Research Article

Diabetology & Vascular Disease Research

Long-Term Clinical Outcomes Of The Vitaflowtm Transcatheter Aortic Valve System For Aortic Valve Stenosis: A Real-World Analysis In Chinese Patients

Zijia Wu[1*], Lulan Gao[2*], Lei Chen[1*] and Zhihai Lin[1#]

[1]Department of Cardiology,Yulin First People's Hospital, The Sixth Affiliated Hospital of Guangxi Medical University, Yulin, 537000, Guangxi, China

[2]Department of Laboratory,Yulin First People's Hospital, The Sixth Affiliated Hospital of Guangxi Medical University, Yulin, 537000, Guangxi, China

*Equal contributors.

Corresponding author:

ZijiaWu,

Department of Cardiology, Yulin First People's Hospital, The Sixth Affiliated Hospital of Guangxi Medical University, No.495 Education Middle Road, Yuzhou District, 537000, Yulin, Guangxi, China,

Tel: +86-775-2695131

E-mail: linzhihai2002@163.com

Received Date: 26 March 2024

Accepted Date: 12 April 2024

Published Date: 18 April 2024

Citation:

ZijiaWu. Long-Term Clinical Outcomes Of The Vitaflowtm Transcatheter Aortic Valve System For Aortic Valve Stenosis: A Real-World Analysis In Chinese Patients. Diabetology & Vascular Disease Research 2024.

1. Abstract

1.1 Background:

VitaFlowTM transcatheter aortic valve system is a novel self-expanding transcatheter aortic valve replacement technology. It has now become an alternative treatment for patients with severe aortic valve stenosis (AS) who are at high surgical risk or have surgical contraindications. However, there is limited information regarding the safety and efficacy of the VitaFlowTM system in the real-world environment of Chinese patients. Therefore, this study aims to investigate the clinical efficacy and safety of the VitaFlowTM transcatheter aortic valve system during follow-up in Chinese patients.

1.2 Methods:

A retrospective analysis was conducted on 101 patients with severe symptomatic AS who underwent transcatheter aortic valve replacement (TAVR) in our hospital from April 2020 to September 2021. The primary endpoint of this study was the mortality rate or complications within one year after TAVR.

1.3 Results:

The baseline characteristics of the patients in this study are reported as follows. The average age of the cohort was 69.5±7.9 years, with 39.6% (n=40) being female. The Society of Thoracic Surgeons risk score averaged 3.5±2.7%. At one-year follow-up, the all-cause or cardiovascular disease mortality rate was 7.9% (n=8). Importantly, no reports of major stroke or coronary artery obstruction occurred during the one-year follow-up, and the prognosis of patients with bicuspid aortic valve and tricuspid valve stenosis was comparable.

1.4 Conclusion:

The VitaFlowTM transcatheter valve replacement system is a safe and effective treatment option for Chinese patients with severe aortic valve stenosis. Future multicenter, larger-scale randomized controlled trials are needed to verify that the VitaFlowTM system can provide long-term benefits.

2.Keywords:

Aortic valve stenosis, transcatheter aortic valve replacement VitaFlow TM transcatheter valve replacement system

3. Introduction

Over the past two decades, transcatheter aortic valve replacement (TAVR) has emerged as an established therapeutic approach for elderly patients with severe symptomatic aortic valve stenosis (AS)[1-4].Compared with traditional surgery, TAVR has many advantages, such as minimally invasive procedures, faster recovery, and reduced surgical risk. The clinical guideline has recommended TAVR as an option for patients with varying levels of surgical valve replacement (SVR) riskwho are not suitable for open-heart surgery [5]. Nevertheless, the varied valve disease characteristics in Chinese patients [6-8], including a higher prevalence of bicuspid valve morphology and a more pronounced burden of valve calcification[9, 10] have been challenging the effectiveness of TAVR. Furthermore the prevalence of degenerative AS is anticipated to increase due to the expanding elderly population, consequently leading to a growing demand for TAVR in China. Therefore, it is imperative to continually enhance and innovate TAVR technology and devices to improve treatment outcomes, reduce complications, and meet the increasing needs of patients[11-13]. The VitaFlowTM transcatheter aortic valve system (MicroPort®, Shanghai, China) is an innovative

self-expanding TAVR system specifically designed for Chinese patients with severe valve calcification and bicuspid valve morphology. Its unique features, including double-layer skirts, hybrid density cells, and nitinol frames, aim to reduce paravalvular leaks (PVL) and enhance the valve's radial force, which effectively expands the calcified leaflets. Although several studies have evaluated the practicality of utilizing the VitaFlowTM transcatheter aortic valve system [14-16], there is currently insufficient research data to ascertain the efficacy and safety of the initial implementation, particularly considering the relative lack of experience among novice surgeons performing the procedures.This deficiency in surgical expertise could potentially affect the reliability of the research findings and their applicability to real-world clinical scenarios in Chinese patients.This investigation aims to assess the safety and efficacy of the VitaFlowTM system during its initial implementation in real-world settings among Chinese patients with severe AS.

4. Methods

4.1 Patients

This is a retrospective, observational, single-center study conducted in a clinical setting at Yulin First People's Hospital (Guangxi, China) between April 2020 and September 2021. One hundred and one patients with severe AS who underwentTAVRwere enrolled. The study protocol was approved by the hospital's ethical committee and adhered to all relevant Chinese laws as well as the Declaration of Helsinki (2013 revision). Written informed consent, authorizing the obtaining of surgical records and clinical procedures, was signed by patients or their guardians. Before TAVR, the patients' baseline assessments involved clinical data, including sociodemographic data, comorbidities, and routine laboratory testing, as well as transthoracic echocardiography, electrocardiogram, and cardiac computed tomography angiography (CTA). All TAVR candidates were evaluated by a team of experienced clinical and interventional cardiologists, cardiovascular surgeons, imaging specialists, and anesthesiologists, who determined whether the procedure should proceed.Our research protocol was approved by the Ethics Committee of The Sixth Affiliated Hospital of Guangxi Medical University (No: YLSY-IRB-RP-2023014).

4.2 Study device

The VitaFlowTMAortic Valve System comprises a self-expanding nitinol frame and a tri-leaflet anti-calcification bovine pericardial valve and represents the first system of its kind to receive approval in China. This system offers four different sizes of aortic prosthesis valves (21mm, 24mm, 27mm, and 30mm) for implantation in native aortic annulus diameters ranging from 21mm to 30mm. The aortic valve features innovative inner and outer polyethylene terephthalate (PET) skirts at the left ventricular outflow tract (LVOT) which aim to reduce the incidence of postprocedural PVL. The valve's high-density cells and nitinol frame provide a high outward radial force, addressing patients with severe calcification and bicuspid aortic valve (BAV) by allowing better stability and control during valve development and effective expansion of calcified leaflets. Results of the tests reveal that the VitaFlowTM frame has a radial resistive force of approximately 50% greater than that of the Evolut R frame[16]. Meanwhile, low density and large cell sizes at the ascending aorta enable the easy crossing of the aorta arch and access to the coronary artery after TAVR. VitaFlowTM utilizes a motorized, non-retrievable delivery system, enabling accurate manipulation of the guidewire by a single surgeon, and the distal end of the delivery system catheter is reinforced with an inner and outer shaft designed to combine softness and strength, thus reducing vascular complications and ensuring stability and precise positioning. The system uses a 16/18 Fr capsule for low-profile delivery.

4.3 Valve implantation

All TAVR procedures were performed in a cardiac catheterization laboratory with patients under general anesthesia and transesophageal echocardiogram guidance. Transfemoral arterial access was applied to all patients to deliver the valve. For tricuspid aortic valve patients (TAV), the selection of device size was primarily based on annulus measurement obtained through cardiac computed tomography angiography (CTA), but supra-annular measurements were used for severe calcification and bicuspid valves. Prior to device deployment, balloon pre-dilation was performed under rapid pacing, and the outcome of balloon pre-dilation was used to guide the prosthesis size selection. Under fluoroscopic guidance, the device was launched at optimal angles as determined by CT. Aortic angiography and echocardiography were utilized to evaluate postoperative regurgitation. If there was inadequate device expansion or PVL, a post-dilatation procedure was performed to better fit the aorta. This procedure ensures that the device is properly aligned and reduces the risk of complications.In cases of severe malposition or significant aortic regurgitation following post-dilatation, an additional valve (valve-in-valve) may be implanted.

4.4 Follow-up

Adverse event follow-up data, including all-cause mortality, cardiovascular mortality, major stroke, major vascular complications, coronary artery obstruction, and new pacemaker implantation, were collected via outpatient visits or phone interviews at 1,3-, and 12 months post-procedure. Transthoracic echocardiography measured degrees of PVL and valve performance, and electrocardiography assessed cardiac function. The last follow-up was conducted in September 2022.

4.5 Statistical analysis

The statistical analysis used the SPSS Version 25.0 software package (SPSS Inc., Chicago, IL, USA). Continuous variables, such as age, STS risk score, MPG, and peak jet velocity,are presented as the mean value ± SD. Categorical variables, such as gender, Sievers valve morphology, and newpacemaker implantation, are presented as percentages. Categorical variables between the tricuspid and bicuspid groups were compared using either the chi-square or Fisher's exact test, while the independent t-test was used for continuous variables.

5. Results

5.1 Baseline characteristics

One hundred and one patients, consisting of sixty-one men and forty women, all of whom had severe aortic stenosis with a mean age of 69.5±7.9 years, underwent operation utilizing the VitaFlowTM transcatheter system between April 2020 and October 2021. The follow-up phase was completed in October 2022, and Table 1 outlines the patients' baseline characteristics. The mean Society of Thoracic Surgeons (STS) score was 3.5±2.7%.Of the 32 patients diagnosed with BAV morphology, the majority (78%; n=25) displayed Sievers type 1 valve morphology, while the remaining patients were identified with TAV morphology through cardiac imaging and echocardiography. Calcium stenosis was confirmed in 86 patients, representing 85% of the cases. The mean trans-aortic pressure gradient (MPG) was 43.7±18.4mmHg, peak jet velocity (Vmax) was 4.3±0.8 m/s, and the mean left ventricular ejection fraction (LVEF) was 56±15.9%.

Table 1: Baseline Patient Characteristics

Characteristics	Patients, n=101	Echocardiog raphy Characteristics	Patients, n=101
Age, year	69.5 ± 7.9	Bicuspid aortic valve	32
Male sex	61	Tricuspid aortic valve	69
STS score	3.5± 2.7	Annulus Caficification	86
Diabetes	8	AR moderate or more	28
Hypertension	31	MR moderate or more	38
Coronary artery disease	8	TR moderate or more	14
Previous myo cardial infarction	0	LVEDD, mm	51.7± 9.3
Previous PCI	2	LVEF, %	56± 15.9
Angina	15	Mean valve gradient, mmHg	43.7 ± 18.4
Previous CABG	0	Peakjetvelocity, m/s	4.3 ± 0.8
Periphera vas cular disease	2		
COPD	2		
Liver disease	0		
Renal insuffi ciency (CKD≥3)	6		
Cerebral vascu lar disease	4		

STS = Society of Thoracic Surgeons; PCI = Percutaneous Coronary Intervention; CABG = Coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; CKD = Chronic Kidney Disease; LVEF = Left Ventricular Ejection Fraction; LVEDD = Left Ventricular end diastolic diameter; AR = Aortic Valve Regurgitation; MR = Mitral Valve Regurgitation; TR = Tricuspid Valve Regurgitation.

5.2 Perioperative data and 30 days follow-up results

The peri TAVI procedure results are showed in Table 2. A total of 103 patients had scheduled elective TAVRbetween April 2020 and October 2021. All patients underwent TAVR via transfemoral access while under general anesthesia in the cardiac catheterization lab. No cases required conversion to open thoracotomy during the procedure; however, two deaths occurred due to severe ventricular fibrillation.

Table 2: Peri-TAVR Procedure Outcomes

Characteristics	Patients, n=101
General anesthesia	101
Transfemoral	101
Pre-balloon dilatation	101
Initial Prothesis size	
21 mm	9
24 mm	35
27 mm	38
30 mm	19
Post balloon dilatation	90
Procedure Death, n (%)	2
Convert to surgery	0
Valve Malposition	2
Aortic root Injury/Rupture	0
Major vascular complication	8
Coronary artery obstruction	0
Need for second valve	12
Pericardial tamponade	4
Femoral artery pseudoaneurysm	4

AVR = transcatheter aortic valve replacement.

Ultimately, 101 patients received TAVR successfully, while four presented with femoral artery pseudoaneurysm. More than a third of patients (37.6%) had an implanted valve size of 27 mm, while 34.6%, 18.8%, and 8.9% had valve sizes of 24 mm, 30 mm, and 21 mm, respectively. The majority of patients received one valve, while 12 required two valves (valve-in-valve) due to an unsatisfactory position of the initial valve. At the 30-day follow-up, the cardiovascular mortality rate was recorded at 5.9%,with no occurrences of stroke or myocardial infarction observed. Among this cohort, four individuals experienced pericardial tamponade, resulting in two fatalities. Furthermore, two patients succumbed to severe ventricular fibrillation, and an additional two patients passed away due to cardiac arrest. Additionally, four patients required a new permanent pacemaker after TAVR due to high-degree atrioventricular block (HAVB) or complete heart block (CHB). To assess the impact of experience on outcomes, TAVR patients were categorized into four groups based on their number of operations, and a comparison was made between each group's results. Finally, the study revealed a significant reduction in cardiovascular mortality after 30 procedures, with the incidence of cardiovascular death showing a linear correlation to the number of procedures performed.

Diabetology & Vascular Disease Research

As more procedures were conducted, there was a notable decrease in cardiovascular mortality (P=0.001). However, no linear association was observed for the occurrence of new permanent pacemakers (P=0.4) (Table S1).

5.3 1-Year Follow-up outcomes

Table 3 illustrates a summary of clinical outcomes for 101 individuals at different time intervals. A 1-year mortality rate of 8% was observed for all causesorcardiovascular mortality.

Table 3: Clinical Outcomes Through

Clinical endpoints	Discharge N=101	30-day	3-month N=101	1-Year
		N=101		N=101
All-cause mor tality	0 (0)	0 (0)	0(0)	2% (2)
Cardiovascular mortality	5.9% (6)	5.9% (6)	5.9% (6)	5.9% (6)
All stroke (Ma jor and Minor)	0 (0)	0 (0)	0 (0)	0 (0)
Myocardial in farction	0 (0)	0 (0)	0 (0)	0 (0)
Major vascular complication	5.9% (6)	7.9% (8)	7.9% (8)	7.9% (8)
New Pacemaker	4% (4)	4% (4)	5.9% (6)	5.9% (6)
Hemodynamic Results	0 (0)	0 (0)	0 (0)	0 (0)
Peakjetvelocity, m/s	1.8±0.5	1.97±0.48	1.96±0.47	1.99±0.47
Mean transval vular gradient, mmhg	8.2±4.6	8.68±4.18	8.65±4.31	8.71±4.26
LVEF, %	56.01±15 .91	58.17±11 .97	61.83±10.5	64.86±8 .19
LVEDD, mm	51.73±9.27	49.78±7.08	47.79±6.11	45.49±4. 95
paravalvular leaks ≥ mild	7	7	3	2

Additionally, the incidence of all strokes (including minor ones), significant vascular complications, myocardial infarction, and new pacemaker implantation at one year were found to be 0%, 7.9%, 0%, and 5.9% respectively.A subsequent echocardiographic assessment conducted at 1-month, 3-month, and 1-year intervals revealed significant improvements in the left ventricular ejection fraction (LVEF) and left ventricular end-diastolic diameter (LVEDD) for 31 patients diagnosed with heart failure (HF) and reduced ejection fraction (HFrEF). Compared to the pre-TAVR levels, the patients exhibited notable increases of 13%, 16%, and 22% in LVEF, along with reductions of 6mm, 9mm, and 11mm in LVEDD at the corresponding time points.Conversely, among patients with normal cardiac function, no notable changes in LVEF or LVEDD were observed. After conducting a 1-year follow-up echocardiogram, it was determined that the mean pressure gradient (MPG) remained relatively stable, measuring 8.71±4.26 mmHg, which did not show a significant difference compared to the 8.76±4.71 mmHg obtained during the 30-day (8.68±4.18 mmHg)or 3-month (8.65±4.31) follow-up. Furthermore, the peak jet velocity (Vmax) measured 1.99±0.47 m/s during the 1-year follow-up, which was not significantly different from the values obtained during the 30-day (1.97±0.48 m/s) or 3-month (1.96±0.47 m/s) follow-ups (Figure 1).

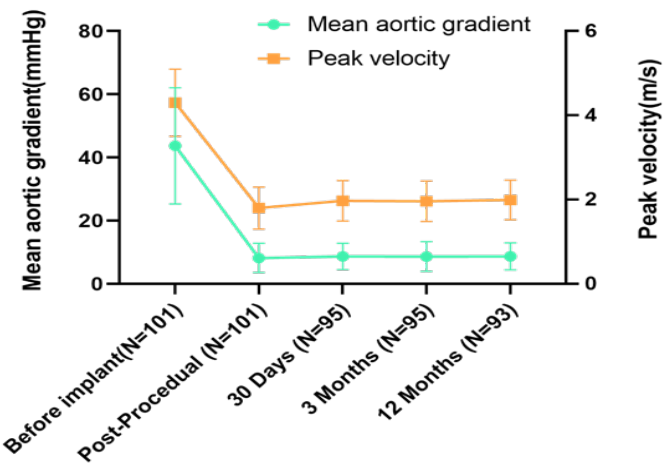

Figure1: Incidence of paravalvular leak thorough 12 months follow-up.

The distribution of PVL resulting from the commercial use of VitaFlowTM in our study at the 30-day follow-up showed that 62.4% had none or trace levels, while mild levels were observed in 30.7%, and moderate to severe levels were found in 6.9%. At the 3-month follow-up, these percentages changed to 69.3% for none or trace levels, 21.7% for mild levels, and only 2% for moderate to severe levels. Notably, the percentage of patients with moderate to severe PVL remained consistently low at a mere 2% at the one-year follow-up (Figure 2).

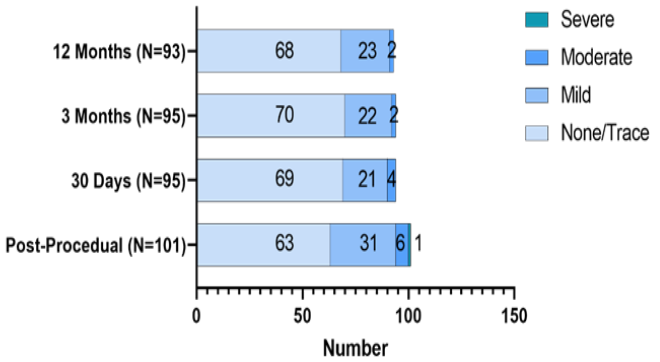

Figure2: Hemodynamic outcomes during the 12-month follow-up period.

5.4 Tricuspid VS Bicuspid

According to the data outlined in Table 4, no substantial distinctions were observed between the two groups concerning their primary characteristics. Moreover, both groups exhibited analogous rates of 1-year clinical outcomes. However, The MPG for the bicuspid group was slightly higher post-procedure compared to tricuspid patients at both 30 days (9.8 ±5.8 mm Hg vs. 8.1 ±3.0 mm Hg; p= 0.02) and 1 year (10.4 ± 5.4 mm Hg vs. 8.2± 3.4 mm Hg; p= 0.04).Additionally, the incidence rates of moderate or severe PVL at the 30-day (15.6 % vs 2.8%,P=0.02) and 1-year (2.9% vs 0, P =0.04) follow-upwere variable among patients with BAV and TAV.

Table 4: Comparison of 1-year clinical outcomes between tricuspid and bicuspid patients

	Tricsupid (n=69)	Bicuspid (n=32)	Pvalue
Baseline			
Age, year	70.22±8.11	68.06±7.62	0.2
Male sex	41	20	0.7
Coronary artery disease	6	2	0.6
STS score	3.57±2.37	3.57±3.35	0.6
Mean valve gradient (mmHg)	41.96±18.52	47.56±17.77	0.2
Peakjetvelocity, m/s	4.17±0.75	4.52±0.85	0.054
LVEF, %	55.13±15.69	57.91±16.47	0.4
1-year follow-up			
All-cause mortality, n (%)	1	1	0.57
Cardiovascular mortality, n (%)	4(5.8%)	2(6.25%)	0.9
All stroke (Major and Minor)	0 (0)	0 (0)	1
Myocardial infarction	0 (0)	0 (0)	1
Major vascular complication	5 (0)	3 (0)	0.7
New pacemaker, n (%)	3 (4.3%)	3(9.3%)	0.32
paravalvular leak≥Moderate, n (%)	0/(0)	2(6.25%)	0.04
valve-in-valve	9(13.4%)	3(6.25%)	0.8
Peakjetvelocity, m/s	1.9±0.4	2.18±0.54	0.06
Mean aortic gradient (mmHg)	8.28±3.41	8.68±4.47	0.07
LVEF, %	65.02±8.8	64.52±6.8	0.14

STS: Society of Thoracic Surgeons; LVEF: Left ventricular ejection fraction;

6. Discussion

This study reports the single-center dataanalysisaboutthe effectiveness and safety ofTAVR utilizing VitaFlowTMin China.During the follow-up period,the in-hospital cardiovascular mortality rate, without major stroke and severe paravalvular leak (PVL), was found to be 6%, while the 1-year all-cause and cardiovascular mortality rate was 8%.Approximately 32% of the patients had a bicuspid aortic valve (BAV), and the clinical outcomes are comparable between those with bicuspid aortic valve and tricuspid aortic valve (TAV). All the data support the safety and effectiveness of VitaFlowTMprosthesis. The patients had an average STS score of 3.42±2.6%, indicating a low surgical risk. However, the in-hospital cardiovascular mortality rate was 6%, which exceeded previous reports utilizing VitaFlowTM and TaurusOne[14, 16].This marked the initial commercial implementation of a first-generation TAVR device at our center, and the suboptimal outcomes may have been attributed to the inexperienced operators during the early stages of the procedures. Our study demonstrated a noteworthy correlation between the number of procedures performed and a substantial decrease in cardiovascular mortality, indicating a significant reduction in cardiovascular mortality following 30 procedures. However, no linear relationship was observed regarding the occurrence of new permanent pacemakers.Hence, during the learning phase, novice TAVR operators must accumulate a minimum of 30 experiences related to procedures to reduce perioperative cardiovascular mortality. Furthermore, due to limited experience in the initial phase of the procedure, two out of six patients experienced pericardial tamponade as a result of temporary pacing electrodes. However, after repositioning the pacing leads intraoperatively to avoid the apex and using a balloon-tipped floating catheter, no further instances of pericardial tamponade were observed. In order to enhance surgical outcomes and minimize complications, it is essential to develop and implement various strategies. Primarily, novice practitioners can enhance their surgical skills and experience through improved training and guidance. Additionally, simulation training and virtual reality technologies can help them elevate their skill levels in a safe environment. Furthermore, mentorship programs with experienced doctors can support their gradual progress. Lastly, the careful selection of patients is crucial as it allows for thorough screening to identify suitable candidates for new techniques, thereby enhancing surgical success and reducing complications.

Despite the advancements in TAVR devices that have led to a reduction in PVL, it has not been completely eradicated[17, 18].Both short- and long-term trials have shown that moderate to severe PVL significantly increases the risk of stroke and mortality [19, 20].The present study conducted an analysis on the distribution of paravalvular leakage (PVL) associated with the utilization of VitaFlowTM during our investigation at the 30-day follow-up. Our findings revealed that the distribution of PVL, as indicated by the percentages of none or trace (62.4%), mild (30.7%), and moderate or severe cases (6.9%), was superior to the distribution reported in a previous study that employed CoreValve (58.4% none or trace, 33.8% mild, and 7.8% moderate or severe)[21].Furthermore, the percentage of cases demonstrating moderate or severe PVL notably decreased to a mere 2% at the 1-year follow-up, providing further evidence to support the advantages associated with the utilization of prostheses possessing high radial force, which enables them to endure calcific burden, as well as double-layer PET skirts that effectively mitigate valve compression on the ventricular outflow tract and minimize the occurrence of PVL.It's worth noting that reducing PVL may increase the risk of conduction system disturbances[22]. In our study, the VitaFlowTM prosthesis demonstrated

a low incidence of newpacemakers (5.9%) when compared to the Evolut PRO (11.9%)[23].This implies that the VitaFlow TM prosthesis could potentially provide benefits by eliminating the necessity for a new pacemaker implantation. Previous studies have demonstrated that Chinese patients with AS undergoing TAVR exhibit a higher prevalence of leaflet calcification and BAV compared to Western populations[9, 24, 25]. These structural characteristics of BAV stenosis, such as an oval-shaped aortic annulus accompanied by an enlarged aorta and asymmetrical calcium distribution with calcified raphes[24, 25],contribute to increased periprocedural complications including annular rupture and stroke, as well as inadequate hemodynamic outcomes such as PVL and high transvalvular gradients, improper positioning, and high PPI rates.An international, multicenter, observational study has reported that despite similar performance between early and new-generation devices regarding 30-day all-cause mortality (3.9% vs. 4.5%), stroke (2.0% vs. 2.5%), and vascular complications (2.9% vs. 4.5%) in patients with TAV and BAV, but significant differences were noted in patients with valve-in-valve (1.0% vs. 6.5%, P = 0.04) and moderate or severe PVL (0 vs. 8.5%, P =0.002) with the new-generation devices[26]. Chinese researchers have explored the feasibility of TAVR for BAV stenosis and have proposed several methods for selecting valve size based on supra-annular structure assessment [27], supra-annular sizing[28], and “TAVR reshaping”[29].

Despite the high prevalence of calcification in 69% of AS patients and BAV stenosis in 32%, both groups consistently exhibited low MPG (<10mmHg) and gradual reduction in PVL throughout the one-year follow-up period after TAVR. However, the bicuspid group exhibited slightly higher post-procedure MPG and moderate or severe PVL rates compared to tricuspid patients at 30-day and 1-year follow-up. This increased occurrence of PVL may have contributed to the greater frequency of valve-in-valve procedures in patients with a bicuspid valve. Nevertheless, no noteworthy dissimilarities in cumulative event rates for all-cause or cardiovascular mortality, pacemakers, stroke, or vascular complications were observed in both groups at the 30-day, 3-month, or 1-year follow-ups, which is consistent with previous research[26, 30]. Although VitaFlowTM is specifically designed with a high radial force to effectively overcome the calcific burden and double-layer PET skirts, retrievable TAVR devices may reduce the rate of valve-in-valve occurrences, and moderate post-balloon expansion[31]may improve stent morphology and reduce PVL. The outcomes observed during the 1-year clinical follow-up indicate comparable clinical results for patients with stenosis either in the BAV or TAV who received treatment with the VitaFlowTM transcatheter aortic valve system, suggesting its efficacy for both BAV and TAV patients. We have conducted a summary analysis of this study, but there are still some limitations: this was a retrospective, single-center, non-randomized controlled trial with a small sample size and the partial attrition of follow-up, which prevented a more convincing clinical outcome; Thus, further prospective studies with a large number of participants will be required to validate our research results. Furthermore, the clinical outcome may be affected by operators’ inexperience and inappropriate postoperative management in the early stages.

7. Conclusion

The results of this study demonstrate the safety and efficacy of the MicroPort VitaFlowTM transcatheter valve system in treating AS patients after 1-year follow-up. In addition, both BAV and TAV patients had similarfavorable outcomes in terms of all-cause mortality, major stroke, and PPI.

8. Disclosure of funding

This trial was conducted with no external funding, and its costshave been assumed by researchers.

9. Author contribution

Conception and design: Zijia Wu, Lulan Gao. Data analysis and interpretation: Lei Chen, Zhihai Lin. Manuscript writing: Zijia Wu, Lulan Gao. All authorscontributed to the article and approved the submitted version.

10. Ethical approval

This study design was reviewed and approved by Ethics Committee of The Sixth Affiliated Hospital of Guangxi Medical University (No: YLSY-IRB-RP-2023014).

References

1. Avvedimento M,Tang G H L. Transcatheter aortic valve replacement (TAVR): Recent updates. Progress in Cardiovascular Diseases[J] 2021; 69: 73-83.
2. Yudi M B, Sharma S K, Tang G H L, et al. Coronary Angiography and Percutaneous Coronary Intervention After Transcatheter Aortic Valve Replacement. Journal of the American College of Cardiology[J] 2018; 71: 1360-1378.
3. Auffret V, Puri R, Urena M, et al. Conduction Disturbances After Transcatheter Aortic Valve Replacement Current Status and Future Perspectives. Circulation[J] 2017; 136: 1049-+.
4. Eleid M F,Holmes D R. Transcatheter Aortic Valve Replacement: State of the Art and Future Directions. Annual Review of Medicine, Vol 68[J] 2017; 68: 15-28.\
5. Otto C M, Nishimura R A, Bonow R O, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation[J] 2021; 143: e35-e71.
6. Hayashida K, Bouvier E, Lefèvre T, et al. Transcatheter aortic valve implantation for patients with severe bicuspid aortic valve stenosis. Circ Cardiovasc Interv[J] 2013; 6: 284-291.
7. Mack M J, Brennan J M, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the United States. Jama[J] 2013; 310: 2069-2077.
8. Kim W K, Liebetrau C, Fischer-Rasokat U, et al. Challenges of recognizing bicuspid aortic valve in elderly patients undergoing

TAVR. Int J Cardiovasc Imaging[J] 2020; 36: 251-256.

9. Jilaihawi H, Wu Y, Yang Y, et al. Morphological characteristics of severe aortic stenosis in China: imaging corelab observations from the first Chinese transcatheter aortic valve trial. Catheter Cardiovasc Interv[J] 2015; 85 Suppl 1: 752-761.
10. Liu X B, Jiang J B, Zhou Q J, et al. Evaluation of the safety and efficacy of transcatheter aortic valve implantation in patients with a severe stenotic bicuspid aortic valve in a Chinese population. J Zhejiang Univ Sci B[J] 2015; 16: 208-214.
11. Tarantini G, Sathananthan J, Fabris T, et al. Transcatheter Aortic Valve Replacement in Failed Transcatheter Bioprosthetic Valves. Jacc-Cardiovascular Interventions[J] 2022; 15: 1777-1793.
12. Otto C M,Newby D E. Transcatheter Valve Replacement for Bicuspid Aortic Stenosis. Jama-Journal of the American Medical Association[J] 2021; 326: 1009-1010.
13. Reddy K P, Groeneveld P W, Giri J, et al. Economic Considerations in Access to Transcatheter Aortic Valve Replacement. Circulation-Cardiovascular Interventions[J] 2022; 15:
14. Liang Y, Wang W, Wang X, et al. A single-center analysis of outcomes, risk factors, and new valves in Asian patients treated with early transcatheter aortic valve implantation. Cardiovasc Diagn Ther[J] 2021; 11: 967-979.
15. Wang R, Kawashima H, Gao C, et al. Comparative Quantitative Aortographic Assessment of Regurgitation in Patients Treated With VitaFlowTM Transcatheter Heart Valve vs. Other Self-Expanding Systems. Front Cardiovasc Med[J] 2021; 8: 747174.
16. Zhou D, Pan W, Wang J, et al.VitaFlowTM™ transcatheter valve system in the treatment of severe aortic stenosis: One-year results of a multicenter study. Catheter Cardiovasc Interv[J] 2020; 95: 332-338.
17. Bax J J, Delgado V, Hahn R T, et al. Transcatheter Aortic Valve Replacement Role of Multimodality Imaging in Common and Complex Clinical Scenarios. Jacc-Cardiovascular Imaging[J] 2020; 13: 124-+.
18. Kalogeropoulos A S, Redwood S R, Allen C J, et al. A 20-year journey in transcatheter aortic valve implantation: Evolution to current eminence. Frontiers in Cardiovascular Medicine[J] 2022; 9:
19. Kodali S K, Williams M R, Smith C R, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med[J] 2012; 366: 1686-1695.
20. Feldman T E, Reardon M J, Rajagopal V, et al. Effect of Mechanically Expanded vs Self-Expanding Transcatheter Aortic Valve Replacement on Mortality and Major Adverse Clinical Events in High-Risk Patients With Aortic Stenosis: The REPRISE III Randomized Clinical Trial. Jama[J] 2018; 319: 27-37.
21. Forrest J K, Kaple R K, Tang G H L, et al. Three Generations of Self-Expanding Transcatheter Aortic Valves: A Report From the STS/ACC TVT Registry. JACC Cardiovasc Interv[J] 2020; 13: 170-179.
22. Sinning J M,Sedaghat A. Choosing a Self-Expanding Transcatheter Heart Valve in 2018: Is it Worth it to “Go PRO”? JACC Cardiovasc Interv[J] 2018; 11: 2323-2325.
23. Kalogeras K, Ruparelia N, Kabir T, et al. Comparison of the self-expanding Evolut-PRO transcatheter aortic valve to its predecessor Evolut-R in the real world multicenter ATLAS registry. Int J Cardiol[J] 2020; 310: 120-125.
24. Xiong T Y, Li Y M, Yao Y J, et al. Anatomical characteristics of patients with symptomatic severe aortic stenosis in China. Chin Med J (Engl)[J] 2021; 134: 2738-2740.
25. Li Y M, Xiong T Y, Xu K, et al. Characteristics and outcomes following transcatheter aortic valve replacement in China: a report from China aortic valve transcatheter replacement registry (CARRY). Chin Med J (Engl)[J] 2021; 134: 2678-2684.
26. Yoon S H, Lefèvre T, Ahn J M, et al. Transcatheter Aortic Valve Replacement With Early- and New-Generation Devices in Bicuspid Aortic Valve Stenosis. J Am Coll Cardiol[J] 2016; 68: 1195-1205.
27. Liu X, He Y, Zhu Q, et al. Supra-annular structure assessment for self-expanding transcatheter heart valve size selection in patients with bicuspid aortic valve. Catheter Cardiovasc Interv[J] 2018; 91: 986-994.
28. Xiong T Y, Feng Y, Li Y J, et al. Supra-Annular Sizing for Transcatheter Aortic Valve Replacement Candidates With Bicuspid Aortic Valve. JACC Cardiovasc Interv[J] 2018; 11: 1789-1790.
29. Zhao Z G, Feng Y, Liao Y B, et al. Reshaping bicuspid aortic valve stenosis with an hourglass-shaped balloon for transcatheter aortic valve replacement: A pilot study. Catheter Cardiovasc Interv[J] 2020; 95 Suppl 1: 616-623.
30. Montalto C, Sticchi A, Crimi G, et al. Outcomes After Transcatheter Aortic Valve Replacement in Bicuspid Versus Tricuspid Anatomy: A Systematic Review and Meta-Analysis. JACC Cardiovasc Interv[J] 2021; 14: 2144-2155.
31. Tchetche D, de Biase C, van Gils L, et al. Bicuspid Aortic Valve Anatomy and Relationship With Devices: The BAVARD Multicenter Registry. Circ Cardiovasc Interv[J] 2019; 12: e007107.