Structural Valve Deterioration after Transcatheter Aortic Valve Implantation Using J-Valve: A Long-Term Follow-Up

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Purpose: Our study aimed to investigate the structural valve deterioration (SVD) after transcatheter aortic valve implantation (TAVI) using J-Valve.

Methods: In all, 14 patients with aortic stenosis (AS) and 4 patients with pure aortic regurgitation (PAR) were available in the study. Four-year follow-up was performed in all patients, and the clinical data and echocardiographic findings were recorded and analyzed.

Results: All patients survived at the 4-year follow-up. There was no evidence of morphological SVD or prosthetic valve thrombosis in enrolled patients. None of the hemodynamic SVD occurred in patients with PAR. Mean gradients decreased from 61.93 ± 15.42 mm Hg (pre-TAVI) to 19.64 ± 9.16 mm Hg (discharge) in patients with AS (p <0.001); subsequently, a slight increase was observed in the mean trans-aortic gradient throughout follow-up (p = 0.967). Overall, in patients with AS, six individuals suffered moderate (3/14, 21.4%) or severe (3/14, 21.4%) hemodynamic SVD at 4-year follow-up.

Conclusions: The limited number of cases provides a preliminary indication of the long-term efficacy of TAVI using J-Valve in patients with PAR. In patients with AS, although the higher rate of SVD was observed, the overall transcatheter heart valve (THV) hemodynamics remained stable over time after prosthetic valve implantation and the long-term durability of J-Valve was convincing.

Keywords: transcatheter aortic valve implantation, structural valve deterioration, aortic stenosis, pure aortic regurgitation, bicuspid aortic valve

Introduction

Transcatheter aortic valve implantation (TAVI) is a common alternative to surgical aortic valve replacement for severe aortic stenosis (AS) in patients with high surgical risk1 and the procedure exhibited a convincing long-term outcome for these patients.2,3) However, pure aortic regurgitation (PAR) was once recognized as a relative contraindication for TAVI, and the inoperable patients with PAR who were recommended to accept medical management followed with high morbidity and unfavorable outcomes. With the development of transcatheter heart valve (THV) devices and the technique of TAVI procedure, the second-generation THV has revolutionized the interventional treatment for PAR.4,5)
There are multiple reports presenting the feasibility of transcatheter approach for the treatment of PAR, and second-generation devices associated with an excellent procedural success rate and favorable perioperative outcomes compared with first-generation THV. In second-generation devices, the advantage is more pronounced on the “on-label” THVs (J-Valve and JenaValve) than “off-label” THVs. The J-Valve (Jie Cheng Medical Technologies, Suzhou, China) is a self-expandable TAVI device featuring three U-shaped anatomically oriented “graspers” for the accurate positioning to the Valsalva sinus. In previous studies, we have described J-Valve performed satisfactory early outcomes in high-risk surgical patients with AS or PAR. However, it was not reported that the long-term validity of the THV over time.

In this study, we evaluated the structural valve deterioration (SVD) of J-Valve through the periodically continuous long-term follow-up, which aimed to assess the long-term durability of J-Valve.

Materials and Methods

Study design and participants

This study was approved by the local ethical committee and all patients signed informed consent before enrollment. This single-center, prospective, randomized trial was conducted at Fuwai hospital (Beijing, China). The patients with severe aortic valve dysfunction were consecutively enrolled between July 2014 and June 2015, and the indication for TAVI, inclusion criteria, and other detail information were described in the methods of our previous study. In all, 18 patients, including 14 patients with AS and 4 with PAR, were performed echocardiographic examination during the periodic follow-up.

TAVI devices and procedures

The J-Valve system is a second-generation THV, which comprises a set of porcine aortic valve attached to a cylindrical nitinol stent featuring three U-shaped graspers encircled and attached with the THV stent. Before the THV deployment, the released graspers can anatomically be oriented to Valsalva sinus and serve as a land marker. The detail information of J-Valve system has been well presented in previous studies. All patients received transapical TAVI using the J-Valve system under fluoroscopic guidance and general anesthesia. The procedure of implantation has been described in detail previously.

Definitions and follow-up

Aortic valve was evaluated by two-dimensional echocardiography that performed by the same cardiologist to ensure comparability in terms of morphological structure, paravalvular leakage, trans-aortic mean gradient, effective orifice area, and intra-prosthetic aortic regurgitation (graded from 0 to 4, with higher grades indicating greater severity). Multi-detector computed tomography was performed for the patients suspected with valve thrombosis based on two-dimensional echocardiography. The hemodynamic SVD and morphological SVD were determined according to the standardized definitions proposed by EAPCI/ESC/EACTS. Morphological SVD was detected based on imaging examination, including the assessment of leaflet integrity, leaflet structure, leaflet function, and strut/frame. Hemodynamic SVD was classified as two degrees: (1) moderate SVD was defined as followings: (i) mean trans-aortic pressure gradient ≥20 and <40 mm Hg and/or (ii) ≥10 and <20 mm Hg change from discharge baseline, and/or (iii) moderate intra-prosthetic aortic regurgitation (new or worsening from discharge baseline, >1+/4+). (2) Severe SVD was defined as followings: (i) mean trans-aortic pressure gradient ≥40 mm Hg and/or (ii) ≥20 mm Hg change from discharge baseline, and/or (iii) severe new or worsening (>2+/4+) central aortic regurgitation.

Clinical status and echocardiographic follow-up data were collected at discharge, 1 month, 6 months, and 1, 2, 3, and 4 years. Data on adverse events, survival, and New York Heart Association (NYHA) class were obtained through periodically outpatient visits and telephone interviews.

Statistical analysis

The normality of continuous variables was evaluated by Shapiro–Wilk test. Based on data normality or not, the data were presented as the mean ± standard deviation or median (interquartile range). Categorical variables are presented as number (n) and percentage (%). Student’s t-test (paired or unpaired) was used for two-groups comparisons of values. One-way analysis of variance with LSD post hoc test was performed to compare the difference of mean aortic valve gradient and aortic valve orifice area among the time points reported. All analyses used SPSS software, version 25 (IBM Inc., Armonk, NY, USA).
Four-year follow-up was available in all enrolled patients. During follow-up, no death reported in these patients. The baseline and procedural characteristics are shown in detail in Table 1. The mean age of the patients was 74.50 ± 5.22 years, and 72.2% (n = 13) were men. In these patients, 11 individuals had tricuspid aortic valve, while the remaining 7 had bicuspid aortic valve. Among them, the majority of the individuals (88.9%) had NYHA functional class III/IV preoperatively. One patient underwent prior coronary artery bypass grafting surgery.

### Preoperative echocardiographic assessment

The mean preoperative left ventricular ejection fractions of the patients with AS and PAR were

| Table 1 Baseline and procedural characteristics |
|-----------------------------------------------|
| Characteristics | AS (n = 14) | PAR (n = 4) | Total (n = 18) |
|-----------------|-------------|-------------|----------------|
| Demographics    |             |             |                |
| Male sex, n (%) | 10 (71.4)   | 3 (75.0)    | 13 (72.2)      |
| Age, year       | 74.07 ± 4.87| 76.00 ± 6.88| 74.50 ± 5.22   |
| Height, cm      | 160.29 ± 7.30| 159.25 ± 8.69| 160.06 ± 7.37  |
| Weight, kg      | 64.58 ± 14.91| 63.25 ± 4.86 | 64.28 ± 13.21  |
| Aortic valve phenotypes, n (%) |             |             |                |
| BAV             | 7 (50.0)    | 0 (0)       | 7 (38.9)       |
| TAV             | 7 (50.0)    | 4 (100.0)   | 11 (61.1)      |
| Medical history, n (%) |             |             |                |
| Prior heart surgery | 1 (7.1)  | 0 (0)       | 1 (5.6)        |
| Prior stroke    | 6 (42.9)    | 1 (25.0)    | 7 (38.9)       |
| Cardiovascular risk factors, n (%) |             |             |                |
| Hypertension    | 11 (78.6)   | 4 (100.0)   | 15 (83.3)      |
| Diabetes mellitus | 4 (28.6)  | 1 (25.0)    | 5 (27.8)       |
| Atrial fibrillation | 1 (7.1)  | 1 (25.0)    | 2 (11.1)       |
| Coronary artery disease | 8 (57.1) | 1 (25.0)    | 9 (50.0)       |
| Risk scores (median; IQR) |             |             |                |
| EuroSCORE II    | 11.00 (10.00–11.25) | 12.00 (11.25–12.00) | 11.00 (10.75–12.00) |
| Logistic EuroSCORE II | 28.17 (23.92–31.73) | 31.73 (28.10–35.55) | 28.70 (24.77–32.32) |
| Echo parameters |             |             |                |
| Peak velocity, m/s | 4.93 ± 0.68 | 1.98 ± 0.21 | 4.28 ± 1.40   |
| Peak pressure gradient, mm Hg | 99.01 ± 27.81 | 15.70 ± 3.28 | 80.50 ± 43.17 |
| Mean pressure gradient, mm Hg | 61.93 ± 15.42 | 5.50 ± 1.29 | 49.39 ± 27.65 |
| Effective orifice area, cm² | 0.63 ± 0.17 | 2.53 ± 0.22 | 1.05 ± 0.83   |
| Aortic annular diameter, mm | 21.00 ± 1.92 | 24.25 ± 0.96 | 21.72 ± 2.22  |
| LVDD, mm         | 50.43 ± 8.36 | 61.50 ± 2.08 | 52.89 ± 8.75  |
| LVEF, %          | 62.64 ± 13.73 | 64.10 ± 4.43 | 62.97 ± 12.16 |
| Functional status, n (%) |             |             |                |
| NYHA functional class III/IV | 13 (92.9) | 3 (75.0)    | 16 (88.9)      |
| Procedural characteristics, n (%) |             |             |                |
| Valve size       |             |             |                |
| 21 mm            | 5 (35.7)    | 0 (0)       | 5 (27.8)       |
| 23 mm            | 6 (42.9)    | 0 (0)       | 6 (33.3)       |
| 25 mm            | 2 (14.3)    | 1 (25.0)    | 3 (16.7)       |
| 27 mm            | 1 (7.1)     | 3 (75.0)    | 4 (22.2)       |
| Device embolization | 1 (7.1)  | 0 (0)       | 1 (5.6)        |
| Perivalvular leakage |             |             |                |
| None/trivial     | 6 (42.9)    | 4 (100.0)   | 10 (55.6)      |
| Mild             | 8 (57.1)    | 0 (0)       | 8 (44.4)       |
| Moderate and severe | 0 (0)      | 0 (0)       | 0 (0)          |

Based on data normality, continuous variables were reported as mean ± standard deviation or median (interquartile range); categorical variables were presented as number (n) and percentage (%).

BAV: bicuspid aortic valve; EuroSCORE: European system for cardiac operative risk evaluation; LVDD: left ventricular end-diastolic diameter; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; TAV: tricuspid aortic valve

**Results**

Four-year follow-up was available in all enrolled patients. During follow-up, no death reported in these patients. The baseline and procedural characteristics are shown in detail in Table 1. The mean age of the patients was 74.50 ± 5.22 years, and 72.2% (n = 13) were men. In these patients, 11 individuals had tricuspid aortic valve,
62.64% ± 13.73% and 64.10% ± 4.43% (p = 0.840), respectively. The mean left ventricular end-diastolic dimension was 50.43 ± 8.36 mm and 61.50 ± 2.08 mm (p < 0.001), respectively. Patients with AS had a mean aortic gradient of 61.93 ± 15.42 mm Hg and a mean effective orifice area of 0.63 ± 0.17 cm². Patients with PAR had a mean effective orifice area of 2.53 ± 0.22 cm². The mean aortic annulus diameter of patients with AS and PAR was 21.00 ± 1.92 mm and 24.25 ± 0.96 mm (p = 0.005), respectively.

Clinical follow-up outcomes

Significant clinical improvement was observed in the majority of enrolled patients. At 4-year follow-up, 77.8% of patients were in NYHA functional class I/II, and the left ventricular end-diastolic dimension had a decrease in patients with AS (46.14 ± 7.53 mm, p = 0.066) and PAR (43.75 ± 8.73 mm, p = 0.029) when compared to preoperation, respectively. At the end of the 4-year follow-up, four patients reported major adverse cardiovascular events, of which two suffered stroke that required hospitalization, one reported myocardial infarction, and one required hospitalization due to paroxysmal atrial fibrillation that was converted to sinus rhythm by drug therapy. The clinical results and echocardiographic findings are presented in Tables 2 and 3.

Hemodynamic performance and durability

The echocardiographic assessment was available for 18 patients. There was no evidence of morphological SVD or prosthetic valve thrombosis in these patients. Aortic mean pressure gradients decreased from 61.93 ± 15.42 mm Hg (pre-TAVI) to 19.64 ± 9.16 mm Hg (discharge) in patients with AS (p < 0.001); subsequently, a slight increase was observed in the mean trans-aortic gradient throughout follow-up (p = 0.967). Four-year post-surgeries, aortic valve gradients in patients with AS was 21.71 ± 12.66 mm Hg, and the mean effective orifice area was 1.39 ± 0.35 cm² (Fig. 1A). In patients with PAR, there was no statistical difference in the change of mean aortic valve orifice area over time (p=0.272), and the aortic valve gradients and mean effective orifice area were 5.50 ± 0.58 mm Hg and 2.55 ± 0.62 cm² at 4-year follow-up, respectively (Fig. 1B). According to the standardized definitions of SVD and valve failure from EAPCI/ESC/EACTS, three patients with AS had moderate hemodynamic SVD at discharge, and three more AS patients suffered moderate hemodynamic SVD at 1-year follow-up. Overall, six patients with AS were determined as hemodynamic SVD at 4-year follow-up, among which, three were moderate degree and three were severe (Fig. 2). In patients with AS, mild paravalvular regurgitation was observed in five patients (35.7%) at discharge, and two of them progressed to moderate degree at 2-year follow-up. Mild or more than mild paravalvular regurgitation was not found in patients with PAR during the whole period of follow-up visits.

Discussion

Our results demonstrated the sustained 4-year clinical benefit of TAVI using a second-generation THV (J-valve) in patients with AS and PAR at high-risk for surgery. None of morphological or hemodynamic SVD was observed in patients with PAR. After discharge, overall THV hemodynamics remained stable over time in patients with AS. According to the definitions of SVD from EAPCI/ESC/EACTS, three patients with AS were determined as hemodynamic SVD at discharge, and three more patients were diagnosed during 4-year follow-up. None of morphological SVD was reported in patients with AS. J-Valve presented a favorable performance of hemodynamics and durability in long-term follow-up.

The treatment of PAR with TAVI was considered as a relative contraindication due to the increased risk for paravalvular regurgitation and THV embolization and migration in the absence of aortic valve leaflets calcification. The inoperable patients with PAR were recommended to accept medical management; however, these patients suffered an annual mortality risk of 20%. Therefore, an unmet need highlighted to treat this patient population with TAVI. With the THV and the technique advanced, the second-generation devices for TAVI provide credible treatment for patients with PAR. J-Valve and JenaValve have been certified for PAR and had a significantly higher procedural success rate compared to other “off-label” second-generation devices. In addition, the feasibility of TAVI for patients with PAR was proven in several second-generation THV, including Evolut-R, SAPIEN 3, ACURATE neo, Direct Flow Medical, Lotus et al. The 1-year outcome of TAVI using a second-generation THV (J-Valve and JenaValve) for PAR has been reported, and it presented a satisfactory outcome. However, the long-term durability and efficiency of these devices were not demonstrated. Our study first reported the long-term follow-up of TAVI using J-Valve for PAR, and the dependable durability and
## Table 2  Major adverse cardiovascular events and periodic echocardiography results in patients with aortic stenosis

| Characteristics                          | Preoperation | Discharge | 1 month | 6 months | 1 year | 2 years | 3 years | 4 years |
|------------------------------------------|--------------|-----------|---------|----------|--------|---------|---------|---------|
| Peak velocity, m/s                       | 4.93 ± 0.68  | 2.90 ± 0.69 | 2.78 ± 0.74 | 2.76 ± 0.65 | 2.70 ± 0.85 | 2.77 ± 0.76 | 2.70 ± 0.76 | 2.88 ± 0.91 |
| Peak pressure gradient, mm Hg            | 99.01 ± 27.81 | 35.45 ± 16.50 | 33.02 ± 16.15 | 32.06 ± 14.36 | 34.79 ± 15.92 | 32.73 ± 16.66 | 28.50 ± 17.07 | 36.31 ± 21.94 |
| Mean pressure gradient, mm Hg            | 61.93 ± 15.42 | 19.64 ± 9.16 | 18.43 ± 8.74 | 18.50 ± 8.80 | 20.29 ± 8.51 | 18.71 ± 8.52 | 18.71 ± 9.68 | 21.71 ± 12.66 |
| Effective orifice area, cm²              | 0.63 ± 0.17  | 1.39 ± 0.22 | 1.50 ± 0.36 | 1.48 ± 0.33 | 1.47 ± 0.34 | 1.52 ± 0.40 | 1.52 ± 0.36 | 1.39 ± 0.35 |
| Perivalvular leakage n (%)               | None/trivial | 9 (64.3) | 9 (64.3) | 9 (64.3) | 9 (64.3) | 9 (64.3) | 9 (64.3) | 9 (64.3) |
|                                           | Mild         | 5 (35.7) | 5 (35.7) | 5 (35.7) | 5 (35.7) | 5 (35.7) | 3 (21.4) | 3 (21.4) |
|                                           | Moderate/severe | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 2 (14.3) | 2 (14.3) | 2 (14.3) |
| Intra-prosthetic AR n (%)                | None/trivial | 14 (100.0) | 14 (100.0) | 14 (100.0) | 13 (92.9) | 13 (92.9) | 13 (92.9) | 13 (92.9) |
|                                           | Mild         | 0 (0) | 0 (0) | 0 (0) | 1 (7.1) | 0 (0) | 0 (0) | 0 (0) |
|                                           | Moderate and severe | 0 (0) | 0 (0) | 0 (0) | 1 (7.1) | 1 (7.1) | 1 (7.1) | 1 (7.1) |
| LVDd, mm                                 | 50.43 ± 8.36 | 48.50 ± 6.91 | 49.21 ± 6.75 | 47.93 ± 6.23 | 46.57 ± 5.56 | 46.50 ± 5.42 | 46.64 ± 7.44 | 46.14 ± 7.53 |
| LVEF, %                                  | 62.64 ± 13.73 | 65.51 ± 9.16 | 62.36 ± 5.82 | 62.68 ± 7.24 | 65.26 ± 5.79 | 61.79 ± 9.71 | 60.86 ± 4.99 | 63.71 ± 4.68 |
| Major adverse cardiovascular events, n (%) | None | 0 | 1 (7.1) | 0 | 0 | 0 | 2 (14.3) | 1 (7.1) |

Continuous variables were performed as mean ± standard deviation. Categorical variables were reported as number (percentage). The number of major adverse cardiovascular events was reported on the time point that the events occurred.

LVDd: left ventricular end-diastolic diameter; LVEF: left ventricular ejection fraction
Table 3  Major adverse cardiovascular events and periodic echocardiography results in patients with pure aortic regurgitation

| Characteristics                              | Preoperation | Discharge | Follow-up |
|---------------------------------------------|--------------|-----------|-----------|
|                                             | 1 month      | 6 months  | 1 year    | 2 years   | 3 years   | 4 years   |
| Peak velocity, m/s                          | 1.98 ± 0.21  | 1.91 ± 0.40 | 1.53 ± 0.27 | 1.81 ± 0.25 | 1.76 ± 0.25 | 1.63 ± 0.19 | 1.70 ± 0.14 | 1.68 ± 0.15 |
| Peak pressure gradient, mm Hg               | 15.70 ± 3.38 | 14.93 ± 6.40 | 9.60 ± 3.39 | 13.33 ± 3.62 | 12.55 ± 3.43 | 10.65 ± 2.56 | 11.60 ± 1.98 | 11.78 ± 2.01 |
| Mean pressure gradient, mm Hg               | 5.50 ± 1.29  | 8.50 ± 3.32 | 5.75 ± 2.22 | 7.75 ± 1.50 | 7.00 ± 2.16 | 6.25 ± 1.89 | 6.00 ± 0.82 | 5.50 ± 0.58  |
| Effective orifice area, cm²                 | 2.53 ± 0.22  | 2.33 ± 0.39 | 2.08 ± 0.17 | 2.05 ± 0.25 | 2.53 ± 0.37 | 2.67 ± 0.41 | 2.68 ± 0.69 | 2.55 ± 0.62  |
| Perivalvular leakage, n (%)                 |              |           |           |           |           |           |           |             |
| None/trivial                                | –            | 4 (100.0) | 4 (100.0) | 4 (100.0) | 4 (100.0) | 4 (100.0) | 4 (100.0) | 4 (100.0)  |
| Mild                                        | –            | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)      |
| Moderate/severe                             | –            | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)      |
| Intra-prosthetic AR, n (%)                  | –            | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)      |
| LVEDd, mm                                   | 61.50 ± 2.08 | 53.00 ± 3.74 | 53.50 ± 3.87 | 50.25 ± 5.25 | 45.00 ± 3.37 | 41.50 ± 4.12 | 44.00 ± 6.68 | 43.75 ± 8.73 |
| LVEF, %                                     | 64.10 ± 4.43 | 59.73 ± 2.66 | 52.90 ± 3.33 | 59.70 ± 6.33 | 60.53 ± 2.67 | 60.75 ± 3.10 | 60.00 ± 4.69 | 61.00 ± 5.35 |
| Major adverse cardiovascular events, n (%)  | –            | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)     | 0 (0)      |

Continuous variables were performed as mean ± standard deviation. Categorical variables were reported as number (percentage). The number of major adverse cardiovascular events was reported on the time point that the events occurred.

LVDD: left ventricular end-diastolic diameter; LVEF: left ventricular ejection fraction.
Long-Term Follow-Up of J-Valve of TA VI in patients with PAR. In patients with AS, J-Valve had a higher aortic valve mean gradient than other second-generation THVs at discharge, but it still had a non-inferior long-term durability outcome in 4-year follow-up and the THV hemodynamics remained stable over time after implantation.

Fig. 1 The data of mean trans-aortic pressure gradient and aortic valve orifice area were showed at all time points reported. The mean gradient was presented with box and whiskers, and valve area with dots in the plot. (A) Aortic stenosis and (B) pure aortic regurgitation.

Fig. 2 The mean aortic pressure gradient for each patient (n = 6) who diagnosed with SVD was presented in the plot. A slight reduction in mean aortic valve orifice area over time was maintained after discharge in these patients. The data of mean aortic valve orifice area was presented with box and whiskers and aortic mean pressure gradient of the six patients was presented with symbols of different shapes. The symbols that filled with white color represented the occurrence of moderate SVD at the time point, and these filled with black color represented the occurrence of severe SVD. SVD: structural valve deterioration.
Disclosure Statement

The authors declare that they have no conflict of interest.

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