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Original Article

Preliminary Study of a Degenerated Tricuspid Bioprosthetic Valve Implanted via Transcatheter Valve-in-Valve Implantation Guided by 3-Dimensional Printing

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ABSTRACT

Background: The procedures of transcatheter tricuspid valve-in-valve (TTViV) replacement are challenging, and the clinical outcomes are still unclear. Our goal was to report the short- and mid-term clinical outcomes of patients who underwent a TTViV implantation guided by 3-dimensional (3D) printing.

Methods: A retrospective analysis was performed on 6 patients who had TTViV implantation from May 2021 to March 2022. The median age was 51 years (range: 18-71 years), and 50.0% of the patients were male. Imaging assessments and 3D printing were performed on all 6 patients before the procedures. The perioperative data were evaluated, and the patients were followed up.

Results: Among the 6 patients, the etiologies of conditions affecting the tricuspid valves at baseline varied widely, including 1 case of Ebstein anomaly, 2 cases of infective endocarditis, 1 case of ventricular septal defect, and 2 cases of rheumatic heart disease. TTViV implantation was successfully performed in all 6 patients via the femoral vein approach; postoperative tricuspid regurgitation disappeared

RÉSUMÉ

Contexte : Les interventions de remplacement par cathéter de la valve tricuspide avec la technique dite « valve-in-valve » (TTViV) sont délicates, et les résultats cliniques sont encore peu clairs. Notre objectif était de rapporter les résultats cliniques à court et à moyen terme obtenus chez des patients ayant subi une implantation TTViV guidée par l'impression en trois dimensions (3D).

Méthodologie : Une analyse rétrospective portant sur six patients ayant subi une implantation TTViV entre mai 2021 et mars 2022 a été réalisée. L'âge médian était de 51 ans (min.-max. : 18-71 ans), et 50,0 % des patients étaient des hommes. Des examens d'imagerie et des impressions 3D ont été effectués avant l'intervention pour chacun des six patients. Les données périopératoires ont été analysées, et les patients ont fait l'objet d'un suivi.

Résultats : Les affections initiales touchant la valve tricuspide chez les six patients avaient des causes variables, soit un cas de maladie d'Ebstein, deux cas d'endocardite infectieuse, un cas de défaut de communication interventriculaire, et deux cas de cardiopathie

Most tricuspid valve (TV)-related diseases involve tricuspid regurgitation (TR), and they are usually secondary conditions. Studies have shown that the prevalence of ≥ moderate TR is 0.55%; the prevalence in patients aged > 75 years is nearly 4%.[1] The clinical treatment of patients with TV disease is most frequently surgical repair, but for patients with complex TR or severe tricuspid stenosis (TS), surgical TV replacement is the preferred treatment. Studies have found that mechanical valves and biological valves have the same short- and long-term effects postoperatively.[2] However, biological valves are favoured because of the high risk of thrombosis caused by mechanical valves.[3] Bioprosthesis degeneration after surgical TV replacement is a possibility, and the durability is approximately 10-15 years, which manifests as TR or TS.[4] The reported failure rate (TR or TS) of bioprostheses requiring reoperations ranged from 10% to 22% during the follow-up period.[5-9] These rates are even higher in patients with Ebstein anomaly, with a reoperation rate of 18%-26% within 10 years.[5,10,11] In patients with degenerated bioprostheses, surgical TV replacement is still a major intervention.[12] Despite improvements in myocardial protection and postoperative care, morbidity and mortality rates are still high, especially in the presence of right ventricular (RV) dysfunction.[13-15] With the development of minimally invasive treatments, transcatheter tricuspid valve-in-valve (ViV) implants have become a possible option for these patients, providing new treatment approaches for patients who have degenerated tricuspid bioprostheses.[16-19] However, studies supporting their efficacy have thus far been limited to a few

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immediately, and the hemodynamic results were satisfactory. During the follow-up, all patients had significant improvement in symptoms and functional status.

Conclusions: TTViV implantation for the treatment of degenerated tricuspid bioprostheses should be considered safe and effective. Multimodal imaging and 3D printing may provide effective guidance for conducting the procedure.

Clinical Trial Registration: ClinicalTrials.gov Protocol Registration System (NCT02917980).

rhumatismale. Une implantation TTViV a été réalisée chez les six patients, par cathétérisme fémoral. La régurgitation tricuspide postopératoire a disparu immédiatement et les résultats hémodynamiques étaient satisfaisants. Durant le suivi, tous les patients ont obtenu une amélioration significative de leurs symptômes et de leur état fonctionnel.

Conclusions : L'implantation TTViV pour le traitement d'une bioprothèse tricuspide dégénérée devrait être considérée comme sûre et efficace. L'imagerie multimodale et l'impression 3D peuvent fournir des directives efficaces pour la réalisation de l'intervention.

Enregistrement des essais cliniques : ClinicalTrials.gov Protocol Registration System (NCT02917980).

case reports or small-scale case series because the procedures are challenging .[20-25] In this study, with the guidance of multimodal imaging and 3-dimensional (3D) printing, 6 patients with degenerated tricuspid bioprostheses were treated with transcatheter tricuspid ViV implantation via a femoral vein approach and completed a 1-year follow-up for evaluation.

Materials and Methods

Baseline characteristics and data collection

A retrospective analysis was performed on 6 patients who underwent transcatheter tricuspid ViV implantation in Xijing Hospital from May 2021 to March 2022. The median age was 51 years (range: 18-71 years), and 50.0% were male. Inclusion criteria were as follows: (i) patients with severe TR after surgical TV replacement; (ii) multidisciplinary assessment of the risk of surgical TV replacement in high-risk patients (Society of Thoracic Surgeons score $\geq$ 8%); (iii) left ventricular ejection fraction $\geq$ 50%; and (iv) New York Heart Association (NYHA) functional class $\geq$ III. Exclusion criteria included the following: (i) pulmonary hypertension [systolic pulmonary artery pressure $>$ 60 mm Hg (1 mm Hg = 0.133 kPa)]; (ii) a distance from the center of the tricuspid annulus (TA) to the RV wall $<$ 50 mm; (iii) contraindications for cardiac catheterization (coagulation dysfunction; an acute infection; heart failure or cardiac insufficiency; pneumonia or pneumonia complicated with pulmonary edema; and liver and kidney insufficiency). The clinical trial was registered in the ClinicalTrials.gov Protocol Registration System (NCT02917980), and all patients signed informed consent forms.

Preoperative imaging evaluation

Preoperative transthoracic echocardiography was used to measure the length of the aortic valve, the mitral valve, and the TV, the end-diastolic volume, and the end-systolic volume of the left ventricle (LV), left ventricular ejection fraction, and fractional shortening. Furthermore, computed tomography angiography (CTA) was used preoperatively to measure the anatomic structures of the right heart (TA maximum diameter, TA minimum diameter, and TA area) using CVI42 cardiac postprocessing software (Circle Cardiovascular Imaging, Calgary, Alberta, Canada; Fig. 1).

Device description

A Prizvalve balloon-expandable valve (Newmed Medical Co., Ltd., Shanghai, China; Fig. 2), made of bovine pericardium, was used in the study. The bottom of the stent valve is covered with a polyester membrane that can reduce the incidence of paravalvular leakage. The delivery system is a double-adjustable bendable sheath, which is more compatible with the coaxiality of the valve. At present, Prizvalve has not been proved by the State Food and Drug Administration (SFDA) of China, and it has been used as an "off-label" indication. Furthermore, a clinical registration study of the Prizvalve is underway to enhance the information about the types of interventional valves independently developed in China and provide significant treatment methods for older patients with severe valvular disease.

3D-printed models for simulation

To produce the 3D-printed model, the preoperative CTA data of the patient were imported into Materialise Mimics version 21.0 (Materialise, Leuven, Belgium) for 3D reconstruction of the RV, and the collected images were converted to the standard format of Digital Imaging and Communication of Medicine for storage. Moreover, a comprehensive reconstruction of RV morphology was performed using Materialise 3-matic software (Materialise, Leuven, Belgium). The digital model was exported to Standard Tessellation Language format, and then the Standard Tessellation Language files were imported into a Polyjet 850 multimaterial full-color 3D printer (Stratasys, Inc., Eden Prairie, MN) for printing; different materials were selected to represent different tissues (Fig. 3). The 3D-printed model and the Prizvalve were used to simulate the process during the bench test, to determine the bioprosthesis type selection and the release position, to evaluate the risk of surgery, and to develop personalized surgical strategies (Fig. 4). After several simulations were completed, the size of the bioprosthesis and the type of procedural strategy were determined.

Procedural steps

The patient was placed in the supine position. After general anesthesia was administered to the patient, a 6-F pigtail catheter was placed into the LV from the femoral artery. The pacing system was placed into the LV, and the position of the pacemaker was adjusted. Then, a 6-F sheath tube was inserted

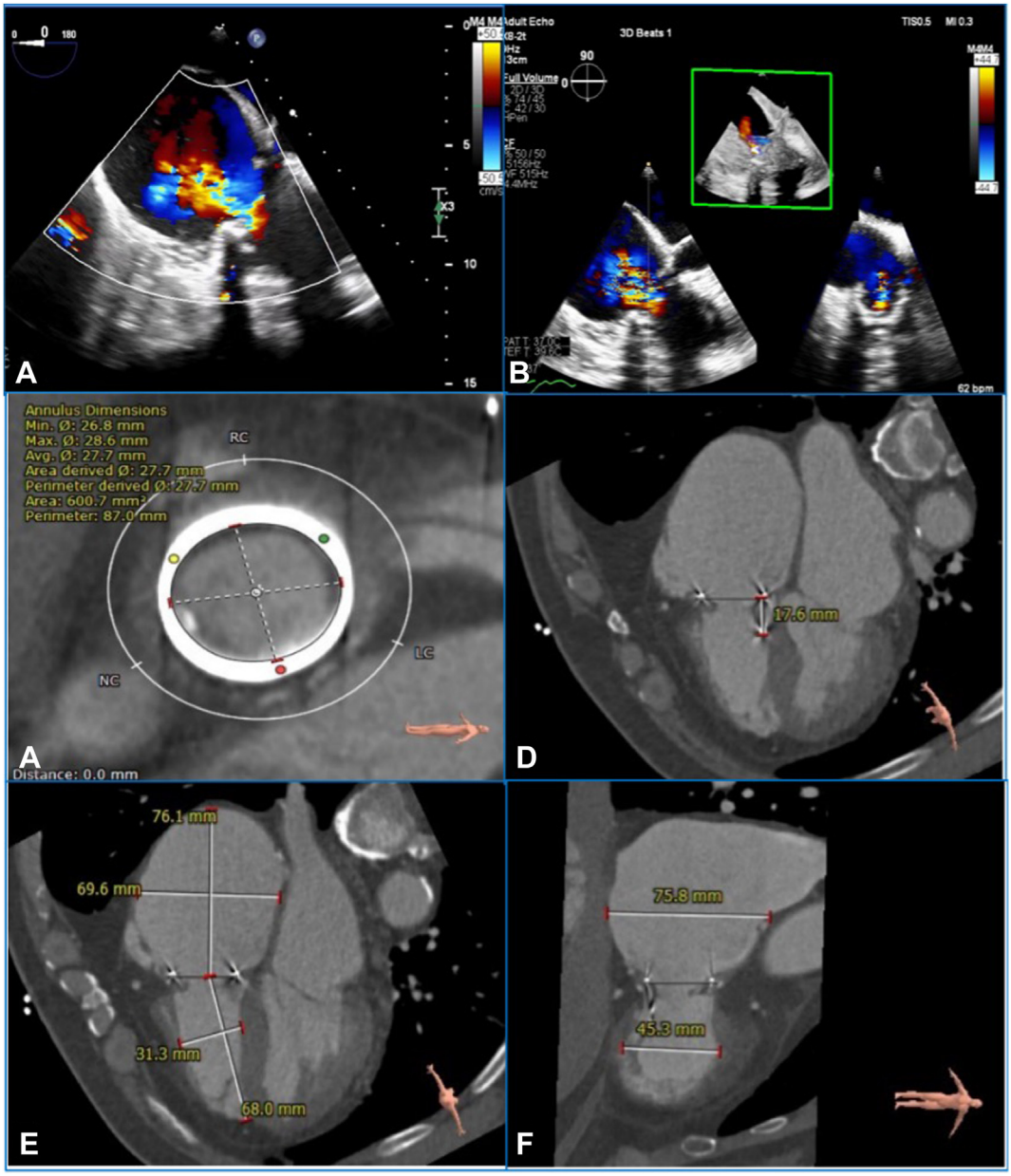

Figure 1. Preoperative assessment of transesophageal echocardiography and evaluation of computed tomography angiography using Circle Cardiovascular Imaging CVI42 software (Calgary, Alberta, Canada; eg, data for patient #3). (**A**,**B**) Preprocedural transesophageal echocardiography showed a large bundle of regurgitation in the tricuspid valve. (**C**) Annular area of the prosthetic tricuspid valve was 600.7 mm^2. (**D**) The annulus of the prosthetic tricuspid valve was 17.6 mm. (**E**) The right ventricle was 68.0 mm in the long axis, and 31.3 mm in the short axis, and the right atrium was 76.1 mm in the long axis, and 69.6 mm in the short axis. (**F**) The left and right axes of the right ventricle and right atrium were 45.3 mm and 75.8 mm, respectively.

into the femoral vein via the right inguinal region, and a 5-F pigtail catheter and 1.5-m loach guidewire were used to pass through the TV opening. The pigtail catheter was placed successively into the right pulmonary artery and the RV to measure blood pressure, and the TV was examined by CTA in the RV. Then, a Lunderquist guidewire (Cook Medical Tech Co. Ltd, Bloomington, IN) was inserted into the apex of the RV, and a Gore sheath was delivered to the femoral vein along the Lunderquist guidewire (Fig. 5A). According to the preoperative evaluation, the Prizvalve was selected to be delivered to the degenerated bioprosthesis along the Lunderquist guidewire; the depth and coaxiality of the Prizvalve were adjusted, and the pacing rate was up to 180 times per minute (Fig. 5B). The Prizvalve was rapidly expanded (Fig. 5C), and the 6-F pigtail catheter was exchanged along the Lunderquist guidewire and delivered to the RV apex (Fig. 5D). The postoperative TV closure and position were examined by CTA and transesophageal echocardiography (Fig. 5, E and F).

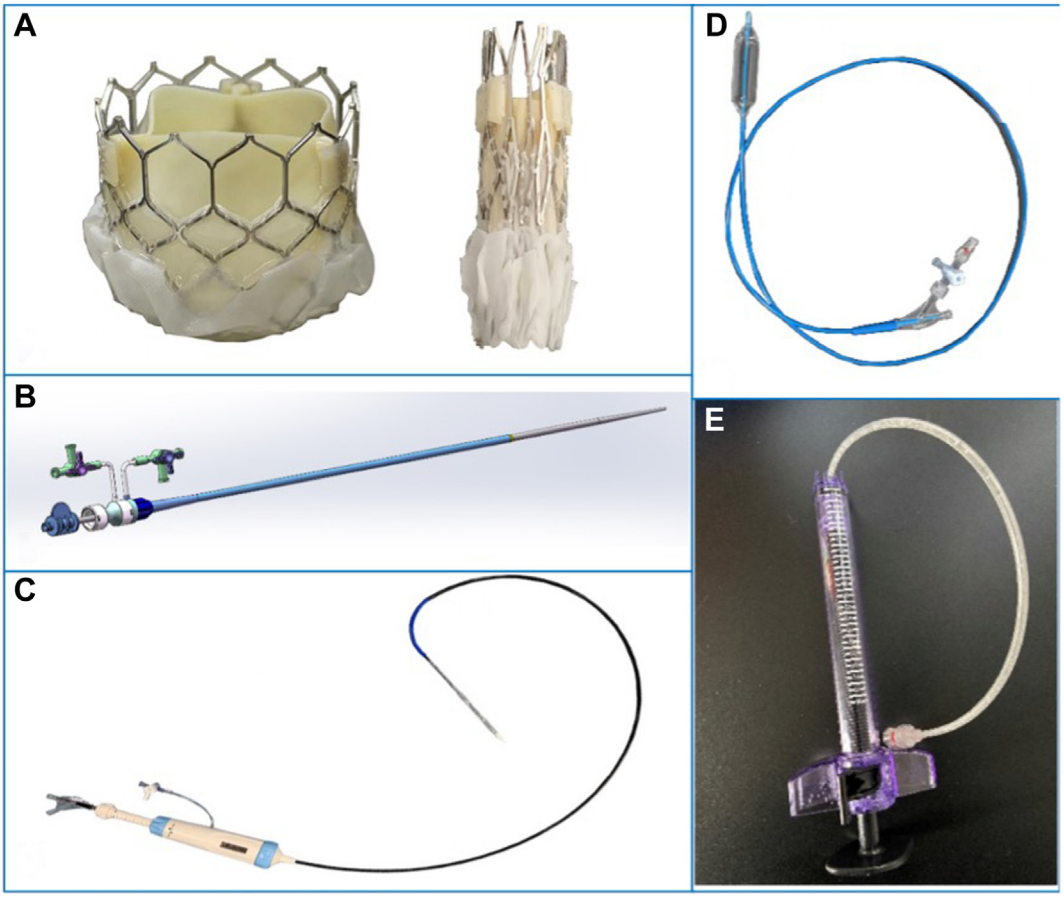

Figure 2. Prizvalve balloon-expandable valve (Newmed Medical Co., Ltd., Shanghai, China) made of bovine pericardium. The bottom of the stent valve is covered with a polyester membrane that can reduce the occurrence of paravalvular leakage. (**A**) Transcatheter bioprosthesis. (**B**) Expandable arterial sheath. (**C**) The delivery system. (**D**) The balloon. (**E**) The balloon pressure pump.

Follow-up data

Follow-up data were collected from enrolled patients at baseline, before discharge, 30 days after surgery, and 1 year after surgery. The primary indicators included the success rate of procedures, the TR level, and the prognosis status.

Statistical analyses

Continuous variables were reported as the median, whereas classified variables were expressed by frequency and percentage. A 2-tailed P value of < 0.05 was considered statistically significant. All statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS, IBM, Armonk, NY), version 26.0.

Results

Baseline characteristics

The baseline data of the 6 patients are listed in Table 1. Among the 6 patients, the etiologies of the conditions affecting the TVs at baseline varied widely, including 1 case of Ebstein anomaly, 2 cases of infective endocarditis, 1 case of ventricular septal defect, and 2 cases of rheumatic heart disease. All patients had a significant comorbidity burden, with Society of Thoracic Surgeons scores ranging from 8.363% to 14.042%, and 100.0% of patients had NYHA functional class $\geq$ III. Of the 6 patients, 3 had isolated TR, and the other 3 had mixed TS and TR. Patient #5, who had tetralogy of Fallot had a previous operation to treat pulmonary artery stenosis. This condition is not considered an absolute contraindication to the procedure. Baseline imaging data are listed in Table 2. All 6 patients had moderate-to-severe TR at baseline. Preoperative right heart catheterization showed that 2 patients (33.3%) had pulmonary hypertension before surgery.

Intra- and postoperative outcomes

The intraoperative and in-hospital details are shown in Table 3. Surgical success was achieved in all patients (100%), with the bioprosthetic valves in place, and no immediate paravalvular leakage after procedures in all cases. The median operation time was 87.5 minutes (range: 80.0-185.0 minutes), all patients tolerated the operation well, and no intraoperative complications were reported. None of the patients required positive inotropic drugs or mechanical support after the operation. The median number of days in the postoperative intensive care unit was 2 (range: 1-4 days), and the median number of in-hospital days was 11 (range: 9-20 days). In addition, no pulmonary embolisms, cerebrovascular

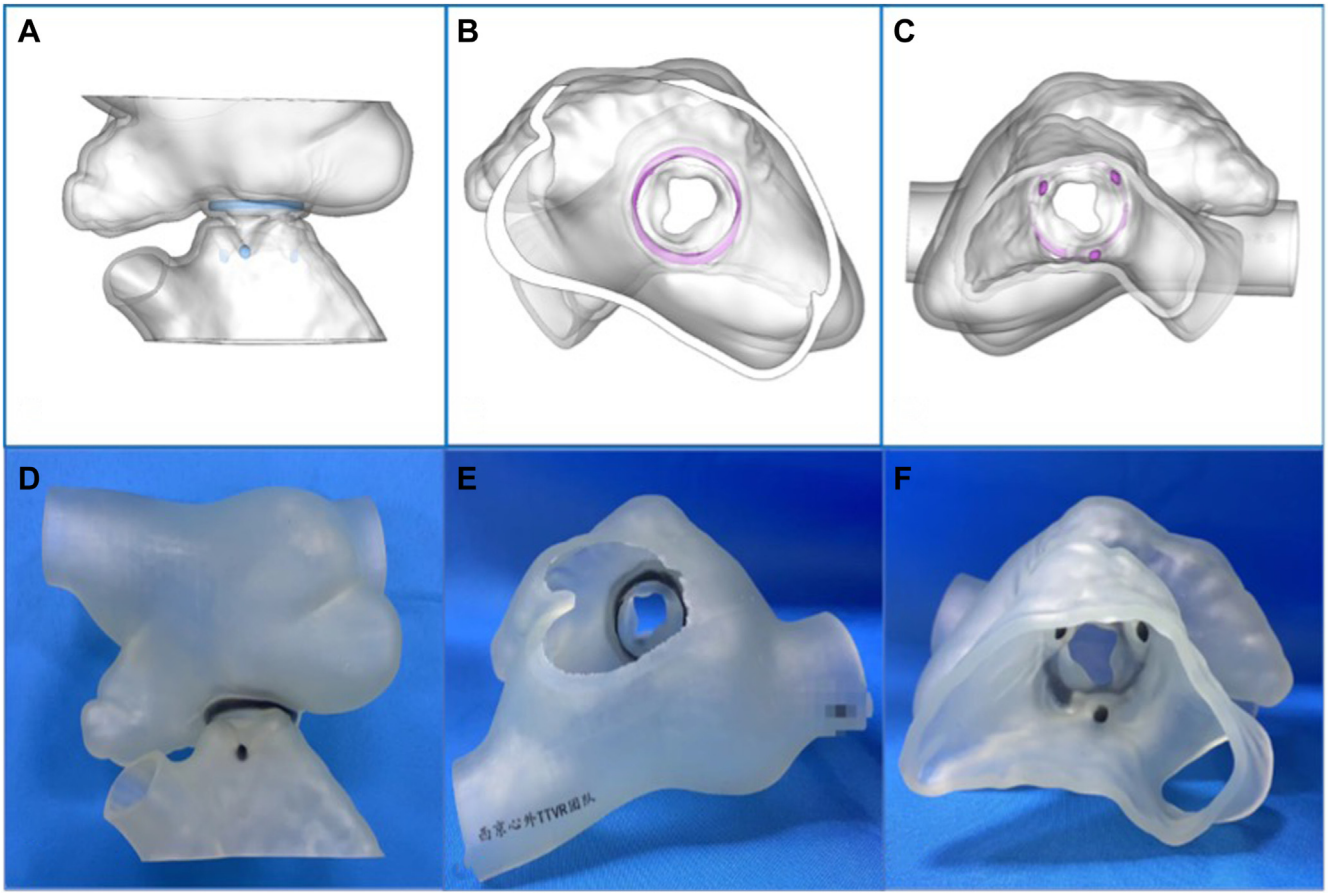

Figure 3. Preoperative 3-dimensional (3D) reconstruction and 3D-printed model of patient #3, to help surgeons understand the anatomic structures and make the surgical plan. (**A-C**) Preoperative 3D reconstruction of the patient's right cardiac system: (**A**) lateral view; (**B**) right atrial (RA) view; and (**C**) right ventricular (RV) view. (**D-F**) 3D-printed model of the patient's right cardiac system: (**D**) lateral view; (**E**) RA view; and (**F**) RV view.

events, or new conduction blocks occurred during hospitalization. All discharged patients were treated with anticoagulants. All patients met the criteria for the primary endpoint, and the ideal relationship of the anatomic structures was verified in the postoperative 3D-printed models (Fig. 6).

1-year follow-up results

The follow-up results are shown in Table 4. The ejection fraction increased significantly compared with preoperative values (60.33% ± 3.67% vs 57.33% ± 3.72%, $P = 0.012$). Most patients showed either no or trace paravalvular TR (100%; 6 of 6). Moreover, a significant reduction in the mean diastolic gradient through the TV, from 3.50 ± 1.38 mm Hg to 10.50 ± 1.87 mm Hg, was observed ($P = 1.9 \times 10^{-5}$). All patients presented with NYHA functional class I (n = 2) or II (n = 4). No rehospitalization was necessary during the follow-up period. As of March 2023, no patients had reported any adverse events. Kansas City Cardiomyopathy Questionnaire (KCCQ) scores also improved significantly (61.0 [58.0, 63.0] vs 30.0 [29.0, 34.0], $P = 6.0 \times 10^{-7}$; Fig. 7).

Discussion

TV-related disease is an important clinical problem that results mainly in regurgitation. The etiology may be divided into primary and secondary causes, most of which are caused by TA expansion and RV enlargement, accompanied by pulmonary hypertension.[26,27] For such patients, due to the low blood pressure and the rate of the right heart, surgical TV replacement by mechanical valves is prone to causing thrombosis, so biological valves are mostly recommended in clinical practice.[28,29] However, the biological valve degenerates over the long term, and patients with degenerated bioprostheses have a higher mortality rate after reoperations. Therefore, the need is urgent for new methods to treat such diseases. With the continuous development of minimally invasive treatments, a transcatheter tricuspid ViV implant offers bright prospects for patients. In 2010, the first transcatheter tricuspid ViV implantation was successful via the jugular vein, and a ViV implant via the femoral vein also has been implemented successfully.[30-32] In 2016, McElhinney et al.[18] reported a multicentre registration study on the treatment of transcatheter tricuspid ViV implants, with a sample size of 156 cases, which is the largest study to date.

Currently, there is no self-developed and listed balloon-expandable valve in China, and PrizValve has the potential to become the first one. For some reasons, the transcatheter heart valve need to be adjusted to local conditions based on the actual situation in China. However, due to challenges presented by the procedures, experience with ViV implants has

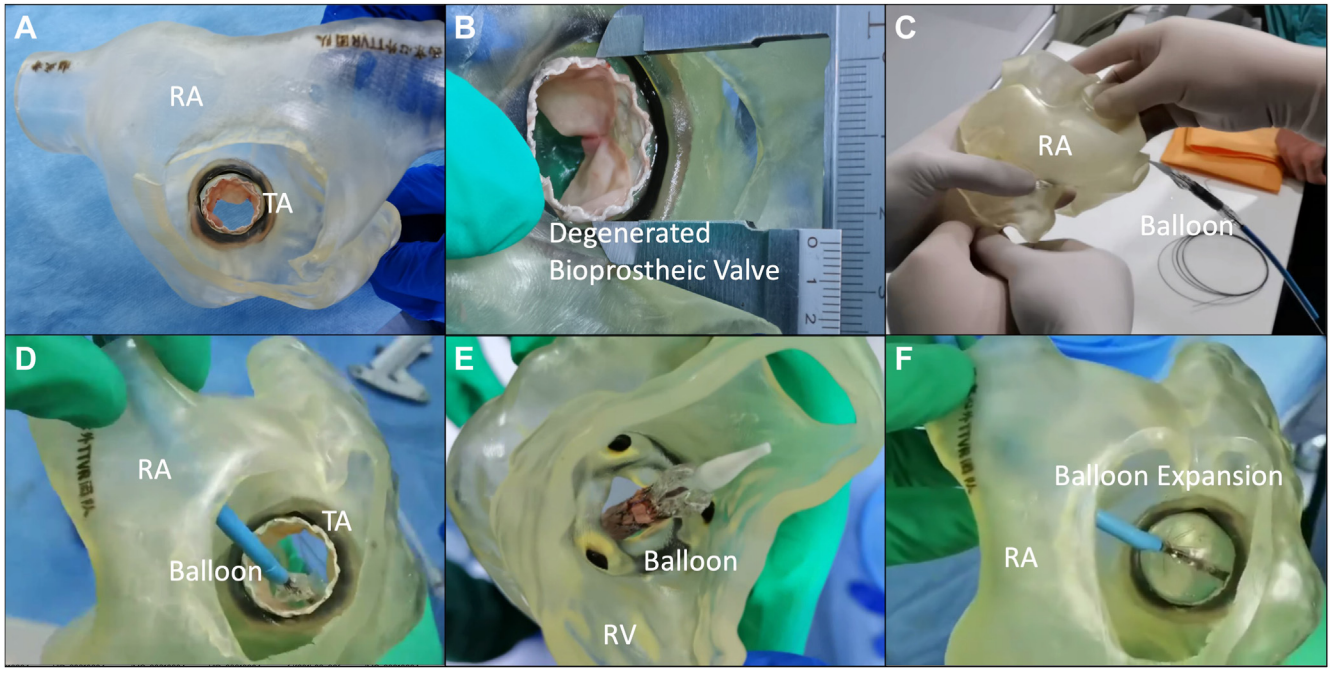

Figure 4. A 3-dimensional (3D)-printed model used to simulate the procedure during the bench test (eg, data for patient # 5). (**A**) The 3D-printed model from the plane of the right atrium (RA). (**B**) A Vernier caliper was used to measure the inner diameter of the biological annulus. The result (22.10 mm) was equal to the result from the assessment made using computed tomography angiography. (**C**) A 5-F pigtail catheter and a 1.5-m loach guidewire were used to pass through the tricuspid valve. (**D, E**) A Prizvalve balloon-expandable valve (Newmed Medical Co., Ltd., Shanghai, China) was selected to be delivered to the degenerated bioprosthesis; the depth and coaxiality of the Prizvalve were adjusted. (**F**) The balloon was fully expanded, and the position and size were able to be determined. RV, right ventricle; TA, tricuspid annulus.

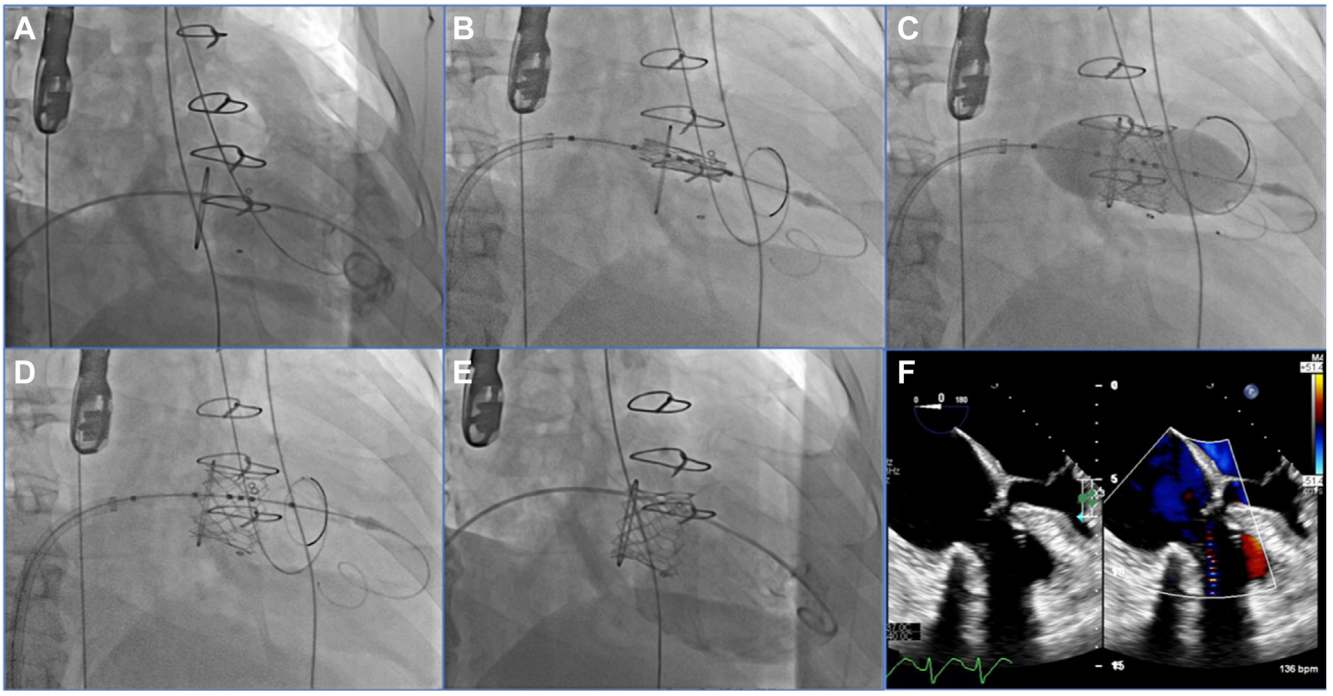

Figure 5. Transesophageal echocardiography and digital subtraction angiography (DSA) images showed that the procedure achieved good results (as shown by data from patient #2). (**A**) Preprocedural DSA displayed a large amount of blood flow (colored) at the tricuspid valve. (**B**) The delivery system was positioned in relation to the tricuspid valve. (**C**) After adjusting the position and the coaxiality, the balloon-expandable valve was inflated. (**D**) After expansion, the stent was fully unfolded. (**E**) When the guidewire was withdrawn, DSA showed that the position and shape of the tricuspid valve were ideal and that the stent fit closely to the valve. (**F**) Postprocedural transesophageal echocardiography showed that the balloon-expandable valve was properly closed, with no paravalvular regurgitation.

Table 1. Demographics of patients receiving transcatheter tricuspid valve-in-valve implantation

Demographic	Patient # 2	3	4	1	5	6
Age and sex	26; F	46; M	71; M	56; F	18; M	59/; F
Native TV diseases	EA	IE	IE	RHD	VSD	RHD
Years from initial surgery	15	10	14	18	12	18
Original valve (size, mm)	Int (26)	Car (29)	Int (29)	Int (26)	Int (26)	Car (29)
Current valve status	TR	TR	TR	TS + TR	TS + TR	TS + TR
Comorbidities	MR	SAVR, SMVR	HF, PH, HT	SAVR SMVR, HT, Hyp	MR	PH, MR, HT
Creatinine, μmol/L	47	60	126	86	70	69
Albumin, g/dL	4.4	3.9	4.2	3.5	5.4	4.6
NT-proBNP, pg/mL	202.4	724.4	611.8	254.0	132.4	1116.0
NYHA functional class	III	III	IV	IV	III	IV
STS score, %	8.363	9.921	11.383	13.660	8.910	14.042
KCCQ score	34.0	29.0	27.0	29.0	36.0	31.0

Cardioband (Car; Edwards Lifesciences Inc, Irvine, CA); Intrepid (Int; Medtronic, Inc., Minneapolis, MN).

EA, Ebstein anomaly; F, female; HF, heart failure; HT: hypertension; HYP, hyperbilirubinemia; IE, infective endocarditis; KCCQ, Kansas City Cardiomyopathy Questionnaire; M, male; MR, mitral regurgitation; NT-proBNP, N-terminal prohormone B-type natriuretic peptide; NYHA, New York Heart Association; PH, pulmonary hypertension; RHD, rheumatic heart disease; SAVR, surgical aortic valve replacement; SMVR, surgical mitral valve replacement; STS, Society of Thoracic Surgeons; TR, tricuspid regurgitation; TS, tricuspid stenosis; TV, tricuspid valve; VSD, ventricular septal defect.

been limited to small case series and case reports.[23,30-38] According to a midterm report of the **V**alve-**i**n-**V**alve **I**nternational **D**ata (VIVID) registry, 306 patients received tricuspid ViV implants, and the cumulative 3-year incidences of death, reintervention, and adverse outcomes (endocarditis, thrombosis, or significant dysfunction) were 17%, 12%, and 8%, respectively.[16] To find a feasible approach, 3D-printed models were used to formulate strategies in our study. Moreover, Prizvalve in this study has the advantage that measures can be adjusted to local conditions based on the actual situation in China.

Although this case series was limited to only a few cases, it presents a range of primary TV pathologic conditions, as well as a range of baseline characteristics and comorbidities, which indicates that the level of demand for transcatheter tricuspid ViV implants in the future may be high. Preoperative planning, based on understanding of the degenerated bioprosthesis, selection of the correct bioprosthesis size, and development of deployment techniques, is critical to procedural success. The 3D printing provides an opportunity for doctors to gain an intuitive understanding of the anatomic structures of the TV, and simulations performed during the bench test may be used effectively to formulate preprocedural plans.[38-40] In this study, the surgeons successfully completed 6 cases of transcatheter tricuspid ViV implantation via the femoral vein approach, by combining multimodal imaging and 3D-printed models. In this case series, 6 3D-printed TV models were made in accordance with the 1:1 ratio, and the balloon expansion process was simulated during the bench test, which effectively guided bioprosthesis type selection and determination of the release position. After carrying out the simulations, surgeons may determine the level of difficulty of the operation and make surgical plans before the procedure that are personalized to the patient, activities that not only can shorten the operating time but also may guarantee the safety and correctness of the operation.

Overall, a degenerated tricuspid bioprosthesis can be treated by implanting the Prizvalve as a transcatheter tricuspid ViV

Table 2. Preprocedural evaluations of patients undergoing transcatheter tricuspid valve-in-valve implantation

Measure	Patient # 1	2	3	4	5	6
TAPSE, mm	11.2	12.4	15.8	15.4	14.7	15.6
Fractional area change, %	33.8	40.1	38.5	39.7	42.3	41.5
LVEDV, mL	40	102	87	58	79	67
LVESV, mL	14	45	34	26	29	26
LVEF, %	56	55	61	55	63	54
Mean gradient, mm Hg	9	10	8	12	11	13
FS, %	31	30	33	28	31	3361
RVSP, mm Hg	36	31	28	26	33	26
RVF	ModR	ModR	SevR	SevR	ModR	SevR
TR	Mod	Mod	Sev	Sev	Mod	Sev
TV area, mm^2	2.9	4.8	4.5	2.8	3.1	3.6
TA maxdiam, mm	43.1	48.6	55.4	50.9	48.5	54.2
TA min diam, mm	37.7	41.2	46.8	43.4	40.6	43.3

FS, fractional shortening; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; max diam, maximum diameters; min diam, minimum diameters; Mod, moderate; ModR, moderately reduced; RVF, right ventricular function; RVSP, right ventricular systolic pressure; Sev, severe; SevR, severely reduced; TA, tricuspid annulus; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; TV, tricuspid valve.

Table 3. Procedure and in-hospital outcomes

	Patient #					
	1	2	3	4	5	6
Approach	TF	TF	TF	TF	TF	TF
THV brand (size, mm)	PV (26)	PV (29)	PV (29)	PV (26)	PV (26)	PV (29)
PVL grade (immediate post)	None	None	None	None	None	None
Mean gradient, mm Hg	2	4	3	4	3	5
Dose of contrast agent, mL	60	40	30	50	20	50
Procedure time, min	185.0	65.0	80.0	85.0	90.0	120.0
Procedural complications*	—	—	—	—	—	—
ICU stay, d	2	1	3	4	2	1
Hospitalization, d	12	9	9	20	15	10

Prizvalve balloon-expandable valve (PV; Newmed Medical Co., Ltd., Shanghai, China).
—, not applicable; ICU, intensive care unit; PVL, paravalvular leakage; TF, transfemoral; THV, transcatheter heart valve.
*Procedural complications included conversion to surgery, life-threatening bleeding, major vascular complications, and malpositioning.

implant, which is likely a viable and reliable alternative to the surgical treatment of degenerated bioprostheses in patients with a high surgical risk. In our case series, a transcatheter tricuspid ViV implantation has proven to be an attractive alternative to redoing a conventional operation, with results of clinical and hemodynamic improvements and no major complications. In addition, preoperative multimodal imaging and an intuitive display of 3D-printed models under intraoperative fluoroscopic guidance play an important guiding role in transcatheter tricuspid ViV implantation to ensure safety and a positive result. Using transcatheter tricuspid ViV implantation to treat a degenerative bioprosthesis is expected to become the standard treatment in the future, but further research is needed to improve the level of evidence and quality of outcomes for the transcatheter tricuspid ViV implantation procedure. Toward this end, larger series and randomized clinical trials are needed.

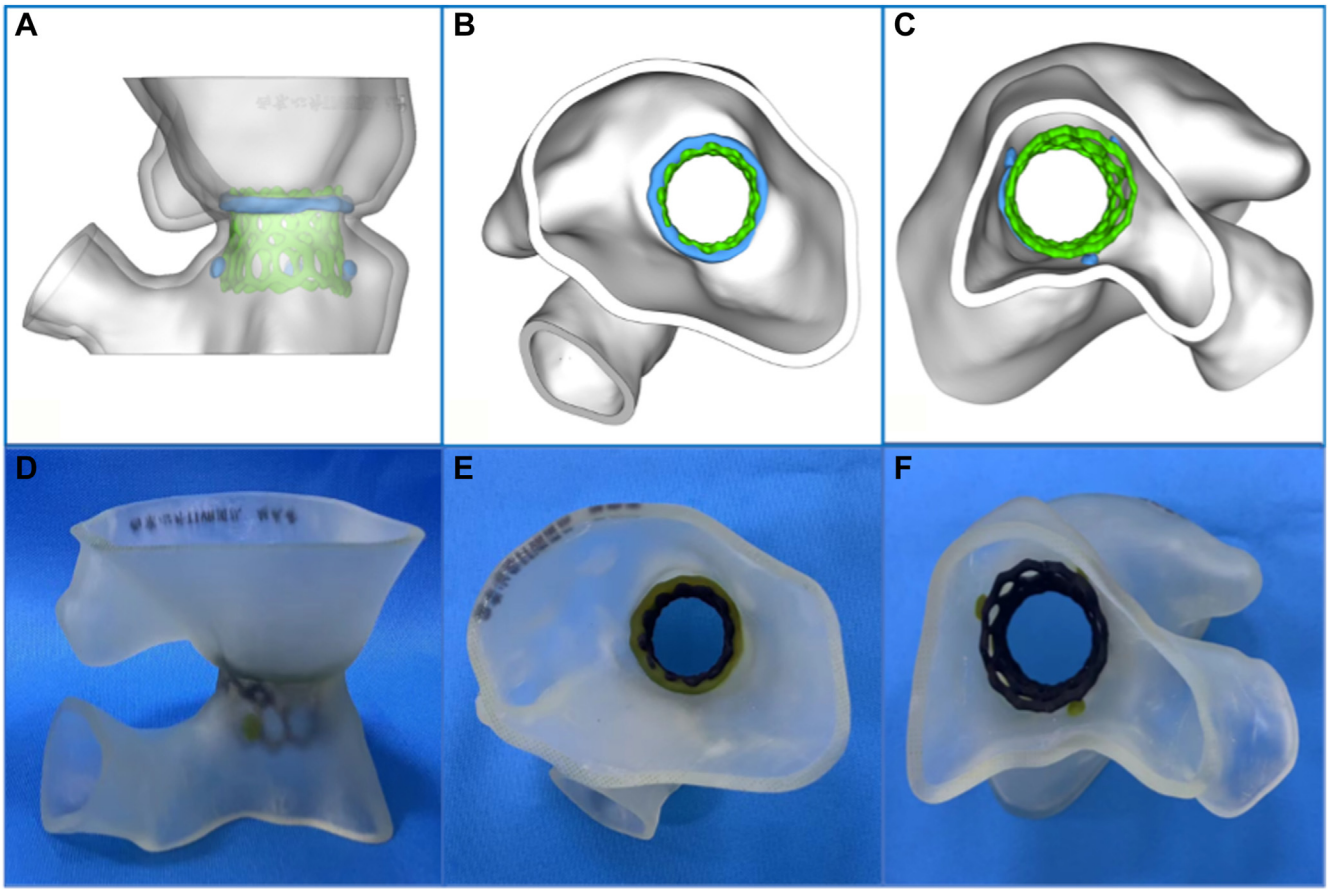

Figure 6. The postoperative 3-dimensional (3D) reconstruction and the printed model of patient #3 verified the position of the stented valve. (**A-C**) Postoperative sD reconstruction: (**A**) lateral view; (**B**) right atrial view; and (**C**) right ventricular view. (**D-F**) The 3D-printed model of the patient's right cardiac system: (**D**) lateral view; (**E**) right atrial view; and (**F**) right ventricular view.

Table 4. Follow-up of patients who underwent transcatheter tricuspid valve-in-valve implantation

Measure	Patient #											
	1		2		3		4		5		6	
	30-d	1-y	30-d	1-y	30-d	1-y	30-d	1-y	30-d	1-y	30-d	1-y
Edema	—	—	—	—	Yes	—	—	—	—	—	—	—
Ascites	—	—	—	—	—	—	—	—	—	—	—	—
NYHA functional class	II	I	II	II	II	II	III	II	II	I	II	II
RVF	MiR	Nor	MiR	Nor	ModR	ModR	ModR	MiR	MiR	Nor	ModR	MiR
RVSP, mm Hg	38	37	33	35	30	33	31	35	36	39	31	32
LVEF, %	66	61	63	57	64	65	60	56	66	64	62	59
Mean gradient, mm Hg	1	2	3	2	2	5	3	3	3	4	4	5
TR	None	None	None	Trace	None	Trace	None	Trace	None	None	Trace	Trace

—, not applicable; LVEF, left ventricular ejection fraction; MiR, mildly reduced; ModR, moderately reduced; Nor, normal; NYHA: New York Heart Association; RVF, right ventricular function; RVSP, right ventricular systolic pressure; TR, tricuspid regurgitation.

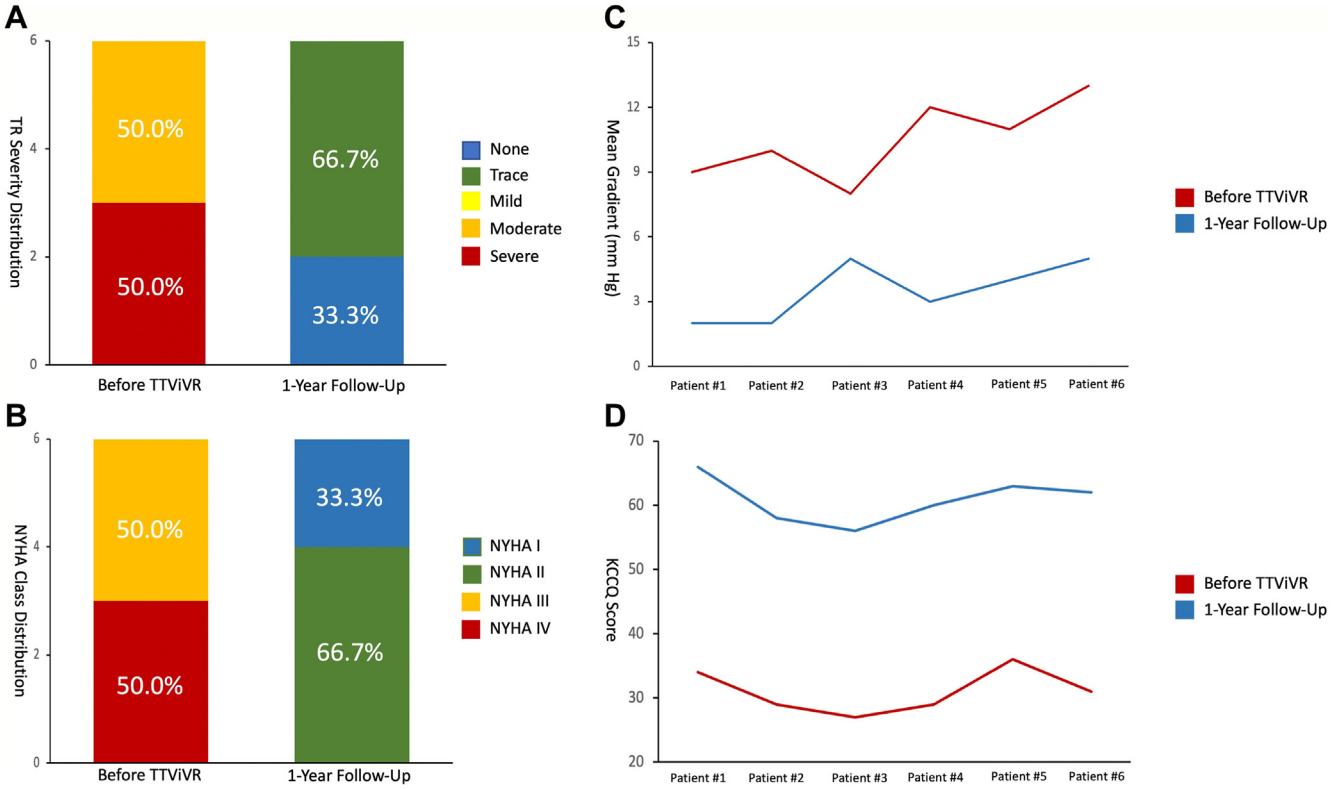

Figure 7. 1-year follow-up results showed reduced tricuspid regurgitation (TR) severity and improved clinical, functional, and quality-of-life outcomes. (**A**) Assessment of TR severity. (**B**) Comparison of New York Heart Association (NYHA) functional class between pre-procedures and 1-year follow-up. (**C**) Comparison of mean tricuspid valve diastolic gradient between pre-procedures and 1-year follow-up. (**D**) Assessment of Kansas City Cardiomyopathy Questionnaire (KCCQ) score. TTViVR, transcatheter tricuspid valve-in-valve replacement.

Conclusion

For patients with degenerated tricuspid bioprostheses, transcatheter tricuspid ViV implantation may be an effective and safe treatment. This case series presents a range of primary TV pathologies, as well as a variety of baseline patient characteristics and comorbidities. These procedures have been adapted to meet sclinical and technical challenges, opening up new options for patients requiring ViV implants with the guidance of multimodal imaging and 3D printing.

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Data Availability

The original data presented in the study are included in the article; further inquiries can be directed to the corresponding author.

Ethics Statement

The studies involving human participants were reviewed and approved by Clinicaltrials Organization: Xijing Hospital, Air Force Medical University.

Patient Consent

The patients provided their written informed consent to participate in this study.

Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

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