Original Article

Comparison of self- and balloon-expandable valves in patients with dilatated ascending aorta undergoing transcatheter aortic valve replacement

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Background: Limited studies have focused on the performance of self-expandable valves (SEVs) and balloon-expandable valves (BEVs) in patients with dilatated ascending aorta (AA) undergoing transcatheter aortic valve replacement (TAVR). The present study compared the performance of widely used Edwards BEVs and domestic SEVs in patients with dilatated AA among Chinese population.

Methods: We identified and reviewed 207 patients who had baseline AA diameter ≥40 mm and underwent transfemoral TAVR. Patients were divided into two groups: SEV and BEV. The SEVs were locally manufactured valves that have received Chinese regulatory approval (Venus-A, Taurus One, and VitaFlow), while the BEVs were Edwards Sapien XT and Sapien3. Procedural device success and post-procedural changes of AA diameters were compared.

Results: The sample size of SEV group was larger than that of BEV group because BEVs were not available in China in the early clinical practice. The overall device success was slightly lower in SEV group compared with BEV group (84.2% *vs*. 95.8%, P=0.213). However, in the univariable and multivariable logistic regression analyses, only bicuspid aortic valve (BAV) was found to be an independent risk factor for device failure (OR: 2.632, CI: 1.107–6.257, P=0.029). During the median follow-up of 21 months, no statistical difference was found between the two groups regarding the overall survival (83.1%±4.7% *vs*. 95.8%±4.1%, P=0.533), and no aortic dissection nor rupture was observed. In a subgroup of patients who had follow-up CTs ≥12-month intervals, the AA diameter appeared to remain stable in SEV group with an aortic expansion rate of 0 (–0.4 to 0.8) mm (P=0.102), while it slightly enlarged in BEV group with an aortic expansion rate of 0.4 (–0.4 to 0.6) mm/y (P=0.038). In addition, the AA diameter also slightly enlarged in patients with BAV [0.2 (0 to 1.0) mm/y, P=0.015], while it remained stable in patients with tricuspid aortic valve (TAV) [0 (–0.8 to 0.6) mm/y, P=0.640].

Conclusions: In patients with dilatated AA who underwent TAVR, the type of THVs did not affect the procedural device success. BAV appeared to be a risk factor for both device failure and higher aortic expansion rate in these patients.

Keywords: Transcatheter aortic valve replacement (TAVR); ascending aorta (AA); device success; aortic expansion rate

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Introduction

Ascending aortic (AA) dilatation is a common feature in patients with aortic stenosis (AS), especially in those with bicuspid aortic valve (BAV) (1,2). For patients undergoing surgical aortic valve replacement (SAVR), current guidelines recommend concomitant aortic repair or replacement if the diameter of AA exceeds 45 mm to avoid aortic dissection or rupture (3).

Transcatheter aortic valve replacement (TAVR) has profoundly changed the clinical management of AS patients who cannot tolerate SAVR (4,5). For patients who are candidates for TAVR, simultaneous repair of a dilatated AA can be technically difficult. The safety and feasibility of the procedure and the fate of AA after the procedure in these patients remain unclear. Moreover, there are limited data comparing the performance of self-expandable valves (SEVs) versus BEVs in these patients. The aim of the present study is to evaluate the impact of type of transcatheter heart valves (THVs) on intra-procedural device success and post-procedural AA progression in patients with dilatated AA (≥40 mm) undergoing TAVR. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-364/rc).

Highlight box

Key findings

- In patients with dilatated ascending aorta (AA) who underwent transcatheter aortic valve replacement (TAVR), the type of valve was not a risk factor for procedural device failure.

What is known and what is new?

- Early clinical trials regarding TAVR have excluded patients with significant AA dilatation.
- Both self- and balloon-expandable valves (SEVs and BEVs) had satisfactory performance in patients with dilatated AA, although BEVs had slightly higher post-procedural aortic expansion rate.

What is the implication, and what should change now?

- Randomized trials are needed to compare the performance of SEV and BEV in patients with dilatated AA.

Methods

Study population

We retrospectively evaluated all patients who underwent transfemoral TAVR from January 2016 to May 2021 at Beijing Fuwai Hospital. Exclusion criteria were dominant aortic regurgitation, a history of SAVR or TAVR, a history of AA surgery, unavailable preoperative aortic computed tomography (CT), and preoperative maximal AA diameter <40 mm, as shown in *Figure 1*. A total of 207 patients were finally identified. These patients were divided into two groups according to the type of THVs (SEV *vs.* BEV). Electronic medical records were reviewed to obtain baseline characteristics, procedural details, clinical outcomes, and follow-up data. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of Fuwai Hospital (approval No. 2022-1829), and informed consent was obtained from all patients.

CT measurements

All preoperative aortic CTs were electrocardiogram-gated with contrast enhancement. The maximal AA diameter was measured at the broadest level of AA by inner-edge to inner-edge method, perpendicular to the axis of blood flow. The AA diameter was calculated as: (maximal diameter + minimal diameter)/2. Dilatation of the AA was defined as a maximal AA diameter of ≥40 mm, in accordance with previous studies (1,6,7). The post-procedural AA expansion rate was calculated as the change of AA diameters (before the procedure and at the latest follow-up) divided by the follow-up period.

Surgical procedure

All transfemoral TAVR procedures were conducted in accordance with guidelines using standard techniques. In SEV group, the types of THV included Venus-A (Venus MedTech, Hangzhou, China), Taurus One (Peijia Medical, Suzhou, China), and VitaFlow (MicroPort, Shanghai, China). In BEV group, Edwards Sapien XT and Sapien 3

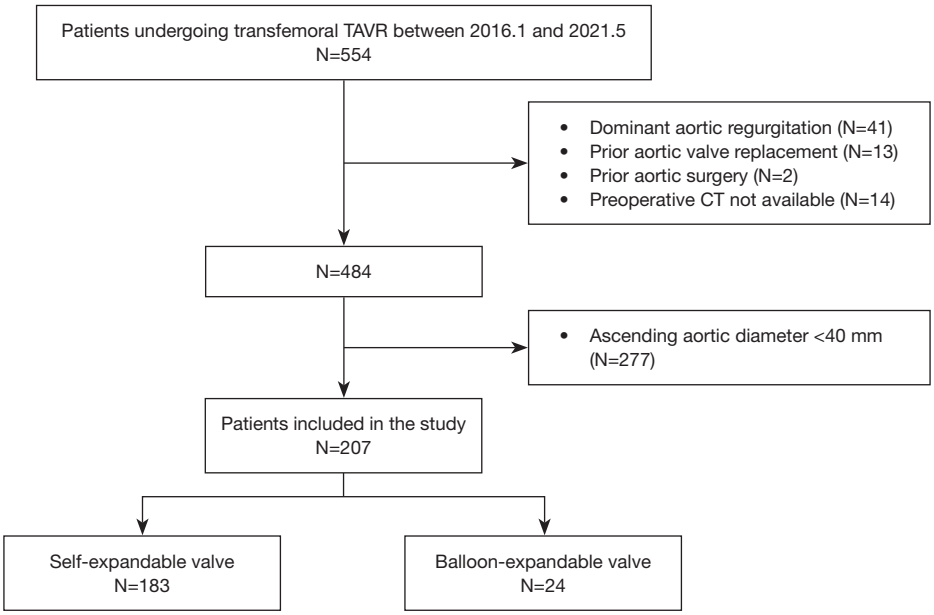

Figure 1 Study flow diagram. TAVR, transcatheter aortic valve replacement; CT, computed tomography.

(Edwards Lifesciences, Irvine, CA, USA) were used.

Follow-up

Follow-up data were collected from the electronic medical record and telephone interview with patients or their family members. The primary endpoint was the device success as defined by Valve Academic Research Consortium-3 criteria (VARC-3) (8). Secondary endpoints included all-cause mortality and the occurrence of aortic dissection and/or rupture during the follow-up.

Statistical analysis

Categorical variables were expressed as frequencies and percentages, and were tested by the chi-square test or Fisher exact test. Normally distributed continuous variables were expressed as means ± standard deviations and non-normally distributed variables as median (interquartile range), and were compared using Student *t*-test or the Mann-Whitney *U* test. Overall survival was estimated using Kaplan-Meier methods and compared with the log-rank test.

All baseline variables were examined in a univariable logistic regression model to identify the risk factors for intra-procedural device failure. Patients were divided into two groups (device success and device failure). Baseline variables that were found to be different in univariable analyses with a P value of <0.1 were identified and included in the multivariable analyses. A backward method was used to leave covariates with P values <0.10 in the final multivariable model.

Aortic expansion rates were determined from a subset of patients who had follow-up aortic CTs ≥12-month intervals, and expressed as millimeter per year. Preoperative AA diameters and follow-up AA diameters were compared with paired Student *t*-test.

SPSS software version 23.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 9.3.1 (GraphPad Software, San Diego, CA, USA) were used for data analyses and visualization. All reported P values were 2-sided, and a value of P<0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 207 patients with AA dilatation (≥40 mm) who underwent transfemoral TAVR were identified (*Figure 1*). Baseline characteristics are summarized in *Table 1*. The majority of procedures were performed using SEVs (88.4%), while BEVs accounted for 11.6%. Patients in SEV group had higher prevalence of BAV (56.8% *vs.* 33.3%, P=0.030). The rates of peripheral artery disease and moderate-to-severe aortic regurgitation were higher in BEV group (P<0.05).

Table 1 Baseline characteristics

Variables	SEV (n=183)	BEV (n=24)	P value
Age, years	74 [69–77]	73 [69–77]	0.816
Female gender	68 (37.2)	9 (37.5)	0.974
Body surface area, m^2	1.71 [1.56–1.85]	1.66 [1.53–1.81]	0.452
STS score, %	4.0 [3.5–5.0]	4.2 [3.5–4.5]	0.997
Smoking	64 (35.0)	9 (37.5)	0.808
Serum creatinine, mg/dL	1.0 [0.9–1.3]	1.0 [0.9–1.3]	0.765
Hypertension	94 (51.4)	11 (45.8)	0.610
Diabetes mellitus	33 (18.0)	6 (25.0)	0.410
History of coronary artery disease	72 (39.3)	10 (41.7)	0.827
History of cerebrovascular disease	28 (15.3)	4 (16.7)	0.771
Peripheral artery disease	42 (23.0)	10 (41.7)	0.047
Prior coronary artery intervention	12 (6.6)	4 (16.7)	0.097
Prior coronary artery bypass grafting	0 (0.0)	1 (4.2)	0.116
Atrial fibrillation	29 (15.8)	2 (8.3)	0.524
Bicuspid aortic valve	104 (56.8)	8 (33.3)	0.030
Left ventricular ejection fraction <40%	40 (21.9)	3 (12.5)	0.288
Mean aortic valve gradient, mmHg	58 [46–70]	57 [49–62]	0.467
Moderate-to-severe aortic regurgitation	47 (25.7)	11 (45.8)	0.039
Preoperative AA diameter, mm	44 [41–48]	43 [41–45]	0.233

Values are presented as n (%) or median [interquartile range]. SEV, self-expandable valve; BEV, balloon-expandable valve; STS, Society of Thoracic Surgeons; AA, ascending aorta.

Perioperative results

Procedural details are shown in *Table 2*. The rates of mild or moderate-to-severe paravalvular regurgitation were higher in SEV group (P=0.006). Implantation of second valve was observed in 9.3% of patients in SEV group, while none occurred in BEV group (P=0.229). Although not statistically significant, the overall device success was lower in SEV group compared with SEV group (84.2% *vs.* 95.8%, P=0.213). In univariable logistic regression analysis, three variables (age, gender, and BAV) had P values <0.10. In the multivariable model, only BAV was found to be an independent risk factor for device failure (OR: 2.632, CI: 1.107–6.257, P=0.029) (*Table 3*). There was no significant difference in 30-day complications between two groups.

Follow-up outcomes

Follow-up was completed in 98.6% (204 of 207) of individuals. The median follow-up was 21 [15–34] months in SEV group and 26 [13–44] months in BEV group (P=0.579). No statistical difference was found between two groups regarding the overall survival (83.1%±4.7% *vs.* 95.8%±4.1%, P=0.533) (*Figure 2*). No definite aortic dissection or rupture was found during the follow-up period, although there were 2 sudden deaths with unknown reasons. In subgroup analyses, we classified patients according to the type of aortic valve [BAV *vs.* tricuspid aortic valve (TAV)], degree of preoperative aortic regurgitation (AR) (≥ moderate AR *vs.* < moderate AR), and whether preoperative AA diameter ≥45 mm or not (AA ≥45

Table 2 Procedural details and in-hospital events

Variables	SEV (n=183)	BEV (n=24)	P value
Implanted valve type			NA
VenusA	141 (77.1)	NA	
VitaFlow	33 (18.0)	NA	
TaurusOne	9 (4.9)	NA	
Sapien XT	NA	7 (29.2)	
Sapien 3	NA	17 (70.8)	
Implanted valve size, mm			0.364
23	49 (26.8)	9 (37.5)	
24	13 (7.1)	0	
26	76 (41.5)	11 (45.8)	
27	18 (9.8)	0	
29	20 (10.9)	4 (16.7)	
30	2 (1.1)	0	
32	5 (2.7)	0	
Conversion to open surgery	5 (2.8)	1 (4.2)	0.527
Implantation of second valve	17 (9.3)	0	0.229
Device success	154 (84.2)	23 (95.8)	0.213
Pre-dilation	176 (96.7)	21 (87.5)	0.073
Post-dilation	50 (27.5)	4 (16.7)	0.258
Paravalvular regurgitation*			0.006
None or trace	81 (44.8)	19 (79.2)	
Mild	94 (51.9)	5 (20.8)	
Moderate to severe	6 (3.3)	0	
Post-procedural mean aortic valve gradient, mmHg	13 [9–18]	14.0 [11–19]	0.440
30-day outcome			
Mortality	3 (1.6)	0	1.000
Stroke	1 (0.5)	0	1.000
Permanent pacemaker	12 (6.6)	1 (4.2)	1.000
Myocardial infarction	0	0	NA
Major vascular complication	3 (1.6)	0	1.000
New requirement for dialysis	1 (0.5)	0	1.000

Values are presented as n (%) or median [interquartile range]. *, available in 205 patients. SEV, self-expandable valve; BEV, balloon-expandable valve; NA, not applicable.

Table 3 Univariable and multivariate logistic regression analysis of device failure

Variables	Univariable analysis			Multivariable analysis		
	Odds ratio	Confidence interval	P value	Odds ratio	Confidence interval	P value
Age, years	0.960	0.919–1.003	0.067			
Female gender	0.465	0.190–1.142	0.095			
Body surface area, m^2	4.077	0.575–28.921	0.160			
STS score, %	0.924	0.696–1.226	0.583			
Smoking	1.491	0.679–3.274	0.319			
Serum creatinine, mg/dL	0.980	0.258–3.721	0.976			
Hypertension	1.323	0.606–2.885	0.482			
Diabetes mellitus	0.841	0.300–2.357	0.742			
History of coronary artery disease	0.864	0.388–1.926	0.721			
History of cerebrovascular disease	1.850	0.719–4.765	0.202			
Peripheral artery disease	0.893	0.359–2.221	0.807			
Prior coronary artery intervention	0.832	0.179–3.859	0.814			
Prior coronary artery bypass grafting	NA	NA	NA			
Atrial fibrillation	0.855	0.276–2.645	0.785			
Bicuspid aortic valve	2.658	1.124–6.289	0.026	2.632	1.107–6.257	0.029
Left ventricular ejection fraction <40%	1.803	0.758–4.284	0.182			
Mean aortic valve gradient, mmHg	1.001	0.980–1.021	0.944			
Moderate-to-severe aortic regurgitation	1.120	0.480–2.613	0.794			
Preoperative AA diameter, mm	1.003	0.920–1.092	0.951			
SEV	4.331	0.563–33.344	0.159			

STS, Society of Thoracic Surgeons; AA, ascending aorta; SEV, self-expandable valve; NA, not applicable.

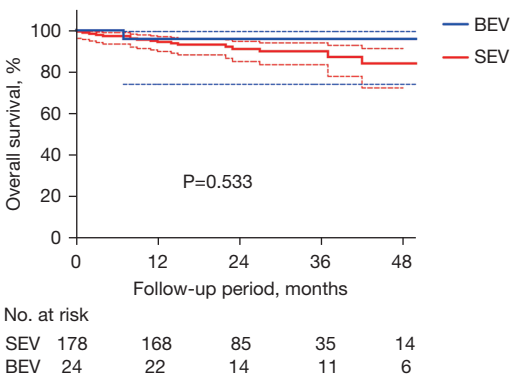

Figure 2 Kaplan-Meier curves for overall survival in patients using SEVs and BEVs (P=0.533). BEV, balloon-expandable valve; SEV, self-expandable valve.

vs. <45 mm). No statistical differences were found regarding the overall survival (Figures S1-S3).

Postoperative AA progression

Follow-up CT assessments beyond 12 months from the procedure were available for 68 patients (32.9%), including 51 in SEV group and 17 in BEV group. The median CT follow-up time was 22 [16–34] months in SEV group and 24 [16–33] months in BEV group (P=0.793). In this subset of patients, the AA diameter appeared to remain stable in SEV group with an aortic expansion rate of 0 (–0.4 to 0.8) mm/y (P=0.102), while it slightly enlarged in BEV group with an aortic expansion rate of 0.4 (–0.4 to 0.6) mm/y (P=0.038)

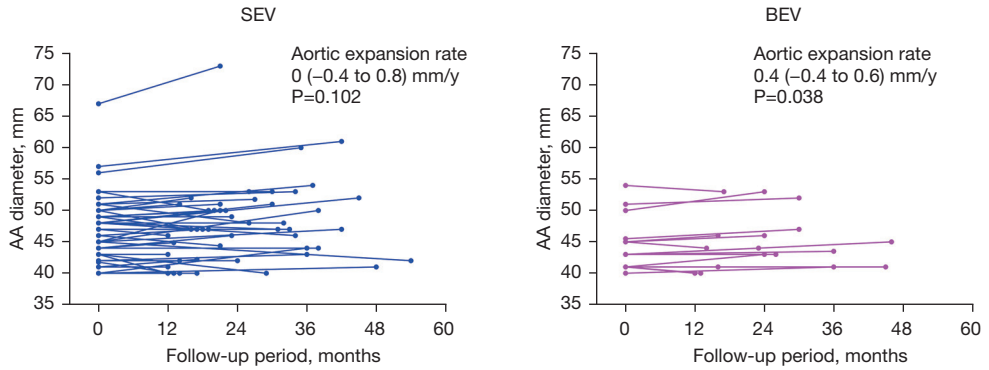

Figure 3 Post-procedural aortic expansion rates in patients using SEVs and BEVs. Each line connects the baseline AA diameter with the latest follow-up AA diameter for each patient. AA, ascending aorta; SEV, self-expandable valve; BEV, balloon-expandable valve.

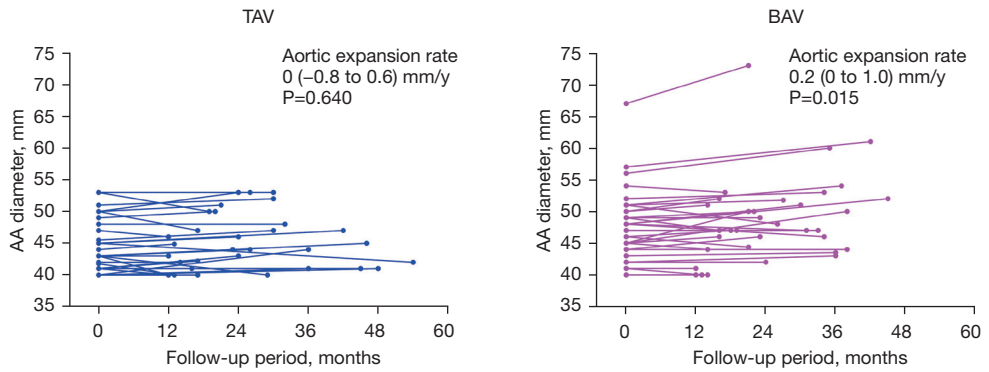

Figure 4 Post-procedural aortic expansion rates in patients with BAV and TAV. Each line connects the baseline AA diameter with the latest follow-up AA diameter for each patient. AA, ascending aorta; TAV, tricuspid aortic valve; BAV, bicuspid aortic valve.

(*Figure 3*). When classifying these patients into BAV group and TAV group, the AA diameter slightly enlarged in BAV group with an aortic expansion rate of 0.2 (0 to 1.0) mm/y (P=0.015), while it remained stable in TAV group with an aortic expansion rate of 0 (–0.8 to 0.6) mm/y (P=0.640) (*Figure 4*).

Discussion

In patients with AS, AA dilatation is a common aortopathy with an incidence rate of 20–25% (9,10). The results of our study reveal a higher incidence (42.5%), which might be explained by a high prevalence of BAV in the Chinese population (11). Patients with BAV present more frequently with AA dilatation because both intrinsic disease of the vascular media and modified flow patterns through the stenotic valve contribute to the AA dilatation (12), unlike patients with TAV whose post-stenotic AA dilatation is more related to the hemodynamic disturbance (13,14).

A previous meta-analysis study regarding the comparison of SEVs and BEVs found no differences on all-cause and cardiovascular mortality, although BEVs were associated with a reduced risk of permanent pacemaker implantation and paravalvular leak (15). However, the impact of AA dilatation on device success following TAVR has not been systemically described before. Early PARTNER trials have excluded patients with significant AA dilatation (≥50 mm) (3,4). Manufacturer specifications for CoreValve required that proximal AA diameter should not exceed 40–43 mm for the 3 valve sizes (16,17). As for BEVs, a previous study by Rylski *et al.* reported that Edwards Sapien valves can be safely used in patients with AA dilatation (40–50 mm) without adding intraprocedural risk of adverse aortic events (18).

In a SEV, the long stent frame extends beyond the sinotubular junction into the AA. Although the inflow portion of the stent frame exerts high radial force for anchoring, the outflow portion also helps secure the SEV

in the AA and orients the valve to the blood flow (19,20). In the setting of dilatated AA, the reduced anchoring of the outflow portion may raise the concern for unstable device position (21). On the other hand, a BEV has a short stent frame which does not extend beyond the aortic sinus. The study by Rylski *et al.* suggested that the intra-annular implantation of a BEV might be a safe choice in patients with dilatated AA (18). However, in the present study, the use of SEVs was not an independent risk factor for device failure. The fact that device success rate was slightly lower in SEV group might be explained by the higher prevalence of BAV in SEV group, which is the only significant risk factor for device failure in the present study.

In addition to the perioperative outcomes, it is also important to explore the AA progression and the risk of adverse aortic events after the procedure. In the present study, no aortic dissection or rupture was found in both groups, and the overall survival was not affected by the type of THV during a median follow-up of 21 months. The AA diameter appeared to slightly grow in BEV group, while it remained stable in SEV group despite larger baseline AA diameters and higher rate of BAV. Previous studies demonstrated that SEV offered a better hemodynamic profile compared with BEV (22-25), which might play a role in AA progression. However, these hypotheses need to be confirmed in further studies.

It should be noted that among patients whose follow-up CTs were available, three had baseline AA diameter exceeding 55 mm (all in SEV group). Although perioperative device success was achieved, postoperative AA enlarged rapidly in all of them (4–6 mm). Therefore, indications of TAVR should be evaluated very cautiously in patients with extremely dilatated AA. Both acute procedural success and post-procedural AA progression should be taken into account. In these patients, other strategies and accesses, such as concomitant TAVR and wrapping of AA through mini-sternotomy, might be considered. Postoperative follow-ups are important to evaluate the AA progression. If rapid AA expansion (3–5 mm/y) is noted, further intervention (surgical or endovascular treatment) might be needed. As the indications for TAVR have expanded to low-risk and young patients, AA dilatation should be considered as a criterion to refine risk stratification.

Several limitations should be acknowledged. First, the SEVs used in the present study are locally manufactured valves that have received Chinese regulatory approval. Other widely used SEVs, such as Medtronic CoreValves, are not available in China until very recently. Although studies regarding domestic THVs are limited, several previous reports have verified the safety and feasibility of these THVs (26-28). The BEVs (Edward Sapien XT and Sapien 3) were also not available in the early clinical practice, therefore the sample size of SEV group was drastically larger than that of BEV group. This might affect the external validity of the results. Further studies with larger sample size are required. Second, discrepancies in measurements of the AA may impair clinical assessment (29). In the present study, to minimize the errors, the measurements of the preoperative AA diameters were performed by the same standard: contrast-enhanced, electrocardiogram-gated, and inner-edge to inner-edge. In addition, 75% of the follow-up CTs were performed at our center by the same standard, making the comparison at the same plane and level possible. Third, the calculation of the aortic expansion rate, defined by the changes of AA diameter (preoperative AA diameter- latest follow-up) divided by follow-up period, might not reflect the variations during the follow-up period, although this method has been used in the previous studies (30,31). Finally, the present study represents a single-center experience. The small sample size and the retrospective nature limit generalizability of the findings. Randomized studies would be necessary to compare the performance of SEV and BEV in patients with dilatated AA.

Conclusions

In patients with dilatated AA who underwent TAVR, the type of THVs did not affect the procedural device success. BAV appeared to be a risk factor for device failure and higher aortic expansion rate in these patients.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-364/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-364/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-364/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of Fuwai Hospital (approval No. 2022-1829), and informed consent was obtained from all patients.

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