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RESEARCH LETTER

10-Year Outcomes of the J-Valve Transcatheter Valve for Severe Aortic Stenosis or Aortic Regurgitation

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Transcatheter aortic valve replacement (TAVR) is an established therapy for severe aortic stenosis (AS). Growing evidence supports the extension of TAVR with dedicated transcatheter heart valves (THVs) to patients with severe aortic regurgitation (AR),[1] but there is a lack of long-term outcome data on TAVR for pure AR. The J-Valve (Jiecheng Medical Technology) is a self-expanding, short-stent system incorporating 3 U-shaped anchor rings for leaflet engagement and commissural alignment. We report the first 10-year outcomes of the dedicated J-Valve THV in high-risk patients with severe symptomatic AS or pure AR from a prospective multicenter trial in China (ChiCTR-OPC-15006354). Patients underwent transapical implantation of the J-Valve system, and outcomes followed were similar to those of the NOTION (Nordic Aortic Valve Intervention) trial.[2] Log-rank tests were used to compare differences in clinical outcomes between groups. All statistical analyses were conducted using R version 4.3.3 (R Foundation for Statistical Computing).

Of the 107 high-risk patients with aortic valve disease initially enrolled, 98 patients (62 with AS and 36 with AR) underwent successful J-Valve implantation, without a need for early surgical valve replacement and constituted the study population for the long-term durability assessment. The mean age was 73.9 ± 5.2 years. Ten-year all-cause mortality did not differ significantly between AS and AR patients (29.0% vs 38.9%; $P = 0.32$). The overall 10-year rates of cardiovascular mortality, stroke, and pacemaker implantation were 15.3%, 9.2%, and 12.2%, respectively.

Echocardiographic follow-up was available for 50 patients (76% of survivors) at the 10-year mark. Patients with continuous echocardiographic follow-up were included for paired analysis. AS patients consistently exhibited higher mean transvalvular pressure gradient and smaller valve areas than AR patients ($P < 0.05$), but both AS and AR groups showed relatively stable effective orifice areas and mean pressure gradients over the 10-year follow-up period (**Table 1**). Moderate to severe structural valve deterioration (SVD) was observed in 15 patients (18.3%) with a higher frequency in the AS group than in the AR group (24.5% vs 9.1%). The higher occurrence of severe bioprosthetic valve dysfunction in

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TABLE 1 Bioprosthetic Hemodynamic and Durability Outcomes

10-Year Follow-Up	All[a] (N = 82)	AS (n = 49)	Pure AR (n = 33)	*P* Value
PGmean, mm Hg				
Preoperative	35.94 ± 12.58	54.49 ± 17.01	8.40 ± 4.16	<0.01
Postoperative	12.58 ± 6.85	15.18 ± 7.52	8.72 ± 2.88	<0.01
1 y	12.90 ± 7.41	14.60 ± 8.51	10.50 ± 4.68	<0.01
5 y	13.79 ± 8.77	16.22 ± 10.04	9.96 ± 4.09	<0.01
10 y	14.63 ± 10.99	16.03 ± 12.25	12.34 ± 8.35	0.25
EOA, cm^2				
Preoperative	1.60 ± 1.18	0.66 ± 0.15	2.99 ± 0.42	<0.01
Postoperative	1.81 ± 0.31	1.67 ± 0.27	2.01 ± 0.26	<0.01
1 y	1.72 ± 0.40	1.61 ± 0.34	1.87 ± 0.43	<0.01
5 y	1.64 ± 0.43	1.54 ± 0.43	1.80 ± 0.43	0.02
10 y	1.65 ± 0.52	1.61 ± 0.57	1.72 ± 0.44	0.50
Moderate to severe SVD	15 (18.29)	12 (24.49)	3 (9.09)	0.10
Severe BVD	13 (15.85)	10 (20.41)	3 (9.09)	0.16
Severe SVD	7 (8.54)	5 (10.20)	2 (6.06)	0.51
Severe nonstructural valve deterioration	5 (6.10)	5 (10.20)	0 (0.00)	–
Severe paravalvular leak	1 (1.22)	1 (2.04)	0 (0.00)	–
Severe prosthesis-patient mismatch	4 (4.88)	4 (8.16)	0 (0.00)	–
Thrombosis	1 (1.22)	0 (0.00)	1 (3.03)	–
BVF	10 (12.20)	7 (14.29)	3 (9.09)	0.50
Valve-related death	2 (2.44)	1 (2.04)	1 (3.03)	0.75
Severe SVD	7 (8.54)	5 (10.20)	2 (6.06)	0.51
AV reintervention	3 (3.66)	2 (4.08)	1 (3.03)	0.77

Values are mean ± SD or n (%). [a]Echocardiographic follow-up was available for 50 patients (75.76% of survivors) at the 10-year mark. Therefore, eligibility for data analysis was restricted to 82 patients (49 with AS and 33 with AR) with continued echocardiographic follow-up examination.

AR = aortic regurgitation; AS = aortic stenosis; AV = aortic valve; BVD = bioprosthetic valve dysfunction; BVF = bioprosthetic valve failure; EOA = effective orifice area; PGmean = mean transvalvular pressure gradient; SVD = structural valve deterioration.

the AS group was due to a high frequency of severe paravalvular leak and severe prosthesis-patient mismatch (PPM). Bioprosthetic valve failure was identified in 10 patients (12.2%). Overall aortic valve reintervention was low in both groups, with no statistically significant difference (Table 1).

This long-term follow-up study provides reassurance that TAVR with the J-Valve for both AS and AR provides similar excellent long-term outcomes. Over 10-year follow-up, moderate to severe SVD was quite low in both AS and AR patients, though SVD was higher than the 15.4% observed in the NOTION trial.[2] However, durability data for THVs are derived primarily from elderly populations with an average age exceeding 80 years, among which the risk for death due to limited life expectancy may mask the observation of SVD.[3] Notably, AR patients have significantly lower rates of bioprosthetic valve dysfunction than AS patients. In AR patients, there is little or no aortic valve calcification, which usually allows full expansion of the J-Valve and true anatomical implantation with excellent commissural alignment and achieves superior hemodynamic performance. Furthermore, AS is often associated with uneven calcification and an irregular aortic annular shape that may lead to PPM. According to data from the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry, PPM is frequently observed in AS patients after TAVR (severe PPM, 12%; moderate PPM, 25%).[4] Our reintervention rate over 10 years appears comparable with or better than that of surgical valves. A review of long-term data on surgical bioprosthetic valves revealed that the 10-year SVD rate was approximately 10%, while the 15-year rate surpassed 20%.[5] Therefore, future studies will include follow-up data spanning 10 to 15 years to reflect the extended durability of the J-Valve.

This study had some limitations. First, it was a single-arm investigation without a direct comparator, limiting conclusions on any comparison with other THVs or surgical valves. Second, although this is the longest prospective follow-up study in AR patients, the sample size is still relatively small, reducing statistical power for rare events. Third, echocardiographic follow-up at 10 years was incomplete, which may introduce bias in assessing long-term hemodynamic status and SVD. However, a paired analysis restricted to patients with complete echocardiography data revealed consistent findings.

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This 10-year prospective follow-up study demonstrates that the J-Valve has excellent hemodynamic performance and long-term durability in high-risk patients with either severe AS or AR with a low bioprosthetic valve failure rate (12.2%) and a low reintervention rate (3.7%). The device provides particularly favorable outcomes in AR patients, with superior hemodynamic status and lower rates of SVD compared with AS patients.

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Participating centers are as follows: Department of Cardiovascular Surgery, West China Hospital, Sichuan University; Department of Cardiac Surgery, Zhongshan Hospital, Fudan University; and Department of Cardiac Surgery, Beijing Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College. This study was supported by the National Clinical Research Center for Geriatrics, West China Hospital, Sichuan University (grant Z2024YY001) and the Science and Technology Projects of Xizang Autonomous Region, China (grant XZ202501ZY0036). The J-Valve system for the treatment of patients with severe AS or AR, designed and produced by Jiecheng Medical Technology, was approved by the National Medical Products Administration. Both personnel from Jiecheng Medical and the participating centers took responsibility for patient recruitment and perioperative data collection. The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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