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Self-Expanding Transcatheter Aortic Valve Implantation in Patients with Severe Aortic Stenosis Undergoing Prosthetic Mitral Valve Replacement: A Single-Center Experience

ABSTRACT

Background: Following the encouraging results of several registries and trials, transcatheter aortic valve implantation has become standard therapy for aortic stenosis patients with intermediate or high operative risk for surgical treatment. Good procedural success and good clinical outcomes have been shown, but very limited data exist on transcatheter aortic valve implantation in the setting of a preexisting mitral valve (MV) prosthesis regarding the technique, potential complications, and outcomes. Single-center experience is presented with this special patient cohort.

Methods: Here, 31 cases of transfemoral transcatheter aortic valve implantation with a self-expanding bioprosthesis (CoreValve and Evolut R; Medtronic, Minneapolis, MN, USA) in patients who had previously undergone MV surgery have been reported. Preprocedural, intraprocedural, and post-procedural outcomes and data were analyzed.

Results: Between February 2013 and December 2023, 31 patients with prior MV prostheses were included. The average age was 68.7 years, and 77.4% were female. Mechanical MV prostheses were present in 90.3% of patients. The mean Society of Thoracic Surgeon score was 9.03. Transcatheter aortic valve implantation was performed 14.75 years after MV replacement. Post-procedural complications included access site issues in 25.8% of patients, with 22.5% requiring pacemaker implantation. No procedural mortality occurred. Six out of 31 patients (n = 6/31 patients) died during follow-up, primarily due to respiratory complications, and the mean survival time was 74.9 ± 8.4 months (95% CI: 58.4-91.4).

Conclusion: The experiences showed that transfemoral implantation of a self-expanding aortic valve with MV prostheses patients, via the transfemoral route, is safe and feasible, with maintained long-term results.

Keywords: Aorta-mitral continuityaortic stenosis, mitral prosthesistranscatheter aortic valve implantation

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INTRODUCTION

In recent years, transcatheter aortic valve implantation (TAVI) has become an alternative therapeutic option to treat patients who are at high or intermediate surgical risk or are unsuitable candidates for surgical aortic valve replacement due to significant comorbidities such as older age, multiple previous cardiac operations, chronic obstructive pulmonary disease, and liver or renal failure.[1] Using the percutaneous approach via transfemoral or transapical routes can be performed safely in a cohort of patients with previous cardiac surgery, such as bypass operations. Although patients with previous surgical mitral valve replacement (MVR) are also indicated for TAVI, there might be several concerns that should be kept in mind due to the anatomical close proximity of the aortic and mitral annuli, such as 1) increased risk of malposition of device; 2) risk of post-procedural dysfunction of the mitral prosthesis due to mechanical valve leaflet sticking; 3) paravalvular leakage (PVL); or 4) transcatheter aortic valve embolization due to the "watermelon seeding" phenomenon (balloon or device slippage during launch).[2-4] To prevent or decrease these risks, some authors reported the importance of various

methods for guidance: balloon aortic valvuloplasty of a similar balloon size to the valve stent for assessing the expansion and stability of the balloon and ensuring no interference with the mitral prosthesis; using fluoroscopy and transesophageal echocardiography (TEE) to observe the correct position of the device in relation to the mitral prosthesis; and cardiac computed tomographic angiography (CTA) for assessing the distance between both annuli and the amount of excursion available for the stented valve.[4,5]

There have only been a limited number of reports on the feasibility of TAVI using a CoreValve self-expanding transcatheter heart valve and Evolut R self-expanding transcatheter heart valve (both Medtronic, Minneapolis, MN, USA) in patients with a prosthetic mitral valve (MV). Herein, a real-world, single-center experience including 31 patients with previous MVR who underwent TAVI with CoreValve and Evolut R (Medtronic, Minneapolis, MN, USA) has been presented.

METHODS

Study Population

This retrospective, observational study involved the period between February 2013 and December 2023, and included all patients had previous MVR in whom transfemoral TAVI had been performed at the center. From a total of 410 patients with symptomatic severe aortic stenosis (AS) treated by TAVI at the center, a total of 31 who had a previous MVR were enrolled in this study. Patient evaluation in all cases regarding the severity of AS, symptoms, surgical risk, life expectancy, and quality of life, as well as the possibility and exclusion of contraindications for TAVI, was made by the "heart team," composed of a cardiac surgeon, an interventional cardiologist, the referring cardiologist, a cardiac anesthesiologist, and a radiologist.

After the 'heart team' evaluation, TAVI with a CoreValve and Evolut R (Medtronic, Minneapolis, MN, USA) prosthesis was preferred for 410 patients. In 31 of them (3 bioprostheses, 28 metallic bileaflet prosthetic valves), the TAVI procedure was performed as a reoperation after previous MV surgery. Written informed consent was obtained from all patients, and the local ethics committee approved the procedures.

HIGHLIGHTS

- Transcatheter aortic valve implantation (TAVI) is a feasible and safe option for patients with previous MV replacement, demonstrating promising procedural success and long-term outcomes.
- Preprocedural imaging with computed tomographic angiography and transesophageal echocardiography is essential to assess the anatomical relationship between the aortic and mitral valves, reducing the risk of complications.
- Patient selection and individualized procedural planning, including careful attention to the mitroaortic distance, are crucial for optimizing the success of TAVI in this complex patient population.

As a routine preprocedural approach, standard transthoracic echocardiogram (TTE), TEE, and multislice computed tomography (MSCT) have also been performed before the TAVI procedure in all patients in order to carefully assess (i) aortic root diameters, (ii) peripheral arterial access, and (iii) relationship between the aortic annulus and the mitral prosthetic valve or ring (Figure 1 and 2). Coronary angiography or peripheral angiography has been performed if patients had symptoms or MSCT revealed significant coronary artery stenosis or occlusion.

Echocardiographic Evaluation

All patients underwent a detailed TTE to assess aortic valve morphology, valvular function, and measure the AS severity using Doppler ultrasound techniques (Figure 1). Parameters such as aortic valve area, peak jet velocity, mean gradient, and valve calcification were recorded.

Following TTE, a TEE assessment was performed to provide enhanced visualization of the aortic valve, especially in cases where TTE results are inconclusive or the MV prosthesis impedes acoustic windows. Transesophageal echocardiography was utilized to assess the aortic annulus diameter, shape, and the presence of any adjacent structural abnormalities, which are crucial for the planning of the TAVI procedure. Intraprocedural TEE was selectively performed, particularly in cases where TTE results were inconclusive or when additional imaging support was deemed necessary due to the complexity of the anatomical structures.

Multislice Computed Tomography Evaluation

Cardiac CTA (CCTA) was obtained in all patients for preprocedural planning. Cardiac CTA examinations were analyzed using dedicated software (CT Coronary, syngo.via VB 60, Siemens Healthineers, Germany). Imaging protocols were standardized to encompass a scan range extending from the carotid artery bifurcation to the superficial femoral artery at the level of the knee, with a slice thickness of 0.5 mm. Contrast-enhanced imaging was utilized to enhance the visualization of cardiac structures, aortic root, and vascular access paths. It is crucial to evaluate the existing MV prosthesis's position and its interaction with the intended site for the aortic prosthesis to prevent mechanical interference or disruption during TAVI. In the 3-chamber view, the distance between the aortic anulus plane and the MV prosthesis (Figure 2A.) and also the angle between the aortic and MV planes (Figure 2B.) were measured. Coronary arteries of all patients were evaluated through CCTA, and coronary angiography (CAG) was performed 1 day before the TAVI procedure in patients with hemodynamically significant stenosis. Percutaneous coronary intervention (PCI) was performed on lesions causing hemodynamically significant stenosis. The PCI procedure was performed using either radial or femoral access at the operator's discretion.

Transcatheter Aortic Valve Implantation Procedure

The procedures were performed by the cardiovascular team, composed of interventional cardiologists, cardiac surgeons with expertise in hybrid procedures, and cardiac anesthesiologists. Patients with mechanical MVR were receiving warfarin therapy. After discontinuing warfarin therapy 5 days

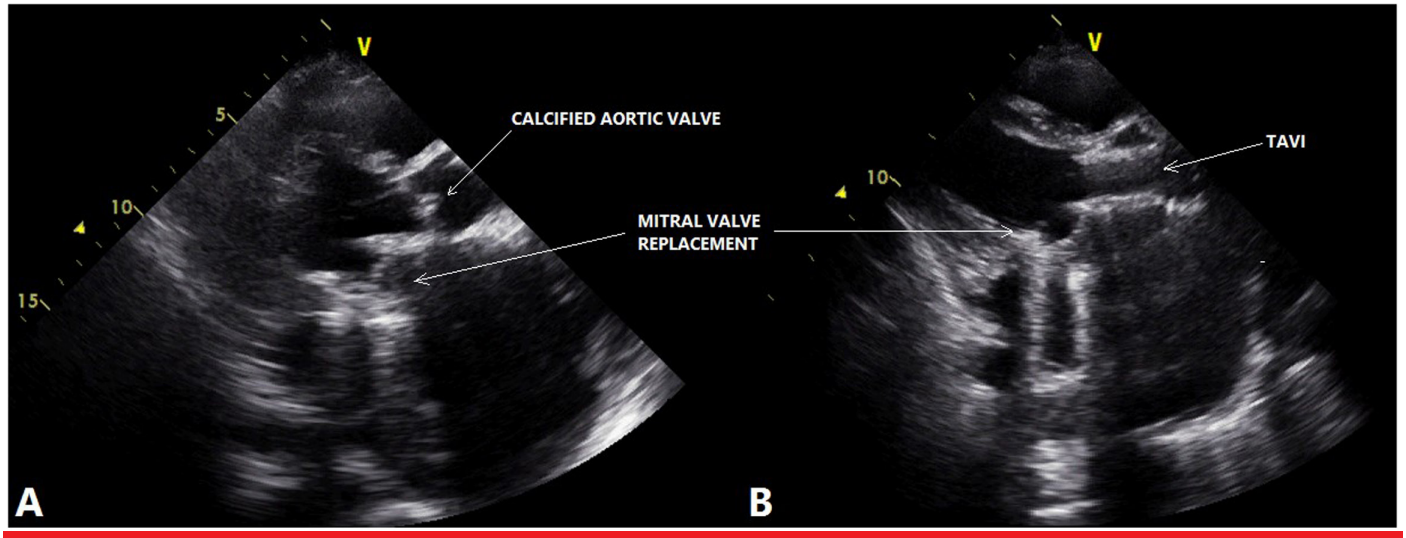

Figure 1. Transthoracic echocardiography images. A. Pre-procedure view from the parasternal long axis (PLAX) window shows a calcified aortic valve and mechanical mitral valve (arrows). B. Post-procedure view from the PLAX window displays the mechanical mitral valve and the transcatheter aortic valve.

before the procedure, when the International Normalized Ratio decreased to <2, enoxaparin bridging therapy was initiated. The enoxaparin doses were administered 12 hours prior to the procedure. In initial cases (n = 4), TAVI procedure was performed via a hybrid approach with cardiac surgeons. In the remaining 27 cases the ProGlide closure system was used for the puncture site. All procedures were performed by transfemoral approach under deep sedation and local anesthesia under fluoroscopic guidance. The following valve types were implanted: CoreValve (first 4 cases) and Evolut R (remaining 27 cases) (Medtronic, Minneapolis, MN, USA). The implantation was safely performed using appropriate fluoroscopic angles, such as Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO), to accurately evaluate the aortico-mitral distance. Heparin was administered at the beginning to keep the activated clotting time >250 seconds throughout the procedure. Hemodynamic measurements were taken before, continuously during, and directly after valve implantation. Rapid pacing during valve implantation was performed using either a transvenous pacemaker placed in the right ventricle apex or by programming patients' permanent pacemakers. During valve implantation and balloon dilatation, rapid pacing was applied at a rate of 150-180 beats/min, typically at 180 beats/min. A final angiogram with 20 mL contrast at a flow rate of 10 mL/s documented the position of the self-expanding aortic valve and possible residual PVL. Paravalvular leakage was angiographically classified into 4 categories: none/trace, mild, moderate, and severe.[6] Preprocedural anti-platelet treatment consisted of acetylsalicylic acid (100 mg qd) and clopidogrel 75 mg qd after a loading dose of 300 mg. Patients were monitored for 6 hours post-procedure; after ruling out pericardial effusion, access site hematoma, and bleeding, and confirming no decrease in hemoglobin levels in complete blood count,

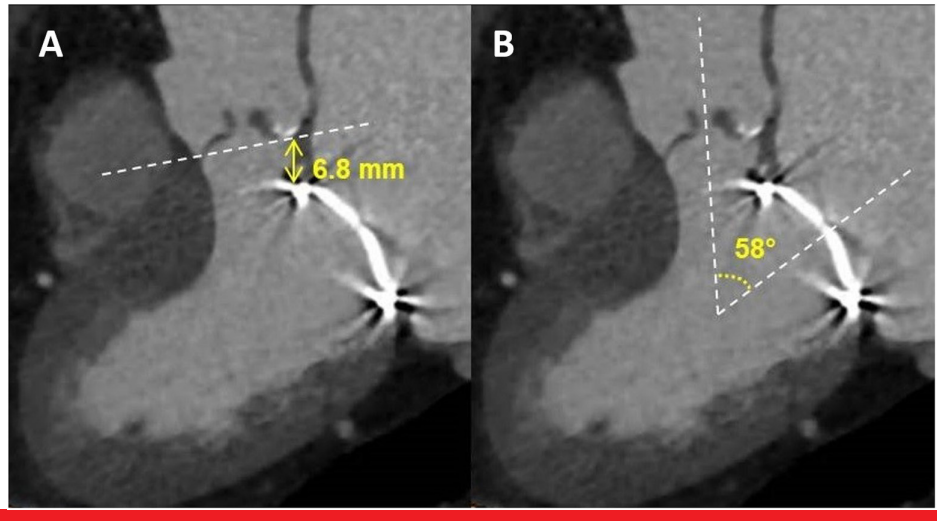

Figure 2. Computed tomography angiography measurments in the 3-chamber view A. Distance between the aortic annulus plane and the mitral valve prosthesis. B. Angle between the aortic and mitral valve planes.

enoxaparin therapy was resumed. Patients were monitored with enoxaparin therapy throughout their hospital stay. At discharge, patients were prescribed a warfarin dosing regimen with enoxaparin bridging therapy. All patients were on warfarin therapy due to their mechanical MVR and received an additional 75 mg of clopidogrel/day for 3 months after the procedure.

Endpoints

The primary endpoint was defined as the procedural success rate, which was assessed based on the VARC-3 (Valve Academic Research Consortium-3) criteria.[7] These criteria include all-cause mortality, stroke, type 2-4 bleeding, major vascular/cardiac structural damage, new permanent pacemaker implantation (PPI), acute kidney injury, moderate-severe aortic regurgitation, the need for surgical intervention, and paravalvular leak (PVL). The secondary endpoints were hospitalization due to valve failure, mortality, and valve dysfunction.

Statistical Analysis

In this study, descriptive statistics for continuous variables are presented as the mean ± SD, while the frequencies of categorical variables are depicted as counts and percentages [n (%)]. Normality distribution was decided according to skewness and kurtosis values. Values between –2 and +2 were assumed to be normally distributed. Kaplan-Meier curves were used to evaluate survival. The Wilcoxon test was used to compare non-parametric dependent values. Multiple linear regression analysis was employed to examine the relationships between variables in this study. The validity of the regression model was evaluated by calculating standardized regression coefficients (β), significance levels (*P*), and 95% CIs. The statistical analysis was carried out utilizing the SPSS software, version 28.0, for Windows, developed by IBM (SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp.).

RESULTS

Between February 2013 and December 2023, a total of 31 patients who had previously undergone surgical MV prosthetic operations were included in the study. The average age of the population was 68.7 ± 9.06 years, with 24 patients (77.4%) being female. The mean Society of Thoracic Surgeon (STS) mortality score of the patients was 9.03 ± 2.32. Eight patients (26%) had a history of coronary artery disease (6 patients (19.4%) had previous coronary artery bypass grafting (CABG), while 2 (%6,5) previous PCI), and 23 patients (74.1%) presented with concomitant atrial fibrillation (AF). Other accompanying conditions are summarized in Table 1.

Of the patients studied, 3 (10.7%) had a bioprosthetic MV, while the remaining 28 (90.3%) had a mechanical MV. Additionally, 3 patients (10.7%) underwent tricuspid valve replacement (TVR) along with MVR, and 2 patients (6.5%) had a history of tricuspid valve repair. There were also 3 patients (10.7%) who had undergone a re-MVR operation. The average duration between the previous MVR surgery and the TAVI procedure was 14.75 ± 9.4 years.

Table 1. Baseline Clinical Charecterics

Variables	All Population (n = 31)
Age (years)	68.7 ± 9.06
Gender	
Female, n (%)	24 (77.4)
Male, n (%)	7 (32.6)
Hypertension, n (%)	18 (58)
Diabetes mellitus, n (%)	8 (25.8)
Atrial fibrillation, n (%)	23 (74.1)
Chronic kidney disease, n (%)	5 (16.1)
History of CAD, n (%)	8 (26)
Previous CABG	6 (19.4)
Previous PCI	2 (6.5)
Previous cerebrovascular disease, n (%)	5 (16.1)
NYHA III–IV, n (%)	14 (45.1)
STS mortality score (mean ± SD)	9.03 ± 2.32
EuroScore II, (mean ± SD)	8.65 ± 3.18
Logistic EuroScore (mean ± SD)	30.25 ± 10.85
Creatinine (mg/dL) (mean ± SD)	0.88 ± 0.42
Hgb (gr/dL) (mean ± SD)	11.3 ± 1.36
BNP (pg/mL) (mean ± SD)	419 ± 176
Previous PM, n (%)	5 (16.1)
Time from MVR to TAVI (years) (mean ± SD)	14.75 ± 9.4
Mechanical, n (%)	28 (90.3)
Biological, n (%)	3 (10.7)

Data shown mean ± SD, and n (%).
BNP, brain natriuretic peptide; CAD, coronary artery disease; CABG, coronary artery bypass grafting; Hgb, hemoglobin; MVR, mitral valve replacement; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PM, Pacemaker; STS, Society of Thoracic Surgeon; TAVI, transcatheter aortic valve implantation.

Turning to the TTE measurements, the mean left ventricular ejection fraction (LVEF), calculated using the modified Simpson method,[8] was 51.6 ± 12.2%. Regarding aortic valve metrics, the average aortic valve area (AVA) was 0.81 ± 0.17 cm^2, while the mean aortic gradient was 41.18 ± 8.65 mm Hg. Notably, severe aortic insufficiency was present in 3 patients (9.6%), and moderate mitral regurgitation was observed in 6 patients (19.4%). All patients had a tricuspid aortic valve. Aortic prosthetic valve function was evaluated by TTE before discharge; the mean peak gradient was recorded as 16.38 ± 4.62 mm Hg. Patients were followed for a median of 20.5 months (IQR: 5.4), and the mean aortic prosthetic valve gradient during follow-up was calculated as 16.23 ± 4.3 mm Hg. There was no statistically significant difference between valve gradients at discharge and during follow-up (*P* = .88, Wilcoxon test). Doppler echocardiographic evaluation revealed no aortic prosthetic valve regurgitation at discharge and during follow-up. Additionally, no paravalvular leak (PVL) was detected in any patient during follow-up. Pre-procedure MSCT measurements calculated the mean aortic perimeter as 76.5 ± 7.1 mm. The average aortico-mitral distance was measured at 6.4 ± 1.46 mm, with the shortest distance at 4.5 mm and the maximum at 10 mm. The angle

Table 2. Peri-Procedural Echocardiographic and Computed Tomography Measurements.

Echocardiographic Measurements	
LVEF (%) (Modified Simpson) (mean ± SD)	51.6 ± 12.2
AVA (cm^2) (mean ± SD)	0.81 ± 0.17
Maximum aortic gradient (mm Hg) (mean ± SD)	74.2 ± 15.5
Aortic gradient (mean, mm Hg) (mean ± SD)	41.18 ± 8.65
Mitral gradient (mean, mm Hg) (mean ± SD)	5.93 ± 1.7
Aortic Regurgitation	
Moderate, n (%)	7 (22.5)
Severe, n (%)	3 (9.6)
Mitral Regurgitation	
Moderate MR, n (%)	6 (19.4)
Severe MR, n (%)	0 (0)
Tricuspid Regurgitation	
Moderate, n (%)	7 (22.5)
Severe, n (%)	6 (19.4)
TVR/TVV n (%)	3 (9.6)
Bicuspid aortic valve, n (%)	0 (0)
Computed Tomography Measurements	
Aortic annular area (cm^2) (mean ± SD)	4.6 ± 0.85
Aortic perimeter (mm) (mean ± SD)	76.5 ± 7.1
Distance between aortic anulus and LMCA (mm) (mean ± SD)	13.1 ± 2.9
Distance between aortic anulus and RCA (mm) (mean ± SD)	14.8 ± 3.1
Aortico-mitral distance (mm) (mean ± SD)	6.4 ± 1.46
Angle between aortic valve and mitral prosthesis (mean ± SD)	57.0 ± 5.3

Data shown mean ± SD, and n (%).
AVA, aortic valve area; LMCA, left main coronary artery; LVEF, left ventricle ejection fraction; LVOT, left ventricle outflow tract; RCA, right coronary artery; TVR, tricuspid valve replacement; TVV, tricuspid valve valvuloplasty.

between the aortic valve and the mitral prosthesis was determined to be an average of 57.0 ± 5.3 degrees. Coronary arteries and grafts in patients with CABG were evaluated by CCTA, and all patients with obstruction greater than 50% underwent CAG the day before the TAVI procedure. CAG was performed in n = 13 (41.9%) patients, and PCI was performed in n = 3 (9.7%) patients due to angiographically detected stenosis >70%. Other echocardiographic and MSCT measurement parameters are summarized in Table 2.

Pre-dilatation was performed in n = 8 (2.8%) patients prior to valve implantation. Post-dilatation was performed in n = 2 (6.5%) patients. No periprocedural pericardial effusion was observed. Moderate-severe aortic regurgitation was not detected in patients during aortography.

Primary Endpoints

Primary endpoints were analyzed according to VARC-3 criteria. There was no periprocedural mortality in this patients during the 30-day follow-up. No stroke occurred in the patients. There was no moderate to severe aortic regurgitation in the patients. According to VARC-3 criteria, no acute kidney injury, coronary obstruction, myocardial infarction, or type 2-4 bleeding occurred during the 30-day follow-up period in these patients. None of the patients required surgical intervention (Table 3).

Table 3. Procedural Charecteristics, In-Hospital Complications and Follow-Up

TAVI Procedure	
Transfemoral approach, n (%)	31 (100)
Predilation, n (%)	8 (25.8)
Postdilation, n (%)	2 (6.5)
Aortic prosthesis size (mm)	28.7 ± 2.9
Primary End-Points	
Tamponade, n (%)	0
Stroke, n (%)	0
Acute kidney injury, n (%)	0
Cardiovascular surgery, n (%)	0
Pacemaker implantation, n (%)	7 (22.5)
Major vascular complications, n (%)	2 (6.5)
Minor vascular complications, n (%)	6 (19.3)
Moderate to severe AR, n (%)	0
Death	
Total deaths during follow-up, n (%)	6 (19%)
Mean survival time (months) (mean ± SD)	74.9 ± 8.4
Follow-up length (months) (median, IQR)	20.5 (IQR:54)
Follow-up completion rate	95% at 2 years

Data shown mean ± SD, median (Interquartile Range) and and n (%).
TAVI, transcathater aortic valve implantation.

Vascular Complications

In all patients, the transfemoral approach was utilized. Surgical closure of the access site was performed in 4 patients (12.9%), while a percutaneous ProGlide closure system (Abbott Laboratories, Illinois, USA) was successfully implemented in 27 patients (87.1%). Based on the updated VARC-3 criteria, major vascular complications occurred in 2 patients (6.5%), including 1 case of arteriovenous fistula requiring surgical intervention and 1 case of pseudoaneurysm managed surgically. Vascular closure was performed using a single ProGlide system in both patients. Minor vascular complications were observed in 6 patients (19.3%), which included 5 pseudoaneurysms and 1 case of hematoma that were managed conservatively without surgical intervention. Total thrombosis was achieved by ultrasound-guided compression of the patients' pseudoaneurysm sacs.

Pacemaker Implantation

As per the VARC-3 guidelines, PPI was required in 7 patients (22.5%) due to new-onset conduction disturbances post-TAVI. Two of these patients had prior tricuspid valve replacement, necessitating pacemaker implantation via the coronary sinus in patients with mechanical tricuspid valves. In regression analysis, there was no significant association between the need for pacemaker implantation and balloon pre-dilatation or post-dilatation (pre-dilatation $\beta_1 = 0.036$, 95% CI [−0.439, 0.368], $P = .84$; post-dilatation $\beta_2 = 0.214$, 95% CI [−0.504, 0.932], $P = .54$). Pre-procedural computed tomography (CT)

imaging was performed to assess the membranous septum length, but in some cases, despite careful pre-procedural planning, the valve's expansion resulted in pressure on the conduction system, necessitating pacemaker implantation.

Secondary End-Points

Following the VARC-3 definitions, no periprocedural mortality (within 30 days of the procedure) was observed. A total of n = 6/31 (19%) patients died during follow-up. The mean survival time was 74.9 ± 8.4 months (95% CI: 58.4-91.4) (Figure 3A). PPI mean survival time was 60.8 ± 8.06 months (95% CI: 45-75.6), and No-PPI mean survival time was 75.29 ± 10.3 months (95% CI: 54.9-95.6; $^{**}P = .718$) (Figure 3B). The analyses showed that hypertension, diabetes mellitus, chronic kidney damage, and heart failure had no effect on mortality. Four of these deaths were attributable to respiratory complications (e.g., pneumonia and ARDS), while the cause of death was unknown in 3 patients due to insufficient data. In addition to mortality, there were no reported cerebrovascular events, and no instances of late PPI beyond the initial post-procedural period. Other major adverse events such as repeat interventions or rehospitalizations for heart failure were also not observed during the follow-up period.

DISCUSSION

Despite the accumulating experience with TAVI procedures, the optimal approach for managing specific conditions or patient subgroups remains ambiguous. Among these groups, individuals with prior MV prostheses represent a unique challenge. The literature includes a limited number of single-center studies discussing TAVI in patients who have previously received biological or mechanical MVR.

When delving into the pioneering case series related to this topic, it becomes evident that the realm of TAVI in patients with prior mechanical MV prostheses is marked by foundational contributions. Notably, the CoreValve prosthesis (Medtronic, Minneapolis, MN, USA) was first employed in 8 instances, a milestone achievement documented by Brushi et al[9] in 2009. The Sapien balloon-expandable (BE) transcatheter heart valve (Edwards Lifesciences, Irvine, CA, USA) was introduced in 12 cases with Dumonteil et al[10] leading the initial exploration. Furthermore, the innovative transapical approach was applied in a cumulative total of 27 cases, a technique first brought to light by Rodés-Cabau et al[4] in 2008. These seminal works collectively underscore the evolving landscape of TAVI procedures, paving the way for subsequent research and clinical practice. This study represents a single-center analysis encompassing a total of 31 patients, marking a significant contribution to the field as there is no other single-center study involving this number of patients reported in the literature to date. This factor alone highlights the value and uniqueness of the work. In 2016, a series involving 6 cases was published, establishing an early footprint in this research area.[11] Another noteworthy contribution to the literature on this topic is the multicenter OPTIMAL STUDY, which aggregated data from 11 centers involving 154 patients.[12] This study stands out as a significant benchmark for comparison and further discussion within the field.

In this study, each case was meticulously carried out through transfemoral access, resulting in a 100% procedural success rate as defined by VARC-3 criteria, which included successful device implantation, no significant PVL, and no major periprocedural complications such as stroke, tamponade, or death. This procedural success rate aligns with the outcomes reported in other studies, demonstrating high standards of procedural success across various centers. Although the success rate is notable, further studies with larger cohorts are needed to fully assess long-term outcomes and potential complications. For example, in the study spearheaded by Amat Santos et al,[13] a commendable success rate of 98.6% was reported, while the investigation led by Luca Baldetti and his colleagues observed a slightly lower yet impressive rate of 97.4%.[14] These comparative figures highlight the procedural success achieved in this study, in line with other published results in the field.

Although these studies also demonstrate high success rates, the patient demographics and procedural techniques differ from those in this study. For instance, Amat Santos et al[13] had a higher proportion of patients with coronary artery disease, which may have influenced the higher complication rates in their study. In contrast, this cohort had a higher prevalence of AF, which is a known risk factor for adverse outcomes following TAVI. These differences highlight the importance of individual patient characteristics in determining procedural outcomes and underscore the need for tailored approaches

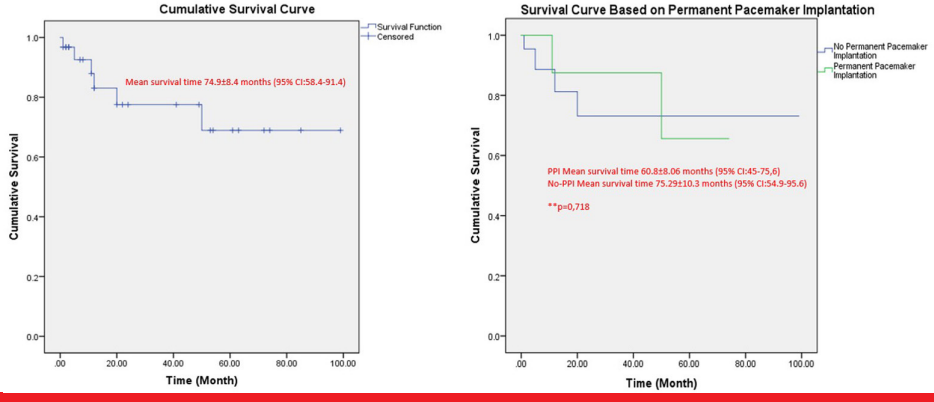

Figure 3. A. All-cause survival curves B. Survival curve due to permanent pacemaker implantation

to valve replacement in patients with complex medical histories.

When TAVI is conducted in patients who already have an MV prosthesis, several significant considerations arise. The presence of a rigid prosthetic mitral ring, along with the limited space between the aortic and MV areas, can present challenges for the successful deployment and expansion of the aortic prosthesis.

Despite the growing experience with TAVI, it remains particularly challenging in patients with prior MVR due to the unique anatomical and procedural considerations. One of the primary challenges in this population is the anatomical proximity of the aortic and mitral annuli, which can complicate the positioning and deployment of the aortic prosthesis.

The presence of a rigid mechanical mitral prosthesis introduces additional risks, such as the potential for device malpositioning, which can lead to inadequate sealing and an increased risk of PVL. Additionally, there is a risk of interference between the mechanical MV leaflets and the newly implanted aortic valve, which may result in post-procedural dysfunction of either prosthesis.

Another challenge is the risk of device embolization due to the "watermelon seeding" phenomenon, where the prosthetic valve may slip during deployment because of the tight space between the 2 annuli. The close spatial relationship between the valves also makes it more difficult to accurately position the aortic prosthesis without compromising the MV's function. Careful pre-procedural imaging, including MSCT and TEE, is essential to assess the distance between the aortic and mitral annuli and to plan for safe deployment.

Moreover, these factors may also adversely affect the performance of the existing mitral prosthesis, potentially compromising its functionality.[14,15] This complex interplay necessitates careful planning and execution of TAVI in such scenarios to ensure optimal outcomes for the patient.

Given these challenges, to mitigate the risk of complications during TAVI in the presence of a preexisting mitral prosthesis, several strategic measures should be implemented. Firstly, a comprehensive evaluation of the mitroaortic junction is crucial, employing transesophageal echocardiography and MSCT to meticulously assess the aortic valve, the mitral prosthesis, and their spatial relationship. Secondly, careful observation of the balloon's behavior during valvuloplasty is essential, with a focus on its inflation dynamics, positional shifts, and the presence of any residual narrowing to ensure precise intervention. Thirdly, selecting an imaging projection that offers a clear view of the mitroaortic distance, such as a LAO angle with cranial tilt, is vital for accurate prosthesis placement (Figure 4).

Furthermore, ensuring the aortic bioprosthesis can fully expand without altering its structural integrity or affecting the valve's functionality is paramount. Attention must also be given to preventing device embolization, which can occur due to the "watermelon seeding" effect, and to avoiding any interference with the mitral prosthetic leaflets or causing deformation that might impair its function. Utilizing TEE plays a key role in precisely positioning the aortic prosthesis, verifying its proper expansion, and evaluating its performance post-implantation. Lastly, selecting the appropriate vascular access point, based on patient-specific anatomy and procedural requirements, is fundamental to the success of the intervention.[15,16] These precautions are designed to enhance procedural outcomes and patient safety during TAVI in this complex clinical scenario.

In preparing for a procedure, particularly when evaluating the mitroaortic space, it is critical to exercise meticulous care and avoid choosing a prosthesis that is too large. A minimum separation of 4 mm between the aortic and MV is essential to

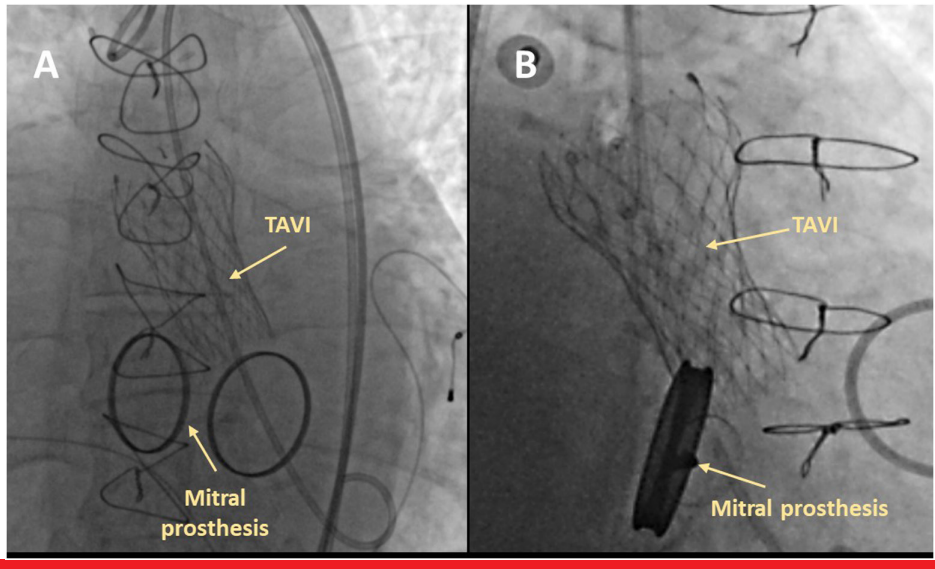

Figure 4. Fluoroscopic imaging to assess mitro-aortic spatial relationship: A. Left anterior oblique (LAO) projection providing an "en face" view of the mitral valve (MV) prosthesis. B. Right anterior oblique (RAO) projection.

ensure the Evolut R's inflow section can be positioned safely without impacting the function of the mitral prosthesis. In this series of patients, CTA confirmed that this distance exceeded 4 mm for all individuals (between 4.5 mm and 10 mm). Notably, the Evolut R system's progressive deployment feature is advantageous, allowing for precise adjustments to be made during implantation. This careful approach ensures there's no interference with existing mitral prostheses, highlighting the importance of detailed preprocedural planning and the benefits of the Evolut R's design for patient safety and effective treatment.

In these cases, the Evolut R valve was consistently chosen, largely due to the significant experience with this self-expandable (SE) valve. The Evolut R system's design allows it to be fully repositioned, recaptured, and resheathed before complete release, enabling precise placement adjustments through a simple turn of the delivery handle. This feature is crucial for ensuring correct valve positioning and minimizing complications, underscoring the preference for the Evolut R in practice.

Despite having less experience with BE valves in the clinic, particularly in cases of prior MVR, the unique anatomical challenges in patients with mechanical mitral prostheses made the SE Evolut R valve the optimal choice in this cohort. BE valves, such as the Sapien BE valve, offer precise deployment due to controlled inflation, but in cases of prior MVR, the forgiving nature of the SE valve, which allows repositioning, recapture, and adjustments during implantation, provides significant advantages. This specific feature is especially valuable in preventing complications such as valve embolization and PVL, common risks in patients with prior valve surgeries.

Regarding the procedural nuances of valve replacement, it is essential to appreciate the mechanical and bioprosthetic mitral valves' distinct architectures. Mechanical valves, with their rigid cages and possible protruding elements, can influence balloon positioning during interventions.[17] Similarly, bioprostheses, with their pronounced commissural struts, may impinge on the left ventricular outflow tract (LVOT), risking valve misplacement or embolization.[18] Despite these challenges, particularly with Evolut R implantations extending into the LVOT, the experience showed no significant issues related to valve displacement or functionality impairment, as confirmed by comprehensive imaging assessments. In this study, 3 patients had bioprosthetic MV, while 28 patients were fitted with mechanical MV.

The relatively high rate of PPI observed in this cohort (22.5%) can be attributed to the specific anatomical challenges posed by mechanical mitral prostheses and the placement of the Evolut R valve. In particular, the Evolut R's expansion, while advantageous for precise deployment, can increase the risk of conduction disturbances if placed too close to the membranous septum. While pre-procedural CT imaging was employed to assess the septum's length and minimize this risk, in some cases the anatomical proximity led to a need for pacemaker implantation. This highlights the importance of careful valve positioning and the need for further research to refine techniques in this patient population. A meta-analysis including 71 455 patients found a 22% need for PPI after TAVI, which is consistent with the study's rate.[19] Another meta-analysis demonstrated that male gender, baseline atrioventricular conduction abnormalities before TAVI (including Mobitz type-1 second-degree heart block, LAFB, and RBBB), and atrioventricular block during the procedure were associated with higher PPI rates, independent of prosthesis type or access site selection.[20] In this study, balloon dilatation did not increase the risk for PPI. A meta-analysis examining 1395 patients demonstrated that balloon pre-dilatation was not associated with an increased risk of PPI, which is consistent with this study.[21] In addition, a meta-analysis of 50 282 patients showed that mortality and rehospitalization were higher in patients who received PPI after TAVR.[22] In this study, it was shown that mortality was not increased in patients who received PPI, but this is probably due to 2 reasons: first, the small number of patients; second, it is an isolated patient group that received MVR. Studies with larger numbers of patients are needed in this patient group.

The clinical practice demonstrates that patients with both mechanical and bioprosthetic MV can undergo transfemoral CoreValve (Medtronic, Minneapolis, MN, USA) implantations with high success rates. The key to minimizing potential complications lies in the thorough pre-procedural and intraprocedural evaluations conducted by a multidisciplinary team. Utilizing a combination of echocardiography, CT imaging, and fluoroscopy, the spatial relationship between the aortic annulus and the mitral prosthesis is meticulously assessed to ensure there is no interference that might compromise the procedure or patient outcomes.

This comprehensive approach not only allows for precise placement of the aortic valve prosthesis but also facilitates the anticipation and management of any anatomical challenges. Emphasizing patient-specific planning, the protocol includes detailed analyses of valve geometries and the mitroaortic interval to tailor the procedure to individual anatomical variances. Furthermore, this strategy underscores the importance of technological proficiency and collaborative expertise in navigating the complexities of valve replacement in patients with preexisting mitral prostheses, thereby enhancing procedural efficacy and safety.

This study is a single-center, retrospective analysis, and the relatively small sample size limits the generalizability of the findings. Furthermore, the follow-up period was variable, and long-term data were incomplete for some patients, making it difficult to fully evaluate the long-term efficacy and safety of the procedure. Additionally, the limited variety of transcatheter valve devices used in the study may have influenced the outcomes, as comparisons with BE valves or other device types could not be made. Future studies with larger, multicenter cohorts and diverse device options are necessary to validate these findings and optimize treatment strategies in this complex patient population.

In conclusion, this study demonstrates that TAVI in patients with preexisting MV prostheses is both feasible and effective when performed with careful pre-procedural planning and a multidisciplinary approach. The use of the Evolut R valve, in particular, was associated with a high procedural success rate and minimal complications. While the single-center experience provides valuable insights into this complex patient population, further studies with larger cohorts and longer follow-up periods are necessary to validate these findings and optimize outcomes for patients undergoing TAVI after MVR.

Availability of Data and Material: The data that support the findings of this study are available on request from the corresponding author, [A.K.].

This study has been accepted as a poster presentation at the EuroPCR 2024 (May, 2024; Paris) conference (Abstract Number: A50974AK).

The submitted article does not use any artificial intelligence (AI)-powered technologies (such as Large Language Models [LLMs], chatbots, or image generators).

Ethics Committee Approval: The study was performed in accordance with the Declaration of Helsinki, and was approved by the Hacettepe University Health Sciences Research Ethics Committee (Approval date: January 9, 2024, Approval no.: 2024/03-38).

Informed Consent: The need for informed consent was waived under the approval of the Local Ethics Committee due to the retrospective design.

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