Transapical implantation of a new second-generation transcatheter heart valve in patients with pure aortic regurgitation: a preliminary report

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Abstract

Transcatheter aortic valve implantation (TAVI) has become an effective treatment option for high-risk or inoperable patients with aortic stenosis. However, experience with TAVI for non-calcified aortic regurgitation is still limited. The new J-Valve™ system is a new second-generation TAVI device that is designed for transapical implantation. It is characterized by three U-shaped, anatomically oriented devices—‘graspers’ that could facilitate intuitive ‘self-positioning’ valve implantation and provide extra-radial fixation by embracing the native valve leaflets. Here, we reported the initial experience of TAVI in high-risk patients with pure aortic regurgitation using the J-Valve™ system.

Keywords: Transcatheter aortic valve implantation • Pure aortic regurgitation • J-Valve™ system • Second-generation transcatheter aortic valve implantation device

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has been recognized as a valuable minimally invasive treatment option for inoperable or high-risk patients with symptomatic aortic stenosis [1]. However, this procedure is still truly challenging for patients with pure aortic regurgitation (AR) due to the absence of an annulus or leaflet calcification, which is required for secure anchoring of a transcatheter heart valve.

The J-Valve™ system is a new second-generation TAVI device that features three U-shaped, anatomically oriented devices—‘graspers’. This unique design could facilitate intuitive ‘self-positioning’ valve implantation and provide extra-axial fixation by embracing the native valve leaflets [2]. We report for the first time on the feasibility and initial results of TAVI in patients with pure AR using the J-Valve™ system.

SURGICAL TECHNIQUE AND INITIAL RESULTS

Between March and September 2014, 7 high-risk patients with pure AR were successfully treated with a TAVI procedure using the J-Valve™ system in our institution (mean age 74.3 ± 5.3 years, including 4 males and 3 females, with a mean logistic EuroSCORE of 22.4 ± 3.6%). All patients met the criteria of (i) symptomatic pure AR (grades III–IV) and presented with severe comorbidities yielding an increased operative risk for surgical replacement including coronary artery disease (n = 1), COPD requiring oxygen (n = 5), previous stroke (n = 2), peripheral vascular disease (n = 2) as well as compromised LVEF <50% (n = 2) and (ii) an aortic annular diameter ranging from 21 to 27 mm with an ascending aorta diameter of <45 mm. A preoperative CT angiogram was employed to assess aortic annulus. The mean annular diameter was 24.9 ± 1.5 mm (derived from CT annulus perimeter in a systolic phase) in the study cohort. Following the manufacturer’s recommendations, a 23-mm prosthesis was chosen for an aortic annulus of 21–22.9 mm, a 25-mm prosthesis for an aortic annulus of 23–24.9 mm and a 27-mm prosthesis for an aortic annulus of 25–27 mm (less than 27 mm). No obvious calcification was noted in the aortic valve or the annulus in a CT image. The informed consent was obtained. Hospital ethics committee approval was granted.

The TAVI procedure was performed in a hybrid suite under general anaesthesia by an interdisciplinary heart team. After general anaesthesia, both right femoral artery and vein were exposed and guide wires were placed as ‘safety lines’ for emergency CPB and angiogram access. Transoesophageal echocardiogram (TOE) was performed throughout the procedure. A temporary pacemaker was placed into the right ventricle through the right internal jugular vein and then the standard apical access was obtained. A bolus dose of 1 mg/kg heparin was administered intravenously. A pigtail
Figure 1: The J-Valve™ prosthesis (B) and Ausper-AS delivery system (A) used in this study. The J-Valve™ prosthesis is composed of a porcine aortic valve attached to a nitinol frame with three U-shaped graspers encircling it. A 27-F Ausper-AS delivery catheter is utilized for the three-step deployment process. (C) Graspers are totally released first and pulled back into coronary sinus. (Note that the graspers are completely separated from the valve frame.) (D) The valve prosthesis is then retrieved into the aortic sinus. (E) The valve prosthesis is then released without rapid ventricular pacing.

Figure 2: Intraoperative angiogram, TOE and perioperative CTA images of a patient with pure aortic regurgitation (AR) who underwent successful TAVI procedure using the J-Valve™ system. (A) Angiogram revealed a non-calcified aortic valve with obvious AR. (B) The delivery sheath was sent into the supra-annular plan through a transapical approach. (C and D) Three graspers were then totally released and pushed back gently into the aortic sinus, and further angiogram was performed to ensure the correct position of the graspers—note that three graspers were totally separated from the valve frame and were connected with each other through the Dacron cord. (E) The valve prosthesis was retrieved into the annular plan with the help of these graspers. (F) The valve prosthesis was deployed without rapid ventricular pacing. Angiogram confirmed good position of the valve prosthesis with no obvious paravalvular leakage. (G–J) Pre- and postoperative TOE as well as CTA image of this patient. Only trivial grade paravalvular leakage was noted after valve deployment, and CT angiogram image confirmed a good valve position.
A catheter was advanced into the ascending aorta through a 5-F femoral artery sheath. The apical puncture was done with a super-stiff guidewire placed into the descending aorta. In parallel, a J-Valve™ prosthesis was crimped into the 27-F Ausper-AS delivery system (JC Medical, Inc., Redwood City, CA, USA; Fig. 1A). The J-Valve™ prosthesis is composed of a porcine aortic valve attached to a nitinol frame with three U-shape graspers encircling the valve stent (Fig. 1B). The delivery system was bluntly inserted into the left ventricle and advanced under fluoroscopic guidance into a supra-annular position. Three ‘U-shaped’ graspers were then completely released first and carefully placed into the corresponding aortic sinus by gently pulling back the delivery system, thereby embracing the native leaflets. The angiogram was then performed to confirm that all the graspers were positioned correctly into the each aortic sinus. The valve was retrieved back gently into the annular plane with the guidance of the graspers and deployed without rapid ventricular pacing. After retrieval of the delivery system, aortic root angiography and TOE were done to evaluate valve position and function (Fig. 2 and Video 1). Patients were then sent to the intensive care unit after wound closure. Both the echocardiogram and the CT angiogram were carried out to evaluate valve position, function as well as the occurrence of paravalvular leakage during the postoperative and follow-up period.

The postoperative period was uneventful in all patients. No death and major complications such as device malposition and third-degree AV block were noted among the study cohort. Three 25-mm and four 27-mm J-Valve™ prostheses were used during the study period. The mean transvalvular gradient was 6.3 ± 2.7 mmHg after implantation. Paravalvular regurgitation immediately after implantation was graded none (n = 4) and trace (n = 3) that remained the same during the 30-day follow-up. No third-degree AV block was noted among the study cohort. Complete left bundle branch block was noted in 2 patients after surgery. All 7 patients were alive with improved exercise tolerance at 30-day follow-up.

**COMMENTS**

Non-calcified or pure AR has been generally considered as a relative contraindication for TAVI due to the risk of valve dislocation [1]. Although several reports have been published describing the off-label use of currently available first-generation transcatheter valve in patients with pure AR, these devices still have major limitations for pure AR because these valves were designed for implantation into calcified aortic valves through radial expansion at the annular plane [3,4].

In recent years, several second-generation devices such as Jena-Valve™ and Medtronic Engager Valve™ have been applied for high-risk patients with pure AR [5,6]. These devices are featured by unique anatomically oriented devices, which are designed to achieve ‘self-positioning’ of the valve stent and minimize the risk of coronary obstruction. The clip fixation between oriented devices and valve stent to the native valve leaflet could also provide extra-axial fixation force, which allows secure implantation even without leaflet calcifications. Several pilot studies have provided the initial experiences of using these devices in patients with pure AR and showed satisfactory initial outcome [5,6].

Compared with other type of second-generation TAVI devices, the J-Valve™ system is characterized by three uniquely designed, U-shaped graspers that can be totally released before the valve frame implantation (Figs 1 and 2). As for second-generation TAVI devices, during the deployment process, rather than directly judging the position of valve stent to aortic annulus, the key step is to ensure the correct position of the anatomically oriented device into the aortic sinus through angiogram images. The unique two-stage releasing design of J-Valve™ could then largely facilitate accurate positioning of the graspers before valve deployment. Meanwhile, the surgeon could also acquire the ‘force feed-back’ from these graspers through pulling back the delivery system to further ensure its correct positioning into the aortic sinus. The U-shaped grasper fits the native anatomy of the aortic sinus, which could minimize the risk of native leaflet perforation and maximize the interface between native valve leaflets and the prosthesis, then subsequently provide additional anchorage force (axial fixation). Our initial results have demonstrated that the J-Valve™ system has the potential to become a valuable treatment option for high-risk patients with pure AR.

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**REFERENCES**


