A New Transcatheter Aortic Valve Replacement System for Predominant Aortic Regurgitation Implantation of the J-Valve and Early Outcome

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ABSTRACT

OBJECTIVES This study introduces a newly designed transcatheter aortic valve system, the J-Valve system, and evaluates its application in patients with predominant aortic regurgitation without significant valve calcification. We also report the early results of one of the first series of transapical implantations of this device and aim to offer guidance on the technical aspects of the procedure.

BACKGROUND Transcatheter aortic valve replacement (TAVR) has been widely used in high-risk patients for surgical aortic valve replacement. However, the majority of the TAVR devices were designed for aortic valve stenosis with significant valve calcification.

METHODS Six patients with native aortic regurgitation without significant valve calcification (age, 61 to 83 years; mean age, 75.50 ± 8.14 years) underwent transapical implantation of the J-Valve prosthesis (JieCheng Medical Technology Co., Ltd., Suzhou, China), a self-expandable porcine valve, in the aortic position at our institution. All patients were considered to be prohibitive or high risk for surgical valve replacement (logistic EuroSCORE [European System for Cardiac Operative Risk Evaluation], 22.15% to 44.44%; mean, 29.32 ± 7.70%) after evaluation by an interdisciplinary heart team. Procedural and clinical outcomes were analyzed.

RESULTS Implantations were successful in all patients. During the follow-up period (from 31 days to 186 days, mean follow-up was 110.00 ± 77.944 days), only 1 patient had trivial prosthetic valve regurgitation, and none of these patients had paravalvular leak of more than mild grade. There were no major post-operative complications or mortality during the follow-up.

CONCLUSIONS Our study demonstrated the feasibility of transapical implantation of the J-Valve system in high-risk patients with predominant aortic regurgitation. (J Am Coll Cardiol Intv 2015;8:1831–41) © 2015 by the American College of Cardiology Foundation.

Transcatheter aortic valve replacement (TAVR) has been proved to be an effective treatment of aortic valve disease in patients considered at high risk of mortality or morbidity with surgical aortic valve replacement. In the majority of TAVR cases performed worldwide, the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, California) and Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) have been used. A small number of other devices have also...
been used. However, for most of these devices, predominant aortic regurgitation remained to be a technological challenge because of questionable anchoring, which can result in a high incidence of valve migration and paravalvular leak. Consequently, the guidelines from the United States and the Europe suggest that candidates with predominant aortic regurgitation (>grade 3+) or noncalcified valve should not undergo TAVR (1,2).

Patients with predominant aortic regurgitation who are at prohibitive risk for surgery need an alternative treatment. A new generation of transcatheter aortic valve devices with secure anchoring is needed.

The off-label use of the current devices in aortic regurgitation has been sporadically reported and includes the SAPIEN valve, CoreValve, JenaValve (JenaValve Technology GmbH, Munich, Germany), and Engager Aortic Valve bioprosthesis (Medtronic) (3–8).

The J-Valve system (JieCheng Medical Technology Co., Ltd., Suzhou, China) is a new generation of transcatheter heart valve (THV) with a unique design of a 2-piece structure that consists of a 3-prong clasper and a support frame. This distinctive design allows the THV to be implanted in 2 stages, which results in precise anatomic positioning and secure anchoring.

We introduce the J-Valve system and report the feasibility and early results of TAVR in 6 patients with predominant aortic regurgitation.

METHODS

PATIENT POPULATION AND DIAGNOSTIC WORKUP.

The TAVR program at the Department of Cardiovascular Surgery, Zhongshan Hospital, began at May 2014. Between May and December 2014, 16 patients were chosen for TAVR. Ten patients presented with symptomatic severe aortic valve stenosis with significant calcified valves. Six patients presented with symptomatic predominant aortic regurgitation without significant valve calcification. All 16 patients were evaluated by the heart team before admission and considered to be at prohibitive or high risk for surgical aortic valve replacement. In addition to a routine workup, transthoracic echocardiography and contrast-enhanced multislice computed tomography (MSCT) were performed. The degree of the aortic regurgitation was graded by transthoracic echocardiography based on the vena contracta width. The diameter of the aortic annulus was measured in the short axis. MSCT was performed to assess the morphology of the aortic valve and root (Figure 1A). The diameter of the aortic annulus for sizing the prosthesis was calculated by measuring the area of the native aortic valve and the perimeter of the annulus (Figure 1B). Patients were placed in the supine position when MSCT scans were performed, which is the same position as for TAVR procedures. Three-dimensional images of the aortic root with proximal segments of left and right coronary arteries in different angles were reconstructed to determine the optimal C-arm angulations (Figure 1C). Two-dimensional images were reconstructed to measure the angulations between the long axis of the aortic root and the left ventricular outflow tract, which helps to determine the optimal curvature of the delivery system during the procedures (Figure 1D). Two-dimensional images were also reconstructed to measure the distance between the ostia of coronary arteries and the annulus (Figures 1E and 1F). The details of coronary arteries were reconstructed to rule out significant coronary stenosis.

PROCEDURE. The procedures were performed in a hybrid operating room with patients under general anesthesia with a single-lumen endotracheal tube. A balloon-tipped bipolar endocardial temporary pacing catheter (St. Jude Medical, St. Paul, Minnesota) was inserted through left internal jugular vein into the right ventricle under fluoroscopic guidance. A pulmonary artery catheter was inserted through right internal jugular vein for hemodynamic monitoring. Transesophageal echocardiography (TEE) was performed to further confirm aortic regurgitation and the annulus diameter (Figure 2A). The size of the prosthesis was determined by the diameter of aortic annulus. Cardiopulmonary bypass was available as a standby during all procedures.

The prosthesis and delivery system were assembled after the size of the prosthesis was confirmed. The projection of left ventricle apex on the chest wall was localized under fluoroscopy to determine the optimal incision. A 5-F introducer was inserted in the common femoral artery followed by insertion of a 5-F AltaFlow pigtail measuring catheter (OptiMed, Etlingen, Germany), which was positioned in the aortic root. A limited left anterolateral thoracotomy was performed in the fifth or sixth intercostal space according to the projection of ventricle apex. After 2 3-0 polypropylene (Ethicon, Somerville, New Jersey) Teflon-reinforced mattress sutures placed on the ventricle apex, 1 mg/kg heparin was administered to keep the activated clotting time at more than 300 s.
The C-arm was set at the optimal angle, and an aortic root angiogram was performed (Figure 3A). By preoperative MSCT, reference angulation of the C-arm was provided perpendicularly in relation to the aortic annulus. A reference line through the nadirs of aortic sinuses was marked on the screen to localize the annulus plane. The positions of the C-arm and the operating table were maintained until the implantation was completed.

A soft hydrophilic Radiofocus guidewire (Terumo, Tokyo, Japan) was inserted in the ventricle apex and used to cross the aortic valve and then positioned in the ascending aorta. The hydrophilic guidewire was exchanged for a standard polytetrafluoroethylene-coated EMERALD guidewire (Cordis Johnson & Johnson, Miami Lakes, Florida), and the latter was positioned across the aortic arch and down into the descending aorta with the guidance of a right Judkins catheter (Cordis Johnson & Johnson).

A small incision ~5 mm long was made next to the guidewire to facilitate insertion of the delivery system. The size of the delivery sheath was 27-F. Four knobs in the delivery system controlled the deployment of the clasper, lowering, deployment, and release of the prosthesis.

The delivery system was inserted in the left ventricle and across the aortic valve without an apical sheath. Implantation was performed in 2 stages and was monitored by both fluoroscopy and TEE. The first stage was positioning the clasper. The clasper was deployed in the aortic root (Figure 3B, Online Video 1). As the surgeon gently pulled back the delivery system, the clasper would be seated in the aortic sinuses, and then an aortic root angiogram was obtained to confirm the position of the clasper (Figure 3C, Online Video 2). The second stage was lowering and deployment of the prosthesis. The prosthetic valve was lowered into the aortic annulus and then deployed without rapid pacing (Figures 3D and 3E, Online Videos 3 and 4). The prosthesis was then released, and the delivery system was removed. The step-by-step implantation was
demonstrated in a heart model in vitro (Figure 4). Functioning of the prosthesis was assessed by TEE immediately (Figures 2B and 2C). After the guidewire was removed, the apical sutures were tied, and 1.5 mg/kg protamine was administered. Then hemostasis was achieved. A final aortic root angiogram was obtained to assess the prosthesis function and to confirm that both coronary ostia were patent.

FIGURE 2 TEE During the Procedure

TEE (Patient #2) before and after implantation of the prosthesis. (A) TEE showed a grade 3+ central aortic regurgitation before prosthesis implantation. (B) TEE after prosthesis implantation. (C) TEE showed no paravalvular leak after the prosthesis implantation. TEE = transesophageal echocardiography.

FIGURE 3 Step-by-Step Implantation

Step-by-step transapical implantation (Patient #6) of a 27-mm J-Valve prosthesis (JieCheng Medical Technology Co., Ltd., Suzhou, China). (A) An aortic root angiogram depicts the morphology of the aortic sinuses and coronary ostia. (B) The clasper was deployed in the aortic root (Online Video 1). (C) Repeat aortic root angiography was performed to confirm the position of the clasper (Online Video 2). (D, E) The prosthetic valve was lowered into the aortic annulus and was deployed there (Online Videos 3 and 4). (F) A final aortic root angiogram showed no paravalvular leak (Online Video 5).
The incision was closed in routine fashion. Post-operative device-specific medical therapy consisted of daily warfarin to keep the international normalized ratio between 2.0 and 3.0 for at least 6 months.

Data Management and Clinical Follow-Up.
All relevant baseline, procedural, and follow-up data were prospectively collected. Clinical and echocardiographic examinations were performed before discharge and at 30 days, 3 months, and 1 year.
after the procedure. MSCT was performed before discharge as well (Figure 5). Outcomes were analyzed in accordance with the updated standardized endpoints defined by the Valve Academic Research Consortium-2 (9).

ETHICS. The J-Valve China Trial 2014 was approved by China Food and Drug Administration. The local ethics committee approved the study protocol at our center. The study was registered with the Chinese Clinical Trial Registry (ChiCTR-OPC-15006354). All patients were fully informed about the procedure and its experimental use of the THV (at the time of implantation). All patients signed written consent forms.

STATISTICS. This was a descriptive study with 6 patients. No inferential statistical analyses were performed. Continuous variables were presented as mean ± SD. All statistical analyses were performed with SAS version 9.2 (SAS Institute Inc., Cary, North Carolina).

RESULTS

BASELINE CHARACTERISTICS. Six patients (mean age, 75.5 ± 8.0 years; 66.7% men) who presented with predominant aortic regurgitation were chosen for the study. All patients had symptoms of left ventricular dysfunction. All the aortic valves were tricuspid. Only 1 patient had mild aortic valve stenosis. No patients had significant mitral valve dysfunction. All patients were in sinus rhythm without any conduction abnormalities. One patient had a history of off-pump coronary artery bypass surgery. Pre-operatively, all patients were evaluated by an interdisciplinary heart team and deemed to be at prohibitive or high risk for surgical aortic valve replacement due to comorbidities. The mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) of these patients was 29.32 ± 7.70%. Detailed patient characteristics are listed in Table 1. The baseline morphology and pathology of the aortic roots and valves are listed in Table 2.

PROCEDURAL OUTCOMES AND VALVE FUNCTION. The implantations of the J-Valve prosthesis in all patients were successful. All procedures were performed without the need of rapid pacing or cardiopulmonary bypass. No pre- or post-dilation was performed. There was no conversion to open surgery. No coronary obstructions or valve malpositioning occurred.

The amount of contrast varied from 60 to 138 ml in each case (mean dose, 86.33 ± 34.42 ml). After pre-operative MSCT was introduced to determine the optimal angle for angiography, the contrast dose was reduced to ~60 ml. The skin-to-skin procedure time varied from 78 to 150 min (mean time, 101.67 ± 26.31 min).

The appropriate size of the prosthesis was determined to be 5% to 10% larger than the native annulus diameter. Based on the aortic annulus diameter measured by MSCT and TEE, 3 25-mm and 3 27-mm prostheses were implanted. Hemostasis was easily achieved in all cases without significant blood loss.

<table>
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<th>Patient #</th>
<th>Age, yrs</th>
<th>Sex</th>
<th>BMI, kg/m²</th>
<th>Log ES, %</th>
<th>NYHA Functional Class</th>
<th>Comorbidities</th>
<th>Creatinine, mg/dl</th>
<th>PAP, mm Hg</th>
<th>MR Grade</th>
<th>TR Grade</th>
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<td>27.08</td>
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<td>69</td>
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BMI = body mass index; log ES = logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE); LVEDD = left ventricular end-diastolic diameter; LVEF = left ventricular ejection fraction; MR = mitral regurgitation; NYHA = New York Heart Association; PAP = systolic pulmonary artery pressure; TR = tricuspid regurgitation.
The functioning of the prostheses was assessed immediately after implantations by TEE and angiography. There was no regurgitation or stenosis of the implanted valves immediately after the procedure in all cases. The mean transvalvular gradient was 6.0 \pm 1.8 \text{ mm Hg}. None of the cases had significant para-valvular leak. Detailed valve function data immediate after implantation are listed in Table 3.

CLINICAL OUTCOMES AND FOLLOW-UP. The first patient was extubated in the operating room, and the other 5 patients were extubated in the intensive care unit on the first post-operative day. The mean length of intensive care unit stay and post-operative hospital stay was 2.17 \pm 1.329 days and 6.00 \pm 1.789 days, respectively. The mean drainage in the first 24 h after surgery was 35.00 \pm 38.859 ml. All patients were followed for at least 30 days (range, 31 to 186 days; mean, 110.00 \pm 77.94 days).

There were no mortality or major post-operative complications during the hospital stay and follow-up. In the latest follow-up, all patients were New York Heart Association functional class I or II. The symptoms of exertional dyspnea and exercise intolerance were significantly improved in all cases.

Three patients had new-onset complete left bundle branch block, and 1 patient had first-degree atrioventricular block after the procedure without bradycardia; 2 of the 3 patients with complete left bundle branch block and the patient with first-degree atrioventricular block recovered spontaneously 1 month after the procedure, whereas 1 patient remained in left anterior fascicular block 2 months after the procedure. One patient had new-onset atrial fibrillation 4 days after the procedure and converted to sinus rhythm within 24 h after administration of amiodarone. No permanent pacemaker implantation was needed. No new arrhythmia resulting in hemodynamic instability occurred during the perioperative period.

No neurological complications (including stroke and transient ischemic attack) occurred during the hospital stay and follow-up. Only 1 patient had stage 1 acute kidney injury after the procedure according to the Acute Kidney Injury Network criteria (10) and recovered spontaneously soon after discharge without the need for dialysis. No myocardial infarction or vascular complications occurred during the perioperative and follow-up periods.

Transthoracic echocardiograms were obtained 1 month, 2 months, and 6 months after surgery to evaluate the function of the implanted valves. Detailed clinical outcomes and follow-up data are listed in Table 4. The results of the latest echocardiographic follow-up are listed in Table 5.
DISCUSSION

According to the latest guidelines, TAVR is recommended for patients with aortic valve stenosis who have a prohibitive risk for surgical aortic valve replacement, and it is considered a reasonable alternative to surgical aortic valve replacement in patients with aortic valve stenosis who have high surgical risk (11). Nevertheless, TAVR in patients with predominant aortic regurgitation has never been widely accepted. TAVR was not recommended for patients with predominant aortic regurgitation (grade 3+) or noncalcified valve in recent guidelines (1,2). The off-label use of the Edwards SAPIEN valve and Medtronic CoreValve was previously reported (3–6). The risk of valve dislocation due to insufficient anchoring and annular rupture as a consequence of excessive oversizing limited the use of these devices in predominant aortic regurgitation. The off-label use of the JenaValve system in 5 patients of noncalcified aortic regurgitation was first reported in 2013 (7). The initial German multicenter experience with the JenaValve system for the treatment of pure aortic regurgitation was reported in 2014. The deployment process of JenaValve system consists of feeler-guided positioning and secure clip fixation. Because of the unmovable connection between the feeler and the stent, unsatisfactory positioning of the feeler could result in an inadequate alignment and suboptimal positioning of the prosthesis, which might render significant para-valvular leak or even dislodgment of the prosthesis (12). The need for an alternative treatment for high-risk patients with predominant aortic regurgitation who meet the indications for surgical aortic valve replacement urged the emergence of a new-generation THV.

THE STRUCTURE OF THE J-VALVE PROSTHESIS AND THE FUNCTION OF THE CLASPER. The J-Valve system is a newly designed porcine valve. The leaflets are mounted in a self-expanding support frame that is connected with a 3-prong clasper by 3 sutures (Figure 6). This unique connection makes the prosthetic valve be movable along the long axis of the clasper. The structure of the clasper is designed according to the normal anatomy of the aortic sinus. The curved portions of the clasper accommodates the aortic sinuses during implantation. The 3 straight portions of the clasper are 120° apart from each other; they can be passed through the aortic commissures and pulled back into the subaortic space, whereas the curved portions are situated in the aortic sinuses. Placement of the clasper in the aortic sinuses could provide the surgeon with tactile feedback and facilitate the accurate deployment of the prosthesis with minimal radiation exposure. The clasper also helps to reinforce the anchoring of the prosthesis by clamping the native valve leaflets between it and the support frame.
ADVANTAGES OF THE MOVABLE CONNECTION AND THE 2-STAGE IMPLANTATION. The movable connection between the clasper and the support frame makes it possible for a 2-stage implantation process (Figure 3, Online Videos 1, 2, 3, 4, and 5). The first stage is the placement of the clasper in the aortic sinuses. The second stage is the positioning and deployment of the prosthesis. Because of the movable connection, the position of the prosthetic valve could be adjusted while the clasper has already been placed in the aortic sinus; therefore, the prosthesis could be deployed in a perfect position coaxially with the left ventricular outflow tract even in the situation when the position of the clasper is influenced by the abnormal structure such as calcified annulus.

INDICATIONS AND ADVANTAGES OF THE J-VALVE SYSTEM. The unique design of the J-Valve system makes it convenient to be implanted in predominant regurgitant aortic valves even without valvular calcification. In choosing candidates for this procedure, it is critical to determine the diameter of the native annulus. Patients with annulus larger than 27 mm were excluded from this study because the maximal size of the prosthesis available is 27 mm. The following were also contraindications for this procedure: patients with congenital bicuspid aortic valve, the diameter of the ascending aorta larger than 50 mm, and the distance between the coronary ostia and the annulus is <5 mm.

Because of the anchoring effect of the clasper, the risk of valve dislocation is alleviated without excessive oversizing. As a result, none of the patients in this study needed a permanent pacemaker because of complete atrioventricular block, and the risk of annular rupture was minimized. During the implantation process in our 6 cases of predominant aortic regurgitation, no rapid pacing or balloon expansion was needed.

In addition to treating predominant aortic regurgitation, the J-Valve system could be implanted in stenotic aortic valves with heavy calcification after balloon valvuloplasty. We have experience with implantations in 9 patients with aortic valve stenosis. Although technical success was achieved in all cases, iatrogenic aortic dissection from excessive balloon valvuloplasty developed in 1 patient; the patient fortunately survived and was discharged after recovery from an aortic valve and hemiarch replacement surgery.

SELECTION OF THV SIZE AND FUTURE PLANS. In this study, the THV was available in 4 sizes: 21 mm, 23 mm, 25 mm, and 27 mm. The size of the delivery sheath was 27-F. According to our experience, it is necessary to have 5% to 10% oversizing of the aortic annulus derived from the MSCT-measured perimeter to minimize the risk of paravalvular leak and insufficient prosthesis expansion. These 4 sizes are designed to fit an effective aortic annulus diameter by MSCT between 19 and 26 mm. Because patients with predominant aortic regurgitation often have large annulus, a THV of size 29 is in development. The transaortic and transfemoral platforms are also in development. With these new approaches, the implantation might be less traumatic.

THE DIFFERENCE BETWEEN THE J-VALVE SYSTEM AND OTHER AVAILABLE DEVICES FOR AORTIC REGURGITATION. There were several available devices on the market for aortic regurgitation such as the JenaValve and the Engager. There were some differences between the J-Valve system and these devices. The JenaValve has 3 nitinol feelers, which facilitated intuitive “self-positioning” valve implantation (13). The 3 nitinol feelers and the frame of the prosthesis are integrated by an unmovable connection. Once each arm of the feelers is brought into the aortic sinuses, the position of the prosthesis could be adjusted only to a limited extent. The stent of the Engager assembly consists of a shaped main frame and a support frame, which are coupled together to form the commissural posts of the valve (14). The connection between the main frame and the support frame is also unmovable.

Although in the J-Valve system, the clasper is connected movably with the support frame, after the clasper is positioned in the aortic sinuses, the position of the prosthesis could still be adjusted upward and downward in a direction vertical to the annulus plane. This is quite useful when the ostia of coronary
arteries are close to the annulus; a lower deployment of the prosthesis could avoid the risk of coronary obstruction. At the same time, the prosthesis can be adjusted axially. When the 3 aortic cusps are asymmetrically calcified, the axial position of the clasper might be influenced by the movable connection and the unique 2-stage deployment, and the coaxial deployment of the prosthesis can be accomplished.

The structure of the clasper in J-Valve system is also different from the feelers in JenaValve and the deployment of the prosthesis can be accomplished. In J-Valve system, there are 3 straight portions that are 120° apart from each other in the clasper. They correspond to the native commissures, whereas the curved portions correspond to the cusps. The aortic annulus and the clasper form a “lock-and-key” relationship, which facilitates precise anatomic positioning.

**EXPERIENCE WITH TRANSAPICAL IMPLANTATION OF THE J-VALVE SYSTEM.** The technique of transapical implantation of the J-Valve system in predominant aortic regurgitation is relatively simple. In our experience, it is critical to determine the diameter of the annulus accurately before implantation. If the THV is not adequately oversized, the incidence of paravalvular leak and valve dislodgment would increase. During the 2-stage implantation, more attention should be paid to the process of positioning the prosthesis in the annulus. Occasionally, the edge of the prosthesis could be trapped by the tip of the clasper. Ignoring this would result in severe deformation of the clasper as well as paravalvular leak and valve malposition after the prosthesis is deployed. We suggest performing a thorough check of the configuration of the clasper before prosthesis deployment. If involvement of the clasper is seen, moving the prosthesis upward, adjusting the alignment of the delivery system, and redeploying the prosthesis could solve this problem easily.

**STUDY LIMITATIONS.** The research was a non-randomized observational study with only 6 patients engaged. The longest follow-up period was limited to 6 months. The future study with more cases and longer follow-up was scheduled.

**CONCLUSIONS**

Our study demonstrated the feasibility of transapical implantation of the J-Valve system in high-risk patients with predominant aortic regurgitation. Procedural and early results of the study on the J-Valve system performance are promising. Further research with a larger patient population and longer follow-up duration are scheduled to confirm the safety and reliability of its application in predominant aortic regurgitation.

**REFERENCES**


KEY WORDS: aortic valve insufﬁciency, minimally invasive surgical procedures, transcatheter aortic valve replacement

**APPENDIX** For supplemental videos, please see the online version of this article.