

One-year Outcome after Transcatheter Aortic Valve Replacement for Aortic Regurgitation: A Single-Center Study

Lulu Liu¹, Xiaoling Yao¹, Ying Peng¹, Weina Huang¹, Jun Shi¹, Hong Qian¹, Yilong Chen¹, and Yingqiang Guo¹

¹Sichuan University West China Hospital

September 24, 2021

Abstract

Background: Presently, there are limited reports in the literature on the post-operative (mid-term) clinical outcome for pure Aortic Regurgitation (AR) following Transcatheter Aortic Valve Replacement (TAVR). **Methods:** Between March 2014 and June 2019, a total of 134 high-risk patients with pure, symptomatic severe AR patients were enrolled in the current study. The outcome was assessed according to the VARC-2 criteria. Procedural results, clinical outcomes, and the patients' hemodynamics for a period of 1-year were analyzed. **Results:** Patient mean was 73.1 ± 6.4 years and 25.4% were female. The average STS score was $9.8 \pm 5.3\%$. Procedural success was 97.1% (130/134), and the device success rate was 96.3% (129/134). Five cases were converted to open surgery, while two patients underwent valvular reinterventions (surgical aortic valve replacement for thrombosis and increasing paravalvular regurgitation). The mean aortic valve gradient was 10.2 ± 4.1 mmHg, while the moderate and severe aortic regurgitation was 1.6% at 1 year. Paravalvular regurgitation was none/trivial in 79.8% and mild in 18.5%. The 1-year all-cause mortality rate was 7.4%. At 1-year, the stroke incidence rate was 2.2%. And pacemaker was implanted in 8.9% of the enrolled patients. **Conclusions:** In high-risk patients undergoing transapical-TAVR for AR, the use of the J-Valve is safe and effective TAVR should be considered as a reasonable option for high-risk patients with pure AR.

Introduction

Transcatheter aortic valve replacement (TAVR) has rapidly become a therapy for severe aortic stenosis (AS) in elderly patients^{1, 2}. There is a growing number of elderly patients with a high-risk profile suffering from aortic valve regurgitation (AR) and an abysmal poor prognosis with medical treatment³. However, there are still some challenges in treating AR with TAVR due to the increased risk of valve embolization, migration and paravalvular leakage (PVL) in the absence of aortic annular calcification. Despite surgical aortic valve replacement (SAVR) being the gold standard for treating AR¹, with an annual mortality rate of 10-20%^{4, 5}, a few elderly patients refuse surgical operations due to the involved surgical risk³.

The initial application of TAVR for AR using first-generation transcatheter heart valve (THV) showed high rates of procedural complications and low device success rates^{6, 7}. With the evolution of THV design, technical improvements were made to overcome the procedural challenges in treating AR. The J-Valve is a self-expanding, porcine aortic valve stitched within a nitinol frame. Novel features of the THV are its 2-piece structure, longitudinal anchoring mechanism, and automatic anatomical ability to reposition⁸. Previous research has demonstrated low mortality and stroke and excellent hemodynamics^{9, 10}.

In 2017, the clinical application of J-Valve was approved by the China Food and Drug Administration for AS and AR patients. TAVR treatment for AR has not yet been validated for a large-scale clinical application. Herein, we report our 1-year institutional experience with transapical TAVR using the J-Valve for the treatment of pure AR patients.

Methods

Study design and patient characteristics

The present case-series is a single-center, retrospective, observational study. The Biomedical Research Ethics Committee of West China Hospital of Sichuan University approved the present study. The study complied with the Declaration of Helsinki. This study was approved by the Biomedical Research Ethics Committee of West China Hospital of Sichuan University. All the patients enrolled were diagnosed to have severe pure AR by transthoracic echocardiographic (TTE). The echocardiography standard criteria were defined as pure AR. A vena contracta area (VCA) on echocardiographic images > 0.6 cm indicates severe AR¹¹. Patients with mixed valve disease or a peak aortic jet velocity of > 2.5 m/s were excluded from the study¹². The inclusion criteria for patients in the study were: (i) patients' age ≥ 60 with NYHA functional class of II-IV; and (ii) patients were assessed to have severe AR with an indication for TAVR by a multidisciplinary heart team. All patients signed written informed consent for prospective data acquisition and follow-up examinations.

Endpoints

The primary endpoint of the study was overall mortality at one and twelve months. Cardiac mortality and procedural results were also considered at the same time points. Device success and the clinical safety endpoint were evaluated and determined according to the Valve Academic Research Consortium-2 (VARC-2) criteria¹³. Other endpoints included device-related complications, and echocardiographic assessment of the valve and cardiac function at post-procedure. The severity of the PVL was qualitatively assessed and graded using TTE¹⁴.

Study device and TAVR Procedure.

Study device

The J-Valve is a self-expandable, porcine aortic valve stitched within a nitinol frame with 3 U-shape anatomically orientating clasps (Figure 1A). All procedures were performed with the patient under general anesthesia delivered via a transapical route. Details of the implantation procedure were previously reported⁹. The stent implantation was performed in two-stages during the procedure.

The graspers can be fully released and wholly seated in each sinus of the tricuspid aortic valve before valve deployment (Figure 1B), enabling correct valve fixation in a supra annular position. Precise positioning of the clasper can also be applied to the bicuspid aortic valve (BAV) (Figure 1C).

The valve's prosthesis is then retrieved into the aortic sinus and released without rapid ventricular pacing (Figure 1D). Five valve sizes were available during the study (21-, 23-, 25 -, 27- and 29-mm). The diameter was measured as the largest possible diameter during systole using the Multidetector computed tomography (MDCT) perimeter¹⁵.

Multidetector computed tomography (MDCT) perimeter-based diameters determined the choice of valve size (21 mm, 18 to 20.9 mm; 23 mm, 21 to 22.9 mm; 25 mm, 23 to 24.9 mm; 27 mm, 25 to 26.9 mm; and 29 mm, 27 to 29 mm). MDCT was performed on all of the patients both before and after the procedure (Figure 2).

Procedures

Aortic annulus, root, and valve morphology were assessed using both contrast-enhanced MDCT and transesophageal echocardiography (TEE). The THV severed to anatomically orient the position for optimal implantation along with the help of the clasper (Figure 3). Evaluations of valve function and quantification of residual aortic regurgitation after TAVR were performed by TEE and angiography (Figure 3, 4).

The procedure was performed in a hybrid operation room under general anesthesia while a full cardiopulmonary bypass circuit was on standby. A pigtail catheter was advanced into the ascending aorta via the right femoral artery and an aortogram was performed. TEE was used for the evaluation of the valve pathology. A temporary pacemaker was placed, and a 4 cm incision in the costal space at the heart's apex was made. Aortic root angiography was used to identify the aortic sinus and annulus. A J-Valve was crimped into the

Ausper-AS delivery system. The delivery system was inserted into the left ventricle through the apex and advanced into a supra-annular position under fluoroscopic guidance.

The three U-shaped anchor rings were ultimately deployed, pulled down and tactile feedback was checked to ensure that the three anchors were inside the aortic sinus (Figure 3A/E). Then aortic root angiography was reperformed. Next, the top part of the delivery system in which the valve was stored was retrieved back gently into the annular plan (Figure 3B/F) and deployed without rapid ventricular pacing (Figure 3 C/G). The aortic root angiography was used to monitor PVL (Figure 3D/H). The functionality was also confirmed via TEE.

Statistical analysis.

Continuous variables following normal distribution were presented as mean \pm standard deviations. Non-normally distributed variables were presented as median and range. Categorical variables were presented as counts and percentages. All data were analyzed with SPSS 23.0 statistical software (SPSS23, Chicago, IL, USA). A p -value of 0.05 was considered statistically significant. A 1-year Kaplan-Meier estimate of all-cause mortality was calculated for patients.

Results:

Baseline characteristics

A total number of 134 patients with severe AR were enrolled. The Mean age was 73.1 \pm 6.4 years and 25.4% were female (Table 1). The mean risk score according to the Society of Thoracic Surgeons (STS) was 9.8 \pm 5.3%, while 131 patients (97.8%) were in New York Heart Association (NYHA) functional class III or IV. Four patients had previous cardiac surgery. Five patients had undergone a previous permanent pacemaker. In the present study, morbidity rates were higher for chronic lung disease (n=73, 54.5%), peripheral vascular disease (n=64, 47.8%), and cerebrovascular diseases (n=67, 50.0%).

Procedural characteristics and prosthesis sizing.

The procedure was successful in 97.1% (130/134) and device success was 96.3% (129/134). Four patients were converted to open-heart procedures during the operation (one coronary obstruction, two valvular embolisms, and one valve migration) (Table 2). We updated our protocol in subsequent cases to prevent this complication, including a mandatory repeat of root angiography from confirming the clasper's position and configuration after deployment. There was no valve dislodgements after that update. In one patient that mismatch led to moderate PVL and cardiac insufficiency six days after the operation.

The mean aortic annular diameter was 24.9 \pm 2.7 mm, resulting in a median prosthesis oversizing by area of 6.4%. The 21-mm, 23-mm, 25-mm, 27-mm, and the 29-mm prosthesis valves were implanted in 2.2%, 10.4%, 23.1%, 41.0%, and 23.1%, respectively in the enrolled patients. Deformation dynamics of the aortic valve annulus in different valve pathologies may vary in different forms of AS. Caution should be used during annular sizing in patients undergoing TAVR. The new permanent pacemaker implantation (PPMI) rate was 7.4%. Myocardial infarction, cerebrovascular events, coronary obstruction requiring intervention, life-threatening bleeding and endocarditis were not observed. The median time of stay in the intensive care unit was one (1-1) day. The average postoperative hospital stay was six (5-8) days.

Echocardiographic outcomes and Functional status.

Echocardiographic assessments of the heart function at baseline and follow-up are shown in Table 3. The mean gradient pressure remained stable at one month, six months and twelve months (8.2 \pm 3.2 mmHg, 9.6 \pm 5.3 mmHg and 10.2 \pm 4.1 mmHg, respectively). The aortic valve peak velocity was 1.9 \pm 0.3 m/s at one month, 2.1 \pm 0.4 m/s at six months and 2.2 \pm 0.5 m/s at one year. Interestingly, 79.8% had no or only traced PVL, 18.5% had mild PVL, while two patients had moderate or severe PVL at twelve months.

Significant changes were observed in echocardiographic parameters such as: left ventricular end diastolic dimension (LVEDD), left ventricular end systolic dimension (LVESD), and left ventricular end-diastolic

volume (LVEDV). However left ventricle ejection fraction (LVEF) increased significantly after twelve months compared to baseline. The LVEF was 52.1±12.8% at baseline and it increased to 57.3±11.4% at the twelve months follow-up (Figure 5).

Clinical outcomes and 1-year Follow-Up.

Clinical outcomes at 30 days and 1-year follow-up are shown in Table 4. No patient was missing in the present study. The 30-day all-cause mortality rate was 2.9%, and no major stroke occurred in any patient. In these patients, 1-year all-cause mortality was 7.4% (Figure 5). Landmark analysis demonstrated that the most mortality occurred after 30 days of the procedure (Figure 6). Three patients had a stroke, resulting in a 1-year stroke rate of 2.2%, where two patients died. One patient had a type-A aortic dissection at six months follow-up, while one patient underwent reoperation due to prosthetic valve thrombosis at seven months postoperatively, although the latter refused further surgical treatment. New PPMI was required in twelve patients (8.9%).

Discussion

We report 1-year outcomes from a single-center experience evaluating the J-Valvefor TA-TAVR in patients with AR. The key findings include 7.4% and 2.2% 1-year mortality and stroke rate, respectively. Echocardiographic measurements confirmed adequate hemodynamic function with a significant improvement in LVEF, a reduction in LVEDD, LVESD, a low rate of residual leakage after TAVR, and excellent aortic valve hemodynamics, with low mean gradients of 8.2±3.2 mmHg maintained to 1-year follow-up.

Procedural Outcomes

Several observational studies show that TAVR is a viable option for patients with pure AR^{6, 7, 16, 17}. It is well known that the first-generation THV primarily relying on calcification of the native leaflets for sufficient anchoring of the expanded prosthesis. Patients with AR have more complex and variable anatomy, and the lack of calcification may lead to inaccurate positioning and difficulty of anchoring, or even worse, valve embolization or residual PVL¹⁸. TAVR using the new-generation devices was associated with improved procedural outcomes in treating patients with AR^{19, 20}. Importantly, with the second-generation valves and advanced technique J-Valve has even been certified in the indication AR. With a novel fixation mechanism associated with a significantly higher procedural success rate, these devices are a reasonable option in AR patients^{21, 22}. In the present study, the device's success is consistent with previous reports of the same valve in patients with AS²³.

The device's success was 96.3%, which corresponds to the J-Valve's initially reported experience for AR treatment, which was 97.6%⁹. A recent meta-analysis has reported that, based on nineteen studies, with a total number of 988 patients, the rate of devices success was 86.2% (78.8%-92.2%)²⁴. Our study demonstrated a higher success rate and a lower mortality rate than the studies mentioned above, indicating a novel device's viable safety profile. However, there was no difference in the device success rate between both devices [J-valve and JeneValve (96.3% vs. 96.8%)]¹⁶.

The feelers in JenaValve have a rigid connection with the support frames and J-valve with mobile nitinol graspers, which are both designed to be placed into the sinus of the aortic root to achieve an anatomically correct position. The unique design make it possible to ensure the optimal positioning of the valve stent after deployment.

Mortality and Stroke

In the present study, the low 1-year mortality rate of 7.4% was consistent with the 1-year rate of 4.7% in forty-three high-risk patients from the China Trial⁹ and a 5.5% mortality of TA-TAVR procedures in Germany in 2014²⁵. The 1-year mortality rates reported with the J-Valve device are lower than the first-generation reported in other studies, namely the CoreValve, 31% in 26 high-risk patients⁷ and 21.4% in the other CoreValve study (n=43)⁶. Silaschi et al reported transapical TAVR with higher a 1-year mortality rate (20.1%) than that the present study²⁶. The initial German experience 6-month mortality was 19.3% with

JeneValve for the treatment of AR¹⁶. Compare to AS, although AR is younger and lower mean STS score, however the mortality was no differences²⁷. These differences suggest differing pathophysiology of the larger left ventricle and the lower LVEF after treatment of AR is quantitatively and qualitatively different from AS²⁸. Notably, a recent meta-analysis of AR patients who underwent TAVR showed that the one-year mortality is 25%²⁴.

The incidence of disabling stroke at 1-year (2.2%) in the present study was consistent with the 2.3% reported in the China clinical Trial⁹. At 1-year, stroke was 4.7% in CoreValve experience and 3.3%⁷ in JeneValve of the JUPITER registry²⁶, which was slightly higher than the present study. However, stroke is uncommon in TAVR treatment for AR. Mainly due to a lack of valve calcification and the simplicity and reliability of the THV implantation in patients.

Hemodynamics.

In the present study, the low mean aortic valve gradient of 8.2+-3.2 at 30-day, 10.2+-4.1 mmHg at 1-year is consistent with previous reports of the same valve⁹. The study result is similar to the 1-month mean valve gradients of other valves (7.9+-4.0 mmHg and 7.7+-5.1 mmHg reported with the Jenevalve⁶ and Direct Flow Medical valve²⁹), although the results provided little information on the effects of the stent on AR hemodynamics. All patients had mild or less PVL at 1-year in the study, with no patients having moderate or severe PVL. These results compare favorably to a recent study that residual moderate or severe aortic regurgitation rate after the procedure was high as 9.2% in other studies²⁴. Several characteristics include enhanced positioning accuracy, controlled and anatomically correct implantation and improved sealing even in eccentric annular calcifications. The low rates of moderate to severe PVL might be a contributing factor in low all-cause mortality rate at 1-year. However, with the low mortality rate at 1-year compared to patients with AS, patients with AR were younger and faced the risk of bioprosthetic valve deterioration and the need for reintervention.

Pacemakers

In the first year, a PPM was implanted in 8.9% of patients. Ten patients received PPM at 30-day, although it was lower than reported with the self-expanding CoreValve^{6, 7} and higher than reported from the JeneValve registry^{16, 26}. AR usually have a larger annulus and lack calcification. These reasons may have contributed to require a deeper depth of implantation and larger size of prosthesis. There is some evidence that THV deeper position in the LVOT is independently associated with a higher PPMI rate and the larger prosthesis size, valve oversizing is also relevant to risk factors for pacemakers³⁰.

Study limitations: Data were obtained in a non-randomized fashion, with the lack of comparative arms of patients with severe AR treated by surgery or medical therapy alone. Also, the sample size was relatively small, and the results were single-center collected, potentially introducing selection bias.

This single-center study reported the outcomes of TAVR in treating pure AR. Our results have demonstrated a favorable 1-year survival rate and symptomatic relieving benefits of TAVR in AR patients.

Conclusion

The 1-year results of the single-center study support the safety and effectiveness of the J-Valve^(r) in treating the elderly, high-risk patients with severe AR. Low all-cause mortality, major stroke and no moderate and severe PVL were observed. J-Valve has the advantages of self-position and anatomically correct implantation. However, the rate of PPMI was slightly high. More clinical studies and longer-term follow-up are needed to validate these promising findings further.

Abbreviations

AR: Aortic regurgitation; AS: Aortic stenosis; BAV: Bicuspid aortic valve; LVEF: Left ventricle ejection fraction; LVEDD: Left ventricular end diastolic Dimension; LVESD: Left ventricular end systolic dimension; LVEDV: Left ventricular end-diastolic volume; LVESV: Left ventricular end-systolic volume; MDCT:

multidetector computed tomography; PPMI: permanent pacemaker implantation; PVL: Paravalvular leakage; SAVR: Surgical aortic valve replacement ; TAVR: Transcatheter Aortic Valve Replacement; THV: Transcatheter heart valve; TTE: transthoracic echocardiographic; TEE: transesophageal echocardiography; VCA: Vena contracta area; VARC: Valve Academic Research Consortium;

Acknowledgements

None.

Ethics approval and consent to participate

The authors assert that all procedures contributing to this work comply with the ethical standards of China and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the Ethics Committee of West China Hospital.

Authors' contributions

LLL and YXL collected clinical materials of these patients, participated in the design of the study and performed the statistical analysis, and drafted the manuscript. PY, HWN, QH, SJ and CYL participated in the study design, data analysis and study coordination. GYQ participated in the design of the study and supervised the trial process. All authors read and approved the final manuscript.

Funding

This study was funded by 1*3*5 project for disciplines of excellence—Clinical Research Incubation Project, West China Hospital, Sichuan University (2017306) which mainly helped with the design of the study and the data collection.

Availability of data and materials

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J*. 2017;38:2739-2791.
2. Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;135:e1159-e1195.
3. Iung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J*. 2003;24:1231-1243.
4. Dujardin KS, Enriquez-Sarano M, Schaff HV, Bailey KR, Seward JB, Tajik AJ. Mortality and morbidity of aortic regurgitation in clinical practice. A long-term follow-up study. *Circulation*. 1999;99:1851-1857.

5. Tarasoutchi F, Grinberg M, Spina GS, et al. Ten-year clinical laboratory follow-up after application of a symptom-based therapeutic strategy to patients with severe chronic aortic regurgitation of predominant rheumatic etiology. *J Am Coll Cardiol*. 2003;41:1316-1324.
6. Roy DA, Schaefer U, Guetta V, et al. Transcatheter aortic valve implantation for pure severe native aortic valve regurgitation. *J Am Coll Cardiol*. 2013;61:1577-1584.
7. Testa L, Latib A, Rossi ML, et al. CoreValve implantation for severe aortic regurgitation: a multicentre registry. *EuroIntervention*. 2014;10:739-745.
8. Zhu D, Chen Y, Zhang J, Hu J, Guo Y. Transapical implantation of a new second-generation transcatheter heart valve in patients with pure aortic regurgitation: a preliminary report. *Interact Cardiovasc Thorac Surg*. 2015;20:860-862.
9. Liu H, Yang Y, Wang W, et al. Transapical transcatheter aortic valve replacement for aortic regurgitation with a second-generation heart valve. *J Thorac Cardiovasc Surg*. 2018;156:106-116.
10. L L, J Z, Y P, et al. Learning curve for transcatheter aortic valve replacement for native aortic regurgitation: Safety and technical performance study. *Clinical cardiology*. 2020;43:475-482.
11. Zoghbi WA, Enriquez-Sarano M, Foster E, et al. Recommendations for evaluation of the severity of native valvular regurgitation with two-dimensional and Doppler echocardiography. *Journal of the American Society of Echocardiography : official publication of the American Society of Echocardiography*. 2003;16:777-802.
12. Baumgartner H, Hung J, Bermejo J, et al. Echocardiographic assessment of valve stenosis: EAE/ASE recommendations for clinical practice. *Journal of the American Society of Echocardiography : official publication of the American Society of Echocardiography*. 2009;22:1-23; quiz 101-102.
13. Kappetein AP, Head SJ, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *Eur Heart J*. 2012;33:2403-2418.
14. Zoghbi WA, Adams D, Bonow RO, et al. Recommendations for Noninvasive Evaluation of Native Valvular Regurgitation: A Report from the American Society of Echocardiography Developed in Collaboration with the Society for Cardiovascular Magnetic Resonance. *Journal of the American Society of Echocardiography : official publication of the American Society of Echocardiography*. 2017;30:303-371.
15. Zhu D, Chen W, Peng L, Guo Y. Valve sizing for pure aortic regurgitation during transcatheter aortic valve replacement: deformation dynamic of the aortic annulus in different valve pathology may be different. *JACC Cardiovasc Interv*. 2015;8:372-373.
16. Seiffert M, Bader R, Kappert U, et al. Initial German experience with transapical implantation of a second-generation transcatheter heart valve for the treatment of aortic regurgitation. *JACC Cardiovasc Interv*. 2014;7:1168-1174.
17. Kiefer P, Seeburger J, Mohr FW, Holzhey DM. Transcatheter aortic valve replacement for isolated aortic valve insufficiency: experience with the Engager valve. *J Thorac Cardiovasc Surg*. 2014;147:e37-38.
18. Webb JG, Sathananthan J. Transcatheter Aortic Valve Replacement for Pure Noncalcific Aortic Regurgitation Is Coming, But Not Yet Primetime. *JACC Cardiovasc Interv*. 2016;9:2318-2319.
19. Sawaya FJ, Deutsch MA, Seiffert M, et al. Safety and Efficacy of Transcatheter Aortic Valve Replacement in the Treatment of Pure Aortic Regurgitation in Native Valves and Failing Surgical Bioprostheses: Results From an International Registry Study. *JACC Cardiovasc Interv*. 2017;10:1048-1056.
20. Yoon S-H, Schmidt T, Bleiziffer S, et al. Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation. *Journal of the American College of Cardiology*. 2017;70:2752-2763.

21. Spina R, Anthony C, Muller DW, Roy D. Transcatheter Aortic Valve Replacement for Native Aortic Valve Regurgitation. *Interventional cardiology (London, England)*. 2015;10:49-54.
22. B W, S E, EP N, et al. Transcatheter aortic valve replacement for pure aortic valve regurgitation: "on-label" versus "off-label" use of TAVR devices. *Clinical research in cardiology : official journal of the German Cardiac Society*. 2019;108:921-930.
23. Luo X, Wang X, Li X, et al. Transapical transcatheter aortic valve implantation using the J-Valve system: A 1-year follow-up study. *J Thorac Cardiovasc Surg*. 2017;154:46-55.
24. Rawasia WF, Khan MS, Usman MS, et al. Safety and efficacy of transcatheter aortic valve replacement for native aortic valve regurgitation: A systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2019;93:345-353.
25. Beckmann A, Funkat AK, Lewandowski J, et al. Cardiac Surgery in Germany during 2014: A Report on Behalf of the German Society for Thoracic and Cardiovascular Surgery. *Thorac Cardiovasc Surg*. 2015;63:e1.
26. M S, L C, O W, et al. The JUPITER registry: One-year outcomes of transapical aortic valve implantation using a second generation transcatheter heart valve for aortic regurgitation. *Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions*. 2018;91:1345-1351.
27. A C, V R, S A, J I, T D. Aortic valve replacement: a safe and durable option in patients with impaired left ventricular systolic function. *European journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery*. 2006;29:133-138.
28. Pai RG, Varadarajan P. Prognostic implications of mitral regurgitation in patients with severe aortic regurgitation. *Circulation*. 2010;122:S43-47.
29. Schofer J, Nietlispach F, Bijuklic K, et al. Transfemoral Implantation of a Fully Repositionable and Retrievable Transcatheter Valve for Noncalcified Pure Aortic Regurgitation. *JACC Cardiovasc Interv*. 2015;8:1842-1849.
30. Fadahunsi OO, Olowoyeye A, Ukaigwe A, et al. Incidence, Predictors, and Outcomes of Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement: Analysis From the U.S. Society of Thoracic Surgeons/American College of Cardiology TVT Registry. *JACC Cardiovasc Interv*. 2016;9:2189-2199.

Figure Legends:

Figure 1. A. The J-Valve prosthesis is constructed from a porcine aortic root (black arrow) mounted and sutured on a two-part self-expanding Nitinol stent frame. The support frame and three anchor rings (asterisk) are connected with three anchor connectors (blue arrow), resulting in an adjustable connection. B. Each anchor ring is wholly seated in each sinus of the Tricuspid aortic valve (TAV). C. Two anchor rings can be completely seated in the same sinus of the Bicuspid aortic valve (BAV). D. Placement of the stent valve at the position of the native aortic annulus, clip and attach the native aortic valve leaflets to the device and release of the stent.

Figure 2. Preoperative and postoperative aortic valve morphology. Multiplanar reconstruction of baseline computed tomography in axial views and coronal views at the Valsalva level (A, B, C) and corresponding reconstruction of the aortic root after THV implantation (D, E, F).

Figure 3. The procedure of implantation. (A/E). The delivery catheter is advanced through the native valve into the ascending aorta and verifies the anchor ring is above the native leaflets. (B/F). The positioning anchors are released and the seating of anchor rings in each sinus was checked using tactile feedback. (C/G). Placing the valve at the native aortic annulus position, clipping and attaching the native aortic valve leaflets to the device, and releasing the stent (D/H). Aortography is performed to assess valve function.

Figure 4. Echocardiographic Valve Performance. Echocardiographic evaluation depicting severe noncalcified central AR before transcatheter aortic valve implantation (A, B). Color Doppler was confirming the optimal function of the implanted J-Valve transcatheter heart valve. No paravalvular leaks were detected (C, D).

Figure 5. Changes in PGmean and AV over time (A), LVEDD and LVESD over time (B), Changes in LVEF over time (C) 1-Year Follow-Up points.

Figure 6. Kaplan–Meier survival curve of TAVR in patients with symptomatic severe aortic regurgitation 1-Year Follow-Up.

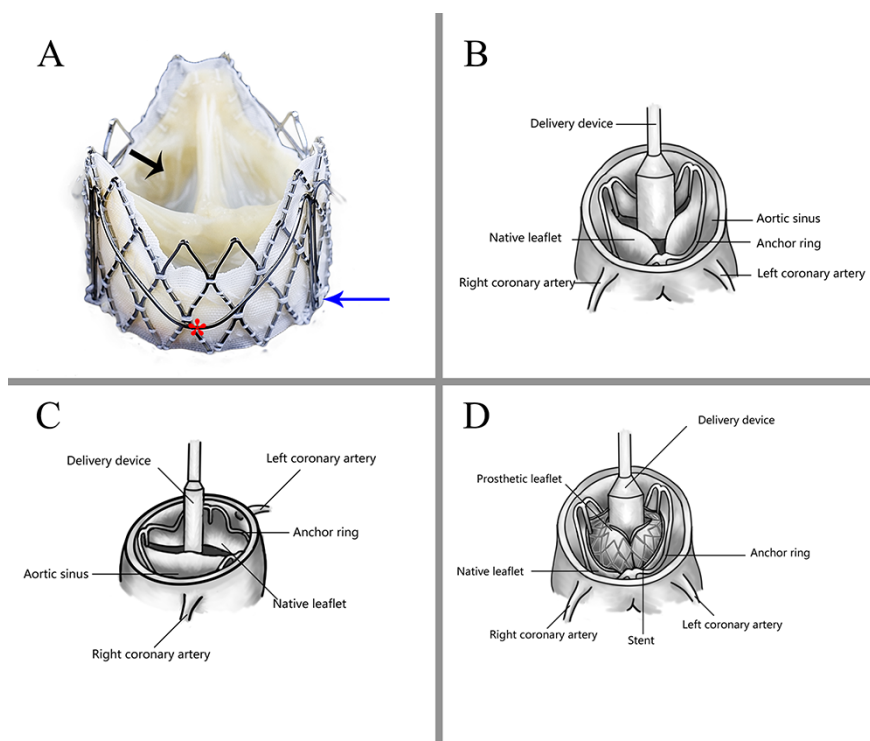
Tables Legends:

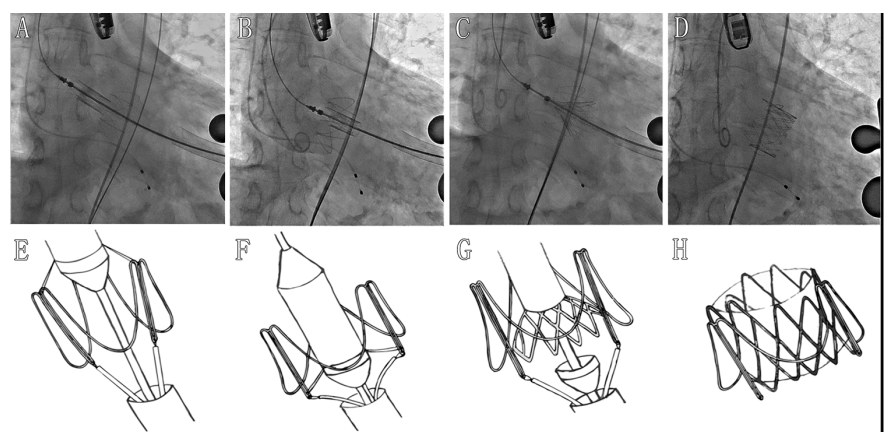
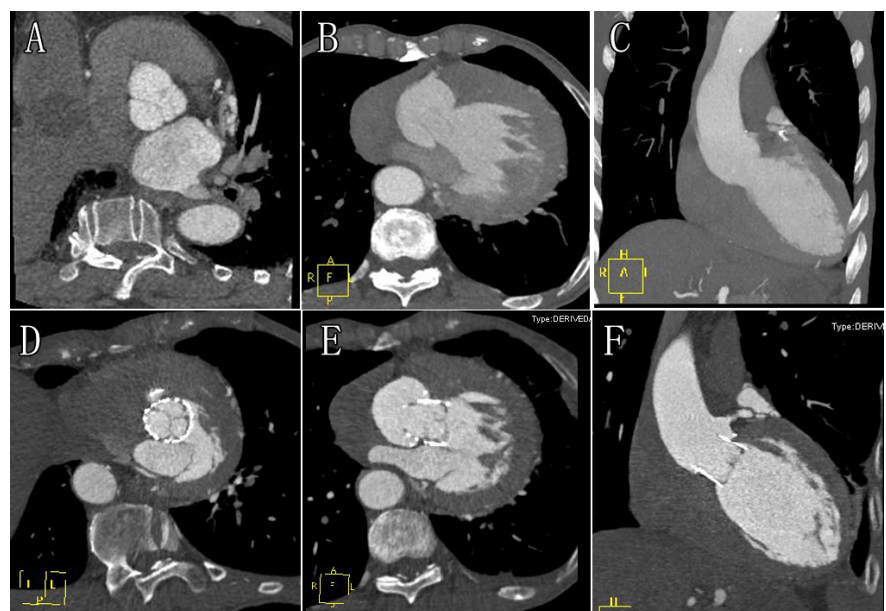
Table 1. Values were presented as mean \pm SD or percentage (%).SD, Standard deviation; NYHA = New York Heart Association; EuroSCORE II =European System for Cardiac Operative Risk Evaluation II; PPMI= permanent pacemaker implantation; PCI = Previous percutaneous coronary intervention; CABG= Coronary artery bypass surgery; LVEF = Left ventricle ejection fraction; LVEDD= Left ventricular end diastolic Dimension; LVESD = Left ventricular end systolic dimension; LVEDV = Left ventricular end-diastolic volume; LVESV= Left ventricular end-systolic volume; STS-PROM= The Society of Thoracic Surgeons–Predicted Risk of Mortality; AV = aortic valve; TAV= Tricuspid aortic valve; BAV = Bicuspid Aortic Valve.

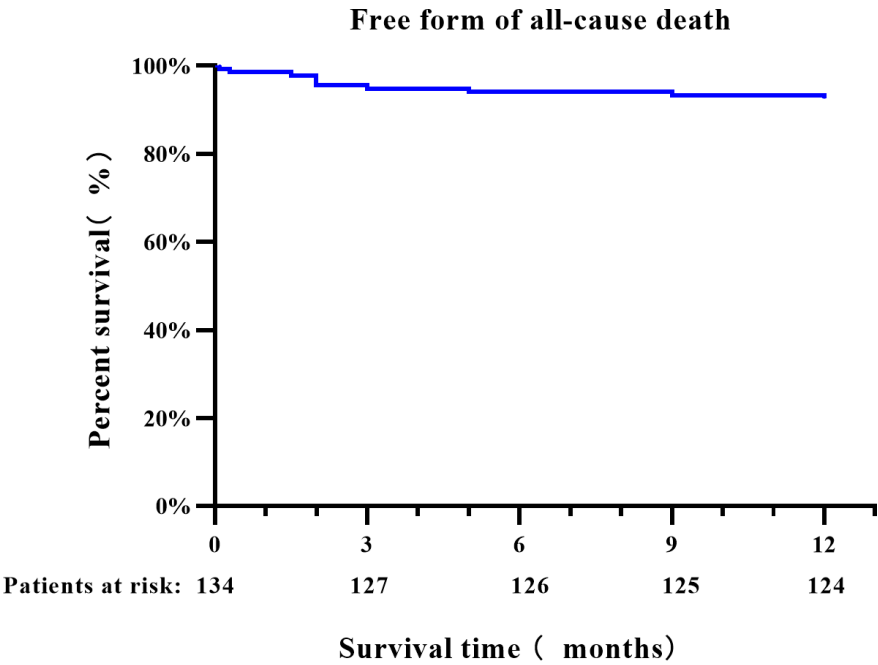
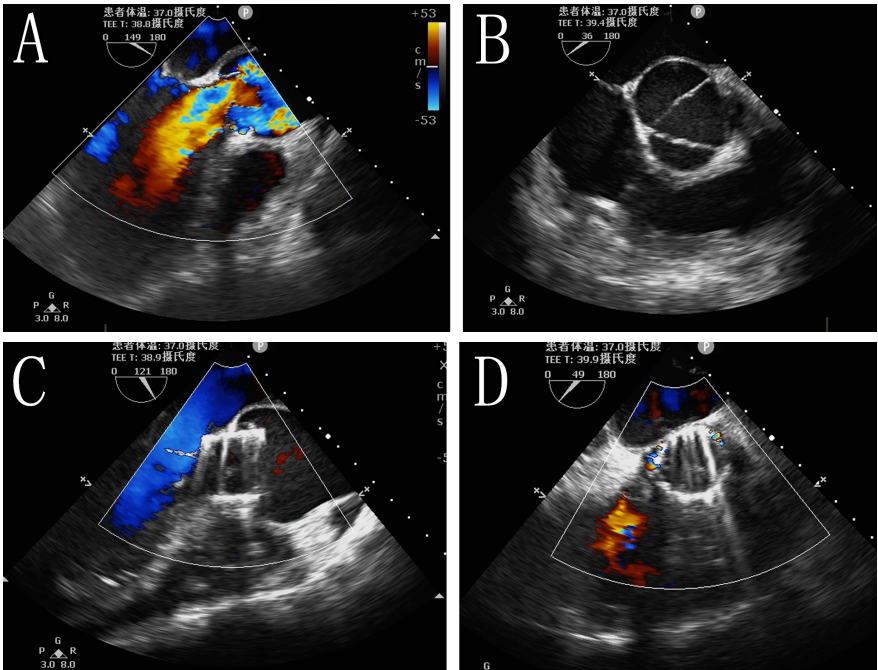
Table 2. Values are mean n (%), or mean \pm SD. SD, Standard deviation; THV= transcatheter heart valve; AVR= Aortic valve replacement; PCI= Percutaneous coronary intervention.

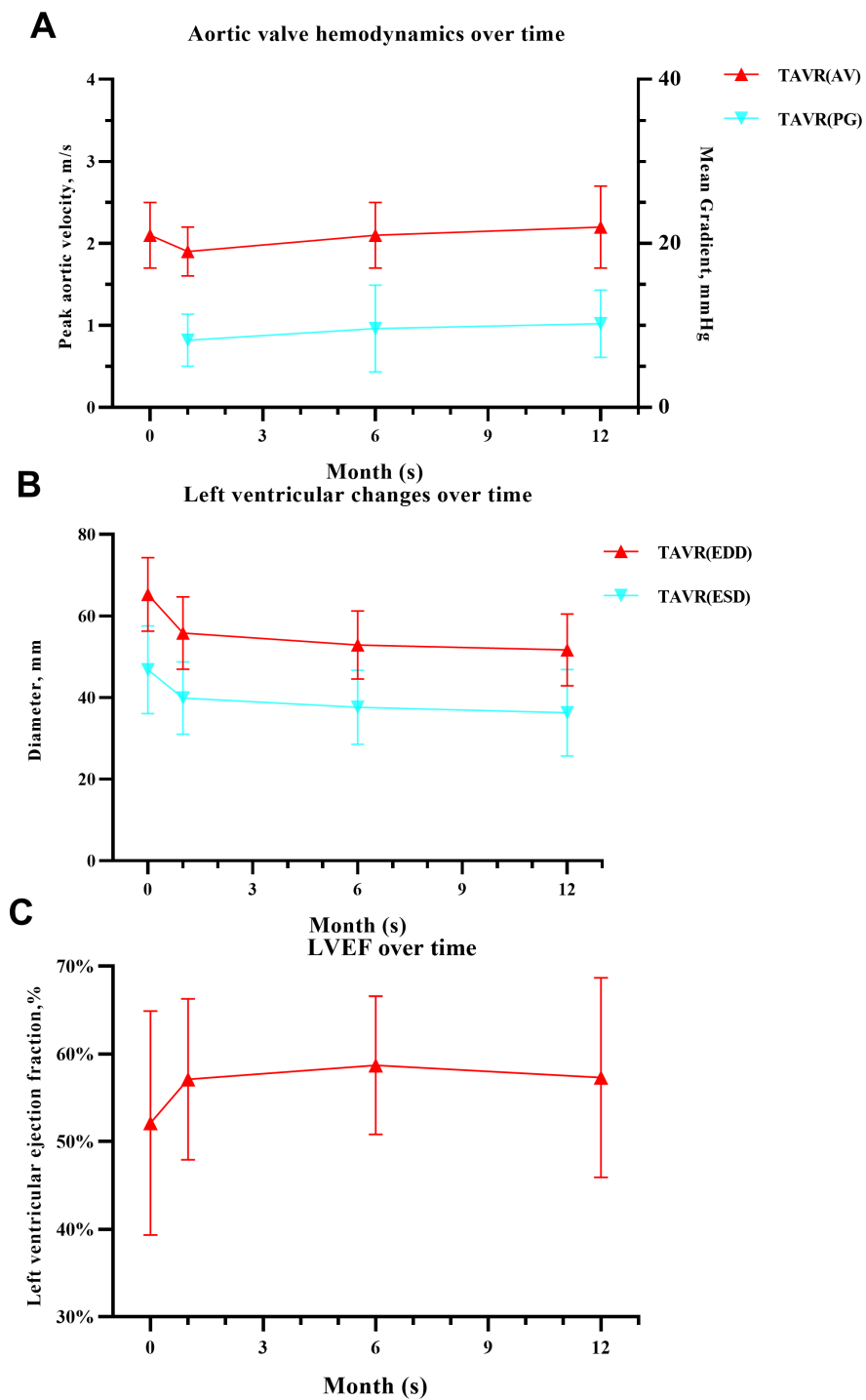
Table 3. Values were presented as mean percentage (%), or mean \pm SD. SD, Standard deviation; NYHA = New York Heart Association; LVEF = Left ventricle ejection fraction; LVEDD= Left ventricular end diastolic Dimension.

Table 4. Values are mean n (%), or mean \pm SD. SD, Standard deviation.









Hosted file

Tables.docx available at <https://authorea.com/users/364028/articles/538396-one-year-outcome-after-transcatheter-aortic-valve-replacement-for-aortic-regurgitation-a-single-center-study>