Long-Term Clinical Outcomes of the Transcatheter Aortic Valve System for Aortic Valve Stenosis

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ABSTRACT

Objective: To evaluate the clinical safety and efficacy of the self-expanding transcatheter aortic valve system in Chinese patients with severe aortic stenosis (AS) during follow-up.

Study Design: Observational study.

Place and Duration of the Study: Department of Cardiology, Yulin First People's Hospital, The Sixth Affiliated Hospital of Guangxi Medical University, Yulin, Guangxi, China, from April 2020 to September 2022.

Methodology: A retrospective analysis was conducted on 101 patients with severe symptomatic AS who underwent transcatheter aortic valve replacement (TAVR) using a self-expanding transcatheter aortic valve system. Inclusion criteria were patients with severe symptomatic AS at high surgical risk or with contraindications for traditional surgery. Exclusion criteria included active infections and untreated severe coronary artery stenosis. The primary endpoint of this study was the mortality rate or complications within one year after TAVR.

Results: The average age of the cohort was 69.5 ± 7.9 years, with 39.6% (n = 40) being female. The average risk score according to the Society of Thoracic Surgeons was 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.

Conclusion: The studied transcatheter valve replacement system is a safe and effective treatment option for Chinese patients with severe aortic valve stenosis. Future multicentre and larger-scale randomised controlled trials are needed to verify that the self-expanding system can provide long-term benefits.

Key Words: *Aortic valve stenosis*, *Transcatheter aortic valve replacement*, *Self-expanding transcatheter aortic valve system*.

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INTRODUCTION

Over the past two decades, transcatheter aortic valve replacement (TAVR)[1,2] has emerged as an established therapeutic approach for elderly patients with severe symptomatic aortic valve stenosis (AS), a condition that can lead to chronic heart failure or death.[3] Compared with traditional surgery, TAVR has many advantages, such as minimally invasive procedures, faster recovery, and reduced surgical risk.[4] The clinical guideline has recommended TAVR as an option for patients with varying levels of surgical valve replacement (SVR) risk who are not suitable for open-heart surgery.[5]

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Nevertheless, the varied valve disease characteristics in Chinese patients,[6] including a higher prevalence of bicuspid valve morphology and a more pronounced burden of valve calcification,[7] 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.[8,9]

The studied self-expanding transcatheter aortic valve system is tailored for Chinese patients with severe valve calcification and bicuspid valve morphology, featuring double-layer skirts, hybrid density cells, and nitinol frames to minimise paravalvular leak (PVL) and improve radial force for calcified leaflets. Despite some studies,[10,11] data on its efficacy and safety upon initial use is lacking. The aim of this study was to assess long-term safety and efficacy in Chinese patients with severe AS.

METHODOLOGY

This retrospective, observational, single-centre study was conducted at the Yulin First People's Hospital, Yulin, Guangxi, China, from April 2020 to September 2022. Patients were included based on an effective valve area <1.0 cm^2 and/or mean transvalvular pressure gradient >40 mm Hg, NYHA functional class >II, suitable aortic root anatomy *via* coronary CT angiography, and refusal or unsuitability for surgery. Exclusion criteria were untreated severe coronary artery stenosis, poor general condition (<12 months expected lifespan), and contraindications to cardiac catheterisation surgery such as thrombus and infection. This retrospective study enrolled 101 patients with severe AS who underwent TAVR. Ethical approval (No: YLSY-IRB-R-P-2023014) was obtained from the hospital's Ethics Committee in September 2023, including statistical analysis of the outcomes.

The aortic valve system, the first domestically approved for commercial use and manufactured in China, integrates a self-expanding nitinol frame with a tri-leaflet anti-calcification bovine pericardial valve. It is designed to address severe calcification and bicuspid aortic valve (BAV) issues by providing enhanced stability, control during valve deployment, and effective expansion of calcified leaflets through its high-density cells and robust outward radial force. Additionally, the valve incorporates innovative polyethylene terephthalate (PET) skirts positioned at the left ventricular outflow tract, aiming to minimise post-procedural PVL.[11]

TAVR procedures were conducted in a cardiac lab under general anaesthesia and transoesophageal echocardiogram, using transfemoral access for valve delivery. Adverse events, including mortality, stroke, vascular complications, coronary obstruction, and pacemaker implantation, were tracked at 1, 3, and 12 months post-procedure *via* visits or calls.

Statistical analyses were conducted using the GraphPad Prism 9 (GraphPad Software Inc., La Jolla, CA, USA). Continuous variables were expressed as mean ± standard deviation (SD) and were analysed using the one-way analysis of variance (ANOVA) for comparisons across multiple groups. Categorical variables were expressed as frequencies and percentages, and comparisons between the groups were made using the chi-square test. A significance level of $p < 0.05$ was set for all statistical evaluations.

RESULTS

One hundred and one patients, consisting of 61 (60.4%) men and 40 (39.6%) women, all of whom had severe AS underwent operation utilising the self-expanding transcatheter system between April 2020 and October 2021. The mean age of the patients was 69.5 ± 7.9 years. The follow-up phase was completed in October 2022, and Table I outlines the patients' baseline characteristics.

At the 30-day follow-up, the cardiovascular mortality rate was recorded at 5.9%, with no occurrences of stroke or myocardial infarction observed. In addition, the study revealed a significant reduction in cardiovascular mortality after 30 procedures.

Table II gives a summary of clinical outcomes for 101 individuals at different time intervals. After performing a one-year follow-up echocardiogram, the peak jet velocity (Vmax) was measured at 1.99 ± 0.47 m/s, which was not significantly different from the values obtained at the 30-day (1.97 ± 0.48 m/s, $p = 0.99$) or 3-month (1.94 ± 0.47 m/s, $p = 0.96$) follow-ups (Figure 1). The distribution of PVL resulting from the commercial use of a self-expanding transcatheter system in this study showed that the percentage of patients with moderate-to-severe PVL remained consistently low, at a mere 2% at the one-year follow-up (Figure 2).

No significant differences were found in primary characteristics between the BAV and tricuspid aortic valve (TAV) groups. Both had similar one-year clinical outcome rates (including mortality, major vascular complications, major stroke, and new pacemaker placement). However, moderate or severe PVL occurrence at one-year follow-up varied with 2.9% in BAV *versus* 0% in TAV.

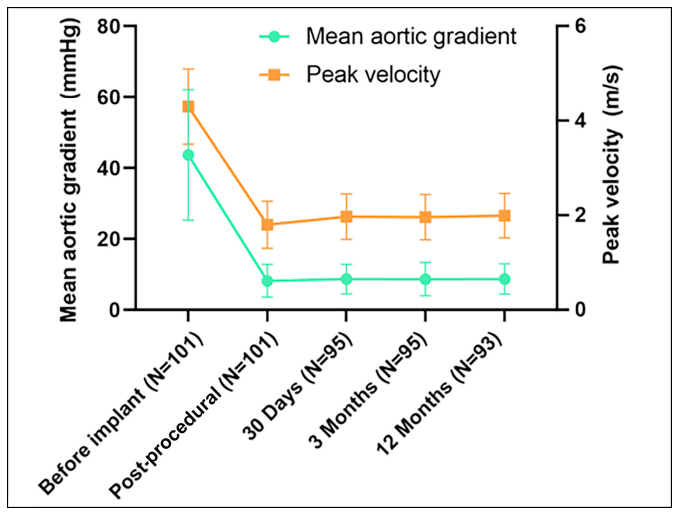

Figure 1: Haemodynamic outcomes during the 12-month follow-up period.

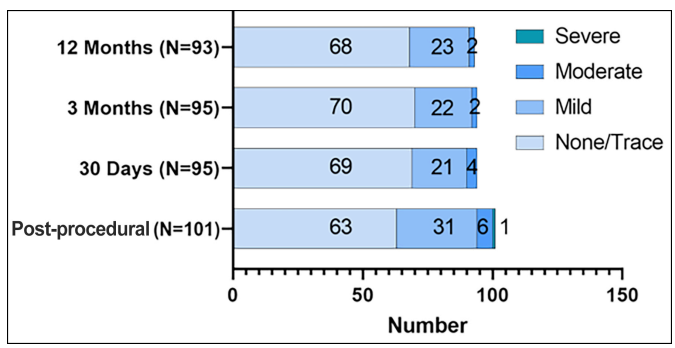

Figure 2: Incidence of paravalvular leak through 12-month follow-up.

Table I: Baseline patient characteristics.

Characteristics	Patients n = 101	Echocardiography characteristics	Patients n = 101
Age (years)	69.5 ± 7.9	Bicuspid aortic valve	32 (31.7%)
Male gender (n, %)	61 (60.4%)	Tricuspid aortic valve	69 (68.3%)
STS score	3.5 ± 2.7	Annulus calcification	86 (85.2%)
Diabetes (n, %)	8 (7.9%)	AR moderate or more	28 (27.7%)
Hypertension (n, %)	31 (30.7%)	MR moderate or more	38 (38.7%)
Coronary artery disease (n, %)	8 (7.9%)	TR moderate or more	14 (13.9%)
Previous myocardial infarction	0	LVEDD (mm)	51.7 ± 9.3
Previous PCI (n, %)	2 (1.9%)	LVEF (%)	56 ± 15.9
Angina (n, %)	15 (14.9%)	Mean valve gradient (mmHg)	43.7 ± 18.4
Previous CABG (n, %)	0	Peak jet velocity (m/s)	4.3 ± 0.8
Peripheral vascular disease (n, %)	2 (1.9%)		
COPD (n, %)	2 (1.9%)		
Liver disease (n, %)	0		
Renal insufficiency (CKD ≥3) (n, %)	6 (5.9%)		
Cerebral vascular disease (n, %)	4 (3.9%)		

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.

Table II: Clinical outcomes through one year.

Clinical endpoints	Discharge n = 101	30-day n = 101	3-month n = 101	1-year n = 101
All-cause mortality (n, %)	0 (0)	0 (0)	0 (0)	2 (2%)
Cardiovascular mortality (n, %)	6 (5.9%)	6(5.9%)	6 (5.9%)	6 (5.9%)
All strokes (major and minor) (n, %)	0	0	0	0
Myocardial infarction (n, %)	0	0	0	0
Major vascular complication	6 (5.9%)	8 (7.9%)	8 (7.9%)	8 (7.9%)
New pacemaker (n, %)	44% (4%)	4 (4%)	6 (5.9%)	6 (5.9%)
Haemodynamic results	0	0	0	0
Peak jet velocity (m/s)	1.8 ± 0.5	1.97 ± 0.48	1.96 ± 0.47	1.99 ± 0.47
Mean transvalvular 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 (n, %)	7 (6.9%)	7 (6.9%)	3 (2.9%)	2 (2%)

DISCUSSION

This study reports the single-centre data analysis about the effectiveness and safety of TAVR utilising self-expanding transcatheter aortic valve system in China. During the follow-up period, the in-hospital cardiovascular mortality rate, without major stroke and severe PVL, was found to be 6%, while the one-year all-cause and cardiovascular mortality rate was 8%. Approximately 32% of the patients had a BAV, and the clinical outcomes are comparable between those with BAV and TAV. All the data supported the safety and effectiveness of prostheses.

The patients had an average STS score of 3.42 ± 2.6%, indicating a low surgical risk. This marked the initial commercial implementation of a first-generation TAVR device at the centre. However, the in-hospital cardiovascular mortality rate was 6%, which exceeded previous reports utilising other systems.[10,11]

Despite the advancements in TAVR devices that have led to a reduction in PVL, it has not been completely eradicated.[12] Both short- and long-term trials have shown that moderate-to-severe PVL significantly increases the risk of stroke and mortality.[13] The present study conducted an analysis on the distribution of PVL associated with the utilisation of prosthesis at the 12-month follow-up. The findings revealed that the distribution of PVL was superior to the distribution reported in a previous study that employed earlier-generation transcatheter valves.[14] It is worth noting that reducing PVL may increase the risk of conduction system disturbances.[15] In this study, the prosthesis demonstrated a low incidence of new pacemakers (5.9%) when compared to other commonly used self-expanding valve systems (11.9%)[16] and earlier-generation transcatheter valves.[17] This implies that the studied self-expanding transcatheter aortic valve system 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 the Western populations.[18] 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,[18] contribute to increased per-procedural complications including annular rupture and stroke. An international, multicentre, observational study has reported that despite similar performance between early and new-generation devices, significant differences were noted in patients with valve-in-

valve and moderate or severe PVL with the new-generation devices.[19]

In this study, despite the high prevalence of calcification in 69% of AS patients and BAV stenosis in 32%, both the BAV and TAV groups consistently exhibited low MPG (<10mmHg) and gradual reduction in PVL throughout the one-year follow-up period after TAVR.[19] Although this self-expanding transcatheter aortic valve system is specifically designed with a high radial force to effectively overcome the calcific burden and double-layer PET skirts, there remains a significant difference in PVL occurrence between BAV and TAV. Retrievable TAVR devices may reduce the rate of valve-in-valve occurrences, and moderate post-balloon expansion[20] may improve stent morphology and reduce PVL. However, this retrospective, single-centre trial was limited by a small sample size and partial follow-up attrition, which hindered a robust clinical outcome assessment. Additionally, inexperienced operators and suboptimal postoperative management might have influenced early-stage clinical outcomes.

CONCLUSION

The results of this study demonstrated that the safety and efficacy of the self-expanding transcatheter aortic valve system in treating patients after a one-year follow-up. Additionally, both BAV and TAV patients exhibited similarly favourable outcomes concerning all-cause mortality, major stroke, and new pacemaker placement.

ETHICAL APPROVAL:
Ethical approval of this study was obtained from The Sixth Affiliated Hospital of Guangxi Medical University Ethics Committee.

PATIENTS' CONSENT:
Informed consent was obtained from patients to publish the data concerning this study.

COMPETING INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
ZW, LG: Conception, designing, and manuscript writing.
LC, ZL: Data analysis and interpretation.
All authors approved the final version of the manuscript to be published.

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