New-Generation Transcatheter Aortic Valves in Patients With Small Aortic Annuli — Comparison of Balloon- and Self-Expandable Valves in Asian Patients —

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Background: Asian patients have smaller aortic annuli. Although 20-mm balloon-expandable (BE) transcatheter heart valves (THV) are manufactured for transcatheter aortic valve implantation (TAVI) in these cases, the supra-annular design of self-expandable (SE) THV is considered more suitable; however, real-world comparative data are scarce.

Methods and Results: Consecutive TAVI cases (n=330) in a single Japanese center were reviewed. Based on the cutoff for the new-generation 20-/23-mm BE-THV, a small aortic annulus was defined as $<330\text{ mm}^2$. A considerable number of patients had small annuli: 49/302 (16%). Of these, 33 BE-THV and 13 SE-THV using new-generation valves were compared. Although the SE-THV group had smaller annulus area (median 297 (interquartile range, 280–313) vs. 309 (303–323) mm^2 ($P=0.022$)), it had more favorable post-procedural parameters; for SE-THV and BE-THV, respectively, effective orifice area (EOA), 1.5 (1.3–1.6) vs. 1.1 cm^2 (0.9–1.3) ($P=0.002$); mean pressure gradient, 7.6 (5.6–11.0) vs. 14.2 mmHg (11.2–18.8) ($P=0.001$); and peak velocity, 1.8 (1.6–2.4) vs. 2.7 m/s (2.3–3.1) ($P=0.001$). Although new left bundle branch block was higher with SE-THV (24% and 62%, $P=0.02$), patient-prosthesis mismatch (PPM) $\geq$ moderate (indexed EOA $<0.85\text{ cm}^2/\text{m}^2$) was significantly less with SE-THV than with BE-THV (8% vs. 55%; $P=0.04$). Hemodynamic findings were consistent up to 1 year.

Conclusions: Small annuli are often seen in Asian patients, for whom SE-THV implantation results in favorable hemodynamics with less PPM.

Key Words: Aortic annulus; Aortic valve replacement; Computed tomography; Complications; Valve prosthesis

Transcatheter aortic valve implantation (TAVI) is increasingly used throughout the world, and in a variety of races, and its indication is shifting towards lower surgical risk.^{1–3} Although this catheter treatment is maturing and outcomes are improving, some controversies persist.

Prosthesis-patient mismatch (PPM) is one of the major concerns following TAVI. The term was invented in 1978,⁴ and has been established as a mortality predictor after surgical aortic valve replacement (SAVR).^{5,6} TAVI results in a larger effective orifice area (EOA) compared with SAVR,^{7,8} and fewer cases of PPM are reported. The incidence rate of PPM following SAVR ranges from 20% to

70%,⁹ whereas moderate and severe PPM (moderate PPM: indexed EOA between 0.65 and 0.85 cm^2/m^2 , and severe PPM: indexed EOA $<0.65\text{ cm}^2/\text{m}^2$) after TAVI were reported by Miyasaka et al in 8.9% and 0.7%, respectively, of cases,⁹ and in 25% and 12% by Herrmann et al.¹⁰ Although the incidence rates of PPM following TAVI are lower, a recent study of a large cohort reported that severe PPM was associated with higher rates of mortality and heart failure rehospitalization at 1 year.¹⁰ Furthermore, another study showed PPM was an independent predictor of structural valve deterioration,¹¹ which may be a significant concern as the TAVI indication expands into lower risk and younger patients in whom the valves are expected

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to function for a longer period.

TAVI emerged from Western countries, and now many procedures are being performed in Asian countries as well. Asian patients have much smaller aortic annuli than Caucasians. Watanabe et al. reported that annulus diameter was significantly smaller in a Japanese cohort than in a French cohort,¹² and a small annulus is an independent predictor for PPM.⁹ A strategy for gaining larger EOA and avoiding PPM is important for patients with small annuli.

The hemodynamic outcomes of the balloon-expandable (BE) transcatheter heart valve (THV) are related to the native annular area,¹³ and the minimum size of the BE-THV (20mm) reveals a high mean gradient and a considerable risk for an increased rate of PPM.^{14,15} On the other hand, the supra-annular design (**Figure 1**) of the self-expandable (SE) THV enables expansion of the EOA and is considered to be suitable for small annuli; however, there is little data comparing the hemodynamic outcomes between the SE-THV and BE-THV in patients with small annuli. This study sought to evaluate the acute hemodynamic and clinical outcomes between BE- and SE-THV in Asian patients with small annuli.

Methods

Study Population and Design

This study retrospectively reviewed 330 consecutive patients undergoing TAVI from January 2016 to March 2019 in a single center in Japan (**Figure 2**). Valve-in-valve TAVI and patients without annulus assessment by contrast computed tomography were excluded. The BE-THV devices were Sapien XT and Sapien 3 (Edwards Lifesciences, Irvine, CA, USA), and the SE-THV were Corevalve, Evolut R and Evolut Pro (Medtronic, Minneapolis, MN, USA). The selection of valve type and other procedural strategies were decided by a multidisciplinary heart team including cardiothoracic surgeons, anesthesiologists, interventional cardiologists and echocardiography cardiologists. During this

study period, there were 8 TAVI operators who were involved in the heart team conference. The selection of BE- or SE-THV was multifactorial. Examples of factors that can influence device selection are: BE-THV preferred cases have low coronary height, small sinus of Valsalva, horizontal aorta and preoperative right bundle branch block, whereas SE-THV preferred cases have low pressure gradient aortic stenosis, high risk of annulus rupture due to severe calcification, high risk for rapid pacing (severe carotid artery stenosis or other severe valve disorder etc.) and small peripheral access. All procedures were performed under general anesthesia using transesophageal echocardiography assessment.

For our comparison of BE-THV and SE-THV, we selected patients with the newer generation devices (Sapien 3, Evolut R and Evolut Pro). A small annulus was defined as having an area $<330\text{ mm}^2$ based on the cutoff for the minimum size BE-THV (20-mm Sapien 3).¹⁵ Procedural, in-hospital, 30-day and 1-year outcomes were reviewed. Echocardiography was performed prior to the procedure, 1–2 days after the procedure and at the 30-day and 1-year follow-ups. Outcomes of newer generation BE-THV and SE-THV in small annuli were compared.

The study was conducted with approval from the institutional review board. All patients agreed to participate in the study and written informed consent was given by all patients. The investigation was performed according to the Declaration of Helsinki.

Endpoint Definition

Outcome data was reviewed up to 1-year follow-up. Endpoints were defined based on the Valve Academic Research Consortium-2 definition.¹⁶

PPM occurs in the setting of a morphologically normal valve and is considered to be hemodynamically insignificant if the indexed EOA is $>0.85\text{ cm}^2/\text{m}^2$, moderate if between 0.65 and $0.85\text{ cm}^2/\text{m}^2$, and severe if $<0.65\text{ cm}^2/\text{m}^2$.

The composite endpoints are briefly described. Device success was defined as (1) absence of procedural death, (2) correct positioning of a single prosthetic heart valve into the proper anatomical location and (3) the intended performance of the prosthetic heart valve (no PPM and mean aortic valve gradient $<20\text{ mmHg}$ or peak velocity $<3\text{ m/s}$ and no moderate or severe prosthetic valve regurgitation). Endpoints for early safety were defined as (1) all-cause death, (2) all stroke (disabling and non-disabling), (3) life-threatening bleeding, (4) acute kidney injury – stage 2 or 3 (including renal replacement therapy), (5) coronary artery obstruction requiring intervention, (6) major vascular complications, and (7) valve-related dysfunction requiring a repeat procedure. Clinical efficacy was defined as (1) all-cause death, (2) all stroke (disabling and non-disabling), (3) requiring hospitalizations for valve-related symptoms or worsening congestive heart failure, (4) NYHA class III or IV, and (5) valve-related dysfunction (mean aortic valve gradient $\geq 20\text{ mmHg}$, $\text{EOA} \leq 0.9\text{--}1.1\text{ cm}^2$ and/or a Doppler velocity index $<0.35\text{ m/s}$, and/or moderate or severe prosthetic valve regurgitation).

Statistical Analysis

The data was collected retrospectively, and all the analyses were performed using the data from the as-treated population. Quantitative variables are expressed as median values (interquartile range), and qualitative variables are expressed as numbers with percentages. The Mann-Whitney U-test was used for quantitative variables, and Fisher's exact test

Table 1. Baseline Characteristics

	BE (n=33)	SE (n=13)	P value
Age (years)	84.0 (79.5~88.5)	84.0 (82.5~87.0)	0.72
Height (cm)	146.0 (140.5~149.5)	140.0 (137.0~149.5)	0.19
Weight (kg)	43.0 (40.5~52.5)	46.0 (42.4~51.1)	0.98
BSA (cm ²)	1.4 (1.3~1.5)	1.3 (1.3~1.4)	0.55
STS score	4.8 (3.5~8.2)	5.6 (3.6~5.9)	0.96
Hemoglobin g/dL	11.4 (10.0~12.0)	11.7 (11.1~12.7)	0.09
Creatinine (mg/dL)	0.8 (0.7~1.0)	0.7 (0.6~1.0)	0.31
Bilirubin	0.5 (0.4~0.7)	0.6 (0.5~0.7)	0.19
Annulus area (mm ²)	309 (303~323)	297 (280~313)	0.022
EF (%)	69.0 (62.5~73.5)	67.0 (65.0~71.0)	0.46
MPG (mmHg)	43.8 (30.7~61.4)	29.4 (23.4~48.6)	0.12
Aortic valve area (cm ²)	0.5 (0.4~0.7)	0.6 (0.5~0.7)	0.41
Aortic valve area index (cm ² /m ²)	0.4 (0.3~0.5)	0.4 (0.4~0.5)	0.22
Female	32 (97)	13 (100)	0.72
Smoker	1 (3)	0	0.72
Diabetes mellitus	7 (21)	4 (31)	0.37
Dyslipidemia	14 (42)	9 (69)	0.1
Hypertension	27 (82)	12 (92)	0.35
Lung disease	2 (6)	0	0.51
Peripheral artery disease	5 (15)	1 (8)	0.45
Cerebral vascular disease	4 (12)	2 (15)	0.55
Cardiovascular surgery	0	1 (8)	0.28
Pacemaker implantation	2 (6.1)	0	0.51
Coronary artery disease	3 (9)	1 (8)	0.69
Atrial fibrillation	4 (12)	1 (8)	0.56
Pulmonary hypertension	6 (18)	2 (15)	0.6
MR ≥ moderate	2 (6)	0	0.51
Right bundle branch block	7 (21)	0	0.08
Low coronary height (≤10mm)	6 (18)	1 (8)	0.35
Subannular calcification	9 (27)	3 (23)	0.54
Less calcified leaflet	7 (21)	1 (8)	0.27

BE, balloon-expandable valve; BSA, body surface area; EF, ejection fraction; MPG, mean pressure gradient; MR, mitral regurgitation; SE, self-expandable valve.

was used for qualitative variables.

A P value ≤0.05 was considered statistically significant. The data were analyzed with SPSS software (PASW v18, SPSS, Inc.).

Results

Patient Population

Of the 330 consecutive cases of TAVI, there were 302 in which preprocedural contrast CT assessments had been performed. There was a considerable number of patients with a small annulus (49 (16%)) and of them, a new-generation THV was used in 46 cases: 33 BE-THV and 13 SE-THV (Figure 2).

Differences in Hemodynamics Between Devices

Native annulus area and the post-TAVI hemodynamics of each device were reviewed (Figure 3). Smaller THV were implanted in smaller annuli, and smaller THV revealed inconvenient parameters for both BE- and SE-THV. Although annulus area was the smallest in the 23-mm SE-THV group (275 (264–291) mm²), the worst hemodynamics was in the 20-mm BE-THV group: pressure gradient, 14.6

(11.8–21.3) mmHg; peak velocity, 2.69 (2.4–3.2) m/s; EOA, 1.03 (0.9–1.2) cm².

Comparison of BE-THV and SE-THV

BE-THV and SE-THV were compared in patients with a small annulus. Table 1 shows a comparison of the baseline characteristics of the 2 groups. At the baseline, there were no significant differences in age, height, weight, or body surface area, except that annulus area was significantly smaller in the SE-THV group compared with the BE-THV group: 297 (280–313) mm² vs. 309 (303–323) mm² (P=0.022) (Table 1).

Procedural and in-hospital outcomes are shown in Table 2. We used the 20-mm and 23-mm BE-THV in 19 and 14 patients, respectively, and the 23-mm and 26-mm SE-THV in 5 and 8 patients, respectively. There was no case of a 20-mm BE-THV being implanted using an under-filled balloon, but there were 2 cases of using an overfilled balloon with 0.5–1 mL. On the other hand, most cases of 23-mm BE-THV (12 cases) were implanted using an under-filled balloon with 1–2 mL. The rates of post-implant dilatation and greater than mild paravalvular leak were not significantly different between groups (9% vs. 8%, and 3%

Table 2. Procedural and In-Hospital Outcomes

	BE (n=33)	SE (n=13)	P value
Valve size			
BE20	19	—	—
BE23	14	—	—
SE23	—	5	—
SE26	—	8	—
Underfilled balloon	12 (36)	NA	
Post-implant dilatation	3 (9)	1 (8)	0.69
Percutaneous closure device failure	0	2 (15)	0.08
Procedural death	0	0	—
Correct positioning of a single valve	32 (97)	13 (100)	0.72
Procedure time (min)	80.0 (58.5–111.5)	77.0 (65.5–102.0)	0.79
New pacemaker implantation	5 (15)	3 (23)	0.4
New left bundle branch block	8 (24)	8 (62)	0.021
Lowest hemoglobin	10.8 (9.9–11.8)	10.2 (9.4–11.3)	0.21
Highest creatinine	0.8 (0.6–1.0)	0.7 (0.6–0.9)	0.49
Hospital stay (days)	9.0 (9.0–18.5)	11.0 (9.0–17.5)	0.65
Paravalvular leak $\geq$ moderate	1 (3)	1 (8)	0.49
EOA	1.1 (0.9–1.3)	1.5 (1.3–1.6)	0.002
EOAI	0.8 (0.7–1.0)	1.0 (1.0–1.3)	0.002
MPG (mmHg)	14.2 (11.2–18.8)	7.6 (5.6–11.0)	0.001
Peak velocity (m/s)	2.7 (2.3–3.1)	1.8 (1.6–2.4)	0.001
PPM $\geq$ moderate	18 (55)	1 (8)	0.04
Severe PPM	6 (18)	0	0.12
Device success	14 (42)	13 (100)	<0.001

PPM $\geq$ moderate is indexed EOA $<0.85\text{ cm}^2/\text{m}^2$; severe PPM is indexed EOA $<0.65\text{ cm}^2/\text{m}^2$. EOA, effective orifice area; EOAI, effective orifice area index; PPM, patient-prosthesis mismatch. Other abbreviations as in Table 1.

vs. 8%, for BE-THV and SE-THV, respectively). Although the difference was not significant, SE-THV showed numerically higher new pacemaker implantation (23% vs. 15%; $P=0.4$). The rate of new left bundle branch block was significantly higher in the SE-THV group (62% vs. 24%; $P=0.021$). Regarding the hemodynamic parameters for the prosthetic valves, the SE-THV group showed more favorable outcomes: EOA 1.1 (0.9–1.3) cm^2 vs. 1.5 (1.3–1.6) cm^2 ($P=0.002$); mean pressure gradient 14.2 (11.2–18.8) vs. 7.6 (5.6–11.0) mmHg ($P=0.001$); peak velocity 2.7 (2.3–3.1) m/s vs. 1.8 (1.6–2.4) m/s ($P=0.001$), for BE and SE-THV, respectively. This led to significantly lower rates of PPM and higher rates of device success: PPM, 18 (55) vs. 1 (8) ($P=0.04$) and device success, 14 (42) vs. 13 (100) ($P<0.001$), for BE- and SE-THV, respectively (Table 2).

30-Day and 1-Year Follow-up

As for the 30-day outcomes (Table 3), there were no deaths or strokes in either group. Although the BE-THV group had a few cases of life-threatening bleeding (bleeding at access site, gastrointestinal hemorrhage and alveolar hemorrhage) and stage 2 or 3 acute kidney injury, there was no significant difference in the early safety between the BE- and SE-THV groups: 29 (91) vs. 12 (100) ($P=0.7$), respectively. Changes in ejection fraction and left ventricular diastolic diameter from baseline were measured by echocardiography, and there were no significant differences in these parameters of systolic function and cardiac size: 1.5% (–2.0–5.8) vs. 4% (2–8) ($P=0.16$) and 1.5 mm (–2.0–5.8) vs. 1 mm (–3–4), for BE- and SE-THV, respectively. The SE-

THV group had better hemodynamic parameters for EOA, EOAI, mean pressure gradient and peak velocity, as reflected in the in-hospital outcomes. The rate of PPM $\geq$ moderate was significantly higher in the BE-THV than the SE-THV group: 19 (59) vs. 2 (18) ($P=0.018$). Moreover, the 30-day follow-up revealed significantly higher incidence of severe PPM as well in the BE-THV group compared with the SE-THV group: 9 (28) vs. 0 ($P=0.05$). The 1-year follow-up found 1 patient in the SE-THV group had died due to intestinal obstruction; however, the difference in mortality was not significant (Table 4). Other findings were consistent with the 30-day follow-up.

Discussion

For treatment of aortic stenosis, various options are becoming available and there are strategies for the prevention and management of PPM in patients with small annuli. Regarding SAVR, most of the valves have stents and sewing rings that reduce the EOA, but the design of the prosthesis can improve this inconvenience. Externally mounted pericardium (Mitroflow (Sorin Group), Trifecta (Abbot Vascular)) can maximize transvalvular flow.¹⁷ In addition, the surgical technique can enable implantation of a larger valve. Supra-annular implantation has been associated with hemodynamic improvement over conventional intra-annular positioning of the prosthesis.¹⁸ Aortic root enlargement, such as the Nicks technique, is an effective option for small annulus. Patients undergoing aortic enlargement reportedly have a lower incidence of PPM $\geq$ moderate:

Table 3. 30-Day Outcomes			
	BE (n=32)	SE (n=12)	P value
All-cause death	0	0	—
Stroke	0	0	—
Life-threatening bleeding	3 (9)	0	0.38
Acute kidney injury stage 2 or 3	2 (6)	0	0.52
Requiring hospitalization	2 (6)	0	0.52
Early safety	29 (91)	12 (100)	0.7
NYHA class III or IV	0	0	—
Clinical efficacy	19 (59)	12 (100)	0.07
Echocardiography findings	(n=32)	(n=11)	
EOA	1.1 (0.9~1.3)	1.4 (1.1~1.6)	0.07
EOAI	0.8 (0.6~1.0)	1.0 (0.9~1.4)	0.09
MPG	15.0 (12.9~21.6)	9.3 (6.2~12.0)	<0.001
Peak velocity	2.7 (2.4~3.2)	2.1 (1.7~2.4)	<0.001
Change in EF (%)	1.5 (−2.0~5.8)	4 (2~8)	0.16
Change in LVDd (mm)	1.5 (−2.0~5.8)	1 (−3~4)	0.63
PPM ≥ moderate	19 (59)	2 (18)	0.018
Severe PPM	9 (28)	0	0.05
Paravalvular leak ≥ moderate	1 (3)	0	0.74
Valve-related dysfunction	13 (41)	0	0.009

PPM ≥ moderate is indexed EOA <0.85 cm²/m²; severe PPM is indexed EOA <0.65 cm²/m². NYHA, New York Heart Association. Other abbreviations as in Tables 1,2.

Table 4. 1-Year Outcomes			
	BE (n=31)	SE (n=12)	P value
All-cause death	0	1 (8.3)	0.28
Heart failure hospitalization	0	0	—
NYHA Class III or IV	0	0	—
Echocardiography findings	(n=28)	(n=11)	
EOA	1.0 (0.8~1.3)	1.2 (1.2~1.4)	0.08
EOAI	0.7 (0.6~1.0)	0.9 (0.9~1.0)	0.046
MPG	17.4 (12.0~20.1)	8.2 (4.2~10.3)	<0.001
Peak velocity	2.8 (2.4~3.1)	1.8 (1.5~2.4)	<0.001
Change in EF (%)	1.0 (−3.8~6.5)	1.0 (−1~9)	0.42
Change in LVDd (mm)	0.5 (−3.3~4.0)	0 (−2~3)	0.83
PPM ≥ moderate	18 (64)	1 (9)	0.02
Severe PPM	10 (36)	0	0.021
Paravalvular leak ≥ moderate	4 (14)	0	0.25

PPM ≥ moderate is indexed EOA <0.85 cm²/m²; severe PPM is indexed EOA <0.65 cm²/m². Abbreviations as in Tables 1–3.

42.6% vs. 69.4% in patients with and without this technique, respectively ($P<0.001$).¹⁹ These strategies enable an increased EOA following SAVR, but the durability of an externally mounted valve is still a concern; some studies revealed accelerated structural valve deterioration and increased reoperation rates with externally mounted valves.^{20–22} Moreover, the aortic root enlargement procedure includes incision of the annulus and patch reconstruction of the root, thus it is more complicated than simple SAVR. There is also expected to be greater chance of bleeding, and longer cardiac-arrest time. The prosthetic valve used in TAVI does not require a sewing ring and thus results in a larger EOA as compared with the surgical valves. Clavel et al revealed lower trans-prosthetic gradi-

ents, higher indexed EOA, and reduced PPM rates with TAVI compared with SAVR.²³ Therefore, TAVI is a potential strategy for small annuli.

TAVI emerged from Western countries, and now many procedures are being performed in Asian countries as well. Asian patients have smaller body size, and the 20-mm BE-THV was specially manufactured for their small annuli; however, comparative data for SE-THV in small annuli are limited. The hemodynamic assessment in the current study showed that less favorable hemodynamics occurred with smaller sized devices, which is consistent with a previous study.¹³ In particular, the 20-mm BE-THV revealed high residual pressure and velocity with a small EOA of 1.03 cm² (Figure 3). SE-THV implantation showed signifi-

cantly larger EOA resulting in lower rate of post-procedural PPM compared with BE-THV implantation. It is mainly owing to the supra-annular design of the SE-THV (**Figure 1**). Even if the native annulus is small, a higher prosthetic annulus enables to acquire extra EOA. This larger EOA is the advantage of the SE-THV, especially in patients with a small annulus. On the other hand, the SE-THV generally shows a higher chance of conduction disturbance. In our study as well, the SE-THV group showed higher rates of new pacemaker implantation and left bundle block. The design of the SE-THV requires deeper deployment and larger expansion in the left ventricular tract, which can cause this disadvantage. In contrast, the shorter metal of BE-THV allows easier access to the coronary artery and less chance of conduction disturbance; however, the prosthetic annulus must be accommodated at the native annulus level and does not create a larger EOA. The difference in the design of the SE- and BE-THV contributes to these strengths and weaknesses of each device.

A large registry of the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) registry reported that severe PPM was associated with higher mortality and heart failure rehospitalization at 1 year; mortality was 17.2%, 15.6%, and 15.9% in severe, moderate, and no PPM patients, respectively ($P=0.02$), and heart failure rehospitalization respectively occurred in 14.7%, 12.8% and 11.9% of patients ($P<0.001$).¹⁰ Our study did not show worse mortality with severe PPM, potentially because of the small number of study subjects. Une et al reported that PPM is an independent predictor of redo aortic valve replacement due to structural valve deterioration (odds ratio: 1.63; 95% confidence interval 1.01–2.63; $P=0.045$).¹¹ As there is a widespread trend of younger patients undergoing TAVI, avoiding PPM is a major concern.

Hahn et al reported that the SAPIEN 3 post-implant EOA was progressively larger for each quintile of annular area ($P<0.001$), and similarly for the Evolut R valve, post-implantation EOA was significantly larger for each quintile of annular perimeter ($P<0.001$).¹³ This is consistent with our findings for the post-TAVI hemodynamics with each device, whereby smaller valves had less favorable parameters (**Figure 3**). Rogers et al reported that the SE-THV in a small aortic annulus was associated with significantly higher dimensionless indexes (0.64 vs. 0.53, $P=0.02$) and lower peak velocities (1.8 vs. 2.4 m/s, $P<0.001$) and a trend towards lower mean gradients (7.5 vs. 10.0 mmHg, $P=0.07$) compared with BE-THV. These differences were attenuated and absent in patients with medium to large annuli.²⁴ In other words, the difference is vitally important in cohorts with small annuli, such as Asian populations.

The report by Rogers et al showed no significant difference in the PPM rate between BE-THV and SE-THV in patients with small annuli; moderate PPM was 8 (42%) vs. 4 (24%) ($P=0.17$) and none of the patients had severe PPM.²⁴ Our study showed significantly higher rates of PPM for BE-THV implantation, potentially because of the different definition of a small annulus. In our study, a small annulus was defined as an annulus area $<330\text{ mm}^2$ based on the cutoff for the minimum BE-THV (20-mm Sapien 3). The previous report divided the patients into textile groups based on perimeter, resulting in perimeter cutoffs of 73 and 80 mm. A small annulus was defined as a perimeter $<73\text{ mm}$. As shown in our study, the 20-mm BE-THV had

inconvenient hemodynamic parameters post-TAVI. Moreover, all patients with severe PPM were implanted with the 20-mm BE-THV, except for 1 patient with a 23-mm BE-THV. The cutoff in our study, which was based on the 20-mm BE-THV, may be reasonable for the purpose of avoiding PPM.

Study Limitations

This was a single-center study using retrospectively reviewed data and no randomization between the different devices was performed. Device selection is multifactorial, including anatomical factors, and the decision was at the discretion of the heart team. The selection bias is the major limitation of this study. As to the baseline characteristics, the SE-THV group showed smaller annulus areas. SE-THV tended to be selected for patients with small annuli, which could be the reason for this difference. Although the SE-THV group had smaller annuli they showed more favorable hemodynamics after TAVI, and the conclusions of this study are consistent. Although multiple devices are available worldwide, the devices used for the study were limited (Sapien 3, Evolut R and Evolut Pro).

Further analysis in a larger multicenter, long-term study is warranted to definitively assess this question.

Conclusions

To our knowledge, this is the first study to show that the SE-THV had a significantly lower PPM rate compared with the BE-THV in patients with a small aortic annulus. As the indication for TAVI expands into lower risk and younger patients in whom the valves are expected to function for a longer period, a strategy to avoid PPM is crucial especially in patients with a small annulus. This study will provide important information for device selection to maximize the EOA and mitigate the risk of PPM in these patients.

Small aortic annulus is commonly seen in Japanese patients, and avoiding PPM following TAVI is an important concern. Due to its supra-annular design, SE-THV implantation results in a larger EOA with more favorable acute hemodynamic parameters with less PPM. This is useful information for the device selection process for TAVI. Additional research with larger cohorts and long-term follow-up is required to solidify the conclusions of this study.

Disclosure

R.M. has received grant support from Edwards Lifesciences and is a consultant for Medtronic. All other authors do not have conflicts of interest to disclose.

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IRB Information

Medical Ethics Committee at St. Marianna University School of Medicine, reference no. 4446.

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None.

Data Availability

The deidentified participant data will not be shared.

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