Original Article

Transapical mitral valve-in-valve implantation for failed bioprosthetic valve using the J-valve system with locator device: early and mid-term outcomes

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Background: Prior to the approval of the Sapien valve in 2020, there were no commercially available short-frame valves for transapical mitral valve-in-valve (MVIV) implantation. In January 2019, we first attempted the reverse mounted J-valve for transapical MVIV implantation with good clinical results. The present study aimed to explore the safety and effectiveness of transapical MVIV implantation with the J-valve reversely mounted on the delivery system.

Methods: Patients who underwent transapical MVIV implantation using the J-valve were analyzed from January 2019 to December 2020 with a 1-year follow-up. Before the procedure, computed tomography (CT) angiography data were analyzed to determine the inner diameter, left ventricular outflow tract (LVOT), and coaxial angel. An oversize rate of 5–10% was used to select the J-valve depending on the scanned inner diameter of the original mitral bioprosthesis. During the procedure, the three U-shape graspers were one-to-one buckled with the three tissue valve struts with the assist of echo and fluoroscopy. The implant depth into the left atrium was a 0–20% part of the J-valve, and the valve was then released under rapid pacing. Post-balloon dilatation was used when needed.

Results: Nineteen patients (mean age 70.05±11.19 years), with a mean Society of Thoracic Surgeons score of 8.01%±4.20%, were included. By transesophageal echocardiography, we found that the mean transvalvular gradient was 6.21±2.63 mmHg. The mean follow-up time was 20.31±7.23 months, and the survival rate was 94.74% at the last follow-up. The transvalvular gradient decreased from 15.06±3.00 mmHg at basal to 7.13±2.28 mmHg at the 1-year follow-up (P<0.001). The left ventricular ejection fractions (LVEF) increased from 60.31%±7.30% to 59.94%±7.72% at the 1-year follow-up (P=0.863). Thirteen (81.25%) patients had no or trace paravalvular leak (PVL), two (12.50%) patients had minor PVL, one (6.25%) patient had moderate PVL, and there were no cases of major regurgitation at the 1-year transthoracic echocardiography (TTE) examination results.

Conclusions: The J-valve reversely mounted on the delivery system can be used for transapical MVIV implantation with less operative morbidity and favourable outcomes.

Keywords: Transapical mitral valve replacement; valve-in-valve; bioprosthetic valve deterioration; the J-valve system; 1-year follow-up

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Introduction

The limited service-life of the bioprosthetic valve restricts its widespread application in middle age patients (1). The perioperative mortality of redo open-heart valve replacement surgery makes it difficult for some elderly or high-risk patients to accept the traditional redo open-heart valve replacement surgery under cardiopulmonary bypass (2). In 2007, Grube *et al.* (3) first applied transcatheter valve-in-valve implantation technology to treat bioprosthetic heart valve failure. In several studies, although the Society of Thoracic Surgeons (STS) scores were higher in patients with transcatheter valve-in-valve implantation than redo heart valve surgery, there was no significant difference in the early clinical outcomes and hemodynamic parameters (4-6). The short-term clinical effects of bioprosthetic valves in the aortic position were similar, but differ in the mitral position (7,8). When the bioprosthetic valve failed, the vast majority of mitral valve-in-valve (MVIV) procedures using short frames were Edwards Sapien valves (Edwards Lifesciences, Irvine, CA, USA) (9,10). In 2017, the American Food and Drug Administration approved the MVIV procedure with the Edwards Sapien system (11).

Considering that no short frame valves designed for transapical MVIV implantation have been approved by the China National Medical Products Administration before the Edward Sapien valve in 2020, we speculate that the short frame features and three graspers structure of the J-valve (Jiecheng Medical Technology, Suzhou, China) is suitable for transapical MVIV implantation. The J-valve system is a second-generation self-expandable transcatheter heart valve (THV) through the apical route. The three U-shape graspers are one-to-one buckled with the three tissue valve struts to avoid J-valve displacement to the left atrium (*Figure 1*). Ye *et al.* (12) first used the J-valve system for transapical aortic valve-in-valve treatment. In 2019, our center first applied the J-valve reversely mounted on the delivery system for transapical MVIV surgery. The data of patients who underwent transapical MVIV implantation from January to November 2019 were summarized and followed up to analyze the characteristics of the J-valve system in the transapical MVIV implantation.

We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/atm-21-6513).

Methods

Patients

All patients were preoperatively assessed independently by at least two cardiac surgeons. The mitral valve replacement algorithm of the STS score system was used to select high-risk patients who required redo mitral valve replacement. All patients in this study provided informed consent prior to undergoing the procedures. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and the study design was approved by the Ethics Review Committee of Beijing Anzhen Hospital (No. 2020079X). All patients underwent transthoracic echocardiography (TTE) to determine the functions of bioprosthesis and other native valves. If the aortic valve had valve stenosis and/or regurgitation, transapical aortic valve implantation was performed.

The bioprosthesis annulus diameter, stent height, mitral valve-aortic valve angle, and mitral valve-apex angle were determined by multi-detector computed tomography (MDCT). The positions of three bioprosthesis struts posts in the left ventricle were primarily determined according to MDCT. It was necessary to make clear the brand and model of the failed bioprosthetic valve through the manufacturer's data. In this way, the inner diameters of the failed bioprosthetic valves could be determined by the manufacturer's data and MDCT to choose the suitable sizes of THVs, with an oversize rate of 5–10%. Computed tomography (CT) or coronary angiography should be performed for routine preoperative examination of the coronary artery.

Procedure details

The procedure was performed in the hybrid operating room. The patient was placed supine position and received tracheal intubation under general anesthesia. The apex of the left ventricle was determined by C-arm fluoroscopy and exposed through a small anterolateral thoracotomy. Two pledged purse-string sutures were placed in the apex myocardium of the heart. After the apical puncture, a soft guide-wire and then a super stiff guide-wire were used to cross the bioprosthetic valve and into the left ventricle. The J-valve was reversely loaded on the conveyor system

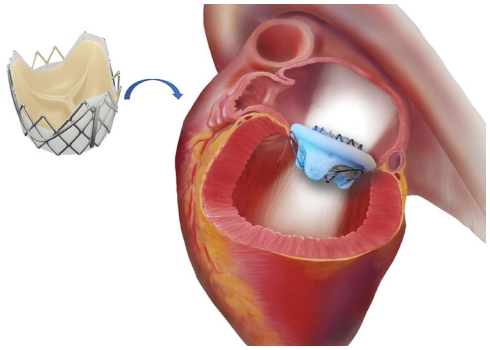

Figure 1 Transapical MVIV implantation with the J-valve. The J-valve has three low frame areas in the middle of the struts posts, which enlarges the outflow area of THV and reduces the probability of left ventricular outflow tract obstruction. The three U-shaped graspers allow the three failed bioprosthetic valve leaflets to be fixed in the middle of shaped graspers and THV frame to avoid THV displacement. MVIV, mitral valve-in-valve; THV, transcatheter heart valve.

and placed along the stiff guide-wire into the left ventricle towards into the left atrium (*Figure 2A*). The conveyor sheath can be bent at certain angel, which helpful for coaxial implantation. The three U-shaped graspers were first released and were then one-to-one buckled with the three tissue valve struts *(Figure 2B)*.

The J-valve was adjusted to the appropriate depth into the left atrium (usually 10–20%) and then released (*Figure 2C*,*2D*). If the struts post of surgical valves were not clearly visible on fluoroscopy, the released three U-shaped graspers of the J-valve could rotate just at the struts level. When encountering resistance, it could be considered as buckle with the three struts posts. When the depth of the J-valve was too shallow into the left atrium, the rotation would not encounter obvious resistance, and the valve could be further transported into the left atrium.

Due to the longer size, it was difficult for the released U-shaped graspers were to enter the left atrium. Re-balloon valvuloplasty of the J-valve was usually needed after the THV release under rapid pacing. The valve position, depth, flow rate, transvalvular pressure, and paravalvular leak (PVL) were determined by transesophageal echocardiography (TEE) and fluoroscopy. Transapical aortic valve implantation can be performed simultaneously. The balloon aortic valve fracture technique (by a powerful non-compliance balloon, Bard Atlas Gold Balloon) was used to enlarge the orifice area, and a bigger size valve was implanted if the original bioprosthetic valve size was less than 21 mm.

Follow-up

Patients took warfarin after surgery and kept the international normalized ratio between 2.0 and 2.5 for 3 months, and then changed to aspirin for thereafter for life. Patients with contraindications to warfarin or with coronary heart disease used double antiplatelet drugs for 3 months and then changed to aspirin alone. Patients were discharged after evaluation by TTE and electrocardiogram, and accepted TTE and electrocardiography 1-year after discharge from the hospital. The 1-year outcomes were determined by telephone, outpatient service, and follow-up system.

Statistical analysis

The outcomes were reported according to the Mitral Valve Academic Research Consortium (MVARC) definitions (13). All continuous variables were expressed as the mean ± standard deviation and tested using the paired student *t*-test. Categorical variables were described by frequencies and percentages. We defined the surveillance period as the time between discharge from the hospital and the last clinical follow-up with the patient. SPSS 26.0 (IBM, Armonk, NY, USA) was used for statistical analysis. $P<0.05$ was considered statistically significant.

Results

Baseline characteristics

From January 2019 to December 2020, 19 patients successfully received transapical MVIV implantation in our center (Beijing Anzhen Hospital, Capital Medical University, Beijing, China). The patients' baseline characteristics are listed in *Table 1*. The mean age of patients was 70.05±11.19 years and 63.16% (12 cases) were female. Their cardiac functions were New York Heart Association (NYHA) functional class III (84.21%) or IV (5.26%), and the mean STS score was 8.01%±4.20%.

Valve characteristics

The mean implant duration of the failed bioprosthetic mitral valves was 11.05±2.84 years (from 5 to 15 years).

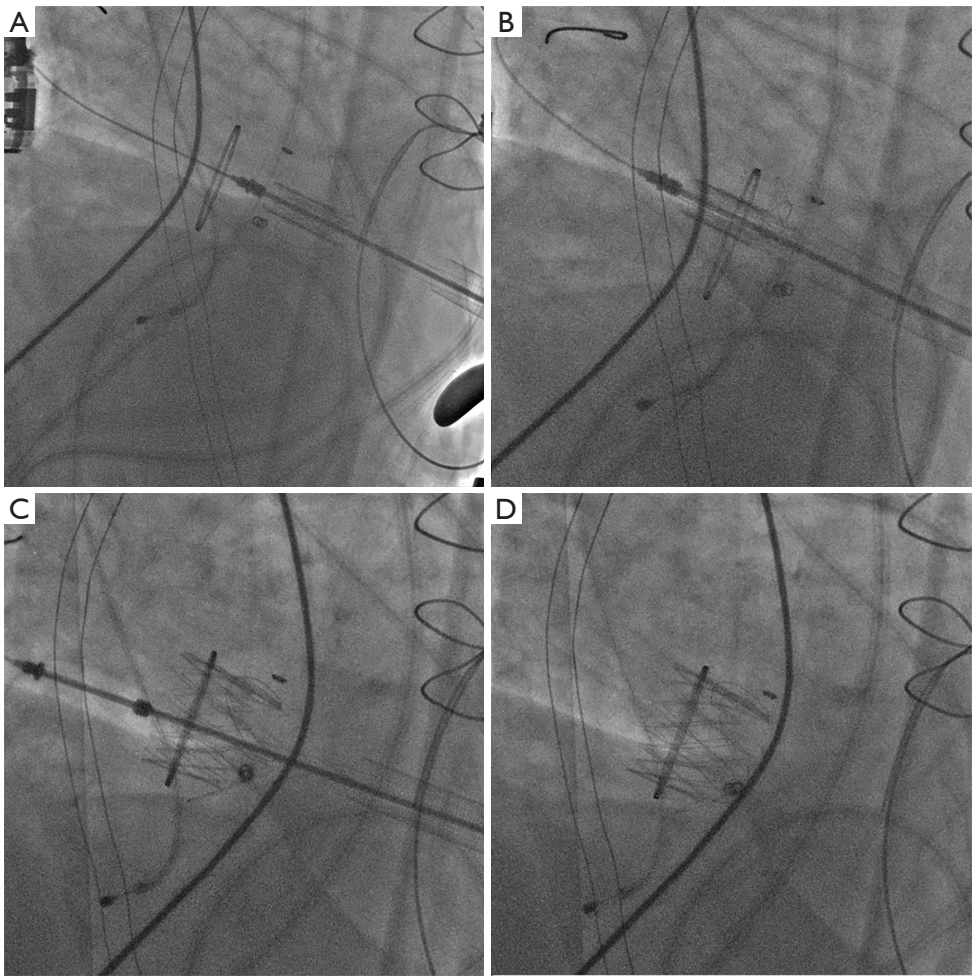

Figure 2 Step-by-step transapical MVIV implantation using the J-valve. (A) The J-valve entered the left ventricle. (B) The three U-shaped graspers were buckled with the three struts posts of the failed bioprosthetic valve. (C) The J-valve was adjusted to the appropriate depth and then released. (D) The J-valve function was good without displacement. MVIV, mitral valve-in-valve.

Among the failed bioprosthetic mitral valves, porcine and bovine pericardial valves were found in 84.21% (16 cases) and 15.79% (three cases) of these patients, including 25 mm in five cases, 27 mm in 10 cases, and 29 mm in three cases, respectively. The primary mechanisms of bioprosthetic failure were valve stenosis in four (21.05%) patients, valve regurgitation in 12 (63.16%) patients, and combined in three (15.79%) patients. The THV size included 23 mm J-valve in seven patients (36.84%), 25 mm J-valve in 10 patients (52.63%), and 27 mm J-valve in two patients (10.53%) (*Table 2*). Two patients required transcatheter aortic valve replacements, and two patients needed transcatheter aortic valve-in-valve replacements at the same time.

Early outcomes

The early clinical results are shown in *Table 3*. All 19 patients were successfully implanted without left ventricular outflow tract obstruction or embolism. Through TEE, we observed that the mean transvalvular gradient was 6.21±2.63 mmHg during the surgery. No auxiliary circulation support was required postoperatively. One patient received second thoracotomy for bleeding exploration. The mean intensive care unit (ICU) time was 43.05±46.36 hours. There were no patient readmissions for 30 days. No new permanent pacemaker, myocardial infarction, stroke, vascular complications, or acute kidney injury were found in these patients.

Table 1 Demographics and characteristics

Demographics and characteristics	Values
Age, years	70.05±11.19
Female	12 (63.16)
Height, cm	162±6.19
Weight, kg	57.26±10.5
Hypertension	8 (42.1)
Diabetes mellitus	3 (15.79)
Stroke	1 (5.26)
Chronic kidney disease	5 (26.31)
Atrial fibrillation	11 (57.89)
Previous CABG	4 (21.05)
Prior pacemaker	3 (15.79)
NYHA class II	2 (10.52)
NYHA class III	16 (84.21)
NYHA class IV	1 (5.26)
Etiology of bioprosthetic valve failure	
Regurgitation	12 (63.16)
Stenosis	4 (21.05)
Mixed	3 (15.79)
Time since surgical valve, years	11.05±2.84
Preoperative echocardiography	
Left ventricular ejection fraction, %	60.11±6.90
Mitral valve area, cm^2	1.79±0.69
STS score, %	8.01±4.20

Values are n (%) or mean ± standard deviation. CABG, coronary artery bypass graft surgery; NYHA, New York Heart Association; STS, The Society of Thoracic Surgeons.

Last follow-up

The mean follow-up time was 20.31±7.23 months. One patient died 3 months after surgery and the survival rate was 94.74% at the last follow-up. One patient developed upper gastrointestinal hemorrhage 9 months after surgery. One patient had fundus hemorrhage 12 months after surgery. One patient suffered a stroke 10 months after surgery. The patients' heart function also improved, with a decrease in the NYHA class III/IV percentage from 94.44% to 11.11% (P<0.001, *Figure 3A*). No valve-related thrombus or frame expansion was observed in the patients.

Echocardiography results

Sixteen patients underwent TTE examination 1-year after discharge from the hospital. No THV regurgitation was observed. The transvalvular gradient was decreased from 15.06±3.00 mmHg at basal to 7.13±2.28 mmHg at 1-year follow-up (P<0.001, *Figure 3B*). The left ventricular ejection fractions (LVEF) increased from 60.31%±7.30% to 59.94%±7.72% at the 1-year follow-up (P=0.863). Thirteen (81.25%) patients had no or trace PVL, two (12.5%) patients had minor PVL, one (6.25%) patient had moderate PVL, with no cases of major regurgitation at 1-year TTE examination results (*Figure 3C*). The moderate or severe tricuspid regurgitation percentage decreased from 75.0% to 37.5% (P<0.001, *Figure 3D*).

Discussion

The J-valve is a uniquely-designed valve with three U-shaped graspers surrounding the THV frame. Unlike the positioning keys of other THVs, the three U-shaped graspers of the J-valve are connected to the THV through sutures so that the THV can move along the long axis of the U-shaped graspers. In the process of transapical aortic valve implantation, the curved part of the three U-shaped graspers extends into the three aortic sinuses easily and helps orientate the valve. After implantation, the aortic valve leaflets can be clamped by the U-shaped graspers and fixed to the surrounding of the THV frame, which is helpful in anchoring the valve and reducing the risk of PVL. The J-valve mainly includes five models: 21, 23, 25, 27, and 29 mm. At present, the J-valve has shown advantages in the application of non-calcified aortic regurgitation in several clinical studies (14-17). In 2017, the China Food and Drug Administration (CFDA) approved the J-valve system for transcatheter aortic valve implantation with aortic stenosis and/or regurgitation.

The J-valve also has advantages in the field of the transapical valve-in-valve implantation. Its low frame valve is suitable for the transcatheter MVIV implantation, which can reduce the influence on left ventricular structure (*Figure 1*). Owing to the higher left ventricular pressure relative to left atrial pressure, MVIVs anchored only by radial forces are at risk of displacement (18). The three U-shaped graspers, which are one-to-one buckled with the three tissue valve struts, are helpful to avoid delayed valve migration. The three arc-shape of the inflow part stents are missing, which means that the J-valve stent is not a

Table 2 Valve characteristics

Patient number	Years after MVR	Failing BP type	Failing mitral BP size (mm)	THV type	THV mitral size (mm)	MG after surgery by TEE (mmHg)
1	14	HAN II	27	J-valve	25	5
2	14	CE perimount plus	27	J-valve	25	6
3	10	Epic	27	J-valve	23	9
4	12	HAN II	25	J-valve	23	6
5	9	CE porcine	27	J-valve	23	3
6	10	HAN II	27	J-valve	23	5
7	12	HAN II	25	J-valve	25	4
8	12	HAN II	27	J-valve	25	3
9	12	HAN II	29	J-valve	27	2
10	9	Mosiac	27	J-valve	25	5
11	10	Epic	27	J-valve	25	8
12	12	CE porcine	25	J-valve	25	10
13	15	HAN II	25	J-valve	23	6
14	9	HAN II	29	J-valve	25	8
15	14	HAN II	31	J-valve	27	3
16	5	Epic	29	J-valve	25	12
17	12	CE SAV	25	J-valve	23	8
18	14	Bovine valve	27	J-valve	25	6
19	5	Bovine valve	27	J-valve	23	9

BP, bioprosthetic valve; CE, Carpentier Edwards; HAN II, Hancock II porcine valve; MVR, mitral valve replacement; THV, transcatheter heart valve; TAVR, transcatheter aortic valve replacement; MG, mean gradient; TEE, transesophageal echocardiography.

completely cylindrical metal stent. This feature, coupled with the three U-shape graspers, reduces the probability of left ventricular outflow tract obstruction (*Figure 1*). Therefore, the J-valve is unexpectedly feasible for transcatheter valve-in-valve implantation. Our center first applied the J-valve reverse loaded on the delivery system for transapical MVIV surgery in January 2019. Since the first application in our center, no patient was intraoperatively converted to thoracotomy due to valve displacement.

A previous multiple center clinical trial reported on 176 patients undergoing transcatheter MVIV surgery in North American and Europe, with a mean STS score of 9.3%±7.0%. These patients had 30-day and 1-year all-cause mortality rates of 5.7% and 12.6%, respectively, and the 30-day incidences of stroke and life-threatening or fatal bleeding were both 2.3% (19). Kamioka *et al.* (4) reported on 62 patients undergoing MVIV implantation with the Sapien valves; the 30-day and 1-year all-cause mortality rates were 3.2% and 11.3% during a follow-up period of 339 days (range, 30 to 1,291 days). In contrast, the J-valve was shown to be safe and effective for transapical MVIV implantation. During a follow-up of 12 patients (mean follow-up time: 20.31±7.23 months), the survival rate was 94.74%, and no incidence of valve displacement, shedding, deflection, or other cardiac events at the last follow-up. Also, postoperative cardiac function improved significantly; 16 patients (84.21%) showed cardiac NYHA class I or II, and only two patients showed NYHA class III at the last follow-up.

TTE showed good results 1 year after surgery without THV regurgitation. After 1 year, the transvalvular gradient was decreased from 15.06±3.00 mmHg at basal to 7.13±2.28 mmHg at 1-year TTE results. In several studies of Sapien valves in the MVIV implantations, the trans-

Table 3 Clinical outcomes

Endpoint	Values
Early outcomes	
ICU time, hours	43.05±46.36
Device success	19 (100.0)
New pacemaker	0 (0.0)
Stroke	0 (0.0)
Myocardial infarction	0 (0.0)
Vascular complications	0 (0.0)
Bleeding	1 (8.33)
Acute kidney injury	0 (0.0)
Readmission at 30 days	0 (0.0)
Mortality at 30 days	0 (0.0)
Last follow-up	
Follow-up time, months	20.31±7.23
Mortality at last follow-up	1 (5.26)
New pacemaker	0 (0.0)
Stroke	1 (5.26)
Myocardial infarction	0 (0.0)
Vascular complications	0 (0.0)
Bleeding	2 (10.52)
Blood transfusion	1 (5.26)
Acute kidney injury	0 (0.0)

Values are n (%) or mean ± standard deviation. ICU, intensive care unit.

mitral gradients were 5–10 mmHg (4,19-21). The trans-mitral gradient in our data seems acceptable or even better than these reports, which indicated that the post-dilatation after J-valve implantation is helping to reduce the gradient. The degrees of tricuspid regurgitation were also significantly decreased. There was no significant improvement in the LVEF values of high-risk patients, with the consideration of the proportion of patients with atrial fibrillation being 57.89% and the mean STS score being 8.01%±4.20%.

Due to the complex anatomical structure of the mitral valve, the straight and short delivery distance of the transapical MVIV implantation procedure allowed coaxial alignment of the THV valve within the failed bioprosthetic valve to achieve successful valve implantation more easily (22). In some cases, previous mitral valve surgeries performed through the atrial septum incision increases the difficulty of atrial septal puncture for MVIV. Although a small incision in the left chest wall was required (usually around 4 cm into the thorax), the safety and success of transapical MVIV implantation were also significantly improved due to the avoidance of cardiopulmonary bypass and the relative shortening of the operation time. Yoon *et al.* (19) showed that although there were no significant differences in clinical outcomes and surgical success rates between transapical and transseptal approaches at 30 days, patients in the transseptal group required more frequent closure of iatrogenic atrial septal defects than those in the transapical group (12.2% *vs.* 0.0%; P<0.001), resulting in a reduced device success rate (78.0% *vs.* 89.1%; P=0.02). Transcatheter aortic valve replacement is also more easily performed via the transapical approach, which reduces the difficulty of surgery. Besides the success MVIV procedures, there were no outflow obstructions or valve displacements in three patients who underwent interventional aortic valve replacements. In order to ensure good coaxial trajectory, the angle between the mitral bioprosthesis annulus plane and left ventricular long axis can be determined preoperatively by MDCT. Since the transporter sheath can be bent, its pre-shaped by hand makes it easier to align the valve with the mitral plane. During the operation, the super stiff guide wire also can assist with valve alignment, and the three positioning graspers can also help determine the valve position.

Selecting the right size THV valve is crucial. Excessively oversized valves are not desirable, as they can lead to considerable overlap of the leaflets and result in higher transvalvular pressure gradients and flexural formation (23). On the contrary, valves that are too small can cause higher transvalvular pressure gradients and increase the risk of PVL and valve migration (23,24). Based on valve data provided by the manufacturer, it is important to select the appropriate THV valve according to the brand and model of the failed bioprosthetic valve (22,25). However, manufacturer data may differ from those obtained by TTE and CT, possibly due to leaflets calcification and even pannus (26). In this situation, CT measurement data is more precise and should be analyzed carefully before the procedure. The balloon valve fracture technique has been used to enlarge the orifice area and widely applied in the aortic valve-in-valve implantation (27). Due to the larger size of mitral tissue valves relative to aortic valves, only a few case reports have detailed the balloon mitral valve fracture

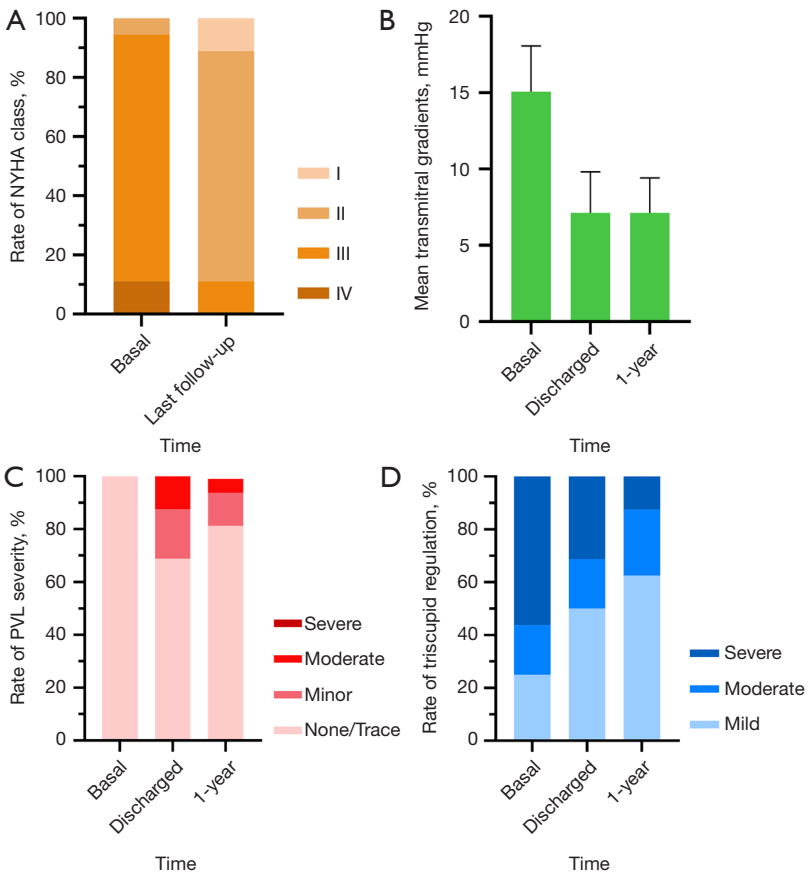

Figure 3 Change in NYHA class and TTE results. (A) The change in NYHA classification (I, II, III, IV) at basal and last follow-up (n=18). (B) The change in transvalvular gradient at basal, discharge, and 1-year follow-up (n=16). (C) The change in paravalvular leak at basal, discharge, and 1-year follow-up (n=16). (D) The change in tricuspid regurgitation degree at basal, discharge, and 1-year follow-up (n=16). NYHA, New York Heart Association; TTE, transthoracic echocardiography.

technique (28,29), and experience is limited. Considering the risk of left ventricular rupture, coronary artery injury, and annular tear caused by balloon mitral valve fracture, this technique was not used for MVIV implantation. The smallest J-valve for MVIV in our cases was 23 mm. Given the high risk of redo of surgical mitral valves, choosing a 23-mm J-valve for MVIV implantation could also provide benefits, and the average pressure difference was less than 10 mmHg at the 1-year follow-up results.

To select the right size of the intervention valve, we paid attention to the leaflet thickness of the failed bioprosthetic valve, and subtracted the leaflet thickness on the label internal diameter size data given by the manufacturer. Combining the MDCT results, the selected leaflets were appropriate, with an oversize rate of 5–10%. The transvalvular gradient at the 1-year follow-up was 7.13±2.28 mmHg. Cheung *et al.* (21) reported on 23 patients using Sapien/Sapien XT valves; three (13%) THV valves sizes were smaller than the internal diameter size of the failed bioprosthetic valves, with a transvalvular gradient of 6.9±2.2 mmHg. In Elmously *et al.*'s study (20), no THV valve size smaller than the internal diameter size was selected, and the transvalvular gradient was 5±3 mmHg. Based on the inner diameter of the failed valve and the thickness of the failed valve leaflet, it is meaningful to select the right THV, and the long-term duration of THV needs further follow-up.

PVL seems to be a low probability adverse event. The 1-year TTE results showed that 13 (81.25%) of 16 patients had no or trace PVL, two (12.5%) patients had minor PVL, one (6.25%) patient had moderate PVL, and there were no cases of major regurgitation. Conradi *et al.* (30) found three patients with moderate PVL and no patients with severe PVL among 17 cases of transcatheter MVIV implantation with Sapien and Lotus valves (Boston

Scientific, Marlborough, MA, USA). No PVL was found in Cheung *et al.* (21) and Elmously *et al.* (20) studies. Although smaller sized THVs with no excessive oversize was chosen in our cases, the PVL ratio was not obviously increased.

Pre-implantation balloon valvuloplasty was not necessary during surgery, which can lead to acute mitral insufficiency and embolization (21). Cheung *et al.* (21) and Seiffert *et al.* (22), reported that no pre-implantation balloon was used in their studies, except for their respective first patients. In our study, pre-implantation balloon valvuloplasty was not used even in patients with bioprosthetic valve stenosis because we are surgeons who are familiar with the tissue valve pathology changes and believe that leaflets with calcium are not difficult to expand. Most THVs require a post-implantation balloon; a post-implantation balloon using a J-valve of the same size can make the interventional and biological valves adhere better, reduce PVL, and lower the transvalvular flow rate and pressure gradient. The self-expanding valves can continuously apply a radial support force on the failed bioprosthetic valves stents, so that the failed leaflets are strongly anchored at the frame. This is also the advantage of the J-valve, with a low frame height and self-expanding frame in transapical valve-in-valve implantation.

Among the failed bioprosthetic valve, the number of porcine valves was more than that of bovine pericardial valves. The present clinical follow-up results proved that the short-term effects of porcine mitral valves and bovine mitral valves were similar, but the use of bovine mitral valves was more effective than that of porcine mitral valves in the long-term effects (31). Bovine pericardial material had stronger mechanical properties than porcine valve and may not be easy to be damaged under the impact of left ventricular blood flow (32).

Conclusions

The J-valve is a self-expandable valve with three U-shaped graspers. The low frame and three U-shaped graspers were the advantages of the J-valve for MVIV, with a high success rate and fewer complications. The postoperative clinical outcomes and hemodynamic outcomes were satisfactory. The J-valve for MVIV procedure via the apical approach is less difficult to operate and can simultaneously deal with the aortic valve procedure, with satisfactory results. Our innovation in the MVIV with J-valve had expanded to almost 10 centers in China and achieved satisfactory clinical results.

There are some limitations to this study that should be noted. The J-Valve system was not a special interventional valve for MVIV surgery. The lack of design details may be the disadvantage of the MVIV implantation. Since the transapical valve-in-valve implantation has only just begun in China, and the number of patients studied was small, long-term follow-up is needed. Also, as a single center experience, this research is limited by personal techniques and conditions, and cannot provide general technical experience. More data, longer follow-up times, and multicenter studies are needed in the future to evaluate the safety and effectiveness of the J-valve in the field of transapical MVIV implantation.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All patients in this study provided informed consent prior to undergoing the procedures. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and the study design was approved by the Ethics Review Committee of Beijing Anzhen Hospital (No. 2020079X).

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