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Long-Term Bioprosthetic Valve Durability After Transcatheter Aortic Valve Replacement With Supra-Annular Self-Expanding Versus Intra-Annular Balloon-Expandable Valves in Patients With a Small Aortic Annulus

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ABSTRACT

Background: The long-term valve durability of supra-annular self-expanding valves (SEV) and intra-annular balloon-expandable valves (BEV) in patients with small aortic annuli remains unexplored.

Aims: This study aimed to determine the long-term bioprosthetic valve durability with SEV versus BEV in patients with small aortic annuli.

Methods: This retrospective study included patients with severe aortic stenosis (AS) and an aortic annulus area of 430 mm^2 or less who underwent transcatheter aortic valve replacement using SEV and BEV between October 2009 and December 2022. Based on the Valve Academic Research Consortium's three definitions, the endpoints were hemodynamic structural valve deterioration (SVD) and bioprosthetic valve failure (BVF). Inverse probability of treatment weighting (IPTW) was used to compare between the two groups and adjust for baseline characteristics. The Fine-Gray subdistribution hazard model accounted for the competing risk of death.

Results: In total, 565 patients (204 treated with SEV and 361 treated with BEV) were included. The median follow-up duration was 3.6 years [2.0 years, 5.7 years], and the maximum was 12.3 years. Hemodynamic SVD and BVF were less frequently identified in the SEV group than in the BEV group (1.1% vs. 9.1% within 5 years, 0.7% vs. 8.1% within 5 years, respectively). On the IPTW adjusted Fine-Gray subdistribution hazard model analysis, hemodynamic SVD was less frequent in SEV compared with BEV (Hazard Ratio [HR]: 0.16; 95% Confidence Interval [CI]: 0.04–0.56, $p = 0.004$). SEV was also associated with a lower BVF risk than BEV (HR: 0.25; 95% CI: 0.08–0.76, $p = 0.015$).

Conclusions: SEV appears to be more suitable for long-term valve durability in patients with a small aortic annulus.

Abbreviations: AS, aortic stenosis; BEV, intra-annular balloon-expandable valves; BVF, bioprosthetic valve failure; EOAi, indexed effective orifice area; IPTW, inverse probability treating weighting; MSCT, multislice computed tomography; PPM, prosthesis–patient mismatch; S3UR, SAPIEN 3 Ultra Resilia; SEV, supra-annular self-expanding valves; STS, Society of Thoracic Surgeons; SVD, structural valve deterioration; TAVR, transcatheter aortic valve replacement.

1 | Introduction

According to recent prospective randomized studies, the indications for transcatheter aortic valve replacement (TAVR) have expanded to include younger, lower surgical-risk individuals worldwide [1–4]. This perspective suggests long-term valve durability should be considered for lifelong aortic stenosis (AS) management through TAVR. In particular, patients with a small aortic annulus are at significant risk of structural valve deterioration (SVD) [5–8]. Recently, the SMART trial, which compared 1-year clinical outcomes and valve performance of supra-annular self-expanding valves (SEV) with those of intra-annular balloon-expandable valves (BEV) in patients with a small aortic annulus, demonstrated the superiority of SEV to 1-year valve dysfunction [8]. However, the suitability of SEV and BEV for long-term valve durability in patients with small aortic annuli remains unexplored. Therefore, this study aimed to determine the long-term bioprosthetic valve durability with SEV versus BEV in patients with a small aortic annulus.

2 | Methods

2.1 | Patient Population

This retrospective, single-center, observational study included consecutive patients with severe AS and small aortic annuli who underwent TAVR using SEV (CoreValve, Evolut R, Evolut PRO, or Evolut PRO+) and BEV (SAPIEN, SAPIEN XT, or SAPIEN 3) at our institution between October 2009 and December 2022. A small annulus was defined as an aortic annulus area of 430 mm^2 or less [8]. In the present study, we analyzed all available clinical follow-up data up to February 2024. The exclusion criteria were (1) patients treated with other devices; (2) TAV in TAV, surgical valves, and bicuspid aortic valves; (3) patients undergoing hemodialysis; and (4) patients with missing preprocedural CT or TTE data (Figure 1). This study complied with the principles of the Declaration of Helsinki and was approved by the Institutional Review Board of Osaka University Hospital. The requirement for written informed consent was waived because of the retrospective design.

2.2 | TAVR Procedure and Follow-Up

Our heart team decided on the TAVR indication per Japanese guidelines [9]. In addition, the choice of valve type and valve sizing and determination of the TAVR access site were left to each operator's discretion, and operators referred to the preprocedural multislice computed tomography (MSCT) analysis using 3mensio software (3mensio Structural Heart ver8.1, Pie Medical Imaging, Bilthoven, The Netherlands). After discharge, TTE follow-ups were performed at the outpatient clinic at 1 month, 6 months, and then yearly.

2.3 | Study Endpoints

We compared the hemodynamic SVD and bioprosthetic valve failure (BVF) between SEV and BEV. We analyzed these outcomes using the Valve Academic Research Consortium's three definitions [10]. Hemodynamic SVD was defined as moderate or severe hemodynamic valve deterioration. Moderate hemodynamic SVD was defined as increasing in mean gradient ≥ 10 and < 20 mmHg with a final mean gradient ≥ 20 mmHg and any of the following: (1) a decrease in aortic valve area ≥ 0.3 cm^2 or $\geq 25\%$; or (2) a decrease in Doppler velocity index ≥ 0.1 or $\geq 20\%$, and/or ≥ 1 grade new-onset or worsening transvalvular aortic regurgitation with a moderate final grade. Severe hemodynamic SVD was defined as increasing in mean gradient ≥ 20 with a final mean gradient ≥ 30 mmHg and any of the following: (1) a decrease in aortic valve area ≥ 0.6 cm^2 or $\geq 50\%$; or (2) a decrease in Doppler velocity index ≥ 0.2 or $\geq 40\%$, and/or ≥ 2 grade new-onset or worsening transvalvular aortic regurgitation with a severe final grade. A baseline postprocedural echocardiogram was assessed 1 month after TAVR (or discharge, if 1-month data were unavailable).

BVF was categorized as stage 1 (any bioprosthetic valve dysfunction associated with clinically expressive criteria or irreversible severe hemodynamic valve deterioration), stage 2 (aortic valve reoperation or reintervention), or stage 3 (valve-related death) [10].

Prosthesis–patient mismatch (PPM) was categorized as moderate or severe based on the indexed effective orifice area (EOAi).

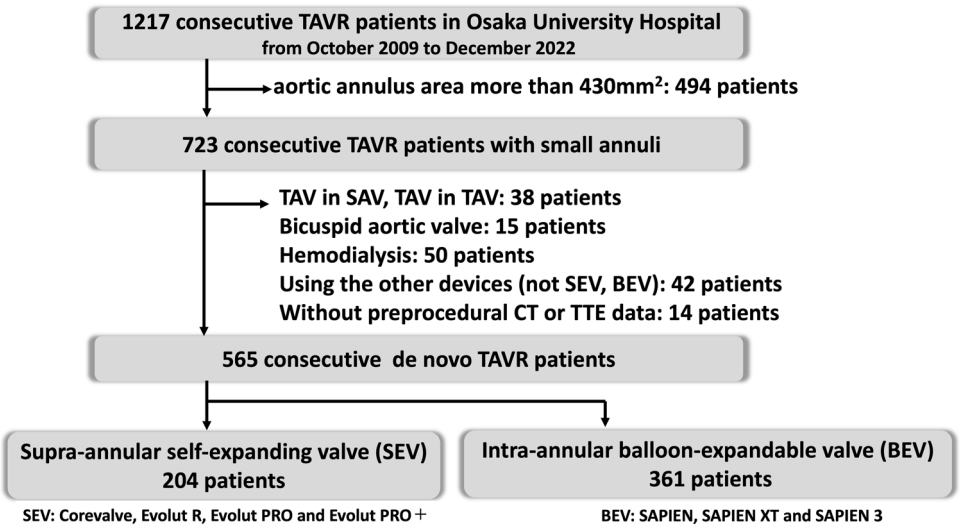

FIGURE 1 | Study flow chart.

Moderate PPM was defined as EOAi > 0.65 and ≤ 0.85 cm^2/m^2, and severe PPM was defined as EOAi ≤ 0.65 cm^2/m^2. If the patient was obese (body mass index ≥ 30), EOAi > 0.55 and ≤ 0.70 cm^2/m^2 was graded as moderate, and EOAi ≤ 0.55 cm^2/m^2 was graded as severe [10].

2.4 | Statistical Analysis

Categorical variables were compared using the χ^2 or Fisher's exact test, as appropriate, and presented as numbers (percentages). Continuous variables were compared using a Student's *t* test and the Mann–Whitney *U* test, based on the distribution and stated as the mean ± standard deviation or median (interquartile range; Q1, Q3). Time-to-event data were evaluated using Gray's test and summarized as cumulative incidence curves between SEV and BEV. Fine-Gray subdistribution hazard models, which account for patients censored due to competing events (death), were constructed to evaluate the association between valve type and SVD or BVF. Hazard ratios (HRs) and 95% confidence intervals (CI) were determined. Because the patient background and anatomical factors were associated with valve type selection, multivariate and inverse probability treatment weighting (IPTW) analyses were performed to adjust for confounding factors. The IPTW analysis calculated the propensity score using a multivariable logistic regression model based on relevant variables that may influence valve type selection and study outcomes. The variables included clinical variables (age, sex, body surface area, hypertension, diabetes, dyslipidemia, chronic obstructive pulmonary disease, history of atrial fibrillation, history of coronary artery disease, NYHA class III or IV, eGFR, and administration of oral anticoagulants), variables measured using TTE (aortic peak velocity, mean pressure gradient, aortic valve area and left ventricular ejection fraction), and variables measured using CT (area-derived annulus mean diameter, mean Valsalva sinus diameter, mean sinotubular junction diameter, and amount of calcium) [7, 11–16]. The amount of calcium (Table 1) was quantified in contrast-enhanced images using a predefined Hounsfield unit threshold of 650 using the 3mensio software.

Moreover, a sensitivity analysis was performed using the following two cohorts to confirm the robustness of the association between valve type and SVD or BVF. Because the transapical approach was unique to TAVR treated with BEV, only the transfemoral approach was extracted from the overall cohort (cohort A). It has been reported that device generation may affect valve durability in BEVs [11]. We selected consecutive patients who underwent TAVR after May 2016, when the SAPIEN 3 was approved in Japan, to exclude patients treated with SAPIEN and SAPIEN XT (cohort B). Statistical analyses were performed using the R software (version 4.3.2; R Foundation for Statistical Computing, Vienna, Austria; http://www.r-project.org/).

3 | Results

A total of 565 patients (204 treated with SEV and 361 treated with BEV) were included in this study (Figure 1). Their mean age was 84 years, 87% were female, and the median Society of Thoracic Surgeons (STS) score was 6.71% in the overall cohort. The SEV group was older than the BEV group. The prevalence of diabetes, dyslipidemia, and NYHA class (III or IV) was higher in the BEV group than in the SEV group. In the preprocedural TTE assessments, the aortic peak velocity and mean pressure gradient were higher, and the aortic valve area was smaller in the SEV group than in the BEV group. In the MSCT assessment, the amount of calcium was higher in the SEV group than in the BEV group (Table 1).

The prevalence of the transfemoral approach was low (65.7%) in the BEV group, and the transapical approach was performed in almost 25% of the patients. New pacemaker implantation was higher in the SEV group than in the BEV group (Table 2). In the antithrombotic regimens at discharge, the administration of dual antiplatelet therapy was higher in the SEV group, while the administration of oral anticoagulants tended to be lower in the SEV group (Table 2). The echocardiographic data obtained after TAVR are also shown in Table 2. The SEV achieved lower transvalvular gradients and a larger EOA than the BEV. The incidence of severe PPM was low, and there were no differences between the two groups, although moderate or severe PPM was less frequent in the SEV group than in the BEV group (2.7% vs. 9.1%, $p = 0.009$). Moderate or severe paravalvular regurgitation rarely occurred in either group.

In the follow-up analysis, the median follow-up duration was 3.6 years (2.0 years, 5.7 years) and the maximum duration was 12.3 years. Hemodynamic SVD and BVF were observed in 32 (8.9%) and 27 (7.5%) patients treated with BEV, respectively. In contrast, in patients treated with SEV, three (1.4%) had hemodynamic SVD, and four (2.0%) had BVF. Severe hemodynamic SVD was observed in 10 patients (2.8%) treated with BEV and in one patient (0.5%) treated with SEV. Stage 1 BVF occurred in 10 patients (2.8%) treated with BEV and one patient (0.5%) treated with SEV, stage 2 BVF in nine patients (2.5%) treated with BEV and one patient (0.5%) treated with SEV, and stage 3 BVF in eight patients (2.2%) treated with BEV and two patients (1.0%) treated with SEV. Seven of nine stage 2 BVF cases in patients treated with BEV were due to SVD (AS in six and aortic regurgitation in the remaining), and the remaining were due to infectious endocarditis. Stage 2 BVF in patients treated with SEV was due to SVD (severe aortic regurgitation). The cumulative incidence curves for hemodynamic SVD and BVF are shown in Figure 2. Hemodynamic SVD was identified less frequently in the SEV group than in the BEV group (0% vs. 2.9% within 3 years, 1.1% vs. 9.1% within 5 years, and 3.9% vs. 10.5% within 7 years). BVF was also less frequent in the SEV group than in the BEV group (0.7% vs. 2.6% within 3 years, 0.7% vs. 8.1% within 5 years, and 5.0% vs. 8.7% within 7 years).

On Fine-Gray subdistribution hazard model analysis, hemodynamic SVD was less frequent in SEV compared with BEV (HR: 0.19; 95% CI: 0.06–0.61, $p = 0.005$). SEV was also associated with a lower BVF risk than BEV (HR: 0.30; 95% CI: 0.11–0.85, $p = 0.024$). These results were consistent with the multivariate and IPTW-adjusted analyses (Table 3). Sensitivity analyses, including the transfemoral approach, demonstrated similar results (Table 3). Furthermore, the sensitivity analysis excluding SAPIEN and SAPIEN XT revealed similar results (Table 3).

TABLE 1 | Baseline characteristics.

	Overall ($n = 565$)	BEV ($n = 361$)	SEV ($n = 204$)	p value
Age, years	84.2 (5.5)	83.8 (5.8)	85.0 (4.8)	0.009
Female sex	492 (87.1)	307 (85.0)	185 (90.7)	0.073
BMI	22.10 (3.72)	21.99 (3.84)	22.30 (3.50)	0.34
BSA (m^2)	1.38 (0.14)	1.38 (0.15)	1.38 (0.13)	0.97
NYHA class (III or IV)	237 (41.9)	163 (45.2)	74 (36.3)	0.049
Previous stroke	81 (14.3)	57 (15.8)	24 (11.8)	0.24
Previous cardiac surgery	41 (7.3)	32 (8.9)	9 (4.4)	0.073
Coronary artery disease	129 (22.8)	91 (25.2)	38 (18.6)	0.092
Hypertension	449 (79.5)	292 (80.9)	157 (77.0)	0.32
Diabetes	181 (32.0)	129 (35.7)	52 (25.5)	0.016
Dyslipidemia	318 (56.3)	219 (60.7)	99 (48.5)	0.0070
COPD	95 (16.8)	59 (16.3)	36 (17.6)	0.78
AF	99 (17.5)	66 (18.3)	33 (16.2)	0.61
STS score (%)	6.71 [4.86, 9.50]	6.70 [4.85, 9.78]	6.92 [4.88, 9.30]	0.93
Laboratory data				
Hemoglobin (g/dl)	11.19 (1.63)	11.17 (1.68)	11.23 (1.55)	0.71
eGFR (mL/min/1.73 m^2)	50.17 (18.67)	50.05 (18.80)	50.38 (18.47)	0.84
BNP (pg/mL)	339.24 (480.04)	339.16 (508.24)	339.37 (426.94)	1.00
TTE assessment				
Peak velocity (m/s)	4.47 (0.76)	4.39 (0.73)	4.62 (0.80)	< 0.001
Mean PG (mmHg)	50.38 (18.54)	48.11 (16.52)	54.39 (21.11)	< 0.001
AVA (cm^2)	0.67 (0.19)	0.69 (0.20)	0.63 (0.17)	< 0.001
LVEF (%)	65.23 (11.82)	65.24 (11.94)	65.22 (11.63)	0.98
MSCT assessment				
Area derived annulus diameter (mm)	21.69 (1.13)	21.68 (1.14)	21.72 (1.12)	0.69
Valsalva sinus (mean diameter, mm)	28.58 (2.18)	28.51 (2.27)	28.69 (2.01)	0.34
Amount of calcium (mm^3)	331.00 [193.00, 568.00]	301.00 [178.00, 534.20]	374.45 [235.55, 599.62]	0.010
STJ (mean diameter, mm)	24.76 (2.45)	24.78 (2.56)	24.72 (2.25)	0.80

Note: Data are presented as mean ± SD or number (%) or medians and interquartile ranges [IQR; Q1, Q3].
Abbreviations: AF, atrial fibrillation; AVA, aortic valve area; BMI, body mass index; BNP, brain natriuretic peptide; BSA, body surface area; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; mean PG, mean pressure gradient; MSCT, multislice electrocardiogram-gated computed tomography; STJ, sino-tubular junction; STS score, Society of Thoracic Surgeons score; TTE, transthoracic echocardiography.

4 | Discussion

Our study revealed that SEV was associated with a lower hemodynamic SVD and BVF risk in patients with a small annulus. These results were consistent in the transfemoral and new-generation BEV cohorts.

4.1 | TAVR in Patients With a Small Annulus

Recently, the SMART trial demonstrated that SEV was superior to BEV in terms of bioprosthetic valve dysfunction within 1 year [8]. Severe PPM and hemodynamic SVD primarily contributed to these findings. At the 30-day TTE assessment in the study, severe PPM was identified in 1.8% of patients with SEV and 7.1% with BEV [8]. Conversely, the incidence of severe PPM was less than 1% in our study population and overall did not differ significantly between SEV and BEV groups. The lower mean body surface area ($1.38 \pm 0.14\ m^2$) in our study contributes to this difference and is consistent with previous Japanese TAVR data [17]. High residual transvalvular gradients are known to increase the risk of hemodynamic SVD and may accelerate valve deterioration and reduce valve durability [6, 11]. In line with previous studies, our data showed a marked hemodynamic advantage, such as lower transvalvular gradients and larger EOAi, in patients treated with SEV compared with BEV [17–19]. Therefore, our findings suggest that the extended durability of SEV is not solely due to a low incidence of severe PPM but also to early hemodynamic advantages and the maintenance of these advantages during follow-up. Although the exact mechanism of this favorable SEV result remains unclear, lower residual transvalvular gradients, as mentioned above, supra-annular design, self-expanding design, and bioprosthetic materials might be potential factors for favorable valve durability.

TABLE 2 | TAVR procedure, and medication and TTE data after TAVR.

	Overall ($n = 565$)	BEV ($n = 361$)	SEV ($n = 204$)	p value
TAVR procedure				
Approach				< 0.001
Transfemoral	420 (74.3)	237 (65.7)	183 (89.7)	
Transapical	92 (16.3)	92 (25.5)	0 (0.0)	
Subclavian	9 (1.6)	1 (0.3)	8 (3.9)	
Transaortic	18 (3.2)	11 (3.0)	7 (3.4)	
Transiliac artery	23 (4.1)	19 (5.3)	4 (2.0)	
Carotid	2 (0.4)	0 (0.0)	2 (1.0)	
Other	1 (0.2)	1 (0.3)	0 (0.0)	
Device				< 0.001
Corevalve	36 (6.4)	—	36 (17.6)	
Evolut R	101 (17.9)	—	101 (49.5)	
Evolut pro	18 (3.2)	—	18 (8.8)	
Evolut pro+	49 (8.7)	—	49 (24.0)	
SAPIEN	21 (3.7)	21 (5.8)	—	
SAPIEN XT	154 (27.3)	154 (42.7)	—	
SAPIEN 3	186 (32.9)	186 (51.5)	—	
TAV size (mm)				< 0.001
20	31 (5.5)	31 (8.6)	—	
23	309 (54.7)	292 (80.9)	17 (8.3)	
26	191 (33.8)	38 (10.5)	153 (75.0)	
29	34 (6.0)	—	34 (16.7)	
New PMI	62 (11.0)	28 (7.8)	34 (16.7)	0.0020
Medication at discharge				
DAPT	125 (22.1)	60 (16.6)	65 (31.9)	< 0.001
SAPT	375 (66.4)	261 (72.3)	114 (55.9)	< 0.001
Oral anticoagulants	236 (41.8)	161 (44.6)	75 (36.8)	0.085
TTE assessment after TAVR				
Peak velocity	2.12 (0.48)	2.27 (0.42)	1.84 (0.44)	< 0.001
Mean PG	10.03 (4.96)	11.49 (4.89)	7.41 (3.91)	< 0.001
EOA	1.70 (0.41)	1.60 (0.34)	1.88 (0.45)	< 0.001
EOAi	1.24 (0.31)	1.17 (0.27)	1.37 (0.34)	< 0.001
PPM				0.017
None	493 (93.2)	310 (90.9)	183 (97.3)	
Moderate	32 (6.0)	28 (8.2)	4 (2.1)	
Severe	4 (0.8)	3 (0.9)	1 (0.5)	
PVL ≥ moderate	3 (0.5)	3 (0.8)	0	0.48
LVEF	66.96 (10.48)	67.06 (10.40)	66.77 (10.64)	0.75

Note: Data are presented as mean ± SD or number (%) or medians and interquartile ranges [IQR; Q1, Q3].
Abbreviations: DAPT, dual antiplatelet therapy; EOA, effective orifice area; EOAi, effective orifice area index; LVEF, left ventricular ejection fraction; mean PG, mean pressure gradient; PMI, pacemaker implantation; PPM, prosthesis-patient mismatch; PVL, para-valvular leak; SAPT, single antiplatelet therapy; TAVR, transcatheter aortic valve replacement; TTE, transthoracic echocardiography.

4.2 | Long-Term Valve Durability in SEV and BEV

Recent studies have revealed the promising long-term durability of both SEV and BEV [11, 12, 20]. In the CHOICE trial, SVD was observed in 6.6% of BEV and 0% of SEV within 5 years [20]. A recent pooled analysis showed that 2.2% of SEV reached SVD within 5 years [12]. Compared with these results, our population, in which only small aortic annuli were included, showed that a

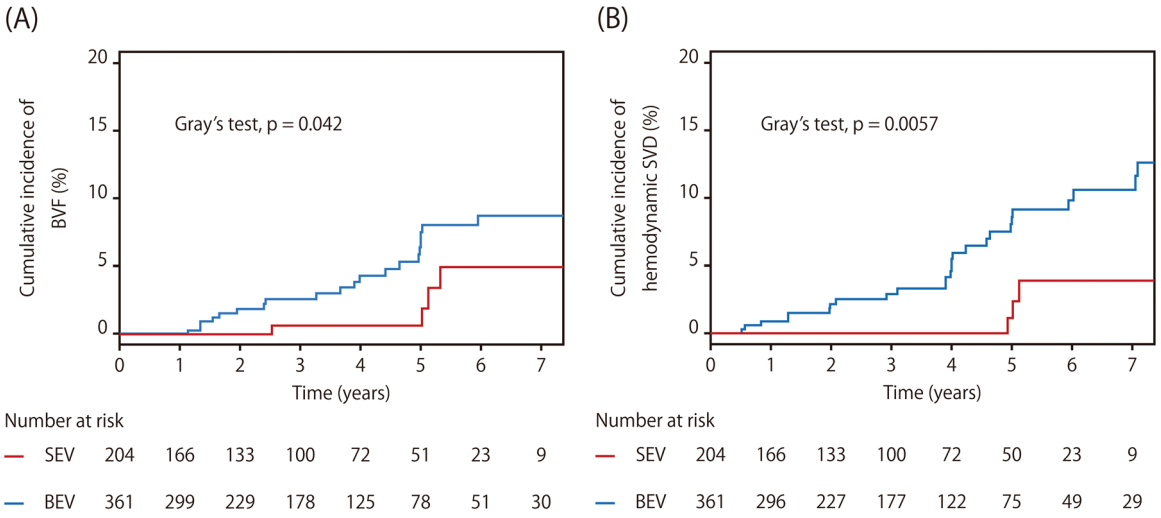

FIGURE 2 | (A) Cumulative incidence curve of bioprosthetic valve failure (BVF) between the supra-annular self-expanding valve (SEV) and the intra-annular balloon-expandable valve (BEV). (B) Cumulative incidence curve of hemodynamic structural valve deterioration (SVD) between SEV and BEV. [Color figure can be viewed at wileyonlinelibrary.com]

high incidence of SVD (9.1% within 5 years) was identified in the BEV group but similar in the SEV group (1.1% within 5 years). Although the definition of SVD differed in each study, these results implied that a small aortic annulus affects BEV valve durability but not SEV. Indeed, the UK TAVI registry indicated that the incidence of SVD was higher in patients treated with small-size BEV than in those treated with small-size SEV but was not different in patients treated with large-size BEV and large-size SEV [7]. However, there is no data about head-to-head comparison of long-term durability between BEV and SEV in patients with a small aortic annulus. Although the present study was retrospective design, multivariate and IPTW analyses were conducted to adjust for baseline characteristics. We believe that this study's findings suggest the potential long-term efficacy of SEV, which is expected to be demonstrated by the long-term follow-up results of the SMART trial in the future [8].

4.3 | Valve Generation and Valve Deterioration

SAPIEN XT is reportedly associated with a higher risk of SVD and SVD-related BVF than SAPIEN 3 [11]. The literature indicated that SAPIEN 3 may allow more complete valve expansion due to the elimination of stent posts [11]. According to the results, valve generation, particularly in BEV, can affect outcomes. Therefore, we performed a sensitivity analysis (cohort B) that included only SAPIEN 3 patients in the BEV group. The superiority of SEV was consistent in this cohort. This result implies that a small annulus, which causes high residual transvalvular gradients, diminishes the advantage of a larger valve opening in SAPIEN 3 than in SAPIEN XT. A recent large study demonstrated that a size of 20 or 23 mm for SAPIEN 3 Ultra Resilia (S3UR) improves stent design and achieves larger EOA than the same size of SAPIEN 3/SAPIEN 3 Ultra [21]. Moreover, S3UR utilizes the bovine pericardial leaflet tissue, reducing leaflet calcification risk and SVD [21]. A surgical valve that utilizes the same tissue rarely causes SVD within 5 years [22]. From this perspective, our results cannot be extrapolated to current-generation valves. Further studies are warranted to compare new-generation BEV with SEV in patients with a small annulus.

5 | Clinical Implication

Our study focused on small aortic annuli. Although a small annulus is more common in Asians than in other populations, 20%–30% of TAVR candidates have a small annulus in recent worldwide studies [8]. Therefore, our results will help physicians select TAVR valves. Our study demonstrated that hemodynamic SVD and BVF were less frequent in patients treated with SEV.

While the TAV-in-TAV procedure holds promise, its feasibility is limited by anatomical factors such as the risk of coronary obstruction [23]. Moreover, whether a second TAV is more durable than the first remains uncertain, especially in patients with a small aortic annulus due to elevated postprocedural transvalvular gradients. Therefore, valve selection should be individualized according to each patient's anatomy, background, and life expectancy. Several recent studies have revealed the promising long-term durability of SEV [12, 24, 25]. In the NOTION trial, the incidence of severe SVD was lower, and that of BVF was similar between SEV and SAVR for up to 10 years [24]. According to the long-term durability of SEV, comparable to that of surgical valves and extending the durability of BEV, SEV implantation should be considered for patients with a small annulus who are not suitable for TAV-in-TAV procedures and have an expected long life expectancy.

6 | Limitations

This study has several limitations. First, it had a retrospective design and a relatively small sample size. Valve type selection was left to the discretion of the heart team. Second, device generation may affect hemodynamic SVD or BVF. Our multivariate and IPTW analyses partially resolved these limitations; however, the possibility

TABLE 3 | Fine-Gray subdistribution hazard model analyses of relative risk of hemodynamic SVD and BVF.

	SEV (vs. BEV)	
	Hazard ratio (95% CI)	***p* value**
Hemodynamic SVD		
Overall cohort		
Univariate	0.19 (0.06–0.61)	0.005
Multivariate	0.16 (0.05–0.50)	0.002
IPTW	0.16 (0.04–0.56)	0.004
Cohort A		
Univariate	0.14 (0.03–0.59)	0.007
Multivariate	0.10 (0.02–0.38)	< 0.001
IPTW	0.08 (0.02–0.35)	< 0.001
Cohort B		
Univariate	0.17 (0.04–0.72)	0.016
Multivariate	0.05 (0.009–0.32)	0.001
IPTW	0.09 (0.02–0.43)	0.002
BVF		
Overall cohort		
Univariate	0.30 (0.11–0.85)	0.024
Multivariate	0.29 (0.10–0.85)	0.025
IPTW	0.25 (0.08–0.76)	0.015
Cohort A		
Univariate	0.27 (0.08–0.92)	0.037
Multivariate	0.19 (0.05–0.68)	0.011
IPTW	0.16 (0.04–0.59)	0.006
Cohort B		
Univariate	0.29 (0.06–1.33)	0.110
Multivariate	0.16 (0.02–1.40)	0.098
IPTW	0.17 (0.03–0.88)	0.034

Abbreviations: BEV, intra-annular balloon-expandable valves; BVF, bioprosthetic valve failure; IPTW, inverse probability treatment weighting; SEV, supra-annular self-expanding valves; SVD, structural valve deterioration.

of unmeasured residual confounders cannot be completely ruled out. Third, our study population was elderly and predominately female with a relatively high risk of undergoing surgical procedures (mean STS score: 6.71%). Caution is needed when applying our results to younger and lower-surgical-risk populations.

7 | Conclusions

SEV appears to be more suitable for long-term valve durability in patients with a small aortic annulus.

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Ethics Statement

Medical Ethics Committees of Osaka University Graduate School of Medicine, approval number 23310.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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