Original Article

Mid to Long-term Echocardiographic Follow-up of Patients Undergoing Transcatheter Tricuspid Valve-in-Valve Replacement for Degenerated Bioprosthetic Valves: First Single-Center Report from Iran

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Abstract

Background: *Transcatheter tricuspid valve-in-valve (TTViV) replacement has become an alternative treatment in high-risk patients with bioprosthetic valve degeneration. This is the first report on the mid to long-term echocardiographic findings of patients who underwent TTViV replacement in a cardiac referral center in Iran.*

Methods: *Data of 12 patients, consisting of 11 women and 1 man, who underwent TTViV replacement between 2015 and 2021 were reviewed retrospectively. The patients underwent echocardiography before the procedure and at a mean follow-up time of 3.17±1.75 years.*

Results: *All the patients had New York Heart Association (NYHA) function class III/IV before TTViV. Six patients had tricuspid regurgitation, 1 had tricuspid stenosis, and 5 had both. All the patients had successful TTViV. The mean time from the initial valve surgery to TTViV was 6.25±2.45 years. At follow-up, 2 patients had died: 1 due to COVID-19 pneumonia and 1 without a known cause. The remaining 10 patients experienced improvements in the NYHA functional class. Echocardiographic measures showed significant improvements. Transvalvular mean gradient pressure decreased from 7.08±1.98 mm Hg to 5.29±1.63 mm Hg (P=0.028), tricuspid valve pressure half time decreased from 245.00±49.46 ms to 158.64±57.41 ms (P=0.011), tricuspid regurgitation gradient decreased from 39.91±7.31 mm Hg to 26.72±8.99 mm Hg, and left ventricular ejection fraction increased from 47.71±4.70% to 49.79±4.58% (P=0.046). There was no significant paravalvular or transvalvular leakage at follow-up.*

Conclusion: *This is a single-center report on the mid and long-term echocardiographic follow-up of patients after TTViV replacement. Our study showed that TTViV was a safe and efficient method in treating high-risk patients with degenerated bioprosthetic tricuspid valves and had favorable echocardiographic and clinical results.*

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Keywords: *Tricuspid valve insufficiency; Echocardiography; Bioprosthesis; Tricuspid valve stenosis*

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Introduction

Bioprosthetic valves are mostly preferred to mechanical valves for right-side valve replacement, chiefly because there is no need for long-term anticoagulation therapy after bioprosthetic valve replacement in contrast to mechanical valve replacement.[1]

On the other hand, bioprosthetic valves have undergone degenerative changes over time,[2] leading to valve regurgitation or stenosis, which causes symptoms and in the long-term, ventricular dysfunction. Patients who become symptomatic due to bioprosthetic valve degeneration and need reoperation are at high risk for redo surgery, primarily due to existing comorbidities such as diabetes and chronic kidney disease, as well as a history of prior cardiac surgery.[3] According to the Society of Thoracic Surgeons registry, reoperation for tricuspid valve replacement is a high-risk surgical operation. Hence, transcatheter tricuspid valve-in-valve (TTViV) replacement has become an attractive alternative treatment method in patients with degenerated bioprosthetic tricuspid valves.[4]

In the current study, we present a brief single-center report on the mid to long-term follow-up echocardiographic findings of patients who underwent TTViV replacement in our institution. To our knowledge, the echocardiographic follow-up of patients following TTViV has not been reported in Iran previously.

Methods

Twelve patients underwent TTViV replacement in Tehran Heart Center, Tehran, Iran, between 2015 and 2021. The procedure was performed if patients had deteriorating clinical symptoms and were at high risk for cardiac reoperation. The 12 patients' demographic and clinical data were reviewed retrospectively. Data regarding primary bioprosthetic valves, including the kind and size of the valve, were obtained from initial valve replacement surgery records. Transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) were performed using GE S60 and Phillips Affinity 70 ultrasound machines. The internal diameters of the bioprosthetic valves were measured using a dedicated application (Valve-in-Valve by Vinayak Bapat) and in some cases using multidetector computed tomography (CT) scan. The patients had been presented and discussed by the heart team and chosen for TTViV replacement after surgical reoperation risk assessments and the patients' preferences.

Tricuspid bioprosthetic valve degeneration was defined as stenosis with the thickening and calcification of the leaflets and/or regurgitation. According to the current guidelines,[5] normal functioning tricuspid prosthetic valves have a transvalvular mean pressure gradient (MPG) of less than 6 mmHg. Therefore, in our study, a transvalvular MPG of 6 mmHg or greater was defined as stenosis. In addition, a regurgitation severity degree of equal to or greater than moderate was considered significant regurgitation.

Right femoral vein catheterization was performed under general anesthesia or conscious sedation.[6,7] After the insertion of the guidewire into the pulmonary wedge, an Edwards balloon was inserted. In 2 patients, predilation was performed using an Edwards balloon number 23. Ventricular pacing was performed in 1 patient. In 2 other patients, transient asystole was achieved using adenosine. In the rest of the patients, rapid pacing or transient arrest was not necessary. Then, under TEE or TTE and fluoroscopic guidance, one of bioprosthetic Edwards SAPIEN valves (SAPIEN XT or SAPIEN 3) was deployed. Postdilation with balloon expansion was not needed in our patients. After the procedure, paravalvular and transvalvular regurgitation and the gradient measures of the newly inserted valve were evaluated using TEE or TTE. Procedure complications were also evaluated.

To rule out subvalvular clots as the underlying cause of valve stenosis, we commenced anticoagulation treatment in patients with tricuspid stenosis not having received anticoagulants previously. These patients were re-evaluated after 2 to 3 weeks; subsequently, the patients became candidates for TTViV. In patients with tricuspid stenosis already under anticoagulation therapy, the anticoagulant dose was increased to the safest dosage.

The outcome of interest after the TTViV procedure was defined as an improvement in transvalvular or paravalvular regurgitation, valve gradient, size and function of the right ventricle, size of the right atrium, and pulmonary artery pressure (if it was technically feasible). All these parameters were measured before the procedure and at follow-up.

Continuous variables were expressed as the mean ± the standard deviation (SD). Echocardiographic measurements before and after the procedure were compared using the Wilcoxon Signed Rank test. A P value of 0.05 or less was used to identify significant changes. We used IBM SPSS Statistics, version 26, for the statistical analyses.

Results

The study population consisted of 12 patients: 1 man and 11 women. The mean age of the patients was 59.67±11.70 years (range=33–73). All 12 patients had degenerated biologic tricuspid valves prior to the procedure, including regurgitation and/or stenosis. Six patients presented with isolated tricuspid regurgitation, 1 had isolated tricuspid stenosis, and 5 had concomitant tricuspid stenosis and tricuspid regurgitation. One patient had a history of only tricuspid valve replacement surgery, and 11 patients had a history of other valve surgeries, coronary artery bypass graft,

or other cardiac procedures in addition to tricuspid valve replacement. All the patients underwent a successful TTViV procedure. The mean time from the initial valve surgery to TTViV was 6.25±2.45 years.

The baseline characteristics of the study subjects including age, sex, New York Heart Association (NYHA) functional class, years after the initial surgery, and numbers and types of heart surgeries before TTViV are summarized in Table 1. All the patients had NYHA functional class III/IV before the procedure. The baseline echocardiographic parameters and data related to the primary bioprosthetic valve are summarized in Table 2 and Table 3.

The patients were followed up for a mean of 3.17±1.75 years. Seven out of the 12 patients had a follow-up time of 3 years or longer. Two patients passed away during the follow-up period: 1 patient due to COVID-19 pneumonia and 1 patient without a known cause. Therefore, their assessments were incomplete. Ten living patients reported improvements in clinical symptoms and functional class at follow-up. Follow-up echocardiography was scheduled as follows: in the same admission after the TTViV procedure, 3 to 6 months and 1 year after the procedure, and then annually, except for a few patients who were absent in some follow-up sessions. In the follow-up echocardiography, no-more-than trivial transvalvular or paravalvular regurgitation was detected in the studied patients.

Follow-up echocardiographic parameters are summarized in Table 4, Figure 1, and Figure 2. In 1 patient, whose systolic pulmonary artery pressure was high after TTViV (40 mmHg), no significant change was observed in the NYHA functional class at follow-up (patient number 2). In the other 11 patients, the NYHA functional class improved to less

Table 1. Baseline demographic and historical data of patients with tricuspid bioprosthetic valve degeneration

Case No.	Age (y)	Sex	NYHA Functional Class	Time from the Initial Surgery (y)	Other Valve or Cardiac Surgeries	Number of Prior Heart Surgeries
1	61	F	III-IV	7	MVR, AVR, Redo TVR, PPM	2
2	70	F	IV	8	CABG, MVR, TVR, LAA and PDA closure	1
3	33	M	III-IV	4	Redo TVR	2
4	53	F	III-IV	9	CMVC, MVR, TVR	2
5	48	F	III	7	MVR, TVR	1
6	70	F	III	5	MVR, AVR, Redo TVR	2
7	73	F	III-IV	2	MVR, AVR, Redo TVR	2
8	69	F	III-IV	8	MVR, Redo AVR, Redo TVR	2
9	63	F	III	3	MVR, TVR	1
10	61	F	III-IV	4	MVR, AVR, TVR, Septal myectomy	1
11	65	F	III-IV	10	MVR, TVR	1
12	50	F	III-IV	5	ASD closure, MVR, Redo TVR	2

NYHA, New York Heart Association; F, Female; M, Male; TV, tricuspid valve; MVR, Mitral valve replacement; AVR, Aortic valve replacement; PPM, Permanent pacemaker; CMVC, Closed mitral valve commissurotomy; CABG, Coronary artery bypass graft; LAA, Left atrial auricle; PDA, Patent ductus arteriosus; PTMC, Percutaneous trans-mitral commissurotomy; ASD, Atrial septal defect

Table 2. Echocardiographic characteristics at baseline before TTViV

	Case No.											
RV diameter,(mm)	1	2	3	4	5	6	7	8	9	10	11	12
RVsm (cm/s)	38	46	50	37	25	36	26	30	33	35	37	38
RA area (mm2)	8	6	7	7	7	7	5	5	7	9	9	6
TV MPG	19	31	32	23	19	22	30	17	32	19	24	20
(mm Hg)	6	8	6	8	6	5	10	5	7	8	11	5
TV PHT (ms)	NM	264	196	296	218	191	203	250	250	NM	350	232
Transvalvular regurgitation	Severe	Severe	Severe	Severe	Moderate to severe	Moderate to severe	Mild	Severe	Moderate to severe	Moderate	Moderate	Moderate to severe
Paravalvular regurgitation	None	None	None	None	None	None	None	Moderate	None	None	None	None
TR gradient (mm Hg)	31	36	43	30	45	37	50	53	39	NM	40	35
SPAP (mm Hg)	17	21	23	20	30	27	30	43	29	NM	30	30
TV VTI/LVOT VTI	3.5	7.7	5.6	3.7	3	Missing data	Missing data	2.5	3.3	Missing data	Missing data	Missing data
Ejection Fraction (%)	50-55	45	45	45-50	55	50	50-55	40	40-45	50	50	40-45
Rhythm	AF	AF	AF	Sinus	Sinus	Sinus	Sinus	AF	Sinus	Sinus	Sinus	Sinus

TTViV , Transcatheter tricuspid valve-in-valve; RV, Right ventricle; RVsm, Right ventricular peak systolic myocardial velocity; RA, Right atrium; TV MPG, Transvalvular mean pressure gradient; TV PHT, Tricuspid Valve Pressure Half time; VTI, Velocity time index; LVOT, Left ventricle outflow tract; TR, Tricuspid Regurgitation; SPAP, Systolic pulmonary arterial pressure; AF, Atrial fibrillation, NM, Not measurable

Table 3. Valve characteristics at baseline, degeneration mode, and procedural access

Case No.	Baseline				After TTViV		
	Failed Valve	Failed Valve Size (mm)	Failure Mode	Access	Implanted Valve Brand	Implanted Valve Size (mm)	Follow-up (y)
1	Pericarp	29	R	RFV	SAPIEN 3	29	2
2	Mosaic	31	R+S	RFV	SAPIEN XT	29	4
3	Perimount	29	R	RFV	SAPIEN 3	29	3
4	Epic	29	R+S	RFV	SAPIEN 3	29	1
5	Hancock	31	R	RFV	SAPIEN 3	29	1
6	Hancock™	29	R	RFV	SAPIEN 3	26	3
7	Biocor	27	S	RFV	SAPIEN 3	26	2
8	Mosaic	27	R	RFV	SAPIEN XT	26	3
9	Epic	31	R+S	RFV	SAPIEN 3	29	5
10	Mosaic	31	R+S	RFV	SAPIEN XT	29	6
11	Hancock	29	R+S	RFV	SAPIEN XT	26	6
12	Hancock	31	R	RFV	SAPIEN 3	26	2

TTViV, Transcatheter tricuspid valve-in-valve; R, Regurgitation; S, Stenosis; RFV, Right femoral vein

Table 4. Echocardiographic characteristics after TTViV at the midterm follow-up

	Case No.											
	1	2	3	4	5	6	7	8	9	10	11	12
RV diameter (mm)	33	37	36	31	28	33	29	35	31	27	30	37
RVSM (cm/s)	7	5	7	6	9	6	6	5	7	8	8	7
RA volume (cc/m^2)	31	85	52	57	36	41	57	40	Missed data	Missed data	32	54
TV MPG* (mm Hg)	5	4.5	5	5	8	2	6	6	4	8	5	5
TV PHT (ms)	205	234	128	110	NM	87	221	80	216	153	115	196
iEOA (cm^2/m^2)	1	0.7	0.7	0.9	0.8	1.8	0.99	Missing data	Missing data	0.69	Missing data	0.59
Transvalvular regurgitation	Mild to moderate	Mild	Mild	Trace	none	None	Mild	Mild to moderate	Mild	Trace	None	Mild to moderate
Paravalvular regurgitation	None	None	None	None	None	None	None	None	None	None	None	None
TR Gradient (mmHg)	30	30	20	20	NM	NM	16	45	25	NM	NM	28
SPAP (mmHg)	35	40	25	30	NM	NM	21	55	35	NM		
TV.VIT/LVOT.VIT	Measurable	NM	33									
NYHA functional class	1.9	2.8	2.5	1.9	2.2	1.2	2.1	Missed data	Missed data	Missed data	Missed data	2.4
LVEF (%)	50-55	50	40-45	45-50	55-60	55	55	45	50	45-50	50	45
Rhythm	AF	AF	Sinus	Sinus	Sinus	Sinus	Sinus	AF	Sinus	Sinus	Sinus	Sinus

TTViV, Transcatheter tricuspid valve-in-valve; TV MPG, Transvalvular mean pressure gradient; TV PHT, Tricuspid valve pressure half time; iEOA, Indexed effective orifice area; RV, Right ventricle; RA, Right atrium; VTI, Velocity time index; LVOT, Left ventricular outflow tract; TR, Tricuspid Regurgitation; SPAP, Systolic pulmonary arterial pressure, NYHA, New York Heart Association; AF, Atrial fibrillation; LVEF, Left ventricular ejection fraction; NM, Not measurable
*MPG was not measured in anemia and/or tachycardia. In atrial fibrillation rhythm, a mean of 5 beats was measured.

Table 5. Descriptive characteristics of echocardiographic parameters before the procedure and at follow-up

	Before TTViV				Follow-up after TVIV				P*
	N	Mean±SD	Mini-mum	Maxi-mum	N	Mean±SD	Mini-mum	Maxi-mum	
RV diameter (mm)	12	35.92±7.22	25	50	12	32.25±3.47	27	37	0.054
TV MPG (mm)	12	7.08±1.98	5	11	12	5.292±1.63	2	8	0.028
TV PHT (mm)	10	245.00±49.46	191	350	11	158.64±57.41	80	234	0.011
RVSM	12	6.92±1.31	5	9	12	6.75±1.22	5	9	0.564
TRG	11	39.91±7.31	30	53	8	26.75±8.99	16	45	0.012
SPAP	11	27.27±7.04	17	43	8	34.25±10.32	21	55	0.050
LVEF (%)	12	47.71±4.70	40	55	12	49.79±4.58	42	57.5	0.046

TTViV, Transcatheter tricuspid valve-in-valve; RV, Right ventricle; TV MPG, Transvalvular mean pressure gradient; TVPHT, Tricuspid valve pressure half time; TRG, Tricuspid regurgitation gradient; SPAP, Systolic pulmonary artery pressure; LVEF, Left ventricular ejection fraction
P* was obtained using the Wilcoxon signed ranks test.

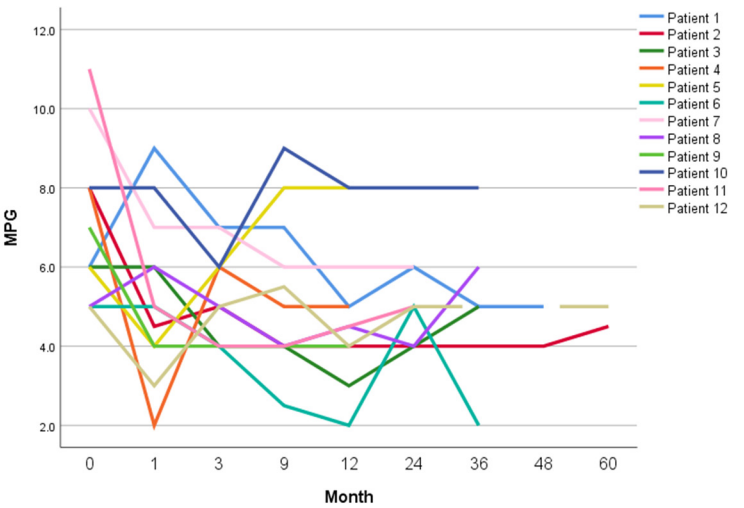

Figure 1. The image illustrates transvalvular MPG after TTViV in the serial follow-up echocardiography (month 0: before the procedure: 12 patients, month 1: same admission: 12 patients, month 3: 12 patients, month 9: 12 patients, month 12: 11 patients, month 24: 8 patients, month 36: 6 patients, month 48: 2 patients, and month 60: 2 patients).
MPG, Mean pressure gradient; TTViV, Transcatheter tricuspid valve-in-valve

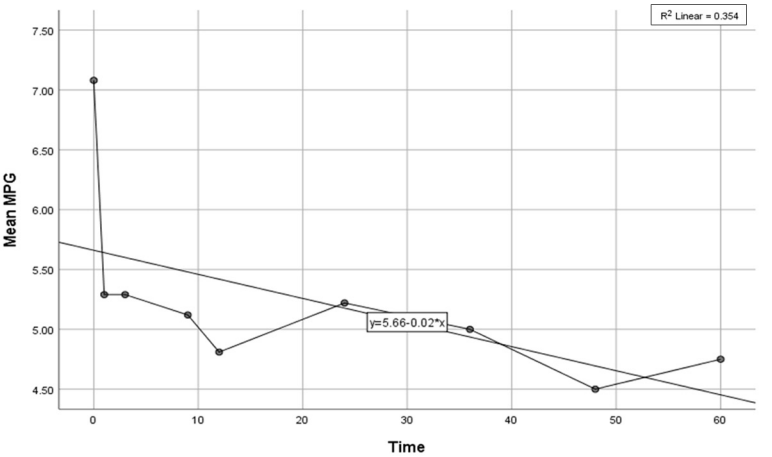

Figure 2. The image depicts changes in the transvalvular MPG after TTViV by the time measured in each follow-up session (month 0: before the procedure: 12 patients, month 1: same admission: 12 patients, month 3: 12 patients, month 9: 12 patients, month 12: 11 patients, month 24: 8 patients, month 36: 6 patients, month 48: 2 patients, and month 60: 2 patients).
MPG, Mean pressure gradient; TTViV, Transcatheter tricuspid valve-in-valve

than II (Table 4). Comparisons between echocardiographic measurements before the procedure and at follow-up are presented in Table 5. The following characteristics showed significant improvements: transvalvular MPG decreased from 7.08±1.98 mmHg to 5.29±1.63 mmHg (P=0.028), tricuspid valve pressure half time decreased from 245.00 ±49.46 ms to 158.64±57.41 ms (P=0.011), tricuspid regurgitation gradient decreased from 39.91±7.31 mmHg to 26.75±8.99 mmHg (P=0.012), and left ventricular ejection fraction increased from 47.71±7.70% to 49.79±4.58% (P=0.046).

Discussion

This study presents the results of the midterm echocardiographic follow-up of patients who underwent TTViV because of degenerative bioprosthetic valves as the first single-center report from Iran. The efficacy and safety of TTViV in our center were compatible with the results of previous international reports.

Transcatheter valve-in-valve implantation is a universally accepted procedure for patients with degenerated bioprosthetic valves who are considered high risk for surgical operations.[8,9] Nevertheless, there are limited data on the clinical and echocardiographic outcomes of patients undergoing the TTViV procedure. It has been shown that postprocedural hemodynamics and clinical outcomes are favorable at the 3-year follow-up of patients undergoing TTViV.[10,11] In the study of 4 patients treated with the TTViV procedure (using Edwards SAPIEN-

XT and SAPIEN-3 bioprosthetic valves),[12] significant improvements were reported in the transvalvular MPG, right atrial pressure, and tricuspid valve area. Additionally, after 9 to 47 months of follow-up, only 1 patient was rehospitalized. Overall echocardiographic assessments showed maintained hemodynamic performance.[12] In our study, we documented consistent echocardiographic improvements in transvalvular MPG in a larger number of patients over a longer follow-up time.

In a multicenter study on the 3-year outcome after TTViV in 306 patients, McElhinney et al[11] reported 3 major complications of this procedure: endocarditis (17%), tricuspid valve dysfunction (8%), and thrombosis (12%). Although the number of patients was small in the current report compared with their study, we had no case of infective endocarditis during our patients' follow-up.

Thrombosis is a rare and acute complication that occurs in the first 6 months following the TTViV procedure. Therefore, anticoagulation therapy in TTViV is needed because of risk factors, such as atrial fibrillation and right heart dilation and failure.[13] As mentioned before, in our patients, anticoagulation therapy was initiated accordingly, and none of them experienced postprocedural thrombosis.

Godart et al[14] published a multicentric study of TTViV in 10 patients (using 22 mm Melody valves in 7 patients and Edwards SAPIEN valves in 3 patients) and reported improvements in NYHA functional class in 9 patients, significant improvements in transvalvular MPG, and no-more-than trivial regurgitation. A review of data from 71 patients who underwent TTViV (using Melody valves in 41 patients, Edwards SAPIEN valves in 29 patients, and the Braile valve in 1 patient) also showed similar short-term results.[14] Our study, albeit a single-center one, also showed consistent improvements in NYHA functional class, transvalvular MPG, and similar findings in valve regurgitation at the midterm follow-up.

With proven techniques in the transcatheter aortic valve implantation method, the insertion of Edwards SAPIEN bioprosthetic tricuspid valves using femoral vein access is achievable.[6] The transfemoral approach for TTViV, using new generations of balloon expandable devices, is a safe and effective treatment method for tricuspid bioprosthetic valve regurgitation. In a study on patients treated with TTViV at the San Raffaele Scientific Institute in Milan, there were no complications at 30-day postprocedural evaluation, and the patients experienced improvements in renal function and hepatic congestion and function.[15] A successful case of TTViV with favorable symptomatic and hemodynamic outcomes in a 21-year-old woman with severe tricuspid regurgitation has also been reported.[16] Our study also showed no acute or early complications during and after the procedure and revealed improved clinical symptoms in all living patients after a mean time of over 3 years; however, we focused on echocardiographic characteristics rather than paraclinical data.

The first data of transcatheter valve-in-valve procedure in Iran was reported by Haji Zeinali et al,[17] who showed acceptable midterm results after the valve-in-valve treatment of different failing bioprosthetic valves (2 mitral, 1 pulmonary, and 2 tricuspid valves) in a case series of 5 patients. The patients had manageable postprocedural complications, including pleural effusions and transient ischemic attacks; furthermore, at follow-up, the patients had improved NYHA functional class without paravalvular leakage or valve thrombosis. Our study focused on transcatheter valve-in-valve replacement only in the tricuspid position and found no postprocedural adverse events, valve thrombosis, and trans- and/or paravalvular regurgitation at a longer follow-up of 12 patients.

Due to the relatively small number of patients and incomplete follow-up in some cases, which led to missing data, we are aware that the computed transvalvular MPG after TTViV (Figure 1 and Figure 2) could be biased. We encourage further prospective studies with larger numbers of patients on this subject.

Conclusion

In the current study, we reported a single-center successful TTViV procedure that was found to be a safe and effective alternative treatment method for cardiac surgery in patients suffering from degenerated bioprosthetic valves. The procedure had favorable echocardiographic and clinical outcomes and no major complications.

Acknowledgments

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