventricular, *LVMI* left ventricular mass index, *LVDd* left ventricular end-diastolic dimension, *LVDs* left ventricular diameter in systole, *IVSth* interventricular septal thickness, *PWd* posterior wall thickness, *LVEDV* left ventricular end-diastolic volume, *LVESV* left ventricular end-systolic volume, *MR* mitral regurgitation, *AR* aortic regurgitation

the 3-year point in ESV (11.6 mmHg, 3-year 10.0 mmHg, $p=0.22$) (Fig. 3). The absolute change in mean PG from FPI to the 3-year point was significantly decreased for the CoreValve compared to the SAPIEN-XT (5.3 ± 4.2, 1.0 ± 4.4 mmHg, $p=0.002$) (Fig. 4). Five patients with CoreValves had a greater than 20 mmHg change in mean pressure

Table 3 Procedural outcomes

	CoreValve, $n=26$	SAPIEN-XT, $n=57$	p value
Valve size			
23 mm, *n*	7 (27)	38 (67)	
26 mm, *n*	13 (50)	19 (33)	
29 mm, *n*	6 (23)		
Approach route			
Transfemoral, *n*	21 (81)	53 (93)	0.103
Non-transfemoral, *n*	5 (19)	4 (7)	
Valve migration	1 (3.8)	2 (3.5)	0.682
Annulus rupture	0	0	
Coronary obstruction	0	0	
New pacemaker implantation, *n*	2 (7.7)	2 (3.5)	0.199

gradient at FPI. All these patients had improved PGs during the observational period. On the other hand, there were no patients with SAPIEN-XT that had a greater than 20 mmHg change in mean PG at FPI. One patient had a change of 24 mmHg in mean PG on the 3-year echocardiogram.

Five patients with CoreValve and one patient with a SAPIEN-XT developed moderate AR at FPI after TAVI. One patient with a CoreValve underwent TAVI in TAVI after 2 months due to valve migration. The degree of AR for two patients with CoreValves showed improvement on the 1-week TTE, while the other 2 patients showed improvement in the 1-year TTE after TAVI. Likewise, in the patients with moderate AR at FPI after SAPIEN-XT implantation, the degree of AR improved in the 1-week TTE. On the other hand, one patient with a SAPIEN-XT and mild AR at FPI experienced a worsening to moderate AR on the 1-week TTE. That patient was hospitalized for decompensated heart failure due to moderate AR after 2 years. Even though she underwent paravalvular leakage closure with an Amplatzer Vascular Plug, she died of heart failure and sepsis.

Altogether, the incidence of paravalvular regurgitation among patients with valvular implants was stable over time for both devices. There was a relatively high rate of no or trace aortic regurgitation after 3 years among patients with CoreValve (70.6% among those with CoreValve vs. 52.9% among those with SAPIEN-XT at 3 years, $p=0.18$) (Fig. 5).

The relationship between AR grade at FPI and AR grade at the 3-year time point for each patient is shown in Fig. 6. The rates of improvement in patients with AR from FPI to the 3-year time point were 52.9% for those with CoreValve and 32.3% for those with SAPIEN-XT.

Discussion

The present study showed that there was at least 3 years' durability in hemodynamic valve performance after TAVI with using CoreValve and SAPIEN-XT. The main findings of present study include: (1) the 3-year valve performance

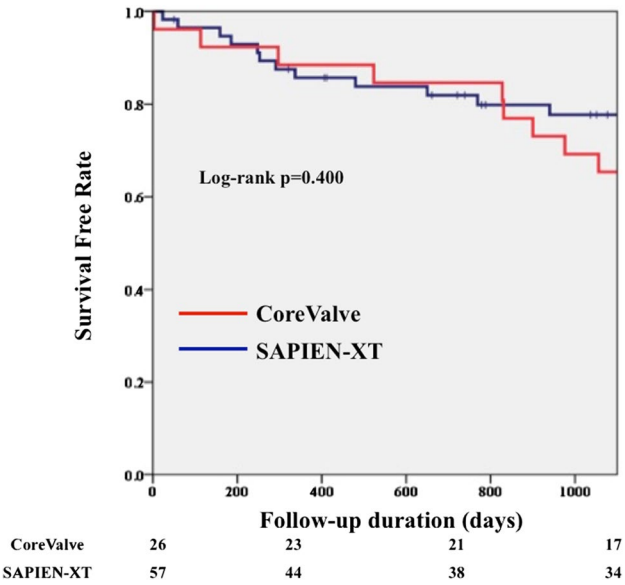

Fig. 2 Long-term clinical outcomes. Kaplan–Meier curve for all-cause mortality among patients with CoreValve and SAPIEN-XT

Table 4. 30 days clinical outcomes

	CoreValve, $n=26$	SAPIEN-XT, $n=57$	p value
All-cause mortality, *n*	1 (3.8)	1 (1.8)	0.454
Myocardial infarction	0	0	
Disabling stroke, *n*	0	0	
Transit ischemic accident (TIA), *n*	0	1 (1.8)	0.679
Major vascular complication, *n*	1 (3.8)	3 (5.2)	0.629
Minor vascular complication, *n*	2 (7.7)	2 (3.5)	0.371
Life threatening or disabling bleeding, *n*	1 (3.8)	3 (5.2)	0.629
Acute kidney injury (AKI), *n*	1 (3.8)	3 (5.2)	0.629

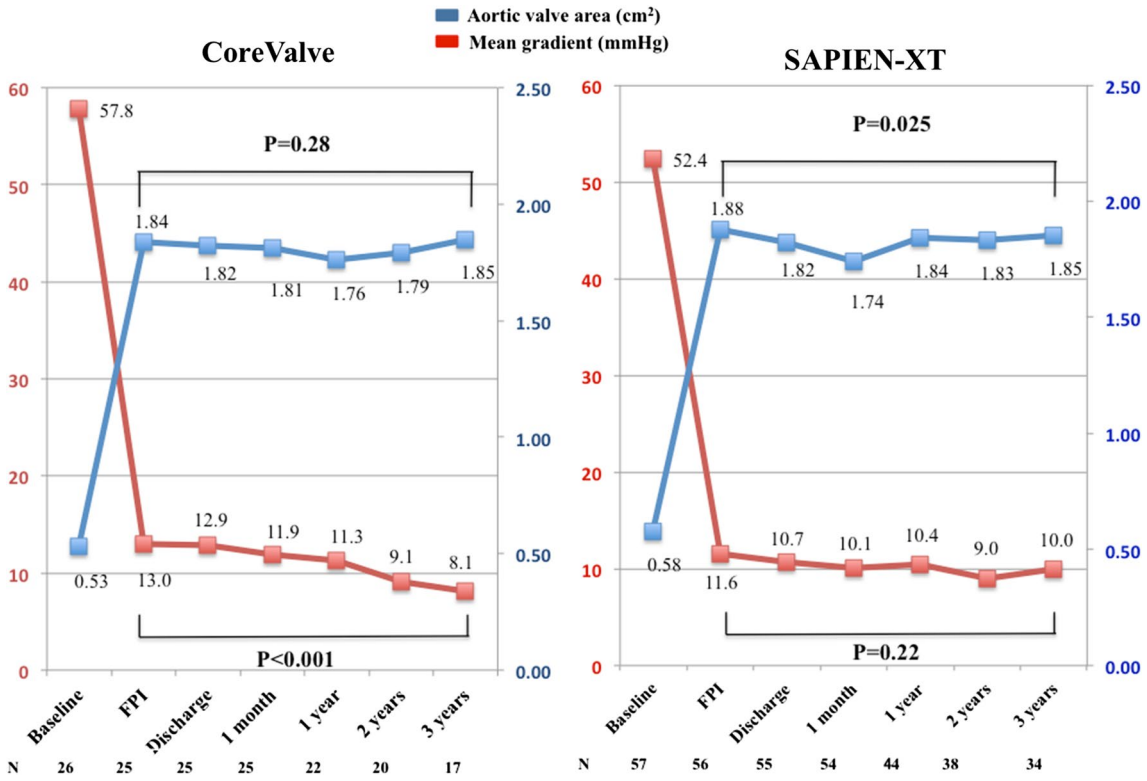

Fig. 3 Hemodynamic changes through 3 years after CoreValve and SAPIEN-XT implantations. Left side: changes in the of mean pressure gradient and aortic valve area in patients with CoreValves. Right side: changes in the of mean pressure gradient and aortic valve area in patients with SAPIEN-XTs. *FPI* first post-implant

for both the CoreValve and the SAPIEN-XT were maintained, and clinical outcomes were also similar between two devices among high surgical risk of Japanese patients after TAVI; (2) the mean PG in the patients with CoreValve significantly decreased from FPI to the 3-year time point, compared to the patients with SAPIEN-XT.

In our results, both valves showed significant reductions in mean PGs after TAVI, and these results remained low and stable over time. These findings are in line with the results of long-term valvular hemodynamic performance after SAPIEN series implantations in the PARTNER 1 trial as well as the Canadian TAVI multicenter registries [13, 14]. Edwards SAPIEN was used in the previous studies, whereas SAPIEN-XT in our study. Regarding the CoreValve system, another report demonstrated that valvular hemodynamic performance was maintained until 2 years compared to surgically placed aortic valves [4]. The ADVANCE study investigated a large cohort of nearly 1000 patients after CoreValve implantation and demonstrated valvular hemodynamic improvement after TAVI at the 3-year follow-up point [15]. The most significant difference in baseline characteristics between our report and other Western studies was body size. The median value of BSA and BMI in this study was obviously small compared with previous studies [9]. In addition, the majority of the used devices were also small ones. Although smaller THV would be generally associated with high aortic PG, the mean PG improvement from FPI to 3-year in CoreValve was observed in patients with specific small anatomy. The supra-annular valve function of the CoreValve allows for a higher effective orifice area (EOA) by providing less material inside the confined stent structure. Despite the in vitro data on the hemodynamic performance of the valve in valve, the EOA was larger and the transvalvular PG was lower for the CoreValve compared to the Edwards SAPIEN valve [16]. Although the hemodynamic performance was maintained in the SAPIEN-XT, improvement in the PG was minimal from FPI to the 3-year point. Because the CoreValve system is a self-expandable device, the force of its self-expansion might have influenced the results showing that the mean PG from FPI to the 3-year point was improved. A few patients had large aortic PG (more than 20 mmHg) just after TAVI, which resolved during follow-up period.

The incidence of aortic regurgitation less than mild grade just after TAVI was 40% among patients with CoreValve, 59% among those with SAPIRN-XT. There a few patients with more than mild grade aortic regurgitation at FPI in our study. In a recently published meta-analysis, the

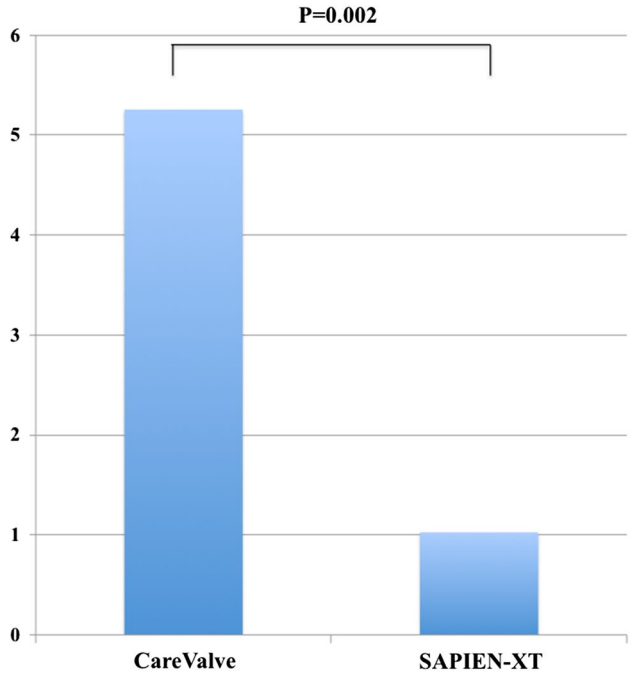

Fig. 4 The absolute change in mean aortic gradient after CoreValve and SAPIEN-XT implantations. Comparison of the absolute change in mean pressure gradient from FPI to 3 years post-TAVI between the CoreValve and the SAPIEN-XT. The absolute change is significantly higher in patients with the CoreValve compared to those with the SAPIEN-XT (5.3 ± 4.2, 1.0 ± 4.4 mmHg, $p = 0.002$)

incidence of more-than-mild aortic regurgitation was 16% after implantation of self-expandable valves compared to 9% after implantation of balloon expandable devices ($p = 0.005$) [17]. However, the number of patients with no or trace aortic regurgitation increased from FPI to the 3 year point after CoreValve implantation. At 3 year, the incidence of aortic regurgitation exceeding a mild grade was 29% in CoreValve, 47% in SAPIEN-XT. Aortic regurgitation improved from FPI to 3-year in more than half of patients with CoreValve (53%). These results were similarly observed in the Japanese clinical trial [8]. The force of its self-expansion might affect the improvement of gap between device and native left ventricular outflow. In addition, this might have influenced reduction of aortic regurgitation during follow-up period.

Our data showed that there were no episodes of symptomatic prosthetic leaflet thrombosis or deterioration of valve hemodynamic in the observational period. Barbati et al. reported late prosthetic valve failure at 5 years in 1.4% of 353 patients included in the CoreValve registry [18]. These different results might be affected by some reasons including small number of patients, the short follow-up duration, and the low number of patients that had cardiac computed tomography in the follow-up period.

In the current study, the 30-day mortality rate was 3.8% among those with CoreValve and 1.8% among those with SAPIEN-XT, which was an acceptable result for high-risk

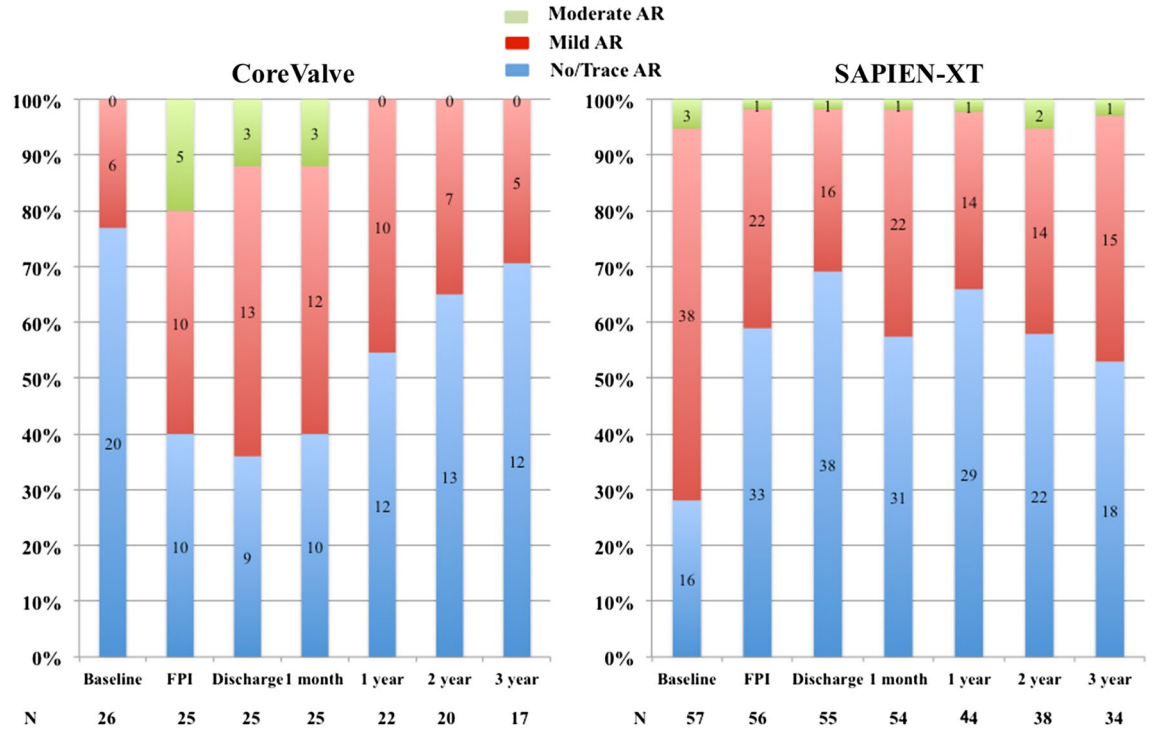

Fig. 5 Aortic regurgitation (AR) at baseline and 3-year follow-up after CoreValve and SAPIEN-XT implantation. Left side: Change in AR from baseline to 3 years after implantation with CoreValve. Right side: Change in AR from baseline to 3 years after implantation with SAPIEN-XT. *AR* aortic regurgitation, *FPI* first post-implant

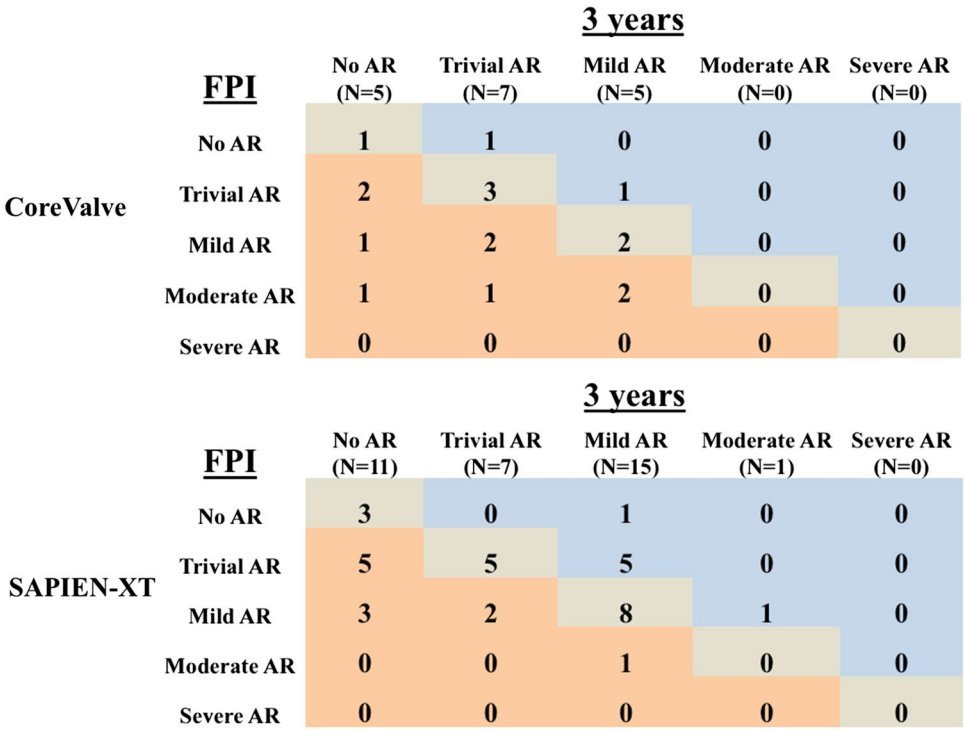

Fig. 6 AR change from FPI to 3-year follow-up for each patient. Upper: relationship between AR grade at FPI and AR grade at 3-year follow-up among patients with the CoreValve. Lower side: relationship between AR grade at FPI and AR grade at 3-year follow-up among patients with the SAPIEN-XT. *AR* aortic regurgitation, *FPI* first post-implant. Lower side: the relationship between AR grade at FPI and AR grade at 3-year in SAPIEN-XT. *AR* aortic regurgitation, *FPI* first post-implant

patients with AS. Moreover, the all-cause long-term mortality rate at 3 years after TAVI was 30.8% among patients with CoreValve and 21.1% among those with SAPIEN-XT. This study included patients that could not undergo surgery or those considered high surgical risk because the patients that received CoreValve had been included in MDT-2111 clinical trial and the patients that received SAPIEN-XT were enrolled in the early phase after approval by insurance. The mortality rate in this study was comparable to that of previous studies involving patients in the early stage after TAVI [3, 18]. The majority of the deaths were due to non-cardiac causes affected by the patients' frail conditions and comorbidities. The deaths in long-term follow-up were not related to the initial TAVI procedure. Valve migration complications occurred in 3 patients in our study; 1 patient with a CoreValve and 2 patients with SAPIEN-XTs. This complication rate was relatively high; however, this would solely affect our early experiences with the TAVI procedure and could be related to the use of older generation devices.

Limitations

This study has several limitations. First, this is a single-center, non-randomized study with a small number of patients. We were unable to choose which TAVI devices could be used for the study patients because the CoreValve was used in the clinical trial from January 2012 to July 2013. Although the SAPIEN-XT was used from October 2013 to September 2014, the CoreValve was not covered by insurance in Japan during this period. Second, the TAVI devices used in this study were SAPIEN-XT and CoreValve, which are early generation devices. These devices are no longer used in the current era. However, we were limited to investigating the clinical outcomes and valve performances among the patients who underwent TAVI with the older generation devices. This long-term device durability information would be valuable. Third, the echocardiographic data were not analyzed by an independent core laboratory. Nevertheless, a small number of experienced echocardiographic physicians performed the procedures, including the follow-up echocardiograms for all patients.

Conclusions

The 3-year performances of both the CoreValve and SAPIEN XT were maintained among Japanese patients after TAVI. Changes in the mean aortic PG from FPI to the 3-year point after CoreValve implantation were significantly decreased compared to those of the SAPIEN-XT.

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Compliance with ethical standards

Conflict of interest Dr. Saito is a clinical proctor for Edwards Lifesciences and Medtronic. The Authors declare that there is no conflict of interest.

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