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*Article*

# Long-Term Clinical Outcomes of Transcatheter Aortic Valve Replacement Using J-Valve System for Patients with Pure Native Aortic Regurgitation

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## Abstract

**Background**: The J-Valve, an "on-label" transcatheter heart valve, has been used for over a decade in patients with pure native aortic regurgitation (PNAR); however, long-term follow-up outcomes have not yet been documented. This study aims to evaluate the long-term safety and efficacy of transcatheter aortic valve replacement (TAVR) in patients with PNAR. **Methods**: We retrospectively reviewed 36 patients with PNAR who underwent TAVR using the J-Valve. Clinical data were collected, and follow-up assessments were performed via telephone or during outpatient visits. **Results**: The median follow-up duration was 5.26 years, and the cumulative 5-year survival rate was 74.0%. The initial procedural success rate of the J-Valve was remarkably high at 94.44%. There was no significant morphological or hemodynamic structural valve deterioration observed among these patients. Only one patient experienced moderate paravalvular leakage, which required surgical aortic valve replacement 4 years after the TAVR. Additionally, no instances of moderate or severe intra-prosthetic regurgitation were detected in this cohort. A significant reduction in left ventricular end-diastolic dimension was observed during the follow-up period compared to pre-operative measurements ($p < 0.001$). **Conclusions**: The J-Valve exhibited favorable long-term clinical outcomes, robust valve durability, and optimal hemodynamic performance in patients with PNAR.

## Keywords

transcatheter aortic valve replacement; pure native aortic regurgitation; long-term follow-up; structural valve deterioration

## Introduction

Transcatheter aortic valve replacement (TAVR) is a common alternative to surgical aortic valve replacement (SAVR) for the treatment of severe aortic stenosis in patients classified as low surgical risk, as well as for severe pure native aortic regurgitation (PNAR) in patients deemed inoperable [1,2]. Over the past two decades, TAVR has undergone significant advancements, attracting considerable attention due to its favorable long-term clinical outcomes [3,4]. Notably, TAVR demonstrates clinical outcomes at the 5-year mark that are comparable to those achieved through SAVR in patients with severe aortic stenosis [2,5].

The J-Valve, an "on-label" transcatheter heart valve (THV) specifically designed for PNAR, has been widely used in TAVR for these patients, demonstrating a significantly higher procedural success rate compared to "off-label" THVs [6]. Moreover, TAVR with the J-Valve for PNAR has exhibited promising mid-term clinical outcomes [7–9]. In previous research, we provided preliminary evidence of the long-term efficacy of TAVR using the J-Valve in patients with PNAR, based on a limited number of cases (n = 4) [10]. However, there are no reports documenting long-term follow-up data on clinical and valve hemodynamic outcomes in larger sample sizes. The paucity of data has been identified as a concern regarding the extension of TAVR to patients with PNAR who have a longer life expectancy. This study aims to present the 5-year clinical outcomes, hemodynamic performance, and valve durability of the J-Valve in a substantial cohort of PNAR patients.

## Materials and Methods

### *Participants and TAVR Procedures*

Ethical approval was secured from the ethics committees of Beijing Anzhen Hospital and Fuwai Hospital. A retrospective review was conducted on patients diagnosed

with PNAR who underwent TAVR at Fuwai Hospital between July 2014 and August 2018, and at Anzhen Hospital between April 2018 and August 2019. Data were extracted from the electronic medical records of both institutions. The surgical criteria for TAVR are comprehensively delineated in our previous study [8]. Thirty-six patients who underwent TAVR utilizing the J-Valve system was enrolled and subsequently monitored. Data pertaining to both clinical outcomes and echocardiographic parameters were systematically collected.

The J-Valve THV, a self-expanding prosthesis, comprises a porcine aortic valve affixed to a cylindrical nitinol stent. This stent is equipped with three U-shaped graspers. Before deployment, these graspers are released and positioned within the Valsalva sinuses to serve as anatomical landmarks. The implantation procedure has been comprehensively detailed in our prior publication [8]. All enrolled patients underwent TAVR under fluoroscopic guidance and general anesthesia.

### *Definitions of Structural Valve Deterioration*

The aortic valve was evaluated utilizing two-dimensional echocardiography to assess its morphological structure, paravalvular leakage, trans-aortic mean gradient, and effective orifice area. Subsequently, multi-detector computed tomography was conducted to further investigate suspected valve thrombosis, which had been preliminarily identified through echocardiographic examination. Paravalvular leakage and intra-prosthetic aortic regurgitation were assessed using a grading scale ranging from 0 to 4, with higher grades denoting increased severity. Hemodynamic and morphological structural valve deterioration (SVD) were defined in accordance with the standardized criteria set forth by the EAPCI/ESC/EACTS [11].

### *Follow-up Schedule*

Data on clinical status, adverse events, survival, New York Heart Association (NYHA) functional class, and echocardiographic findings were systematically collected at three time points: pre-operation, at discharge, and during the follow-up period. The follow-up data were obtained through outpatient visits or telephone interviews.

### *Statistical Analysis*

The normality of continuous variables was assessed using the Shapiro-Wilk test. Depending on the distribution characteristics, continuous data were represented as mean $\pm$ standard deviation or median (interquartile range). Categorical variables were reported as frequencies (n) and percentage (%). To examine differences across the reported time points, either one-way ANOVA or the Kruskal-Wallis rank sum test was employed. Post-hoc comparisons were conducted using the Bonferroni test. All statistical analyses were performed using SPSS software, version 29.0.1.0 (IBM Inc., New York, NY, USA).

**Table 1. Baseline characteristics.**

| Characteristics | |
|---|---|
| Demographics | |
| Male sex | 23 (63.89) |
| Age, year | 75.03 $\pm$ 5.41 |
| BMI | 23.57 $\pm$ 3.18 |
| TAV | 36 (100.0) |
| Medical history | |
| Prior heart surgery | 2 (5.56) |
| Prior stroke | 6 (16.67) |
| Cardiovascular comorbidity | |
| Coronary artery disease | 12 (33.33) |
| Atrial fibrillation | 9 (25.00) |
| Risk scores | |
| STS Score | 7.14 $\pm$ 2.11 |
| Functional status | |
| NYHA functional class I/II | 2 (5.56) |
| NYHA functional class III/IV | 34 (94.44) |

Based on data normality, continuous variables were reported as mean $\pm$ standard deviation or median (interquartile range); Categorical variables were presented as number (n) and percentage (%). BMI, Body Mass Index; TAV, tricuspid aortic valve; STS, Society of Thoracic Surgeons; NYHA, New York Heart Association.

## Results

### *Baseline and Procedural Characteristics*

The baseline characteristics are shown in Table 1. The majority of patients (23, 63.89%) were male, with a mean age of 75.03 $\pm$ 5.41 years. All patients exhibited tricuspid aortic valves. Upon admission, 34 patients (94.44%) were categorized as having NYHA functional class III/IV. The mean STS mortality score for this cohort was 7.14 $\pm$ 2.11.

The procedural characteristics are described detailly in Table 2. In summary, the J-Valve prosthesis was successfully implanted during the initial procedure in 34 patients (94.44%). One patient experienced embolization of the THV into the ascending aorta. The displaced J-Valve prosthesis was subsequently repositioned within the aortic arch, distal to the left subclavian artery, utilizing a snare catheter. Thereafter, a second J-Valve was implanted in the anatomically correct position. In another patient, the J-Valve embolized into the left ventricle, necessitating emergency surgical intervention to extract the prosthesis. Following this procedure, the patient subsequently underwent replacement of the ascending aorta and aortic valve. Three patients succumbed to perioperative complications, which

**Table 2. Perioperative data.**

| | |
|---|---|
| Procedural success | 34 (94.44) |
| Pre-dilation | 0 (0) |
| Post-dilation | 4 (11.11) |
| Operation time, min | 104.00 (96.25–116.75) |
| Conversion to open heart surgery | 2 (5.56) |
| Causes for conversion | |
| LV perforation | |
| THV mispositioning | 2 (5.56) |
| Coronary artery obstruction | |
| Aortic annular rupture | |
| Severe paravalvular leak | |
| CPB using | 2 (5.56) |
| Perivalvular leakage | |
| None/trivial | 27 (79.41) |
| Mild | 7 (20.59) |
| Moderate/Severe | |
| Intra-prosthetic AR | 0 (0) |

Continuous variables are expressed as median (interquartile range). Categorical variables are presented as number (percentage). LV, left ventricular; THV, transcatheter heart valve; CPB, cardiopulmonary bypass; AR, aortic regurgitation.

included cardiac failure, acute renal insufficiency, and massive cerebral infarction. Mild paravalvular leakage was observed in seven patients (7/34, 20.59%) immediately following the implantation of the J-Valve, with no instances of moderate or severe leakage being reported.

### *Clinical Follow-up Outcomes*

Patients were monitored for a follow-up period extending up to 10 years, with a median duration of 5.26 years. During this period, seven patients succumbed to various causes. Specifically, one patient died from myocardial infarction 8.9 years post-implantation, and another from pulmonary infection 6 months postoperatively. Two patients died from COVID-19 at 3.7 and 4.5 years following TAVR, respectively. Additionally, one patient died from lung cancer 3.8 years after the procedure, and two patients experienced sudden cardiac death at 2.4 and 4.7 years post-TAVR, respectively. Among the survivors, 23 patients were categorized as NYHA functional class I or II during the follow-up period. The cumulative survival rate at 5 years was 74.0% (Fig. 1).

### *Hemodynamic Performance and Valve Durability*

No occurrences of prosthetic valve thrombosis or morphological SVD were identified in these patients. Additionally, there were no statistically significant differences in peak velocity, peak pressure gradient, or left ventricular ejection fraction across the pre-operative, discharge, and follow-up assessments. The left ventricular end-diastolic dimension (LVDd) exhibited a statistically significant reduction during the follow-up period compared to pre-operative values ($p < 0.001$), whereas no significant difference was observed between the pre-operative and discharge measurements ($p = 0.086$). The effective orifice area did not demonstrate significant differences at discharge or during follow-up ($p = 0.893$); however, both measurements were significantly lower compared to pre-operative levels ($p < 0.001$). According to the standardized criteria recommended by the EAPCI/ESC/EACTS [11], no moderate or severe hemodynamic SVD was observed among these patients. One patient who developed moderate paravalvular regurgitation underwent SAVR 4 years post-TAVR. Mild paravalvular regurgitation was documented in 5 patients (16.13%) at hospital discharge and in 6 patients (23.08%) during follow-up. Furthermore, mild intra-prosthetic aortic regurgitation was observed in 8 patients during follow-up, with no cases of moderate or severe intra-prosthetic aortic regurgitation detected. Detailed echocardiographic findings are presented in Table 3.

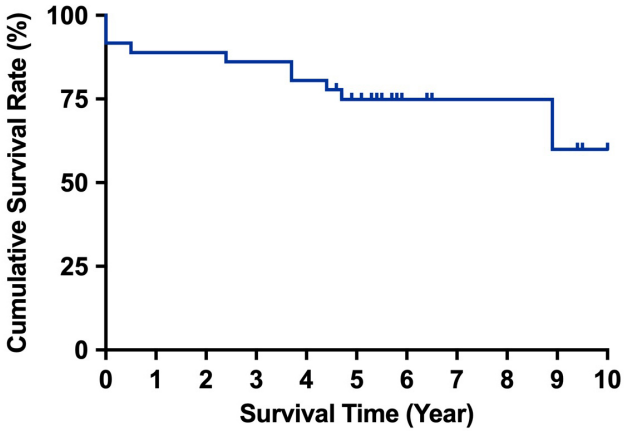


**Fig. 1. Kaplan–Meier survival curves for patients.**

## Discussion

These findings demonstrate the long-term therapeutic efficacy of the J-Valve in patients with PNAR. Throughout the follow-up period, no instances of moderate or severe hemodynamic SVD or morphological SVD were observed. Additionally, a significant reduction in LVDd following TAVR further corroborates the substantial therapeutic benefits of the J-Valve in managing PNAR.

The lack of calcium, coupled with increased stroke volume and aortic root dilation, markedly elevates the risk of THV malposition, migration, or embolization in patients with PNAR [12]. This condition predisposes these patients to an increased probability of requiring surgical conversion, experiencing perivalvular leakage, requiring permanent pacemaker implantation, or facing procedural mortality [13].

**Table 3. Echocardiographic data.**

| Characteristics | Pre-operation (n = 36) | Hospital Discharge (n = 31) | Follow-up (n = 26) |
|---|---|---|---|
| Peak velocity, m/s | 1.78 ± 0.40 | 1.94 ± 0.34 | 1.82 ± 0.45 |
| Peak pressure gradient, mm Hg | 13.85 ± 4.44 | 16.26 ± 4.95 | 14.78 ± 6.31 |
| Effective orifice area, $cm^2$ | 2.56 ± 0.23 | 2.12 ± 0.22* | 2.06 ± 0.20† |
| Perivalvular leakage | | | |
| None/trivial | - | 25 (80.64) | 20 (76.92) |
| Mild | - | 5 (16.13) | 6 (23.08) |
| Moderate/Severe | - | 1 (3.23) | 0 (0) |
| Intra-prosthetic AR | | | |
| None/trivial | - | 27 (87.10) | 18 (69.23) |
| Mild | - | 4 (12.90) | 8 (30.77) |
| Moderate and Severe | - | 0 (0) | 0 (0) |
| LVEF, % | 55.46 ± 9.98 | 51.93 ± 9.86 | 54.65 ± 9.54 |
| LVDd, mm | 60.60 ± 8.50 | 56.23 ± 7.76 | 50.77 ± 7.49† |

Continuous variables were performed as mean ± standard deviation. Categorical variables were reported as number (percentage). LVDd, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction. The values of * $p < 0.01$ represents a statistically significant difference between pre-operation and hospital discharge. The values of † $p < 0.01$ represents a statistically significant difference between pre-operation and follow-up.

Over the past two decades, various valve platforms have been employed in TAVR for PNAR, including both "off-label" and "on-label" THVs [6]. The "off-label" THVs frequently utilized in TAVR for PNAR patients include those produced by Medtronic (CoreValve and Evolut R), Edwards (Sapien XT, 3, and Ultra), and Acurate (Neo and Neo 2) [6,14]. The first-generation "off-label" THVs were associated with elevated mortality rates and suboptimal procedural success rates (ranging from 74% to 89.9%) [6,15,16], largely due to increased incidences of paravalvular leakage, valve migration, and annular rupture. Despite advancements in THV systems and techniques, TAVR continues to present significant challenges in the treatment of PNAR, even with the utilization of second-generation "off-label" prostheses [6]. The PANTHEON registry [17], an international, multicenter, collaborative retrospective study, examines patients undergoing TAVR with new-generation "off-label" THV platforms for PNAR. The registry reported overall technical and device success rates of 83.6% for self-expanding prostheses and 76.1% for balloon-expandable prostheses, both of which are lower than the reported success rates of "on-label" THVs (J-Valve: 97.7%, n = 42; JenaValve: 95%, n = 180) [17–19].

Haddad and his colleagues [20] reported that the 30-day all-cause mortality rate for PNAR patients undergoing TAVR using first-generation "off-label" THVs was 11%, with STS scores ranging from 5.4% to 13.1%. This mortality rate declined to 7% with the introduction of second-generation "off-label" prostheses. Nonetheless, this rate remains higher than the operative mortality rate for PNAR patients undergoing SAVR, which is documented at less than 5% [21]. Besides, the observed mortality rate is substantially higher than the 30-day all-cause mortality rate of 3.4% reported in the PARTNER trial [22], which included patients with aortic stenosis and an average STS risk score of 11.4. The elevated mortality among patients with PNAR underwent TAVR using "off-label" THVs may be attributed to their complex clinical profiles, characterized by aortic dilation, increased LVDd [10], and significant mitral regurgitation. Notably, the 30-day all-cause mortality rate was similar between SAVR (5%) and TAVR using "on-label" THVs (J-Valve: 4.7%; JenaValve: 2%) [9,18,21]. The J-Valve and JenaValve are "on-label" THVs specifically designed for the treatment of patients with PNAR [18,23]. These THVs are equipped with radiopaque locators that limit implant depth and clip onto the native leaflets, thereby providing an anchoring mechanism and enhancing the seal around the THV. This design feature may contribute to the reduction in the 30-day all-cause mortality rate for patients with PNAR.

TAVR for PNAR employing the currently available "off-label" THVs demonstrates short-term outcomes comparable to those observed with SAVR [24,25]. However, Mentias *et al*. [24] reported that the long-term outcomes of TAVR were inferior to those of SAVR in patients with PNAR. The study acknowledges potential limitations due to residual confounding factors, particularly the advanced age and frailty of the TAVR cohort, which may undermine the reliability of the primary findings. Nonetheless, our previous investigation demonstrated the J-Valve system's consistent long-term clinical efficacy in the treatment of PNAR [10]. To substantiate the evidence regarding the long-term efficacy of TAVR in patients with PNAR, it is imperative to conduct well-designed randomized controlled trials that compare TAVR using "on-label" THVs with SAVR.

This study provides the first 5-year follow-up data of patients with PNAR who underwent TAVR using J-Valve, demonstrating its favorable clinical efficacy. To the best of

our knowledge, this is the first report presenting long-term follow-up results that evaluate the performance and durability of "on-label" THVs in patients with PNAR. Given its high procedural success rate and excellent long-term outcomes, TAVR with the J-Valve is recommended as the preferred treatment over SAVR for high-risk patients with PNAR.

## Conclusions

TAVR employing the J-Valve system is a safe and feasible therapeutic option for carefully selected patients with PNAR. Furthermore, it demonstrates reliable long-term durability and superior hemodynamic performance.

## Availability of Data and Materials

Data are available on request from correspondence author.

## Author Contributions

FL and CZ contributed significantly to the drafting of the manuscript and performed statistical analyses. HBZ, XW, WW, DHX, and YTW undertook the TAVR procedures. JGW made substantial contributions to the analysis of clinical data and provided critical revisions to the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

## Ethics Approval and Consent to Participate

The present study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Anzhen Hospital (Approval number: 2024177X), and Fuwai Hospital (Approval number: 2024-2285). The two Ethics Review Boards granted an exemption from the requirement of obtaining written informed consent for this retrospective study.


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## Conflict of Interest

The authors declare no conflict of interest.

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