Original Article

Transcatheter aortic valve replacement in patients with preoperative ascending aortic diameter ≥45 mm

Kang An[1,2,3,4], Fengwen Zhang[1,2,3,4], Wenbin Ouyang[1,2,3,4], Xiangbin Pan[1,2,3,4]

[1]Department of Structural Heart Disease, National Center for Cardiovascular Disease, China & Fuwai Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China; [2]National Health Commission Key Laboratory of Cardiovascular Regeneration Medicine, Beijing, China; [3]Key Laboratory of Innovative Cardiovascular Devices, Chinese Academy of Medical Sciences, Beijing, China; [4]National Clinical Research Center for Cardiovascular Diseases, Fuwai Hospital, Chinese Academy of Medical Sciences, Beijing, China

Contributions: (I) Conception and design: K An, X Pan; (II) Administrative support: F Zhang, X Pan; (III) Provision of study materials or patients: F Zhang, W Ouyang; (IV) Collection and assembly of data: K An, W Ouyang; (V) Data analysis and interpretation: K An, W Ouyang; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Xiangbin Pan, MD. Department of Structural Heart Disease, National Center for Cardiovascular Disease, China & Fuwai Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, No. 167 North Lishi Rd, Xicheng District, Beijing 100037, China; National Health Commission Key Laboratory of Cardiovascular Regeneration Medicine, Beijing, China; Key Laboratory of Innovative Cardiovascular Devices, Chinese Academy of Medical Sciences, Beijing, China; National Clinical Research Center for Cardiovascular Diseases, Fuwai Hospital, Chinese Academy of Medical Sciences, Beijing, China. Email: panxiangbin@fuwaihospital.org.

Background: Current indication for concomitant replacement of ascending aorta (AA) in patients undergoing surgical aortic valve replacement is that AA diameter exceeds 45 mm. However, the impact of AA dilation (≥45 mm) in patients undergoing transcatheter aortic valve replacement (TAVR) remains unclear.

Methods: We retrospectively evaluated 467 consecutive patients who underwent transfemoral TAVR from January 2016 to April 2021. Cox proportional hazards regression was performed to identify risk factors for all-cause mortality. The primary endpoint was the all-cause mortality, and the secondary endpoints were the occurrence of the aortic dissection and/or rupture.

Results: One hundred patients (21.4%) presented preoperative AA ≥45 mm. The median age was 73 years for patients with AA ≥45 mm and 75 years for patients with AA <45 mm (P=0.021). The in-hospital mortality rate was 1.1%. There was no iatrogenic injury to the AA. Only one patient (0.2%) in AA <45 mm group experienced retrograde type B aortic dissection in the descending aorta. The median follow-up was 19 [16–34] months in patients with AA ≥45 mm and 27 [15–37] months in patients with AA <45 mm (P=0.152). No statistical difference was found between the two groups regarding the overall survival (92.5%±3.5% *vs.* 78.3%±6.8%, P=0.198). Only one patient in AA <45 mm group experienced type A aortic dissection 10 months after the procedure. In both univariable and multivariable analysis, AA ≥45 mm was not an independent predictor for all-cause mortality.

Conclusions: Transfemoral TAVR can be performed safely in patients with preoperative AA ≥45 mm with a low intraprocedural risk. The mid-term survival appears not to be affected by the presence of AA ≥45 mm, and adverse aortic events are rare.

Keywords: Transcatheter aortic valve replacement (TAVR); transfemoral route; ascending aorta (AA); adverse aortic event

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Introduction

Ascending aorta (AA) dilatation occurs frequently in patients with aortic stenosis (AS) who are candidates for transcatheter aortic valve replacement (TAVR) (1,2). This pathology has been considered as a risk factor for TAVR treatment, especially for the transfemoral route (3). Considering that the indications for TAVR continue to expand (4), and the transfemoral route is the first-line approach for patients undergoing TAVR (5), there is a severe evidence gap with regard to the outcome of patients with concomitant ascending aortic dilatation.

Previous landmark TAVR clinical trials have excluded patients with significant ascending aortic dilatation (6,7). However, several recently published studies reported that concomitant ascending aortic dilation did not increase perioperative complications, nor did it appear to affect the mid-term survival and the incidence of adverse aortic events such as aortic dissection (1,8-10). For patients undergoing surgical aortic valve replacement (SAVR), current guidelines recommend concomitant aortic repair or replacement if the diameter of AA exceeds 45 mm (11). However, it is unclear whether this cut-off value remains clinically significant in patients undergoing TAVR. The aim of the present study is to evaluate the safety of transfemoral TAVR, as well as the mid-term survival and the fate of AA in patients with preoperative ascending aortic diameter ≥45 mm. We present this article in accordance with the STROBE reporting checklist (available at https://cdt.amegroups.com/article/view/10.21037/cdt-23-324/rc).

Highlight box

Key findings

- Transfemoral transcatheter aortic valve replacement (TAVR) can be performed safely in patients with preoperative ascending aortic (AA) diameter ≥45 mm. The mid-term survival did not differ from that in patients with AA diameter <45 mm.

What is known and what is new?

- Early clinical trials regarding TAVR have excluded patients with significant AA dilatation.
- The mid-term survival appears not to be affected by the presence of AA ≥45 mm in patients undergoing transfemoral TAVR, and the adverse aortic events are rare.

What is the implication, and what should change now?

- The AA dilatation should not be considered as contraindication for transfemoral TAVR. However, further studies are required to evaluated the long-term results.

Methods

Study population

We retrospectively evaluated all patients who underwent transfemoral TAVR from January 2016 to April 2021. Patients with dominant aortic regurgitation, previous aortic valve replacement, and previous aortic surgery were excluded (*Figure 1*). In addition, patients without available preoperative computed tomography (CT) were also excluded. Electronic medical records were reviewed to obtain patient demographics, echocardiographic and CT data, perioperative information (in-hospital events and echocardiographic data before discharge), and follow-up data (clinical outcomes and follow-up echocardiographic data). Follow-up assessment of clinical outcomes and echocardiography were conducted at 1, 3, 6, 12 months after the procedure, and annually thereafter. Echocardiographic parameters included in the present study were left ventricular ejection fraction, aortic valve velocity and pressure gradient, preoperative aortic regurgitation or postoperative paravalvular aortic insufficiency. The CT data were analyzed by a dedicated core laboratory that included personnel who were blinded to the patient information at our center. When multiple echocardiographic or CT assessments were performed, the latest data were used. 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 (No. 2022-1829), and informed consent was obtained from all patients.

Surgical procedure

All transfemoral TAVR procedures were conducted in accordance with guidelines using standard techniques. All TAVR candidates were evaluated by the multidisciplinary heart team of Fuwai Hospital. All patients received TAVR under fluoroscopic guidance and local and/or general anesthesia. The right femoral artery was used for valve-stent delivery, and the left femoral artery was punctured for coronary angiography. A temporary pacing lead was inserted through the right internal jugular vein. Standard transcatheter heart valve implantation techniques were used according to the size and morphological characteristics of the valves. The types of transcatheter heart valve included Venus-A (Venus MedTech, Hangzhou, China) in 302 (64.7%), Taurus One (Peijia Medical, Suzhou, China) in 35 (7.5%), VitaFlow (MicroPort, Shanghai, China) in 68 (14.6%), Edwards SAPIEN XT (Edwards Lifesciences,

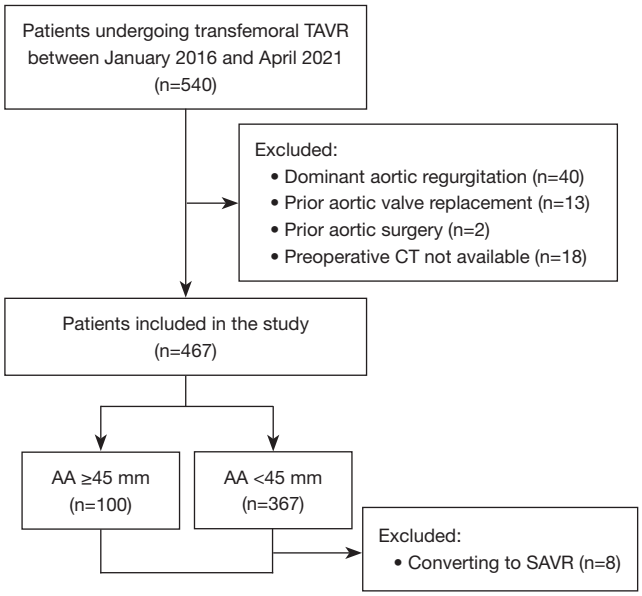

Figure 1 Study flow diagram. TAVR, transcatheter aortic valve replacement; CT, computed tomography; AA, ascending aorta; SAVR, surgical aortic valve replacement.

Irvine, CA, USA) in 16 (3.4%), and Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA) in 46 (9.9%). Individualized antithrombotic strategy was used according to the patients' conditions.

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 all-cause mortality during the follow-up. Secondary endpoints were the occurrence of the aortic dissection and/or rupture during the transfemoral TAVR procedure, as well as during the follow-up.

Statistical analyses

Non-normally distributed variables as median (interquartile range). Categorical data were expressed as counts and proportions. Student's *t*-test was used for normally distributed variables and non-parametric tests were used for non-normally distributed variables. The χ^2 test was used for categorical variables. Univariable and multivariable Cox proportional hazards regression were used to determine hazard ratios (HRs) and 95% confidential intervals (CIs). A backward variable selection approach with a significance level <0.2 was performed, and variables with P value of <0.2 in univariable analysis were included in the multivariable regression analysis. Kaplan-Meier survival curves were constructed between patients with preoperative AA ≥45 mm and AA <45 mm, and log-rank test was used to compare the difference in overall survival. Statistical analyses were performed using the Statistical Package for Social Sciences, version 23.0 (SPSS, Inc., Chicago, IL, USA).

Results

A total of 467 patients were included. These patients were divided into two groups based on the CT-measured preoperative AA diameter. One hundred patients (21.4%) presented preoperative AA ≥45 mm. In particular, 34 patients had AA ≥50 mm, with seven patients having AA ≥55 mm. The other 367 patients (78.6%) had preoperative AA <45 mm. Baseline characteristics were summarized in *Table 1*. The median age was 73 years for patients with AA ≥45 mm and 75 years for patients with AA <45 mm (P=0.021). The rate of patients with bicuspid aortic valve (BAV) was significantly higher in patients with AA ≥45 mm (61.0% *vs.* 21.0%, P<0.001). In addition, patients with AA <45 mm appeared to have higher rates of hypertension, diabetes, history coronary artery disease, prior coronary artery intervention, and prior coronary artery bypass grafting (P<0.05). Patients with AA <45 mm had higher Society of Thoracic Surgery (STS) score compared with those with AA ≥45 mm (4.1% *vs.* 3.9%, P=0.033).

Procedural details are shown in *Table 2*. The in-hospital mortality rate was 1.1%. The incidences of other in-hospital events were similar between two groups. There was no iatrogenic injury to the AA in the entire study cohort. Only one patient (0.2%) in AA <45 mm group experienced retrograde type B aortic dissection in the descending aorta, which was managed conservatively. Post-procedure echocardiography showed no significant difference in the peak velocity, maximum pressure gradient, and paravalvular aortic insufficiency between two groups.

A total of 451 patients (96.6%) were included in the follow-up study. Baseline characteristics of these patients were shown in Table S1. Eight patients (1.7%) who were lost during the follow-up and 8 patients (1.7%) who were converted to SAVR were excluded (Table S2). The median follow-up was 19 [16–34] months in patients with AA ≥45 mm and 27 [15–37] months in patients with AA <45 mm (P=0.152). No statistical difference was found between two groups regarding the overall survival

Table 1 Baseline characteristics

Variables	AA ≥45 mm (n=100)	AA <45 mm (n=367)	P value
Age (years)	73 [69–77]	75 [70–80]	0.021
Male	63 (63.0)	207 (56.4)	0.236
Body mass index (kg/m^2)	23.7 [21.1–26.7]	24.1 [22.1–27.2]	0.188
STS score (%)	3.9 [3.4–5.0]	4.1 [3.7–5.1]	0.033
NYHA class III/IV	89 (89.0)	327 (89.1)	0.977
Smoking	33 (33.0)	118 (32.2)	0.872
Serum creatinine (mg/dL)	1.0 [0.9–1.2]	1.0 [0.9–1.3]	0.740
Hypertension	48 (48.0)	237 (64.6)	0.003
Diabetes mellitus	16 (16.0)	104 (28.3)	0.012
Dyslipidemia	72 (72.0)	292 (79.6)	0.106
History of coronary artery disease	32 (32.0)	189 (51.5)	0.001
History of cerebrovascular disease	17 (17.0)	61 (16.6)	0.928
Peripheral artery disease	27 (27.0)	122 (33.2)	0.235
Prior coronary artery intervention	6 (6.0)	62 (16.9)	0.006
Prior coronary artery bypass grafting	0	19 (5.2)	0.018
Bicuspid aortic valve	61 (61.0)	77 (21.0)	<0.001
Baseline echo characteristics			
Left ventricular ejection fraction (%)	60 [43.5–65]	60 [51–65]	0.115
Peak aortic valve velocity (m/s)	4.7 [4.3–5.2]	4.7 [4.3–5.2]	0.304
Maximum aortic valve pressure gradient (mmHg)	88.4 [74.0–108.2]	88.4 [74.0–108.2]	0.325
Moderate-to-severe aortic regurgitation	22 (22.0)	89 (24.3)	0.639

Values are presented as n (%) or median [interquartile range]. AA, ascending aorta; STS, Society of Thoracic Surgery; NYHA, New York Heart Association.

(92.5%±3.5% *vs.* 78.3%±6.8%, P=0.198) (*Figure 2*). Only one patient in AA <45 mm group (with a preoperative AA of 39 mm) experienced type A aortic dissection 10 months after the procedure. The median AA diameter measured by transthoracic echocardiography (TTE) remained relatively stable in both groups during a median follow-up of 12 months {AA ≥45 mm group: 45 [42–48] *vs.* 46 [44–48] mm, P=0.805; AA <45 mm group: 35 [32–38] *vs.* 35 [31–38] mm, P=0.260}. No aortic growth rate more than 5 mm/years was found in any patient.

In multivariable analysis, AA ≥45 mm was not independent predictor for all-cause mortality. Instead, preoperative serum creatinine (HR =2.39; 95% CI: 1.41–4.05; P=0.001), history of cerebrovascular disease (HR =2.55; 95% CI: 1.29–5.05; P=0.007), and moderate-to-severe paravalvular aortic insufficiency (HR =3.57; 95% CI: 1.07–11.91; P=0.039) were identified as independent risk factors (*Table 3*).

Discussion

There are several possible mechanisms by which injuries to the AA can develop during transfemoral TAVR: stiff wire interaction in the AA, intimal disruption created by transcatheter heart valve injury to the aortic wall, balloon valvuloplasty injury, or post-dilation balloon interaction with the aorta (12,13). Useini *et al.* (3) reported that in patients with ascending aortic dilatation for whom transfemoral TAVR might be contraindicated or not feasible, transapical TAVR was a safe method and showed promising early and mid-term outcomes. However, their study did not specify in

Table 2 Procedural characteristics and in-hospital events

Variables	AA ≥45 mm (n=100)	AA <45 mm (n=367)	P value
Valve type implanted			0.155
Balloon-expandable	9 (9.0)	53 (14.4)	
Self-expandable	91 (91.0)	314 (85.6)	
In-hospital events			
All-cause mortality	0	5 (1.4)	0.590
Conversion to surgery	2 (2.0)	6 (1.6)	0.682
Stroke	1 (1.0)	1 (0.3)	0.383
Permanent pacemaker	13 (13.0)	32 (8.7)	0.198
Myocardial infarction	0	1 (0.3)	>0.99
Coronary obstruction	0	1 (0.3)	>0.99
Major vascular complication	2 (2.0)	11 (3.0)	0.744
New requirement for dialysis	0	1 (0.3)	>0.99
Implantation of second valve	10 (10.0)	42 (11.4)	0.684
Post-procedure echo characteristics			
Left ventricular ejection fraction (%)	60 [47.3–65]	60 [55–65]	0.331
Peak aortic valve velocity (m/s)	2.3 [2.1–2.8]	2.4 [2.0–2.7]	0.346
Maximum aortic valve pressure gradient (mmHg)	21.2 [17.6–30.9]	23.0 [16.0–29.2]	0.355
Paravalvular aortic insufficiency			0.595
None or mild	95 (95.0)	353 (96.2)	
Moderate or severe	5 (5.0)	14 (3.8)	

Values are presented as n (%) or median [interquartile range]. AA, ascending aorta.

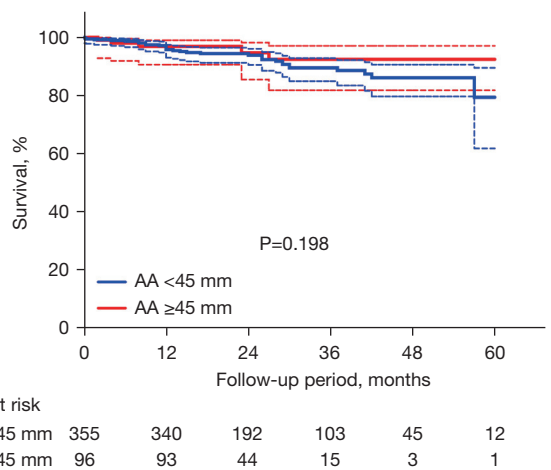

Figure 2 Kaplan-Meier curves for overall survival between two groups (P=0.198). AA, ascending aorta.

which situation the patients with ascending aortic dilatation were considered as having high interventional risk and deemed to be unsuitable for transfemoral route.

In fact, during the past decade, improvement in endovascular guidewire techniques has significantly decreased complications associated with transfemoral TAVR (14,15), even in a vulnerable dilatated AA. The result of the present study demonstrated a very low risk (0.2%) of intraprocedural adverse aortic events, and no injury to the AA was found. In Rylski *et al.*'s study (1), transfemoral route was also the preferred approach in patients with dilatated AA (accounting for 78%), and the risk of intraprocedural adverse aortic events was very low (1%). Several other studies also reported a safe transfemoral TAVR in this particular patient group (8,16).

The results of the present study demonstrate a

Table 3 Univariable and multivariable Cox regression analyses for all-cause mortality

Variables	Death (n=43)	Survival (n=408)	Univariable analysis		Multivariable analysis	
			HR (95% CI)	P value	HR (95% CI)	P value
Age (years)	77 [71–82]	75 [69–79]	1.02 (0.97–1.06)	0.487	–	–
Male	27 (62.8)	233 (57.1)	1.23 (0.66–2.29)	0.571	–	–
Body mass index (kg/m^2)	23.7 [21.1–26.7]	24.0 [22.0–27.1]	0.99 (0.92–1.06)	0.706	–	–
NYHA class III/IV	37 (86.0)	364 (89.2)	1.49 (0.63–3.55)	0.366	–	–
Smoking	16 (37.2)	126 (30.9)	1.24 (0.67–2.31)	0.494	–	–
Serum creatinine (mg/dL)	1.2 [0.9–1.5]	1.0 [0.9–1.2]	2.24 (1.37–3.67)	0.001	2.39 (1.41–4.05)	0.001
Hypertension	31 (72.1)	247 (60.5)	1.43 (0.73–2.79)	0.298	–	–
Diabetes mellitus	17 (39.5)	101 (24.8)	1.72 (0.93–3.18)	0.083	–	–
Dyslipidemia	36 (83.7)	318 (77.9)	1.45 (0.65–3.27)	0.367	–	–
History of coronary artery disease	28 (65.1)	188 (46.1)	1.77 (0.94–3.32)	0.077	–	–
History of cerebrovascular disease	14 (32.6)	61 (15.0)	2.37 (1.25–4.49)	0.008	2.55 (1.29–5.05)	0.007
Peripheral artery disease	18 (41.9)	127 (31.1)	1.41 (0.78–2.59)	0.270	–	–
Prior coronary artery intervention	6 (14.0)	61 (15.0)	0.78 (0.33–1.85)	0.570	–	–
Prior coronary artery bypass grafting	3 (7.1)	16 (3.9)	2.04 (0.63–6.61)	0.235	–	–
Bicuspid aortic valve	8 (18.6)	127 (31.1)	0.65 (0.30–1.40)	0.267	–	–
Baseline echo characteristics						
Left ventricular ejection fraction (%)	59 [47–65]	60 [48.5–65]	0.99 (0.97–1.01)	0.323	–	–
Peak aortic valve velocity (m/s)	4.5 [4.2–5.2]	4.7 [4.3–5.2]	0.76 (0.49–1.17)	0.207	–	–
Maximum aortic valve pressure gradient (mmHg)	81.0 [70.6–108.2]	88.4 [74.0–108.2]	0.99 (0.98–1.01)	0.359	–	–
Moderate-to-severe aortic regurgitation	14 (32.6)	96 (23.5)	1.60 (0.85–3.04)	0.148	–	–
Preoperative AA ≥45 mm	5 (11.6)	91 (22.3)	0.55 (0.22–1.39)	0.206	–	–
Valve type implanted			0.47 (0.14–1.51)	0.204	–	–
Balloon-expandable	3 (7.0)	58 (14.2)				
Self-expandable	40 (93.0)	350 (85.8)				
Post-procedure echo characteristics						
Left ventricular ejection fraction (%)	60 [53.5–64]	60 [53–65]	0.98 (0.95–1.01)	0.194	–	–
Maximum aortic valve velocity (m/s)	2.3 [1.9–2.8]	2.3 [2.0–2.7]	1.02 (0.57–1.85)	0.937	–	–
Maximum aortic valve gradient (mmHg)	21.2 [14.4–30.9]	21.2 [16.0–29.2]	1.01 (0.98–1.04)	0.609	–	–
Moderate-to-severe paravalvular aortic insufficiency	3 (7.1)	13 (3.2)	2.68 (0.82–8.75)	0.102	3.57 (1.07–11.91)	0.039

Values are presented as n (%) or median [interquartile range]. HR, hazard ratio; CI, confidential interval; NYHA, New York Heart Association; AA, ascending aorta.

Table 4 Comparison with other TAVR studies regarding dilatated ascending aorta

First author (year of publication)	Sample size	Inclusion criteria for dilatated AA	Prevalence of dilatated AA	Intraprocedural aortic events	Follow-up period	Survival	Adverse aortic event
Ochiai *et al.* (17), 2020	1,426	≥40 mm	13.7%	NA	391 days (median)	65.5%	NA
Rylski *et al.* (1), 2014	457	≥40 mm	22%	1%	14 months (median)	86.7% (1-year survival)	None
Ancona *et al.* (8), 2019	680	>40 mm	15%	NA	498 days (mean)	85.2%	NA
Lv *et al.* (10), 2019	134	>40 mm	59%	NA	27 months (median)	NA (one death during follow-up)	None
He *et al.* (9), 2019	208	≥45 mm	21.2%	NA	NA (up to 5 years)	NA	None
An (current case), 2023	467	≥45 mm	21.4%	0.2%	19 months (median)	92.5%	None

TAVR, transcatheter aortic valve replacement; AA, ascending aorta; NA, not appliable.

comparable mid-term survival in patients with AA ≥45 mm who underwent TAVR. Several recently published studies from high-volume centers also reported similar results (1,8-10,16) (*Table 4*). The present study focused on the patients with AA ≥45 mm because this is the recommended cut-off value for concomitant aortic surgery in patients undergoing SAVR according to the current guidelines (11), while in most previous studies inclusion criteria for AA dilatation was defined as AA ≥40 mm. These results suggest that maintaining a conservative approach to concomitant AA dilatation might be an option in patients undergoing TAVR. To the best of our knowledge, only one study by Ochiai *et al.* (17) demonstrated a higher mid-term mortality rate in patients with dilatated AA (≥40 mm). However, the incidence of adverse aortic events was not reported in the study.

Previous studies regarding the changes of AA diameters after TAVR are limited. Lv *et al.* (10) reported a very slight decrease in AA diameter (40.7 to 40.6 mm) based on 1-year CT follow-up, and suggested that TAVR could prevent a further progression of aortic diameter by correcting hemodynamic derangements. He *et al.* (9) reported a mild dilatation rate of AA (0.3±0.8 mm/years) based on CT follow-up. In Rylski *et al.*'s study (1), the proximal AA diameter was assessed with TTE, and it remained stable during a median follow-up of 14 months. In the present study, also measured by TTE, the AA diameter remained stable during a median follow-up of 12 months. However, due to the limitation of TTE in measuring AA, this result should be interpreted with caution.

Several limitations should be acknowledged. First, risk factors for adverse aortic events could not be analyzed because of the very small number of these incidents. Second, the cut-off value of 45 mm for AA is arbitrary, although it is the recommended value for concomitant aortic surgery in patients undergoing SAVR according to the guidelines. In addition, in patients with aneurysmatic AA (≥55 mm), the safety of TAVR requires further study, although in the present study, seven patients with AA ≥55 mm experienced uneventful procedure and the prognosis was satisfactory. Third, as mentioned above, TTE has inherent limitations in the evaluation of AA diameters. Although CT is more accurate, only about one third of the patients underwent postoperative CT exam in the present study. Therefore, changes of the AA diameters during the follow-up should be interpreted with caution. Fourth, as the indications for TAVR continue to expand to younger and lower-risk patients, the long-term impact of AA dilation requires more attention. Further studies comparing the outcomes of TAVR, SAVR, and SAVR plus AA repair/replacement (Wheat's procedure) in patients with dilated AA would be helpful. In addition, the present study focused on the baseline characteristics and perioperative data. Other factors, such as medication, blood pressure control, and family history of adverse aortic events, were not considered. Finally, the retrospective and observational nature of the study may bring out bias. Future studies with a larger number of patients and longer follow-up may further clarify the effect of AA dilatation on the clinical outcome following TAVR.

Conclusions

Transfemoral TAVR can be performed safely in patients with preoperative AA ≥45 mm with a low intraprocedural risk. The mid-term survival appears not to be affected by the presence of AA ≥45 mm, and the adverse aortic events

are rare.

Acknowledgments

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://cdt.amegroups.com/article/view/10.21037/cdt-23-324/rc

Data Sharing Statement: Available at https://cdt.amegroups.com/article/view/10.21037/cdt-23-324/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://cdt.amegroups.com/article/view/10.21037/cdt-23-324/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 ethics committee of Fuwai Hospital (No. 2022-1829) and informed consent was obtained from all patients.

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