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ORIGINAL ARTICLE

First Turkish Experience with the PASCAL TEER System

Sinem Özbay Özyılmaz[1,2], Enes Alıç[1], Ahmet Huraibat[1], Mehdi Onaç[1], Mohamed Niang[1], Teoman Kılıç[3], Hakan Uçar[1]

[1]Department of Cardiology, İstanbul Aydın University Faculty of Medicine, Medical Park Florya Hospital, İstanbul, Türkiye

[2]Baylor College of Medicine, Texas Heart Institute, Texas, USA

[3]Department of Cardiology, Kocaeli University Faculty of Medicine, Kocaeli, Türkiye

ABSTRACT

Background: The PASCAL transcatheter edge-to-edge repair (TEER) system was developed for patients with symptomatic severe mitral regurgitation (MR), particularly those at high surgical risk. However, real-world experience with this system remains limited.

Aim: To report procedural success, in-hospital events, and discharge echocardiographic findings from the first Turkish case series of patients treated with the PASCAL system.

Study Design: Retrospective study.

Methods: We retrospectively reviewed consecutive patients who underwent PASCAL-based TEER at a tertiary care center between January 2023 and October 2025. Clinical, procedural, and echocardiographic data were analyzed.

Results: Twenty-three patients underwent PASCAL-based TEER, with 35 devices implanted (11 P10 and 24 advanced closure and enhancement). Procedural success was achieved in all patients according to the prespecified definition. The patient with single-leaflet device attachment had residual MR ≤2+ at discharge and did not require urgent surgery; therefore, the procedure met the predefined success criteria. Two periprocedural complications occurred: one case of single-leaflet device attachment and one episode of decompensated heart failure. No in-hospital deaths occurred. Procedure duration was longer in patients with fibrotic or lipomatous interatrial septal morphology than in those with a normal interatrial septum (118 vs. 53 minutes; p=0.001). Postprocedural pulmonary venous S>D flow was observed in 21 patients (91%). The mitral valve area decreased from 5.13 cm² to 3.70 cm², and the three-dimensional vena contracta area decreased from 0.63 to 0.18 cm² (both p<0.001). Transmitral gradients increased modestly without clinically significant mitral stenosis.

Conclusion: In this small retrospective series, PASCAL-based TEER was technically feasible and was associated with favorable discharge echocardiographic findings. No in-hospital deaths occurred. These findings are preliminary and should be interpreted with caution.

Keywords: Edge-to-edge repair, cardiovascular, interventional, mitral regurgitation, PASCAL, TEER

INTRODUCTION

Severe mitral regurgitation (MR) is a major contributor to heart failure symptoms and is associated with unfavorable clinical outcomes. For patients who are at high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) has become an established therapeutic option.[1] Current guidelines recommend TEER for appropriately selected high-risk patients. Nevertheless, additional real-world evidence is needed to better define clinical outcomes and inform device selection in routine practice.

Although the MitraClip system remains the most widely used device, the Edwards Lifesciences PASCAL system offers several unique design features, including independent leaflet grasping, wider paddles, and a central spacer. These features are intended to enhance leaflet coaptation and reduce leaflet stress, potentially decreasing leaflet-related complications. Given the considerable variability in leaflet anatomy and the distinct mechanisms underlying functional and degenerative MR, device selection should be tailored to each patient's anatomical characteristics to optimize procedural outcomes. Consequently, these design features may offer procedural advantages in carefully selected patients.[2]

Although randomized and observational studies have demonstrated the safety and efficacy of the PASCAL system, additional real-world data are needed, particularly from centers with varying procedural volumes, case mixes, and levels of imaging expertise. Reports from our region remain limited. Therefore, we present our initial single-center experience with PASCAL-based TEER for symptomatic MR.

The aim of this study was to describe patient selection, procedural characteristics, in-hospital events, and echocardiographic findings

Address for Correspondence: Sinem Özbay Özyılmaz Assoc. Prof., Department of Cardiology, İstanbul Aydın University Faculty of Medicine, Medical Park Florya Hospital, İstanbul, Türkiye; Baylor College of Medicine, Texas Heart Institute, Texas, USA

E-mail: drsinemozbey@gmail.com **ORCID ID:** orcid.org/0000-0003-4829-8400

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at discharge in our initial experience with the PASCAL system, with particular attention to the practical aspects of procedural planning.[3]

METHODS

Study Design and Population

This retrospective, single-center case series included 23 consecutive patients with symptomatic MR grade ≥3+ who underwent TEER using the PASCAL system at VM Medical Park Hospital, İstanbul, Türkiye, between January 2023 and October 2025. All patients were evaluated by a multidisciplinary heart team and were considered to be at high or prohibitive surgical risk based on clinical assessment. Society of Thoracic Surgeons (STS) and EuroSCORE II values were not recorded consistently and were therefore unavailable for analysis. Baseline assessment was performed using transthoracic echocardiography, and two-dimensional (2D) and three-dimensional (3D) transesophageal echocardiography (TEE) were used for procedural planning.

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. It was approved by the Institutional Review Board (IRB) of İstanbul Aydın University (approval no: 154/2025, date: 09.07.2025). Written informed consent was obtained from all participants before the procedure.

Inclusion Criteria

Patients were eligible if they had symptomatic grade 3+ or 4+ primary or secondary MR and were considered to be at high or prohibitive surgical risk by the heart team. Anatomical suitability was determined based on the overall mitral valve anatomy rather than a single measurement. Leaflet length and mobility, coaptation gap and depth, calcification, image quality, and the anticipated feasibility of leaflet grasping were evaluated collectively. A posterior leaflet length of approximately ≥9 mm, a coaptation gap of ≤10 mm, and a coaptation depth of ≤11 mm were used as practical reference values, particularly for functional MR. Borderline measurements were accepted when the overall anatomy was considered suitable. Adequate transesophageal echocardiographic image quality was required to ensure clear visualization of the target leaflets and the grasping zone.

Exclusion Criteria

Patients were excluded if any of the following conditions were present: active infective endocarditis, an intracardiac mass or thrombus, rheumatic mitral valve disease, or severe mitral annular calcification that precluded safe device implantation. To minimize the risk of postprocedural mitral stenosis, patients were also excluded if the mitral valve area (MVA) was <4.0 cm^2 or if the baseline mean transmitral gradient was ≥5 mmHg. Additional anatomic exclusion criteria included a posterior leaflet length of <9 mm and severe leaflet calcification within the intended grasping zone that could impair adequate leaflet capture. Patients with known hypersensitivity to device components or contraindications to periprocedural anticoagulation and/or the required postprocedural antithrombotic therapy were also excluded.

Endpoints

The primary endpoint was procedural success, defined as successful PASCAL implantation with residual MR ≤2+ at discharge and no in-hospital death or urgent cardiac surgery. Secondary endpoints included a reduction in MR of at least one grade; changes in the 3D vena contracta area (VCA), MVA, and transmitral gradients; and in-hospital events, including vascular complications, major bleeding, stroke, acute kidney injury, decompensated heart failure, device-related complications, and death. Changes in New York Heart Association (NYHA) functional class and postdischarge outcomes were not evaluated because follow-up data were not consistently available for the entire cohort.

Procedural Technique and Imaging

All procedures were performed under general anesthesia and were guided by fluoroscopy and intraprocedural 2D and 3D TEE using a Philips Affiniti CVx ultrasound system with an X7-2T TEE probe (Philips Healthcare, Andover, MA, USA). TEE was used to guide transseptal puncture, device steering, leaflet grasping, and immediate postimplantation assessment. Procedural characteristics, including the number and type of implanted PASCAL devices and key procedural metrics, were recorded.

Quantitative echocardiographic measurements, including mitral annular dimensions and posterior leaflet length, were obtained using QLAB software (Version 13; Philips Healthcare).

Follow-up and Medical Therapy

Echocardiography was performed at baseline and before discharge according to the institutional protocol. Postdischarge follow-up was incomplete and therefore unsuitable for reliable cohort-level analysis; consequently, these data were not included. Antithrombotic therapy after the procedure was selected according to each patient's underlying indication. Patients who did not require long-term oral anticoagulation received aspirin and clopidogrel for at least 1 month. Those with an indication for oral anticoagulation received oral anticoagulation plus clopidogrel for 3 months, followed by antithrombotic therapy according to the original indication.

Transseptal Puncture Technique

Transseptal puncture was performed under combined fluoroscopic and 2D and 3D TEE guidance. A posterosuperior puncture site on the interatrial septum was targeted to optimize the left atrial device trajectory and alignment with the mitral valve plane.[4]

Mitral Annulus and Leaflet Evaluation

2D and 3D TEE were used for comprehensive assessment of the mitral valve, with 3D TEE preferred for accurate evaluation of the mitral annulus. Measurements were obtained at end-diastole, when annular dimensions are maximal.[5,6] The anatomy of the posterior leaflet guided procedural planning and device selection. Specifically, posterior leaflet length and mobility were assessed using the midesophageal long-axis TEE view (120°-140°) at end-diastole. Patients with a posterior leaflet length of <9 mm were considered anatomically unsuitable for TEER. In patients with restricted posterior leaflet motion despite adequate leaflet length, the PASCAL system was selected because of its independent clasping mechanism, broader paddles, and central spacer.[7]

The estimated number of devices was determined based on the width and segmental extent of the MR jet on baseline TEE, particularly with

respect to commissural involvement.[6] During the procedure, additional devices were implanted incrementally when residual MR jets were present, provided that the mean transmitral gradient remained <5 mmHg. MVA was measured before and after device implantation using planimetry on multiplanar reconstruction (MPR) images derived from 3D TEE datasets.

Three-dimensional Vena Contracta Area Measurement

3D color Doppler full-volume datasets were acquired under electrocardiographic (ECG) gating using an optimized frame rate achieved by narrowing the sector width and reducing the imaging depth, together with optimized color Doppler settings. The Nyquist limit was adjusted (typically by increasing the velocity scale and/or shifting the baseline) to minimize aliasing while maintaining adequate jet definition, and the color gain was set just below the noise threshold. The datasets were cropped to isolate the regurgitant jet and analyzed using MPR with two orthogonal long-axis planes and a corresponding short-axis plane. The imaging planes were iteratively aligned with the narrowest portion of the jet at midsystole, after which the short-axis plane was used to trace the VCA.[8] For multiple jets, VCAs were measured separately and summed. Each measurement represented the average of three cardiac cycles (or ≥5 cycles in patients with atrial fibrillation), while avoiding stitch artifact. Measurements were performed independently by two experienced readers who were blinded to the clinical data, and any discrepancies were resolved by consensus.

Statistical Analysis

Because of the small sample size, the analyses were primarily descriptive. Continuous variables are presented as medians with interquartile ranges (IQRs), and categorical variables as counts and percentages. Independent groups were compared using the Mann-Whitney U test, and paired preprocedural and postprocedural measurements were compared using the Wilcoxon signed-rank test. Multivariable analysis was not performed because the sample size and number of events were insufficient. All statistical tests were two-sided, and a p value of <0.05 was considered statistically significant. Exact p values are reported to three decimal places unless p<0.001. Statistical analyses were performed using Statistical Package for the Social Sciences for Windows, Version 22.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Baseline Characteristics

Baseline characteristics are presented in Table 1. The study included 23 patients, of whom 7 (30%) were women. The median age was 70 years (61-83), and the median body mass index was 27 kg/m^2 (24.0-28.9). Two patients had previously undergone MitraClip implantation. Hypertension was present in 21 patients (91%), diabetes mellitus in 13 (56%), previous myocardial infarction in 16 (70%), heart failure in 18 (78%), and coronary artery disease in 16 (69%). Most patients were classified as NYHA functional class III or IV [class III, 13 (56%); class IV, 2 (9%)]. Medical therapy included beta-blockers in 20 patients (87%), sodium-glucose cotransporter 2 inhibitors in 15 (65%), angiotensin receptor-neprilysin inhibitors in 6 (26%), and furosemide in 18 (78%).

Table 1. Demographic and other characteristics of patients

Variables		Patients [n, median (interquartile), %]
Number		23
Age (year)		70 (61-83)
Gender	Female	7 (30)
	Male	16 (70)
BMI (kg/m^2)		27 (24-28.9)
BSA (m^2)		1.79 (1.7-1.9)
Prior MitraClip		2
Presence of CRT-D		3 (13)
Presence of ICD/pacemaker		4 (17)
History		
Smoking history		3 (13)
Hyperlipidemia		5 (21)
Hypertension		21 (91)
Diabetes mellitus		13 (56)
Myocardial infarction		16 (70)
Heart failure		18 (78)
Presyncope		1 (4)
Syncope		4 (17)
Coronary artery disease		16 (69)
Surgery		4 (17)
Pulmonary arterial hypertension		1 (4)
Chronic obstructive pulmonary disease		1 (4)
NYHA		
I		1 (4)
II		7 (30)
III		13 (56)
IV		**2 (9)**
Use of medication		
Beta blocker		20 (87)
SGLT2 inhibitor		15 (65)
ARNI		6 (26)
Furosemide		18 (78)
Spironolactone		4 (17)
History of CPR		3 (13)
PASCAL device type (device-level denominator, n=35)	P10	11
	ACE	24
Post-procedural need for surgery		0
Complications of procedural		
Clip detachment		1 (4)
Cerebrovascular event		0
Pericardial effusion		0
Bleeding		0
Endocarditis		0
Decompensated heart failure		1 (4)
Death		0

CRT-D: Cardiac resynchronization therapy-defibrillator, ICD: Implantable cardioverter-defibrillator, CPR: cardiopulmonary resuscitation, NYHA: New York Heart Association, SGLT2: Sodium-glucose cotransporter 2

Laboratory and ECG Findings

Baseline laboratory and ECG findings are presented in Table 2. Atrial fibrillation was present in 11 patients (47%), and other conduction and arrhythmic abnormalities are summarized in Table 2. The median N-terminal pro-B-type natriuretic peptide level was 2,913 pg/mL (IQR, 1,102-9,020), and renal function was generally preserved, with a median estimated glomerular filtration rate of 66 mL/min/1.73 m^2 (44-87).

Procedural Characteristics and Device Use

Procedural and echocardiographic data are presented in Table 3. Interatrial septal morphology was normal in 10 patients (43%), fibrotic in 4 (17%), and lipomatous in 9 (39%). A total of 35 PASCAL devices were implanted, including 11 P10 devices (31%) and 24 advanced closure and enhancement devices (69%). The median procedure duration was 78 minutes (50-124). The median procedure duration was 53 minutes (45-67) in patients with a normal interatrial septum and 118 minutes (83-129) in those with fibrotic or lipomatous septal morphology (p=0.001). This comparison was unadjusted, and factors such as case complexity, the number of implanted devices, the presence of intracardiac leads, and operator experience may also have influenced procedure duration.

Safety Outcomes

Two periprocedural complications occurred: one case of single-leaflet device attachment and one episode of decompensated heart failure.

Table 2. Complete Blood Count, biochemical values and ECG findings of patients

Variables	Patients [n, median (interquartile), %]
WBC (×10³/µL)	6.8 (4.9-11.5)
Hb (g/dL)	11.6 (10.6-13.1)
Hct (%)	35.7 (30.8-39.3)
Plt (×10³/µL)	228 (211-262)
Total cholesterol (mg/dL)	153 (145-204)
Troponin I (ng/L)	51.2 (22.2-143.4)
NT ProBNP (pg/mL)	2913 (1102-9020)
Uric acid (mg/dL)	6.7 (4.9-8)
Lactate dehydrogenase (U/L)	316 (283-410)
D-dimer (ng/mL)	612 (447-1224)
GFR (mL/min/1.73 m^2)	66 (44-87)
Findings of ECG	
Premature atrial contraction	7 (30)
Premature ventricular contraction	6 (26)
Right bundle branch block	1 (4)
Left bundle branch block	7 (30)
Atrial fibrillation	11 (47)
Supraventricular tachycardia	0
Ventricular tachycardia	5 (21)

ECG: Electrocardiogram, GFR: Glomerular filtration rate, Hb: Hemoglobin, Hct: Hematocrit, NT-proBNP: N-terminal pro-B-type natriuretic peptide, Plt: Platelets, WBC: White blood cells

There were no in-hospital deaths, strokes, major bleeding events, pericardial effusions, cases of endocarditis, or urgent cardiac surgeries. The patient with single-leaflet device attachment had residual MR ≤2+ at discharge and did not require urgent surgery; therefore, the case met the prespecified definition of procedural success.

Echocardiographic and Hemodynamic Outcomes

Functional MR was present in 21 patients (91%) and degenerative MR in 2 patients (9%) (Table 3). Pulmonary venous Doppler findings were recorded for all assessed veins, and the reported flow patterns were not mutually exclusive. S-wave reversal was present before the procedure in 21 patients (91%) but was no longer observed after TEER. An S>D flow pattern was documented after the procedure in 21 patients (91%). The MVA decreased from 5.13 cm^2 (4.92-5.60) to 3.70 cm^2 (3.56-4.10) at discharge ($p<0.001$), and the 3D VCA decreased from 0.63 cm^2 (0.57-0.68) to 0.18 cm^2 (0.14-0.19) ($p<0.001$). Peak and mean transmitral gradients increased modestly (both $p<0.001$), without clinically significant mitral stenosis. Implant locations are reported according to device type and mitral valve segment. The totals exceed the number of patients because some patients received more than one device, and some devices involved adjacent scallops. MR was reduced by at least two grades in 22 patients and by one grade in 1 patient. Procedural success was achieved in all 23 patients.

DISCUSSION

In this initial single-center experience, PASCAL-based TEER was feasible in selected patients with severe MR who were considered to be at high surgical risk. All 23 patients met the prespecified definition of procedural success, defined as successful device implantation with residual MR ≤2+ at discharge and no in-hospital death or urgent cardiac surgery. Two patients experienced periprocedural complications, and no in-hospital deaths occurred. Given the small, uncontrolled cohort, these findings should be interpreted as a description of our early clinical experience rather than as evidence of the comparative safety or efficacy of the PASCAL system.

The overall procedural and echocardiographic findings are consistent with those of previous clinical studies and real-world reports of the PASCAL system.[9] However, the small sample size and observational design of the present study preclude direct comparisons with other devices or treatment strategies.

Beyond technical success, we observed early hemodynamic and echocardiographic improvement. A reduction of at least two MR grades was achieved in 22 patients, whereas one patient experienced a one-grade reduction. Consequently, residual MR was ≤2+ in all patients, with mild residual MR (MR 1+) observed in 22 of the 23 patients. In parallel, quantitative echocardiographic parameters showed meaningful improvement, including a marked reduction in the 3D VCA.

Pulmonary venous Doppler findings also supported the observed reduction in MR. Systolic flow reversal was no longer observed after TEER, and an S>D flow pattern was documented in 21 patients (91%). Because more than one Doppler flow pattern could be recorded among the assessed veins in an individual patient, these findings were not

Table 3. The echocardiography findings of patients

Variables	Patients [n, median (interquartile)]			
Interatrial septum feature				
Normal	10 (43)			
Fibrosis	4 (17)			
Lipomatosis	9 (39)			
Time of procedure (minutes)	78 (50-124)	IAS normal n=10	53 (45-67)	**p=0.001**
		IAS others n=13	118 (83-129)	
LA measurements				
Anterior-posterior diameter (mm)	47 (44-50)			
Medialateral diameter (mm)	48 (44-52)			
Apicobasal diameters (mm)	61 (57-69)			
Left atrial volume (mL)	83.7 (64-95)			
Left atrial volume index (mL/m^2)	46.4 (35.3-56.3)			
Pulmonary venous measurements				
Pre-procedure pulmonary venous S-wave reversal, n (%)	21 (91)			
Post-procedure pulmonary venous S-wave reversal, n (%)	0			
Pre-procedure pulmonary venous S-wave blunting, n (%)	4 (17)			
Post-procedure pulmonary venous S-wave blunting, n (%)	2 (9)			
Preprocedure pulmonary venous S>D	0			
Post-procedure pulmonary venous S>D, n (%)	21 (91)			
Types of mitral valve regurgitation				
Functional	21 (91)			
Degenerative	2 (9)			
Mitral valve measurements				
Annulus measure (mm)	39 (36-42)			
Pre-procedural area (cm^2)	**5.13 (4.92-5.6)**			**p<0.001**
Post-procedural area (cm^2)	**3.7 (3.56-4.1)**			
Anterior leaflet length (mm)	23 (22-24)			
Posterior leaflet length (mm)	14 (12.8-15.5)			
Pre-procedural three-dimensional vena contracta area (cm^2)	**0.63 (0.57-0.68)**			**p<0.001**
Post-procedural three-dimensional vena contracta area (cm^2)	**0.18 (0.14-0.19)**			
Coaptation depth (mm)	11.4 (9-12.3)			
Coaptation length (mm)	3.7 (3-5.2)			
Preprocedure peak gradient (mmHg)	**4 (2.7-4)**			**p<0.001**
Postprocedure peak gradient (mmHg)	**5 (4-7.2)**			
Preprocedure mean gradient (mmHg)	**1.3 (1.1–1.5)**			**p<0.001**
Postprocedure mean gradient (mmHg)	**2.3 (1.9-3)**			
Device/segment location (non-mutually exclusive; 35 devices)				
A1P1	4 (17)			
A2P2	19 (82)			
A3P3	9 (39)			
Decrease in post-procedural mitral regurgitation	23			
Second-degree mitral regurgitation	1			
First-degree mitral regurgitation	22			
Left ventricular measurements				

Table 3. Continued

Variables	Patients [n, median (interquartile)]
Ejection fraction (%)	33.7 (27-52)
Left ventricular end-diastolic diameter (mm)	57 (53-62)
Left ventricular end-systolic diameter (mm)	42 (31-49)
Interventricular septal thickness in diastole (mm)	12 (11-13)
Left ventricular posterior wall thickness in diastole (mm)	10 (9.2-10.7)
Left ventricular length (mm)	75 (69-81)
Left ventricular area (cm^2)	**35 (30-40)**
Left ventricular volume (mL)	131 (106-162)
Left ventricular mass (gr)	278 (224-298)
Left ventricular mass index (g/m^2)	147 (131-168)
Pulmonary artery systolic pressure via tricuspid regurgitation (mmHg)	32 (25-40)

Pulmonary venous Doppler findings indicate the presence of each pattern and are not mutually exclusive across assessed veins. Device/segment locations are reported at the device level; some implants involved more than one adjacent scallop. Values corrected as typographical errors should be verified against the source dataset before final submission. IAS: Interatrial septum, LA: Left atrium

considered mutually exclusive. Therefore, they should be interpreted as supportive evidence, together with the reduction in the 3D VCA, rather than as an independent measure of treatment efficacy.

As expected, transmitral gradients increased modestly after edge-to-edge repair as MR decreased. Importantly, this occurred without evidence of clinically significant iatrogenic mitral stenosis. Overall, mean transmitral gradients remained low, and procedural decisions were guided by maintaining the mean gradient below a predefined intraprocedural threshold (<5 mmHg). Achieving this balance between effective MR reduction and controlled transmitral gradients is particularly important in patients requiring more than one device and highlights the value of a stepwise implantation strategy guided by residual MR jets and transmitral hemodynamics.

The longer procedure duration observed in patients with fibrotic or lipomatous interatrial septal morphology is of practical interest. Difficult transseptal access and a less favorable catheter trajectory may have contributed to this finding.[10,11] Other factors, including mitral valve anatomy, the number and position of implanted devices, previous transseptal procedures, intracardiac leads, case sequence, and operator experience, may also have influenced procedure duration. However, the study was too small to permit a reliable adjusted analysis. Therefore, although septal morphology may be useful for procedural planning, its independent effect on procedure duration requires confirmation in larger studies.

Most patients had functional MR, and the A2-P2 region was the most common implantation site, consistent with routine TEER practice. Because this study reflects our center's early experience with the PASCAL system, increasing familiarity with device steering, independent clasping, transseptal positioning, and coordination between the imaging and interventional teams may have influenced procedure duration. However, the study was not designed to formally evaluate the learning curve.

Study Limitations

Several limitations should be acknowledged. This was a retrospective, single-center study that included only 23 patients, with no control group and multiple echocardiographic comparisons. STS and EuroSCORE II values were not recorded consistently, limiting the objective assessment of surgical risk. Postdischarge follow-up was incomplete; therefore, changes in NYHA functional class, MR severity, rehospitalization, mortality, and reintervention could not be evaluated for the entire cohort. The analysis of the association between interatrial septal morphology and procedure duration was unadjusted and may have been influenced by mitral valve anatomy, the number of implanted devices, intracardiac leads, case complexity, and operator experience. Echocardiographic measurements were obtained at the treating center without independent core laboratory review. In addition, patient-reported outcomes and objective functional assessments were not uniformly available.

CONCLUSION

This initial Turkish experience suggests that PASCAL-based TEER can be performed successfully in a small, carefully selected cohort, with no in-hospital deaths and favorable echocardiographic findings at discharge. The longer procedure durations observed in patients with fibrotic or lipomatous interatrial septal morphology may have implications for procedural planning, although this observation requires confirmation in larger studies with appropriate adjustment for potential confounders. Multicenter studies with systematic surgical risk assessment and longer-term follow-up are warranted.

Ethics Committee Approval: It was approved by the Institutional Review Board (IRB) of İstanbul Aydın University (approval no: 154/2025, date: 09.07.2025).

Informed Consent: Written informed consent was obtained from all participants before the procedure.

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