

Transcatheter Management of Clinically Significant Paravalvular Leak After Sutureless Aortic Valve Replacement: A Case Series

INTRODUCTION

Sutureless and rapid-deployment aortic bioprostheses shorten cross-clamp and cardiopulmonary bypass times and provide excellent hemodynamic profiles, but paravalvular leak (PVL) remains a recognized complication, occurring more frequently than with conventional stented valves in several series.¹ Contributing mechanisms include incomplete apposition of the stent frame against a calcified or irregular annulus, prosthesis undersizing, and frame tilting or migration, and imaging-based predictors of PVL have been increasingly characterized.² Clinically significant PVL may produce refractory heart failure and hemolytic anemia and is associated with reduced mid-term survival.³ Because redo surgery carries high operative risk in elderly and comorbid patients, transcatheter strategies have emerged as an attractive, less-invasive alternative; however, data specific to sutureless platforms remain limited to small series and isolated reports.^{4,5} Three consecutive patients with clinically significant PVL after sutureless aortic valve replacement were successfully managed using 3 distinct, mechanism-based transcatheter strategies.

CASE REPORTS

Three consecutive patients treated at the institution presented with clinically significant PVL after sutureless aortic valve replacement. Baseline characteristics, surgical risk scores (EuroSCORE II and Society of Thoracic Surgeons [STS] predicted risk of mortality), hemolysis parameters, and procedural details are summarized in Table 1. Written informed consent for the procedures and for publication of anonymized clinical data was obtained from all patients. All were assessed by the multidisciplinary heart team and considered to be at high or prohibitive risk for reoperation based on age, comorbidity burden, and operative risk scores (EuroSCORE II 25.84%, 14.85%, and 12.81%; STS predicted risk of mortality [PROM] 28.1%, 14.6%, and 16.9%, respectively). In every case, the location, size, and mechanism of the leak were defined by transthoracic and transesophageal echocardiography together with electrocardiography-gated cardiac computed tomography, which guided selection of the transcatheter strategy.

Paravalvular leak severity was determined through integrative echocardiographic evaluation by experienced echocardiographers using available parameters, with reference to Valve Academic Research Consortium-3 (VARC-3) criteria as a framework: circumferential extent of the regurgitant jet on parasternal short-axis imaging (mild < 10%, moderate 10%-29%, severe ≥ 30%), vena contracta width, continuous-wave Doppler jet density, and presence of holodiastolic flow reversal in the descending aorta.¹

Laboratory evaluation at presentation documented biochemical evidence of hemolysis in all 3 patients, with mild anemia, elevated serum lactate dehydrogenase (LDH), and low haptoglobin levels (Table 1). Hemoglobin values were 10.5 g/dL, 10.2 g/dL, and 10.5 g/dL, respectively; LDH values were 518 U/L, 396 U/L, and 1684 U/L (upper limit of normal < 248 U/L), respectively; and haptoglobin was at

CASE REPORT

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Table 1. Baseline Characteristics, Hemolysis Parameters, Imaging Findings, and Procedural and Follow-up Outcomes

Variables	Patient 1	Patient 2	Patient 3
Demographics and baseline clinical characteristics			
Age (years)	82	78	75
Sex	Male	Male	Male
Risk factors/comorbidities	Hypertension, diabetes mellitus, atrial fibrillation	Rheumatic aortic stenosis	Hypertension, diabetes mellitus, CAD, prior CABG
EuroSCORE II (%)	25.84	14.85	12.81
STS PROM score (%)	28.1	14.6	16.9
NYHA class at presentation	III	III	III
Baseline cardiac function			
LVEF at presentation (%)	30	40	50
Concomitant MR severity	Moderate (2+)	Moderate (2+)	Not reported
Estimated PASP (mm Hg)	70 (severe TR)	40 (moderate TR)	Not reported
Prosthesis details			
Prosthesis type	Edwards Intuity (rapid-deployment sutureless)	Edwards Intuity (rapid-deployment sutureless)	Perceval M (self-expandable sutureless)
Prosthesis size	19 mm	19 mm	M
Paravalvular leak characteristics			
PVL severity at presentation†	Severe	Severe	Moderate
PVL mechanism	Discrete crescentic defect	Incomplete frame expansion against calcified annulus	Frame tilting + structural valve deterioration
Hemolysis parameters at presentation			
Hemolysis present	Yes	Yes	Yes
Hemoglobin (g/dL)	10.5	10.2	10.5
LDH (U/L)‡	518	396	1684
Haptoglobulin (g/L)	0.3 (lower limit of normal)	0.3 (lower limit of normal)	0.323 (lower limit of normal)
Transcatheter intervention			
Strategy	Device-based PVL closure	Balloon post-dilatation	Valve-in-valve TAVI
Device/balloon/valve	Amplatzer Vascular Plug III 10 × 5 mm	Z-MED balloon 20 mm	Myval transcatheter valve 26 mm
Access route	Retrograde transfemoral	Retrograde transfemoral	Retrograde transfemoral
Technical success	Yes	Yes	Yes
Procedural and follow-up outcomes			
PVL severity after procedure†	Mild	Mild	None
Periprocedural complications	None	None	None
NYHA class at 3-month follow-up	I	I	I

†PVL severity was determined through integrative evaluation by experienced echocardiographers using available parameters, with reference to VARC-3 criteria as a framework (mild < 10%, moderate 10%-29%, severe ≥ 30% circumferential extent).

‡Normal LDH < 248 U/L. [____] = value to be completed by authors.

CABG, coronary artery bypass grafting; CAD, coronary artery disease; LDH, lactate dehydrogenase; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; PVL, paravalvular leak; STS PROM, Society of Thoracic Surgeons predicted risk of mortality; TAVI, transcatheter aortic valve implantation; TR, tricuspid regurgitation.

the lower limit of the reference range in all 3 patients (0.3, 0.3, and 0.323 g/L, respectively; reference range 0.3-2.0 g/L), consistent with PVL-associated hemolysis in all cases.

In Patient 1 (Table 1), a discrete crescentic paravalvular defect was crossed retrogradely and occluded with an Amplatzer Vascular Plug III (Abbott, Plymouth, MN, USA), reducing the leak to mild (Figure 1). In Patient 2 (Table 1), PVL related to incomplete expansion of the prosthetic frame against a calcified annulus was treated with

balloon post-dilatation, improving frame apposition and leaving a mild residual leak (Figures 2 and 3). In Patient 3 (Table 1), a diffuse leak associated with frame tilting and concurrent structural valve deterioration was treated with valve-in-valve transcatheter aortic valve implantation, which sealed the leak and restored valve competence (Figures 4 and 5).

All 3 procedures were technically successful, reducing PVL to mild or less, with no periprocedural death, stroke, coronary

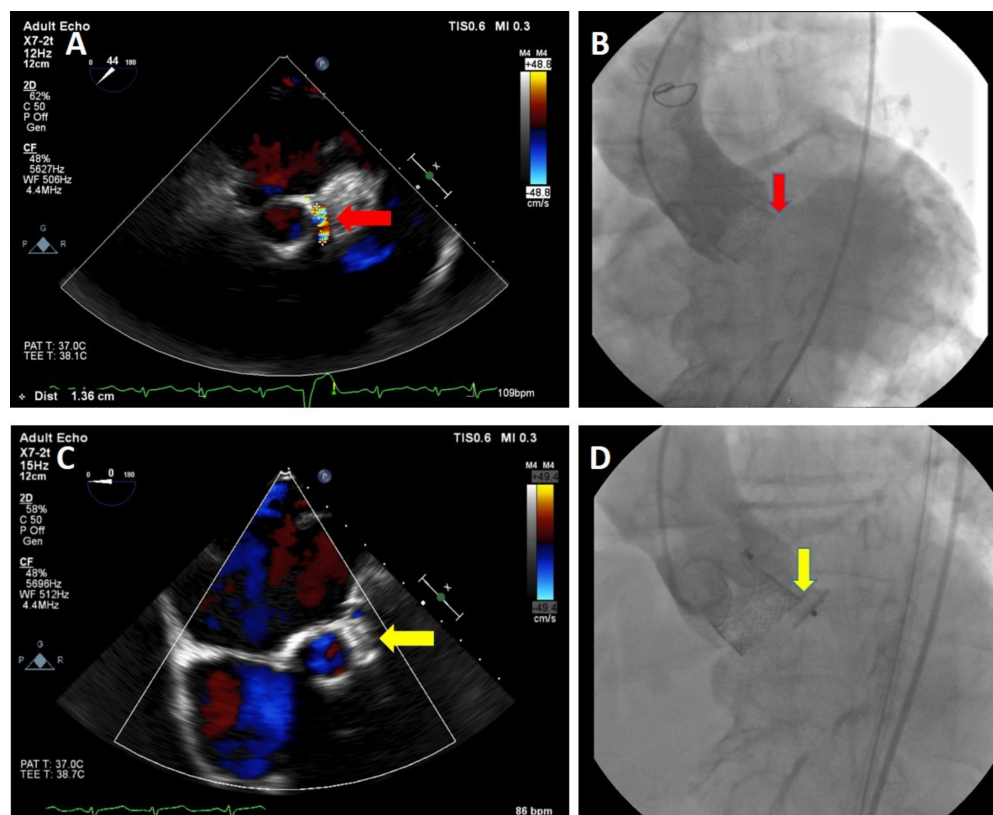


Figure 1. Patient 1. (A) Transesophageal echocardiography, short-axis view, demonstrating severe paravalvular regurgitation adjacent to a 19-mm Edwards Intuity valve. (B) Baseline aortography confirming severe paravalvular leak. (C) Fluoroscopy showing a 10 × 5-mm Amplatzer Vascular Plug III deployed within the paravalvular defect. (D) Post-deployment aortography demonstrating complete resolution of the paravalvular leak.

obstruction, or major vascular complication. At a median follow-up of 3 months, all patients reported marked symptomatic improvement from New York Heart Association (NYHA) class III to class I (Table 1).

DISCUSSION

This series illustrates that clinically significant PVL after sutureless aortic valve replacement can be managed by individualized, mechanism-based transcatheter therapy rather than high-risk reoperation. All 3 patients were deemed at high or prohibitive operative risk, with EuroSCORE II and STS PROM values reflecting substantially elevated perioperative mortality risk. The optimal transcatheter strategy in each case depended on the anatomical substrate defined by multimodality imaging. Discrete, crescentic defects with an adequate sealing zone are well suited to device closure; transcatheter plug closure of aortic PVL has reported technical success rates above 90%, with durable symptomatic benefit and reduced heart-failure hospitalization.⁶ When PVL results from incomplete frame expansion against bulky calcification, balloon post-dilatation can improve apposition and abolish the leak without an implanted device.⁵ When the leak is diffuse or related to frame tilting or structural deterioration, valve-in-valve transcatheter aortic valve implantation provides effective sealing and is increasingly reported for failed sutureless prostheses.^{4,7}

The presence of biochemical hemolysis in all 3 patients—evidenced by markedly elevated LDH (range 396-1684 U/L) and reduced or undetectable haptoglobin—underscores the clinical significance of PVL and provides an additional indication for transcatheter intervention beyond symptoms alone. Correction of PVL with resolution of hemolysis can prevent progressive anemia, renal injury, and deterioration in quality of life, and should be considered alongside functional status when evaluating the need for reintervention.

Across all 3 approaches, transesophageal echocardiography and cardiac computed tomography were essential for localizing the defect, sizing the device, and excluding contraindications such as coronary proximity.^{2,8} These observations are consistent with reports that residual PVL adversely affects prognosis and that its correction improves functional status.^{3,9} Current valvular heart disease guidelines support transcatheter closure of clinically significant PVL in patients at high surgical risk when performed in experienced centers.¹⁰

This report is limited by its small size, single-center retrospective design, and short follow-up. Quantitative echocardiographic parameters of PVL (such as circumferential extent and vena contracta width) were not systematically recorded at the time of the index presentation, and the findings require confirmation in larger prospective cohorts.

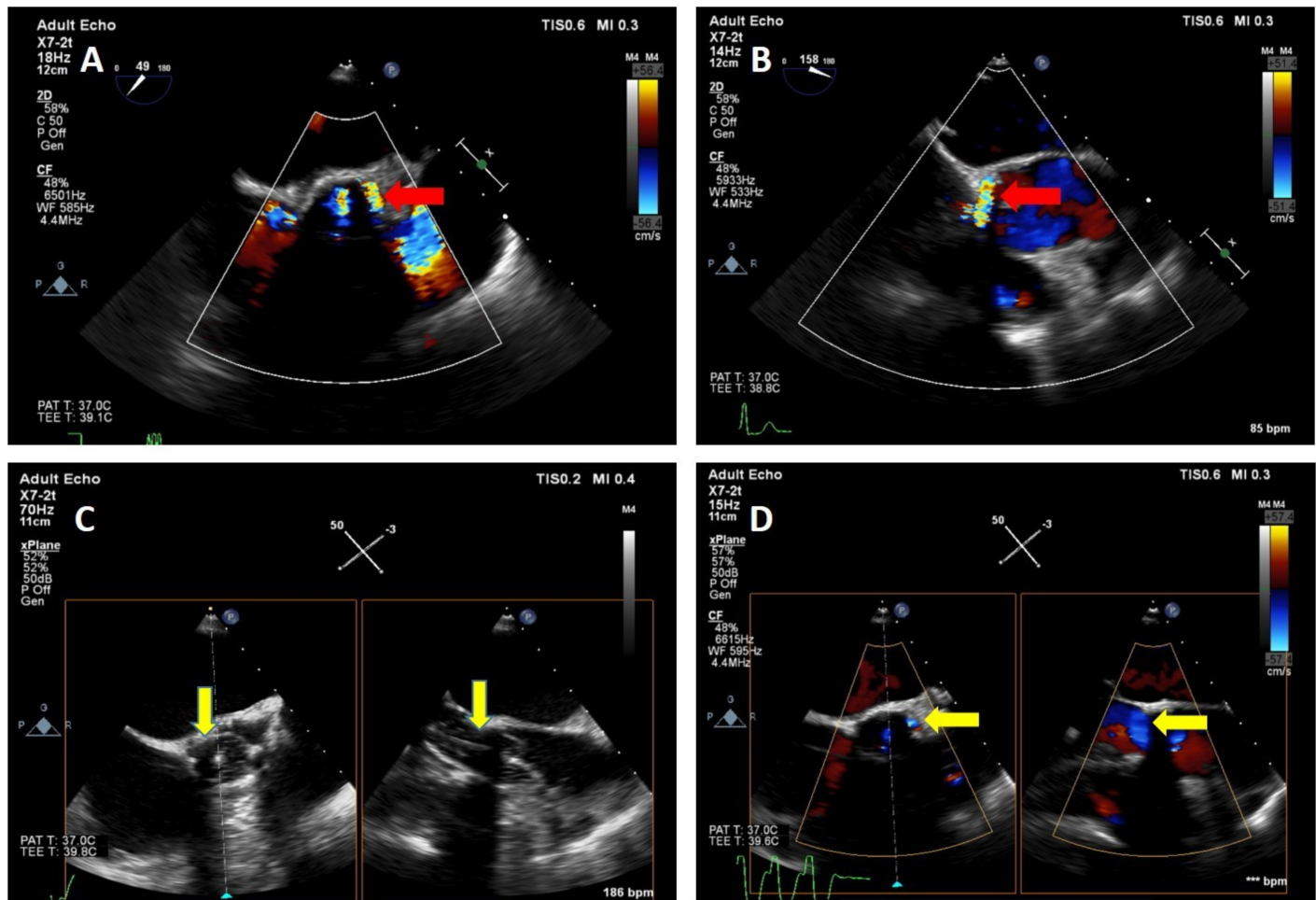


Figure 2. Patient 2. (A, B) Transesophageal echocardiographic short-axis and color-Doppler images revealing a severe paravalvular defect with substantial regurgitation adjacent to the 19-mm Edwards Intuity prosthesis.

CONCLUSION

In selected high-risk patients with clinically significant PVL after sutureless aortic valve replacement, an individualized,

mechanism-based transcatheter approach—device closure, balloon post-dilatation, or valve-in-valve implantation—guided by multimodality imaging can achieve technical success and meaningful symptom relief while avoiding the risks of

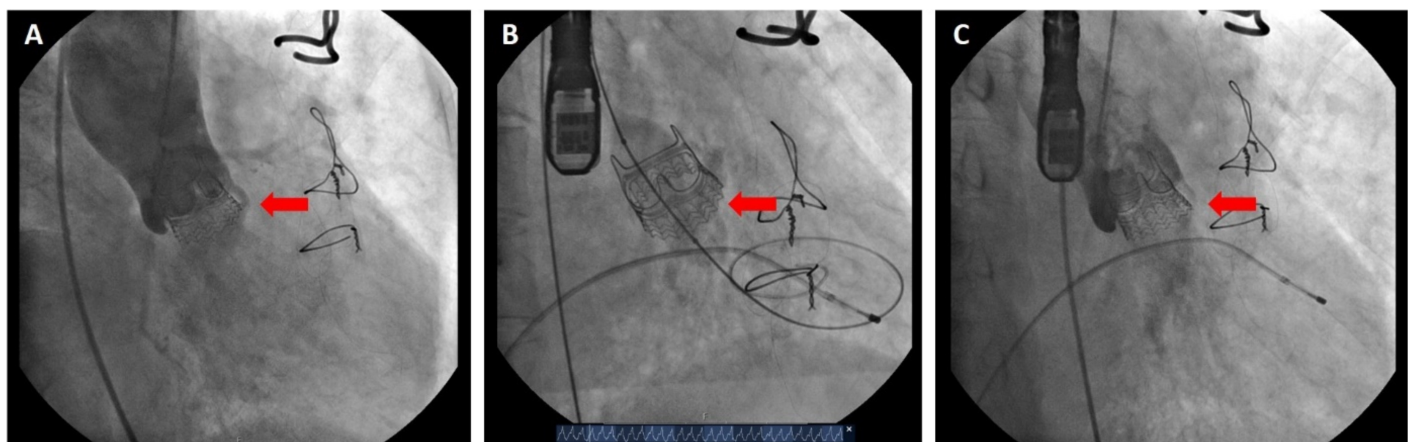


Figure 3. Patient 2 balloon post-dilatation. (A) Baseline aortography during the second session demonstrating severe paravalvular leak. (B) Post-dilatation using a 20-mm Z-MED balloon under rapid ventricular pacing. (C) Follow-up aortography showing marked reduction in paravalvular regurgitation.

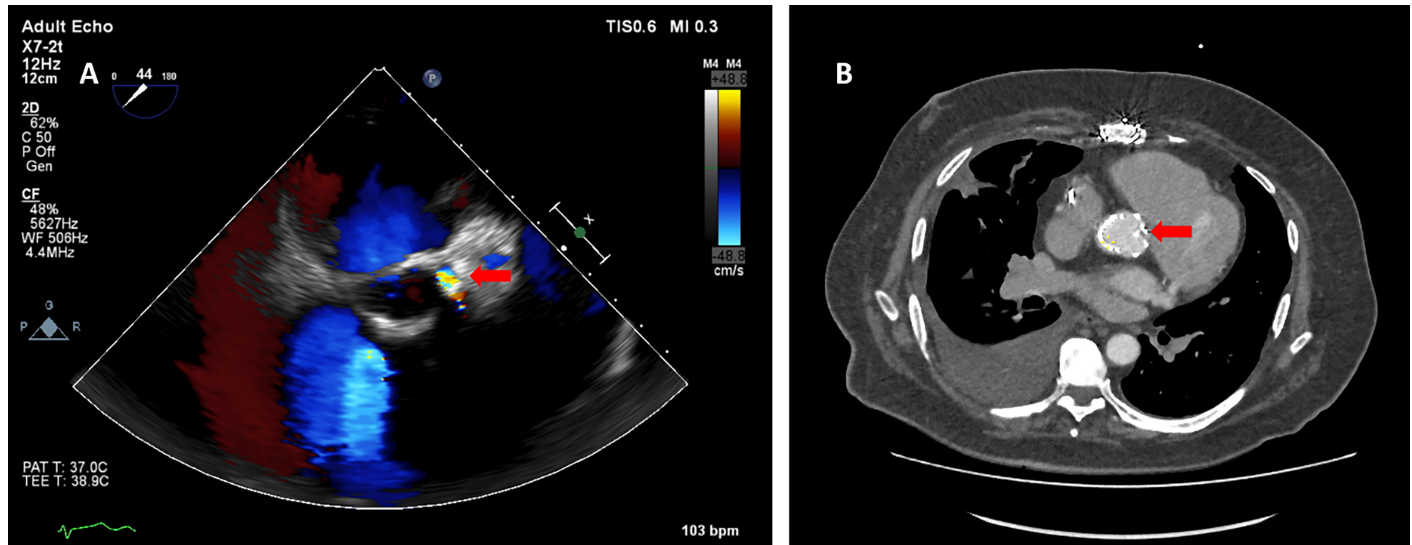


Figure 4. Patient 3. (A) Transthoracic echocardiography showing moderate paravalvular aortic regurgitation. (B) Multidetector computed tomography demonstrating stent infolding and structural deterioration of the Perceval M prosthesis.

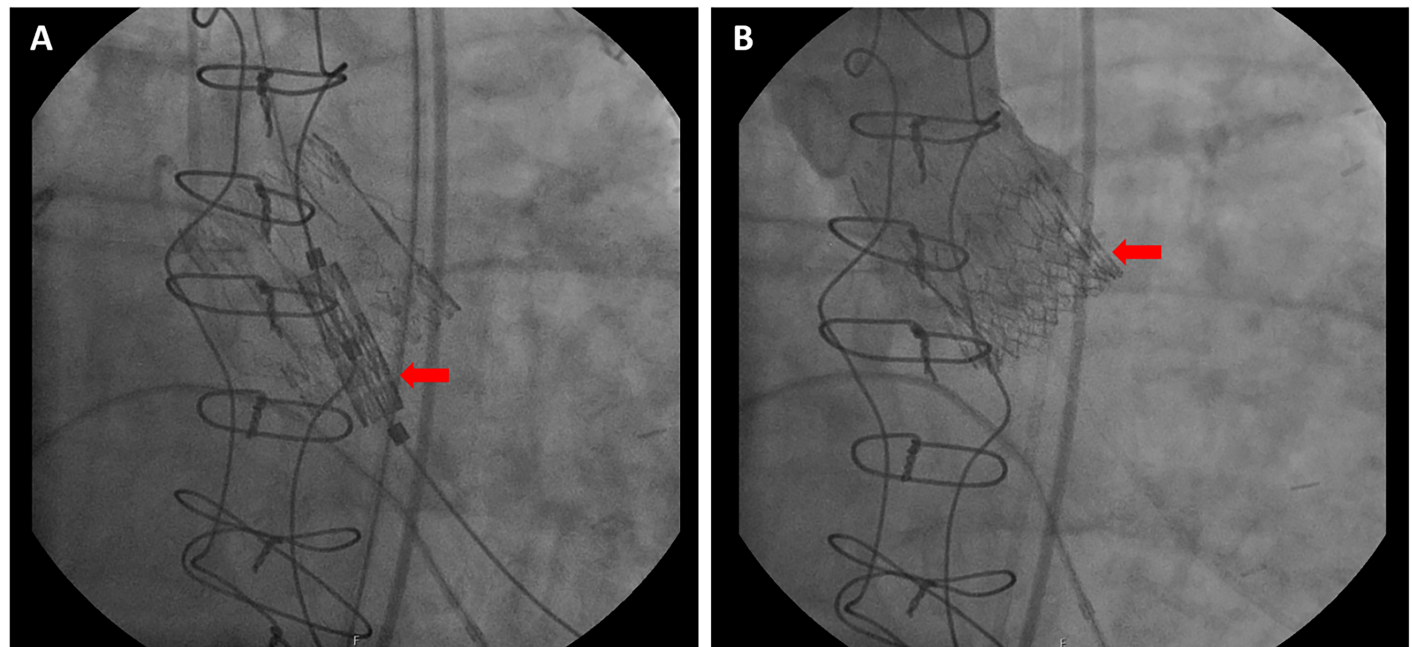


Figure 5. Patient 3 valve-in-valve transcatheter aortic valve implantation. (A) Fluoroscopic image showing deployment of a 26-mm Myval transcatheter valve within the Perceval prosthesis. (B) Final aortography demonstrating optimal valve position and complete elimination of the paravalvular leak.

redo surgery. The concurrent presence of hemolysis reinforces the indication for transcatheter intervention in this population.

Informed Consent: Written informed consent was obtained from all patients who agreed to take part in the study.

Declaration of Interests: T.K. is a member of the Editorial Board of The Anatolian Journal of Cardiology. However, he was not involved in any stage of the editorial decision-making process or peer review of this manuscript. The other authors have no conflicts of interest to declare.

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