Original Article

Transcatheter aortic valve replacement in the treatment of bicuspid aortic stenosis with "down-size" interventional valves: procedural and mid-term follow-up

Kun Liu[1#], Kaisheng Wu[2#], Jinglun Shen[2], Fei Meng[2], Francesco Nappi[3], Fernando Alfonso[4], Shengxun Wang[2], Shuai Zheng[2], Haibo Zhang[2]

[1]Department of Cardiac Surgery, Cardiovascular Medical Center, the University of Hong Kong-Shenzhen Hospital, Shenzhen, China; [2]Department of Cardiac Surgery, Beijing Anzhen Hospital, Capital Medical University, Beijing, China; [3]Department of Cardiac Surgery, Centre Cardiologique du Nord, Saint-Denis, France; [4]Department of Cardiology, Hospital Universitario de La Princesa, Universidad Autónoma de Madrid, CIBERCV, IIS-IP, Madrid, Spain

Contributions: (I) Conception and design: H Zhang; (II) Administrative support: H Zhang; (III) Provision of study materials or patients: H Zhang, S Wang, S Zheng; (IV) Collection and assembly of data: K Liu, J Shen, F Meng; (V) Data analysis and interpretation: K Liu, J Shen, K Wu; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

[#]These authors contributed equally to this work.

Correspondence to: Haibo Zhang, MD. Department of Cardiac Surgery, Beijing Anzhen Hospital, Capital Medical University, 2 Anzhen Road, Chaoyang District, Beijing 100029, China. Email: zhanghb2318@163.com.

Background: Due to the influence of anatomical structure, replacing the bicuspid valve using transcatheter aortic valve replacement (TAVR) would increase the risk of perivalvular leakage and conduction block, affecting the hemodynamic effect of the interventional valve. In this study, for bicuspid and tricuspid valves, we implemented different valve selection strategies to explore the safety and effectiveness of TAVR in the treatment of bicuspid aortic stenosis with "down-size" interventional valves using the VenusA-valve system.

Methods: The operation was performed with the VenusA-valve via transfemoral approach. The selected valves were appropriately sized based on the results of transthoracic echocardiography (TTE), contrast-enhanced computed tomography (CT), and the morphology of intraoperative pre-dilation balloons. For tricuspid valve cases, the VenusA valve is usually larger than the annulus diameter, whereas the "down-size" approach was adopted for bicuspid aortic valve (BAV) cases. The shape of the pre-dilation balloon allowed further sizing of the annulus diameter by the degree of lumbar constriction of the balloon, aiding in intervention valve size selection, particularly in cases of BAVs.

Results: A total of 65 patients underwent TAVR for aortic stenosis with VenusA-valve systems. Of these, 29 cases had a BAV and 36 cases had a tricuspid aortic valve (TAV). The distribution of VenusA-valve sizes differed between TAV and BAV cases (P=0.007). Furthermore, there was a significant decrease in the average mean gradient in TAV patients from 54.7 to 12.2 mmHg (P<0.001), and in BAV patients from 61.6 to 14.3 mmHg (P<0.001). The percentage of paravalvular leakage greater than mild was 6.90% in the BAVs and 5.56% in the TAVs at procedural outcomes (P=0.955). The mean follow-up period was 22.23 months (range, 12 to 39 months). The proportion of New York Heart Association (NYHA) class III/IV decreased from 78.5% preoperatively to 11.3% at the last follow-up (P<0.001). A total of 27 patients with TAV and 19 patients with BAV underwent TTE at 1-year follow-up after operation. There was no significant contrast in the average pressure difference between TAVs and BAVs at 1-year follow-up (11.9 *vs.* 14.3 mmHg, P=0.18).

Conclusions: The VenusA-valve for TAVR produced positive clinical outcomes and valve functionality in both BAVs and TAVs. In the case of BAVs, selecting a smaller interventional valve size was deemed viable.

Keywords: Transcatheter aortic valve replacement (TAVR); bicuspid aortic valve (BAV); tricuspid aortic valve (TAV); valve size selection

Submitted Dec 12, 2023. Accepted for publication Jan 16, 2024. Published online Jan 22, 2024.
doi: 10.21037/jtd-23-1885
View this article at: https://dx.doi.org/10.21037/jtd-23-1885

Introduction

Transcatheter aortic valve replacement (TAVR) is an innovative treatment for severe aortic stenosis (AS) regardless of the inherent surgical risk (1). The technology has been in extensive use since its first application in 2002 (2-5). A study by Smith *et al.* (6) conducted across 25 centers showed that transcatheter and surgical valve replacements had similar 1-year survival rates despite significant variations in perioperative risks between the two groups. The 2020 guidelines for managing heart valves from the American College of Cardiology and the American Heart Association suggest that TAVR is the favored treatment for severe, symptomatic aortic stenosis patients with Society of Thoracic Surgeons (STS) scores of 8 or higher and a life expectancy greater than one year. For patients with STS scores of less than 8, age is an important factor in choosing the most suitable treatment method (7). With the expanding indications and advancements in valve materials and processes, more patients would choose the TAVR for aortic valve disease treatment. In particular, interventional valves made locally in China have been successfully marketed in recent years. TAVR is now widely used for patients with severe aortic stenosis associated with advanced age or high-risk factors. The proportion of bicuspid aortic valve (BAV) has been high among patients treated with TAVR in China, as reported by a study (8). The risk of stenosis is high in BAV due to factors such as cross valve blood flow and heredity (9,10). Furthermore, due to the special anatomical structure of BAV, the interventional valve implant is susceptible to perivalvular leakage, branch block, aortic annulus rupture, and increased valve pressure, as it experiences asymmetric stress compression. Therefore, in this study, we selected "down-size" interventional valves for TAVR in the BAVs. By comparing the cases of TAVR with BAV and tricuspid aortic valve (TAV) in a single valve intervention center, we identified and summarized the characteristics and experience of BAV with TAVR. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1885/rc).

Highlight box

Key findings

- For bicuspid aortic valves (BAVs) undergoing the transcatheter aortic valve replacement (TAVR), it is feasible to select a relatively "down-size" interventional valve.

What is known and what is new?

- TAVR for the BAV is challenging and optimal valve selection remains controversial.
- Usually, the VenusA-valve should be larger than the annulus diameter for the tricuspid valve cases. We chose the "down-size" strategy for BAVs.

What is the implication, and what should change now?

- We confirmed the reliability of our selection through the follow-up. According to the results of this study, it is feasible to select a relatively "down-size" interventional valve for BAVs.

Methods

Patients

We collected aortic stenosis patients using VenusA valve via the femoral pathway from January 2018 to December 2019, excluding patients with iliac artery tortuosity or stenosis and valve surgery history. The primary endpoint was clinical death, and the secondary endpoint was the occurrence of complications (*Figure 1*). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Medical Ethics Committee of Beijing Anzhen Hospital, Capital Medical University (No. 2022193X). All patients were evaluated by more than two cardiac surgeons before the procedure. Transthoracic echocardiography (TTE) was mandatory for all patients to assess their aortic valve function, aortic valve morphology and cardiac function. Preoperative multidetector computed tomography (MDCT) of the aorta and peripheral vessels was evaluated before TAVR to select the appropriate interventional valves and procedures. MDCT through the aortic valve was implemented to ascertain the aortic annulus diameter, the coronary height, the internal diameter of the ascending aorta, and the internal diameter of the left ventricular outflow tract (LVOT), enabling appropriately sized valves to be selected. Transfemoral access was permitted for

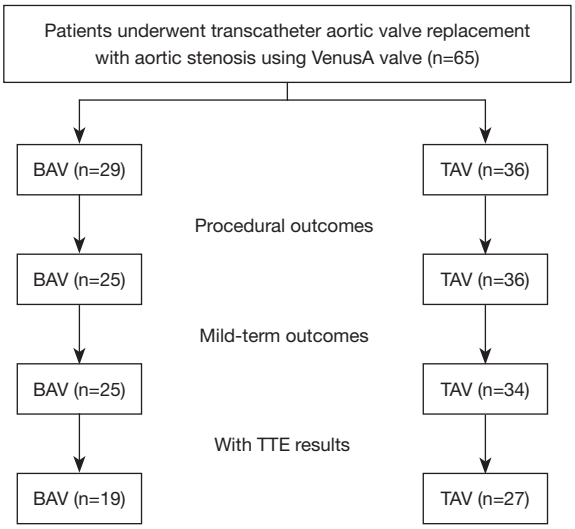

Figure 1 Study flowchart of patients who underwent transcatheter aortic valve replacement. BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; TTE, transthoracic echocardiography.

interventional valves except in cases of peripheral femoral artery tortuosity, stenosis, or low height of the coronary opening. Preoperative coronary examination was performed preoperatively to clarify the coronary artery obstruction situation. If the coronary artery was stenotic, it could be treated with percutaneous coronary intervention (PCI) in the same period or preoperatively to reduce ischemia risk. Informed consent was obtained from all patients before the operation.

Valve size selection

We selected "down-size" interventional valves for TAVR in the BAVs. The procedure utilized the VenusA-valve (Qiming Medical, Hangzhou, China) through the transfemoral route. VenusA-valve provided a long stent transfemoral interventional valve with stronger radial support than other high stent valves, which was suitable for patients with a high degree of valve calcification. Currently, VenusA valves are only approved for treating aortic stenosis in China. They consist of four models: 23, 26, 29, and 32 mm, which correspond to the diameters of the different valve bottoms. Valve selection employed TTE, contrast-enhanced CT, and intraoperative dilation balloons, with a VenusA-valve annulus exceeding the annulus diameter for TAV and a relatively smaller size for BAVs. For aortic annuli with the same diameter, individuals with BAV morphology tend to select smaller valves compared to those with tricuspid morphology. Generally, the oversizing rate falls between 5–10%.

Procedure details

The TAVR procedure was carried out in the hybrid theatre using a combination of intravenous compound anaesthesia and local anaesthesia, aimed at decreasing lung injury, and promoting postoperative recovery. A pre-dilation balloon was employed in each case to expand the stenotic valve leaflet, allowing for easy implantation of the valve. The balloon's shape facilitated annulus diameter sizing in correlation with the extent of lumbar constriction, aiding intervention valve selection, particularly in BAV cases. Post-dilation was considered unnecessary when the valve function was shown to be sufficient by TTE after the valve was released. Balloon post-dilatation was an option for cases of higher than mild paravalvular leak or where mean gradient remained above 20 mmHg. Patients were subsequently transferred to the intensive care unit (ICU) for recovery. If the patient did not have atrial fibrillation or other embolic disease, they were given dual antiplatelet agents in the 3 months of the postoperative period and single antiplatelet agents, typically aspirin, in the following period.

Follow-up

The TTE was performed 1 year after discharge and follow-up was accomplished via telephone, outpatient service, or follow-up database. The trial utilized a primary composite endpoint of all-cause mortality, and secondary endpoints included life-threatening bleeding, stroke, acute renal injury, coronary artery occlusion requiring intervention, major vascular complications, perivalvular leakage, and new permanent pacemaker implantation. All TTE results were evaluated by ultrasound doctors without knowing the clinical results.

Statistical analysis

All continuous variables were expressed as mean (standard deviation) and analyzed by *t*-test. The preoperative and postoperative TTE data were compared using paired *t*-tests. Categorical variables were described by frequency and percentage and tested by analysis of variance (ANOVA). The follow-up period was defined as the time between discharge and the patient's last clinical follow-up. The

Table 1 Demographics and characteristics

Demographics and characteristics	VenusA for BAV (N=29)	VenusA for TAV (N=36)	P value
Age (years), mean (SD)	72.1 (7.6)	73.8 (7.0)	0.35
Weight (kg), mean (SD)	64.2 (11.2)	65.4 (12.2)	0.69
Height (cm), mean (SD)	165.5 (7.9)	164.6 (8.4)	0.68
Female, n (%)	10 (34.5)	15 (41.7)	0.55
Hypertension, n (%)	14 (48.3)	17 (47.2)	0.93
Diabetes mellitus, n (%)	5 (17.2)	6 (16.7)	>0.99
Coronary atherosclerotic heart disease, n (%)	10 (34.5)	16 (44.4)	0.42
Previous PCI, n (%)	0	6 (16.7)	0.06
Previous stroke, n (%)	5 (17.2)	2 (5.6)	0.25
Chronic kidney disease, n (%)	1 (3.4)	5 (13.9)	0.31
LBBB, n (%)	2 (6.9)	3 (8.3)	>0.99
Atrial fibrillation, n (%)	2 (6.9)	3 (8.3)	>0.99
Previous pacemaker, n (%)	2 (6.9)	1 (2.8)	0.85
NYHA class III or IV, n (%)	22 (75.9)	29 (80.6)	0.65
Preoperative echocardiography, mean (SD)			
Peak velocity (cm/s)	490 (74.0)	463.8 (72.9)	0.16
Peak gradient (mmHg)	98.3 (29.1)	88.3 (28.2)	0.17
Mean gradient (mmHg)	61.6 (18.7)	54.7 (19.6)	0.16
Left ventricular ejection fraction (%), mean (SD)	53.7 (13.7)	55.4 (12.7)	0.61
LVEDD (mm), mean (SD)	49.9 (6.7)	55.4 (8.7)	0.21
LVESD (mm), mean (SD)	35.3 (8.0)	37.6 (11.2)	0.36
AR moderate or more, n (%)	4 (13.8)	16 (44.4)	0.008
MR moderate or more, n (%)	8 (27.6)	14 (38.9)	0.34
TR moderate or more, n (%)	6 (20.7)	5 (13.9)	0.69

BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; SD, standard deviation; PCI, percutaneous coronary intervention; LBBB, left bundle branch block; NYHA, New York Heart Association; LVEDD, left ventricular end-diastolic dimension; LVESD, left ventricular end-systolic dimension; AR, aortic regurgitation; MR, mitral regurgitation; TR, tricuspid regurgitation.

software SPSS 26.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Statistical significance was considered when P<0.05.

Results

Baseline characteristics

The patient base condition and clinical characteristics are described in *Table 1*. A total of 65 patients underwent TAVR for aortic stenosis with VenusA-valve systems at our center (Valve Surgery Center, Beijing Anzhen Hospital, Capital Medical University) from January 2018 to December 2019, including 29 cases of BAV and 36 cases of TAV. There were 25 (38.5%) female patients. The mean age was 73.0 years. The proportion of aortic regurgitation valves above moderate in TAV exceeded that in BAV (44.4% *vs.* 13.8%, P=0.008). Other fundamental conditions and indicators showed no substantial discrepancy.

Table 2 Valve characteristics

Characteristics	BAV (N=29)	TAV (N=36)	P value
Major annulus diameter (mm), mean (SD)	26.6 (3.2)	27.8 (3.2)	0.52
Minor annulus diameter (mm), mean (SD)	21.6 (2.8)	20.8 (3.7)	0.32
Mean annulus diameter (mm), mean (SD)	24.5 (2.84)	23.9 (2.8)	0.37
Annulus perimeter (mm), mean (SD)	85.9 (44.0)	76.2 (8.8)	0.2
Ascending AO major diameter (mm), mean (SD)	39.4 (4.8)	36.1 (4.3)	0.005
Ascending AO minor diameter (mm), mean (SD)	37.9 (4.52)	34.7 (4.2)	0.005
Ascending AO mean diameter (mm), mean (SD)	38.6 (4.6)	35.37 (4.2)	0.005
Major STJ diameter (mm), mean (SD)	32.3 (4.3)	30.2 (4.6)	0.065
Minor STJ diameter (mm), mean (SD)	30.1 (3.5)	28.5 (4.6)	0.14
Mean STJ diameter (mm), mean (SD)	31.3 (4.9)	29.3 (4.6)	0.07
LCA height (mm), mean (SD)	15.4 (3.3)	14 (3.23)	0.1
RCA height (mm), mean (SD)	16.6 (2.5)	16 (3.0)	0.39
Prosthesis size, n (%)			0.007
23 mm	11 (37.9)	5 (13.9)	
26 mm	16 (55.2)	18 (50.0)	
29 mm	2 (6.9)	13 (36.1)	

BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; SD, standard deviation; AO, aorta; STJ, Sin-tubular junction; LCA, left coronary artery; RCA, right coronary artery.

Procedural characteristics

Based on preoperative measurements, there was no significant difference in the size of valve annuli between BAVs and TAVs. The major annulus diameter for BAVs was 26.6 mm and for TAVs was 27.8 mm (P=0.523). The minor annulus diameter for BAVs was 21.6 mm and for TAVs was 20.8 mm (P=0.321). The mean annulus diameter for BAVs was 24.5 mm and for TAVs was 23.9 mm (P=0.374) (refer to *Table 2*). Nevertheless, due to the structure and calcification of the two leaflets, a smaller valve was typically chosen. In the TAV cases, there were 5 occurrences of 23 mm VenusA-valves, 18 of 26 mm, and 13 of 29 mm. In comparison, the BAV cases included 11 cases with 23 mm VenusA-valves, 16 with 26 mm, and 2 with 29 mm. A statistically significant difference in VenusA-valve size distribution was observed between the TAV and BAV cases (P=0.007) (*Table 2*). The operations did not result in any valve slippage, bleeding, or sternotomy conversion.

Procedural outcomes

The procedural outcomes are displayed in *Tables 3*,*4*. Patients with BAV experienced four deaths during surgery, while no deaths were reported among those with TAV. There were no incidents of thrombosis, aortic root damage, myocardial infarction, cerebrovascular events, pericardial effusion, or severe bleeding. Additionally, no patients required readmission within a 30-day period. The average mean gradient for TAV patients significantly decreased from 54.7 to 12.2 mmHg (P<0.001). Similarly, for BAV patients, the average mean gradient reduced from 61.6 to 14.3 mmHg (P<0.001). There was no difference between BAV and TAV in average mean gradient after operations (P=0.13). The percentage of paravalvular leakage greater than mild was 6.90% in the BAVs and 5.56% in the TAVs at

Table 3 Procedural outcomes

Characteristics	BAV	TAV	P value
Procedural outcomes	N=29	N=36	
Procedural death	4 (13.8)	0	0.08
Aortic root injury/annulus rupture	0	0	
Myocardial infarction	0	0	
Cerebrovascular event	0	0	
Hemorrhagic stroke	1 (3.4)	0	0.45
Ischemic stroke	0	0	
Pericardial effusion	0	0	
Major vascular complication	0	1 (2.8)	>0.99
Bleeding			
Life-threatening or major	0	0	
Minor	1 (3.4)	0	
Acute kidney injury	0	1 (2.8)	
New LBBB	15 (51.7)	15 (41.7)	0.419
New pacemaker	1 (3.4)	5 (13.9)	0.31
Paravalvular regurgitation			0.955
None/trivial	15 (51.7)	18 (50.0)	
Mild	12 (41.4)	16 (44.4)	
Moderate	2 (6.9)	2 (5.56)	
Severe	0	0	
Mid-term outcomes (median length of follow-up 22.23 months)	N=25	N=36	
Death mortality	0	2 (5.6)	0.51
Bleeding			
Life-threatening or major	0	0	
Minor	1 (4.0)	1 (2.8)	>0.99
New pacemaker	1 (4.0)	2 (5.6)	>0.99
Cerebrovascular event	0	0	
Renal failure	0	0	

Values are n (%). BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; LBBB, left bundle branch block.

early outcomes (P=0.955).

Mid-term outcomes

The average follow-up time was 22.23 months (range, 12 to 39 months). There were no deaths among patients with BAVs, while one patient experienced bleeding and another required pacemaker implantation. Among those with TAV, there were two mortalities, one bleeding incident, and two pacemaker implantations during the follow-up period. The proportion of New York Heart Association (NYHA) class III/IV decreased from 78.5% preoperatively to 11.3% at the last follow-up (P<0.001). Twenty-seven patients with TAV and nineteen with BAV underwent TTE one year after the

Table 4 Mid-term outcomes

Mean gradient	VenusA for BAV		VenusA for TAV		P value
	N	Mean (SD)	N	Mean (SD)	
Before operation (mmHg)	29	61.6 (18.7)	36	54.7 (19.6)	0.16
After operation (mmHg)	25	14.3 (5.9)	36	12.2 (5.0)	0.13
1-year follow-up (mmHg)	19	14.3 (6.9)	27	11.9 (5.1)	0.18

BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; SD, standard deviation.

operation. No significant difference in the mean pressure difference between TAV and BAV was observed at the one-year follow-up (11.9 *vs.* 14.3 mmHg, P=0.18) (*Table 4*).

Discussion

In this article, we have summarized our experience in the VenusA valve system for TAVR in BAV patients, and proposed valve selection method. In our opinion, it is appropriate to choose smaller interventional valves in BAVs. Compared with TAVs, there was no significant difference in the incidence of perivalvular leakage and branch block. During the follow-up time, the average pressure valve pressure significantly decreased compared to preoperative, and there was no significant difference between BAV and TAV at mid-term follow up.

The Edwards Sapien valve (Edwards Lifesciences, Irvine, CA, USA) was approved by the National Medical Products Administration (NMPA) in 2020. The VenusA valve, a type of self-expanding interventional valve, has been available for interventional aortic valve replacement in China since 2017. The VenusA valves used in the study are single-use only and cannot be recycled, requiring precise implantation. However, a new generation of recyclable valves has been released, increasing the number of precise positioning options, and somewhat reducing the complexity of the operation. BAV, which affects 0.5–2% of the population (11,12), is a prevalent congenital malformation of the aortic valve that often results in aortic stenosis and ascending aortic dilation (13). The application of TAVR technology to BAV has been a challenge due to the elliptic annulus of the bicuspid valve, the dilated ascending aorta, and asymmetric calcification (14,15). A study conducted by Yousef *et al.* (16) showed that in 108 patients with BAVs, the total mortality rate at 1 year was 16.9%. During the 1-year follow-up, the total mortality rate was 13.8% among patients with BAVs in our study. The cardiac function of patients improved significantly after operation with the proportion of NYHA class III/IV decreased from 78.5% preoperatively to 11.3% at the last follow-up. There was no notable increase in postoperative complications among BAV patients compared to TAV patients.

Selecting the correct valve has a significant impact on outcomes following valve implantation. Implantation of either oversized or undersized valves was not advised. If the implanted valve was oversized, it will not unfold completely, increasing the risk of leaflet contracture and raising the transvalvular gradient. After implantation, the VenusA valve relies entirely on radial force support. Implanting a valve that is too small can cause it to slip from the aortic annulus (17). As the annulus of BAV was irregular and oval, and there was severe calcification of the leaflet, with an adherent calcified mass, we typically opt for a valve of smaller size based on the diameter of the annulus and the valve root data measured by MDCT. This helps to steer clear of implanting a valve that is excessively large. As a result of the irregular bicuspid aortic annulus and the oval shape, the valve leaflets were heavily calcified and the calcified mass was adherent. We select the small first-order valve typically, utilizing the annulus diameter measured by MDCT and the valve root data, to obtain an appropriate valve size. This avoids implanting overly large interventional valves. After the operation, the valve function was good without any increase in transvalvular pressure or perivalvular leakage degree. Intraoperatively, interventional valve dimensions could be estimated by the pre-dilatation balloon shape observed under C-arm fluoroscopy, which was a helpful adjunctive method for valve selection according to reference (18). Postoperatively, post-dilatation of the valve could target valve plasticity to reduce the transvalvular gradient and degree of paravalvular leakage.

Despite the "down-size" valve application in BAV patients, there was no significant difference in valve pressure between BAVs and TAVs. The average BAVs mean gradient was 14.3 mmHg, whereas that of TAV patients was 12.2 mmHg after operations (P=0.134). Similarly,

there was no marked difference in mean pressure between TAV and BAV at 1-year follow-up (11.89 *vs.* 14.26 mmHg, P=0.183). In the study conducted by Lei *et al.* (19), the average mean pressure was 15.6 mmHg in a cohort of 69 patients with self-expanding valve. Compared to surgical valves, interventional valves have a larger effective orifice area (EOA). Before surgery, the BAV annual can be shaped through pre-implantation balloon, which avoids the need to implant a 21-mm VenusA-valve. The valve frame with aortic annuals can be stretched further and increase the EOA of the interventional valve using post-balloon dilatation of the valve. Additionally, the VenusA-valve frame's high radial force can release the valve closer to the circle. A severe leaflet calcification in BAVs with a large discrepancy between length and diameter may result in an increased risk of paravalvular leakage. Yoon *et al.* (20) conducted a multicenter matched study which found that moderately severe paravalvular leakage occurred in 10.4% of BAV cases compared to 6.8% of TAV cases. In a subsequent follow-up of 343 patients from another multicenter, Barbanti *et al.* (21) showed a 23.6% proportion of postoperative paravalvular leakage. In our study, the percentage of paravalvular leakage greater than mild was 6.90% in the BAVs and 5.56% in the TAVs at procedural outcomes, without severe paravalvular leakage. Unlike a surgical bioprosthesis valve, minor paravalvular leakage was also deemed clinically acceptable. During clinical follow-up, the severity of paravalvular leakage appeared to decrease or even disappear without any negative impacts on hemodynamics. However, it is important to closely monitor moderate or greater paravalvular leakage as it can lead to hemodynamic changes that may result in heart failure and early intervention valve dysfunction (22,23).

The VenusA-valves were sutured on a nitinol stent using porcine pericardium. Despite significant differences in their structure and material, the valves retain a symmetrical trefoil shape with the stress concentration at the stent post position (24). Implantation necessitates compression and release, which has been demonstrated to cause leaflet coiling and opening, affecting the material's durability (25,26). During the follow-up periods, no tear of the valve leaflets has been observed. Nevertheless, the issue of leaflet tear warrants additional follow-up observations in the future.

TAVR has been shown to be a potential treatment option for patients with symptomatic severe aortic stenosis who are at low risk for surgery, as demonstrated in several clinical trials (27-30). Nonetheless, congenitally bicuspid valves are present in the majority of younger low-risk patients (31), and this group of patients has been excluded from all comparative trials of TAVR and surgery. Although there has been improvement in the outcomes of TAVR in BAV with greater experience among operators and newer-generation devices (20), we have yet to meet the high standards set by surgical aortic valve replacement, especially in significant clinical endpoints such as implantation of permanent pacemaker and paravalvular regurgitation (PVR). As TAVR moves towards a younger and less risky patient population, clinicians must recognize the technology's inherent constraints and identify which patients may not be suitable for the procedure on an anatomical basis. Additionally, TAV sizing and positioning during TAVR should be optimised to reduce PVR and conduction disturbances. Patient-specific computer simulation presents an appealing solution to overcome the challenges encountered by TAVR in BAV. Dowling and colleagues (32) disclosed that patients who received TAVR with a self-expanding prosthesis recommended by the heart team achieved successful implantation with either Evolut R or Evolut PRO TAV. Investigators found that patient-specific computer simulation of TAVR in BAV can identify cases where TAVR may lead to a bad clinical outcome. Using patient-specific computer simulations can prove advantageous in guiding TAV sizing and positioning for potentially favorable clinical outcomes.

Calcification of all areas of the BAV complex could indicate mild or greater PVR at the conclusion of TAVR and may necessitate postdilatation. It can be suggested that asymmetry of the annulus in patients with BAV and LVOT might be more crucial than leaflet asymmetry in predicting PVR and the need for postdilatation after TAVR. Postdilatation may mitigate the impact of calcification in causing PVR in patients with BAV. This aspect has been evaluated in trileaflet aortic valve calcifications, wherein the location of PVR corresponds more closely to the heavily calcified annulus and LVOT positions than to the heavily calcified leaflet positions. Leaflet calcification and the Annulus-LVOT-calcifications complex were found to be independent predictors of mild or greater PVR and postdilatation when accounting for the MDCT annulus area coverage index (33). Therefore, biomodelling of young, low-risk patients with BAV who are to undergo TAVR may be necessary to prevent postoperative complications.

Study limitation

This study had some limitations. On the one hand, because

the TAVR surgery has just started in China, there were few surgical cases in a single center. In the future, multi-center studies would compensate for the shortage of surgical cases. On the other hand, a longer follow-up is still needed to verify the effect of BAV using the VenusA-valve system. At the same time, as the study involved a single center, the findings cannot be universally applied. Thirdly, no biomodelling studies have been conducted on VenusA valves, while such studies have been carried out on Medtronic CoreValve (Medtronic, Inc., Minneapolis, Minnesota, USA) and Edwards Sapien devices, as well as comparative analyses between the two types of THV devices (34,35). It is important to note that the success of TAVR is influenced by a range of variables including those related to the patient, the procedure, and the operator. Device-host interactions may also be at play, resulting in incomplete or uneven expansion of the structure and potentially causing aortic regurgitation.

Conclusions

The VenusA-valve for TAVR in aortic showed good clinical results and valve function in both BAVs and TAVs. Postoperative patient survival was high with few complications and good hemodynamics function. For the BAVs, it is feasible to select a relatively "down-size" interventional valve.

Acknowledgments

Funding: This study was funded by the Natural Science Foundation of Beijing Municipality (No. D171100002917003), the National Key R&D Program of China (No. 2020YFC2008105), and the Capital Health Research and Development of Special (No. 2020-2-2065).

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1885/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1885/dss

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1885/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1885/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. All patients in this study provided informed consent prior to undergoing the procedures. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and the study design was approved by the Ethics Review Committee of Beijing Anzhen Hospital, Capital Medical University (No. 2022193X).

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Cite this article as: Liu K, Wu K, Shen J, Meng F, Nappi F, Alfonso F, Wang S, Zheng S, Zhang H. Transcatheter aortic valve replacement in the treatment of bicuspid aortic stenosis with "down-size" interventional valves: procedural and mid-term follow-up. J Thorac Dis 2024;16(1):593-603. doi: 10.21037/jtd-23-1885