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# Transapical Transcatheter Aortic Valve Implantation Using a New TAVI System for High-Risk Patients with Severe Aortic Stenosis

Fei Xu, MB<sup>a,c,1</sup>, Yacine Elhmidi, MD<sup>b,1</sup>, Bengui Zhang, MB<sup>c</sup>,  
 Hong Tang, MD<sup>d</sup>, Da Zhu, MD<sup>c</sup>, Yucheng Chen, MD<sup>d</sup>,  
 Yingqiang Guo, MD<sup>c\*</sup>

<sup>a</sup>Shanghai Medical College, Fudan University, PR China

<sup>b</sup>Department of Cardiovascular Surgery, German Heart Center, Munich, Germany

<sup>c</sup>Department of Cardiovascular Surgery, West China Hospital, Sichuan University, Chengdu, Sichuan, PR China

<sup>d</sup>Department of Cardiology, West China Hospital, Sichuan University, Chengdu, Sichuan, PR China

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## Background

To evaluate the safety and efficacy of transcatheter aortic valve implantation (TAVI) for high-risk patients with aortic stenosis using the J-Valve system.

## Methods

30 high-risk patients with severe AS underwent TAVI procedure were enrolled with mean age  $74.5 \pm 4.5$  years and mean logistic Euro-SCORE-I of  $28.4 \pm 9.6\%$ . All patients were followed up for six months. Outcomes were analyzed in accordance with the updated standardised endpoints defined by the Valve Academic Research Consortium -2 (VRAC-2) criteria.

## Results

VARC-2 defined device success was obtained in 93% (28 of 30 patients). No operative mortality was noted. No major complications such as third-degree AV-block, myocardium infarction or cerebrovascular events were noted during procedure and follow-up. Transvalvular PG was decreased at six months compared with preoperative state (PG mean:  $55.4 \pm 14.9$  vs  $14.6 \pm 6.9$  mmHg  $p < 0.01$ ). No moderate or above degree PVL was noted. All patients with successful valve implantation were alive with improved exercise tolerance.

## Conclusions

Our initial result has demonstrated that the J-Valve system has the potential to become a feasible treatment option for high-risk patients with severe AS.

## Keywords

Transcatheter aortic valve implantation • Aortic stenosis • Second-generation device

## Introduction

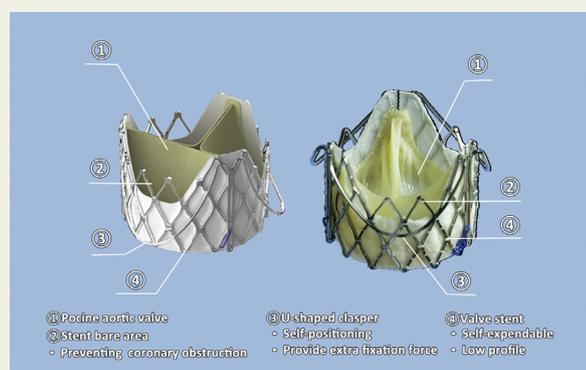
Transcatheter aortic valve implantation (TAVI) has been recognised as a minimally invasive treatment option for patients with high-risk symptomatic aortic stenosis (AS). The J-Valve system is a novel second generation TAVI device featuring a

porcine aortic prosthesis attaching to a self-expandable nitinol stent and three U-shape anatomically oriented devices – “claspers” encircling around the stent (Figure 1). This unique design could facilitate intuitive “self-positioning” valve implantation [1,2]. We report the initial results of TAVI in patients with severe AS using this unique TAVI system.

\*Corresponding author at: Chengdu, Sichuan, 610041, PR China. Fax: +86 028 85422493., Email: [drquoyq@hotmail.com](mailto:drquoyq@hotmail.com)

<sup>1</sup> Xu Fei and Yacine Elhmidi contributed equally to this article.

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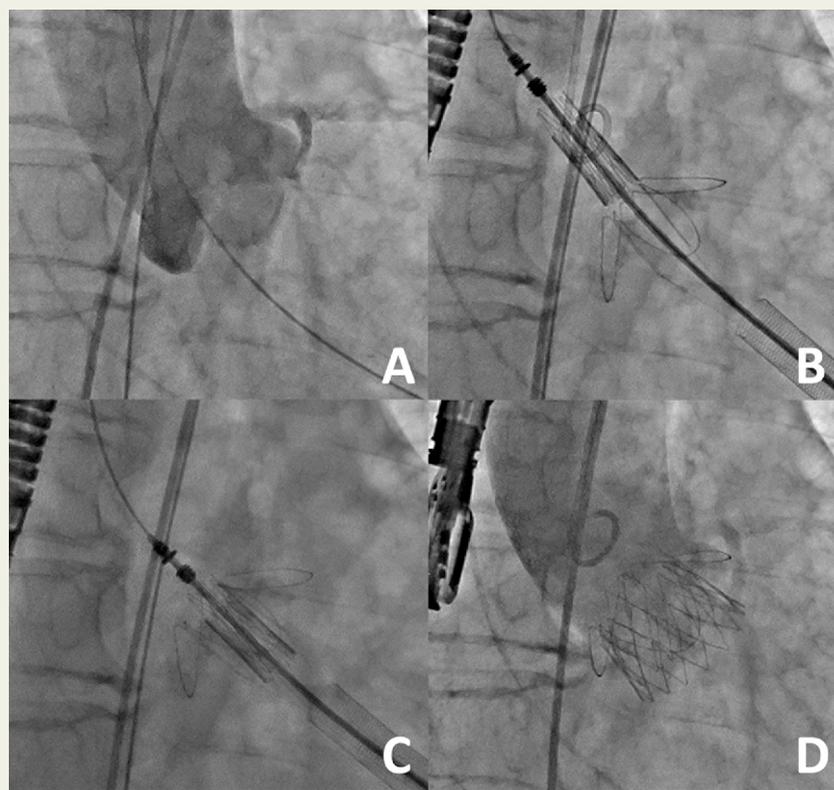


**Figure 1** Real and animation image of J-Valve. This valve is composed of a porcine aortic valve attached to a low-profile nitinol stent with three U-shape “claspers” encircling the valve stent. Design features and advantages of the J-Valve are shown in this figure.

## Study Method

Between March and December 2014, 30 high-risk patients with severe AS underwent TAVI procedure using the J-Valve system (mean age  $74.5 \pm 4.5$  years, including 14

females, with a mean logistic Euro-SCORE-I of  $28.4 \pm 9.6\%$ ). Significantly elevated transvalvular pressure gradient was noted in the echocardiograms with mean pressure gradient (PG)  $55.4 \pm 14.9$  mmHg and maximum PG  $92.4 \pm 23.9$  mmHg. The mean annular diameter (area derived) was  $24.2 \pm 2.2$  mm on CT angiogram. A patient with bicuspid aortic valve was precluded from the study. The TAVI procedure using J-Valve prosthesis was performed through a transapical approach (Figure 2). The procedure detail is described previously [1,2]. Briefly, the apical puncture was done and balloon-valvuloplasty of the native valve was performed under rapid pacing. The 27-F delivery system was bluntly inserted into the left ventricle and advanced into a supra-annular position. In stage one: Three ‘U-shaped’ clasps were then completely released and carefully placed into the corresponding aortic sinus thereby embracing the native leaflets. The angiogram was performed to confirm that all the clasps were positioned correctly into the each aortic sinus. In stage two: The valve was retrieved back gently into the annular plan with the guidance of the clasps and deployed without rapid ventricular pacing. Balloon-valvuloplasty was performed if elevated transvalvular gradients or significant paravalvular leakage (PVL) was noted. All patients were followed up for six months. Outcomes were analysed in accordance with



**Figure 2** Intraoperative fluoroscopy of valve implantation process. A–B: The delivery sheath was sent into the supra-annular plan, the clasper was fully released and pulled back gently into the aortic sinuses. C: The valve was retrieved into the annular plan. Panel D: The valve was fully deployed.

the updated standardised endpoints defined by the Valve Academic Research Consortium -2 (VARC-2) criteria.

## Procedure Outcome

One 21-mm, 9, 23 mm, 14, 25-mm and 6, 27-mm J-Valve™ prostheses were used. VARC-2 defined device success was obtained in 93% (28 of 30 patients). One patient was converted to open-heart surgery due to valve malposition. One patient was noted to have elevated AV gradient with peak velocity >3.0 m/s at follow-up (patient-prosthesis mismatch). No operative mortality was noted at follow-up. No major complications such as third-degree AV-block, myocardium infarction or cerebrovascular events were noted during procedure. A minor access site complication occurred in one patient due to intercostal bleeding. Transit stage-one renal dysfunction was noted in one patient. Concurrent percutaneous coronary intervention (PCI) was performed in two patients after the valve prosthesis was successfully deployed. Transvalvular PG was decreased at six months follow-up compared with preoperative state (PG mean:  $55.4 \pm 14.9$  vs  $14.6 \pm 6.9$  mmHg; PG max:  $92.4 \pm 23.9$  vs  $25.5 \pm 10.7$  mmHg,  $p < 0.01$ ). All patients with successful valve implantation were alive with improved exercise tolerance. No patient was noted to have moderate or above degree PVL during follow-up while 77% (23 of 30 patients) had none or trivial PVL.

## Discussion

The J-Valve system is a novel self-expandable prosthesis that features three U-shape “claspers” around the valve stent serving as an anatomically oriented device. In contrast to

the commercially available Jena-Valve (JenaValve Technology GmbH, Munich, Germany) with design of anatomical orientated devices [3], the J-Valve system has a unique two-stage releasing design. The clasper is operated separately from the valve frame before final deployment. This feature facilitates the optimal alignment between “clasper” and native aortic commissures and then subsequently ensures the optimal positioning of the valve stent even in difficult aortic anatomy such as horizontal aorta. The surgeon can acquire the ‘force feed-back’ from these claspers through pulling back the delivery system to further ensure correct positioning of the clasper into each aortic sinus. Meanwhile, due to the low stent profile design and native leaflet clip mechanism by the “clasper”, this device could also reduce radial expansion forces and provide better sealing to the native aortic annulus, therefore have a relatively low risk of high degree AV block as well as PVL, as shown in our study. Also, the risk of coronary obstruction due to leaflet calcification is also decreased. Our initial result has demonstrated that the J-Valve system has the potential to become a feasible treatment option for high-risk patients with severe AS.

## References

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