

Transcatheter Mitral Valve Replacement in Mitral Annular Calcification Using the Novel Myval Valve: Contribution to the Growing Worldwide Experience

Mitral Anülüs Kalsifikasyonunda Yeni Myval Kapak Kullanılarak Transkateter Mitral Kapak Değişimi: Dünya Geneline Artan Deneyime Katkı

ABSTRACT

Mitral annular calcification (MAC) is a complex structural abnormality often associated with severe mitral stenosis, regurgitation, or both. Mitral valve surgery carries greater risk especially in elderly patients with MAC, making transcatheter mitral valve replacement (TMVR) an emerging alternative. We report the case of an 84-year-old woman with a history of surgical bioprosthetic aortic valve replacement and recurrent hospitalizations due to severe MAC-related mitral valve disease. She was deemed inoperable by the heart team. Detailed multimodal imaging, including multidetector computed tomography (MDCT), revealed extensive MAC with acceptable neo-left ventricular outflow tract (neo-LVOT) dimensions and an acute aorto-mitral angle. Thus, TMVR was successfully performed via a transseptal approach using a 30.5 mm balloonexpandable Myval transcatheter heart valve (THV). Post-procedural imaging confirmed optimal valve position, no paravalvular leak, and no LVOT obstruction. The patient was discharged in stable condition. This is the first reported case from Türkiye of TMVR in MAC using the Myval THV, contributing to the growing worldwide experience. This report also emphasizes the role of advanced imaging in guiding patient selection and procedural planning and illustrates the feasibility of the Myval THV for valve-in-MAC in challenging mitral anatomy.

Keywords: Mitral annular calcification, myval, neo-LVOT, structural heart disease, transcatheter mitral valve replacement

ÖZET

Mitral annüler kalsifikasyon (MAC), genellikle şiddetli mitral darlığı, yetersizliği veya her ikisiyle birlikte görülen karmaşık bir yapısal anormalliktir. Mitral kapak cerrahisi, MAC'la birlikte ciddi mitral darlığı veya yetersizliği olan yaşlı hastalarda riskli olabilir. Seçilmiş hastalarda, transkateter mitral kapak replasmanı (TMVR) cerrahi'ye önemli bir alternatif olarak uygulanabilir. Bu yazıda, cerrahi biyoprotez aort kapak replasmanı öyküsü ve şiddetli MAC ile ilişkili mitral kapak hastalığı nedeniyle tekrarlayan hastaneye yatışları olan 84 yaşındaki bir kadın hasta sunulmuştur. Kalp takımı tarafından açık cerrahi için çok yüksek riskli olarak değerlendirilen hastaya yapılan ayrıntılı multimodal görüntülemeye kabul edilebilir neo-LVOT alanı, akut aorto-mitral açısı ile yaygın MAC saptanmış, hastaya 30,5 mm Myval transkateter kalp kapakçığı (THV) kullanılarak transseptal yaklaşımla başarılı bir TMVR işlemi gerçekleştirilmiştir. İşlem sonrası görüntüleme, optimal kapak pozisyonu ile birlikte paravalvüler kaçak veya akut LVOT tıkanıklığı olmadığını doğrulamış ve hasta klinik durumu stabil durumda taburcu edilmiştir. Bu vaka, Türkiye'den Myval THV kullanılarak ciddi MAC'de TMVR uygulanan ilk vaka olup, dünya genelinde artan TMVR deneyimine katkıda bulunmaktadır. Bu vaka sunumu, hasta seçimi ve prosedür planlamasında ileri görüntüleme yöntemlerinin rolünü ayrıntılı vurgulamakla birlikte; MAC ve zorlu anatomide TMVR uygulanması açısından Myval THV'nin kullanışlı olabileceğini göstermektedir.

Anahtar Kelimeler: Mitral anül kalsifikasyonu, myval, neo-LVOT, yapısal kalp hastalığı, transkateter mitral kapak replasmanı

CASE REPORT OLGU SUNUMU

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Mitral annular calcification (MAC) is a progressive, degenerative disorder of the mitral valve (MV), commonly associated with mitral stenosis, regurgitation, or both.¹ Surgical treatment of severe MAC is technically challenging and carries high perioperative risk, making many patients unsuitable for conventional mitral valve surgery.^{1,2} Transcatheter mitral valve replacement (TMVR) has emerged as a viable

alternative for these high-risk patients.^{1,2} TMVR can be performed using balloon-expandable transcatheter aortic valves in a valve-in-MAC approach or with dedicated novel TMVR devices.^{1,2} However, accurate anatomical evaluation is essential to avoid complications such as left ventricular outflow tract (LVOT) obstruction, valve migration, embolization, and paravalvular regurgitation.^{1,3,4} The Myval (Meril Life Sciences Pvt. Ltd., Vapi, India) is a novel balloon-expandable transcatheter heart valve (THV) system featuring an innovative operator-friendly design that enhances deliverability and enables precise deployment.^{5,6} In this report, we present the first transcatheter valve-in-MAC case in Türkiye performed using the novel balloon-expandable Myval THV, contributing to the growing worldwide experience.

Case Report

An 84-year-old female with a history of degenerative severe aortic stenosis and severe degenerative mitral valve disease had previously undergone surgical aortic valve replacement with a bioprosthetic valve. She was referred to our center for percutaneous transcatheter mitral valve intervention due to recurrent episodes of acute heart failure secondary to advanced mitral valve disease. Over the past year, she had been hospitalized four times for pulmonary edema and pneumonia, two of which required intubation and mechanical ventilation.

Preprocedural Imaging

Transthoracic and transesophageal echocardiography confirmed a normally functioning bioprosthetic aortic valve and demonstrated severe MAC, with a mean transmitral gradient of 11 mmHg, planimetric mitral valve area (MVA) of 1.3 cm², pressure half-time (PHT)-derived MVA of 1.2 cm², and severe eccentric mitral regurgitation (Figure 1). Multidetector computed tomography

ABBREVIATIONS

BATMAN	Balloon Assisted Translocation of the Mitral Anterior leaflet
IAS	Interatrial septum
LAMPOON	Laceration of the Anterior Mitral leaflet to Prevent Outflow Obstruction
MAC	Mitral annular calcification
MDCT	Multidetector computed tomography
MV	Mitral valve
MVA	Mitral valve area
MVR	Mitral valve replacement
neo-LVOT	Neo-left ventricular outflow tract
NYHA	New York Heart Association
PHT	Pressure half-time
TEE	Transesophageal echocardiography
THV	Transcatheter heart valve
TMVR	Transcatheter mitral valve replacement

(MDCT) confirmed heavy and circumferential MAC with a MAC score of 8 (Figure 2, Table 1). Annular dimensions were found suitable for a 30.5 mm Myval THV. Virtual valve modeling predicted a neo-LVOT area of 303.7 mm² at 40% systole and 217.2 mm² at 75% diastole. Additional findings included an aorto-mitral angle of 36.2°, an inverse angle of 143.8°, and septal bulging, which are well-known risk factors for LVOT obstruction (Figure 2). However, the calculated neo-LVOT and skirt-neo-LVOT areas remained above critical thresholds, and no other anatomical contraindications were identified (Figure 2). Thus, we decided to perform TMVR in this high-risk patient. Written informed consent was obtained from the patient before the procedure.

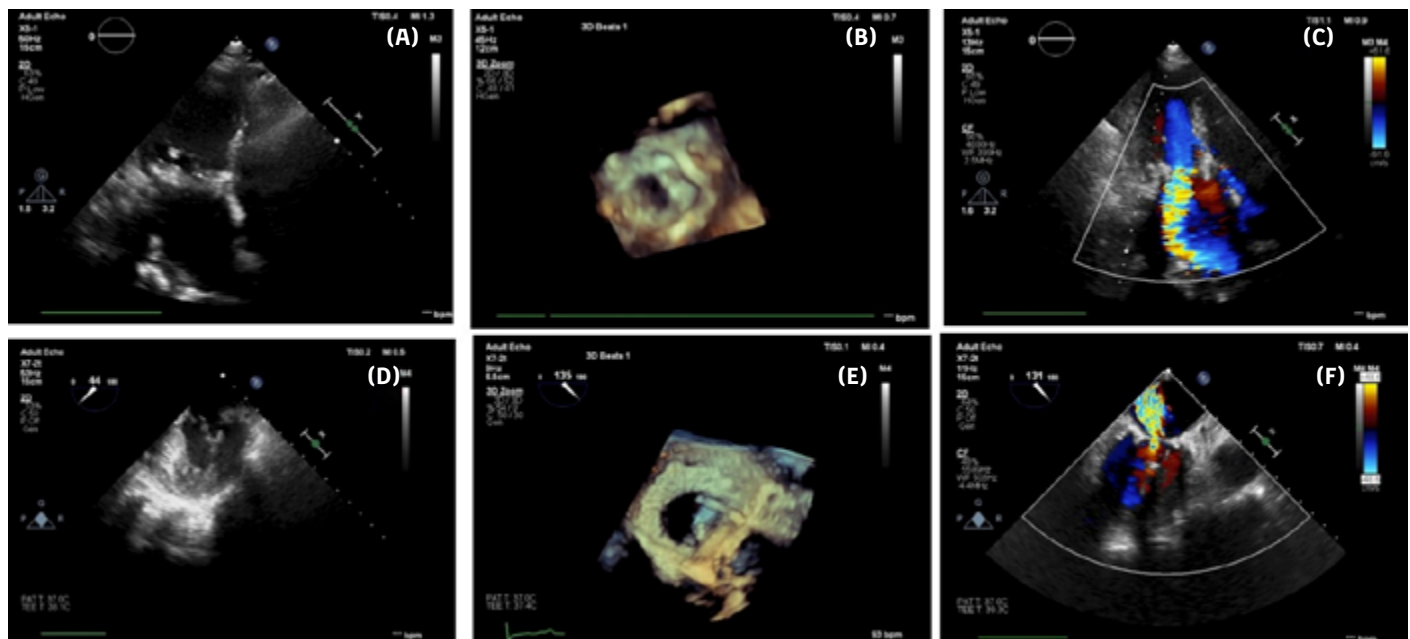


Figure 1. (A) Two-dimensional (2D) transthoracic echocardiography (TTE) image showing a calcific, degenerative mitral valve. (B) Three-dimensional (3D) TTE image showing severe circumferential calcification of the mitral valve. (C) Color Doppler TTE image showing severe mitral regurgitation. (D) Two-dimensional transesophageal echocardiography image showing calcific degenerative mitral valve disease. (E) Three-dimensional TEE image showing severe circumferential calcification of the mitral valve. (F) Two-dimensional TEE image showing severe mitral regurgitation.

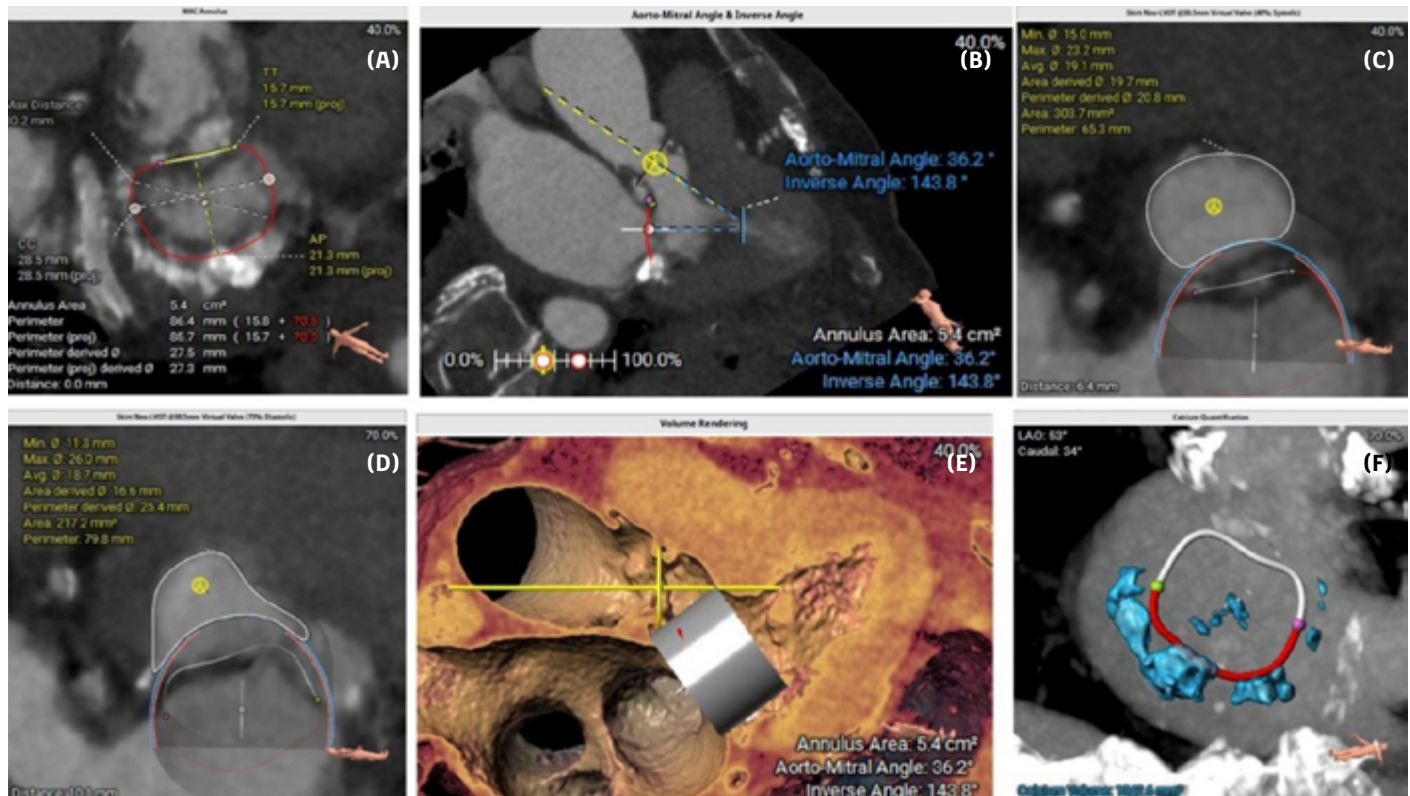


Figure 2. (A) Gated computed tomography (G-CT) image showing heavy and circumferential mitral annular calcification (MAC). **(B)** G-CT image showing an acute aorto-mitral angle (AMA). **(C)** G-CT image showing the predicted skirt neo-left ventricular outflow tract (LVOT) area using a virtual 30.5 mm Myval valve: 303.7 mm² (40% systole). **(D)** G-CT image showing the predicted skirt neo-LVOT area using a virtual 30.5 mm Myval valve: 217.7 mm² (75% diastole). **(E)** G-CT image showing an acute AMA using a virtual 30.5 mm Myval. **(F)** G-CT image showing calcium quantification of MAC.

Table 1. CT-based MAC severity score calculation of the patient

CT-based MAC severity score*		
CT findings	Points	Patient's points
Ca thickness		
<5	1	2
5-9.99	2	
>10	3	
Ca distribution		
<180	1	2
180-270	2	
>270	3	
Trigone involvement		
None	0	1
Anterolateral	1	
Posteromedial	1	
Leaflet involvement		
None	0	1
Anterior	1	
Posterior	1	
Total points		8

CT, Computed tomography; MAC, Mitral annular calcification. *, MAC grade severity: mild: <3 points; moderate: 4-6 points; severe: >7 points.

Procedure

Under general anesthesia and transesophageal echocardiography (TEE) guidance, the patient underwent transseptal TMVR. Right femoral venous access was used for two venous sheaths and left femoral artery access for monitoring. An inferoposterior transseptal puncture was performed with a 0-1 Brockenbrough needle (BRK™, Abbott Vascular, IL, USA). A coiled-tip guidewire (Toray, Tokyo, Japan) was placed in the left atrium, followed by insertion of an 8.5F-Agilis™ NxT steerable sheath (Abbott Vascular, IL, USA). A 7F multipurpose guiding catheter was advanced through the mitral valve into the left ventricle, allowing placement of the first Safari (Boston Scientific, USA) guidewire. To enhance stability and facilitate device delivery, a second Safari wire was placed in the left ventricle alongside the first one.^{7,8} Balloon atrial septostomy was performed to accommodate the delivery system. A 30.5 mm balloon-expandable Myval THV (Meril Life Sciences, Vapi, Gujarat, India) was deployed across the MAC under rapid pacing (Figure 3). Post-deployment imaging confirmed successful implantation with no paravalvular leak, no LVOT obstruction, and complete resolution of mitral stenosis and regurgitation (Figure 4). The patient was transferred to intensive care in stable condition.

Postoperative Status and Follow-up

The postoperative course was uneventful, with complete resolution of the initial signs of congestion. The patient was discharged after ten days on warfarin anticoagulation. At clinical

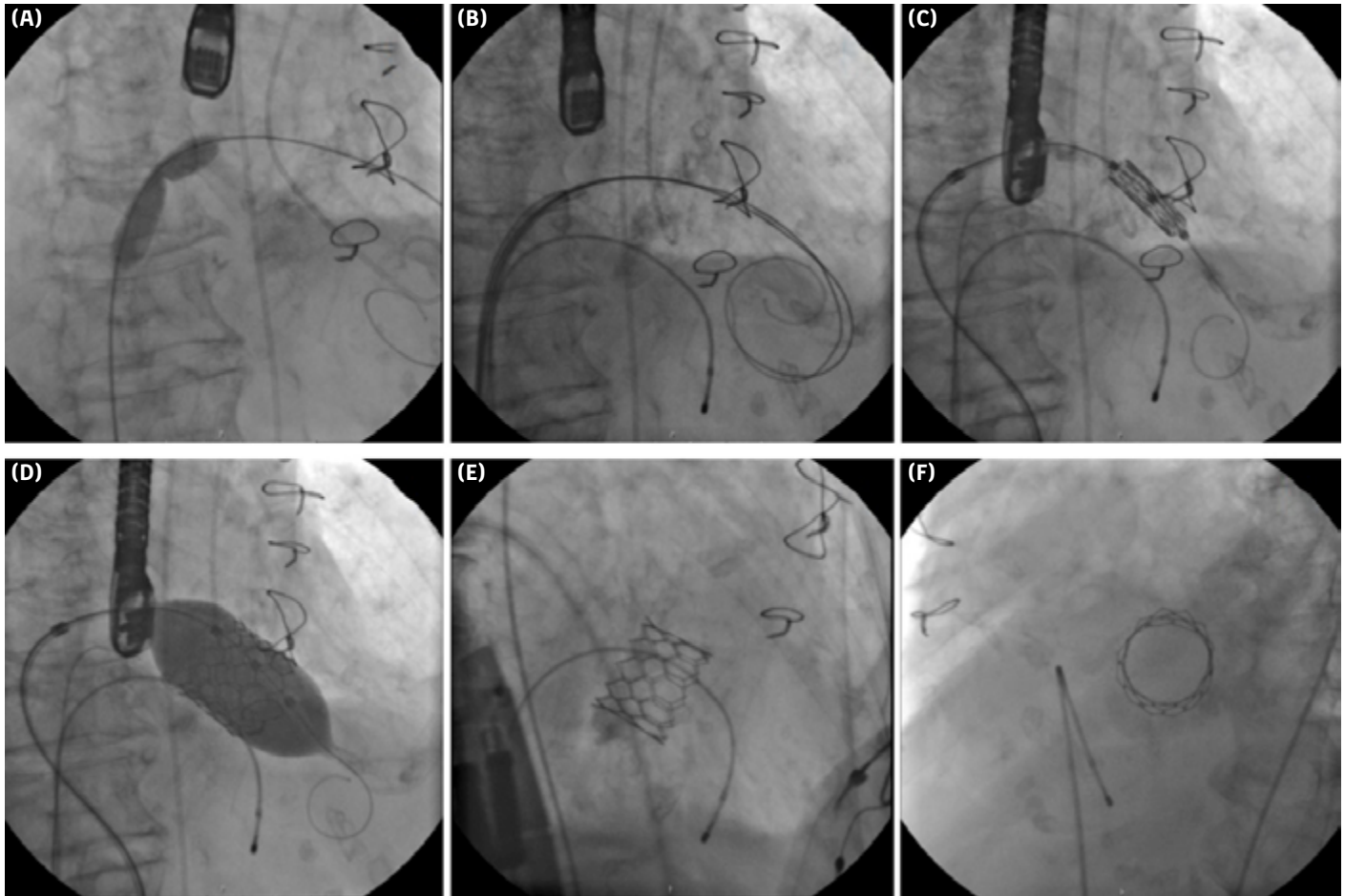


Figure 3. (A) Fluoroscopy image showing balloon dilation of the interatrial septum. (B) Fluoroscopy image showing the double-stiff wire technique. (C) Fluoroscopy image showing alignment of the 30.5 mm Myval valve. (D) Fluoroscopy image showing deployment of the 30.5 mm Myval valve. (E) Fluoroscopy image showing final position of the 30.5 mm Myval valve. (F) Fluoroscopy image showing the 30.5 mm Myval valve opened properly and symmetrically.

follow-ups performed at 1, 3, and 6 months, the patient remained in New York Heart Association (NYHA) functional class I, with a stable mean mitral diastolic gradient of 5 mmHg, a significant reduction in pulmonary artery systolic pressure, and no evidence of LVOT obstruction.

Discussion

Mitral annular calcification presents a particularly challenging clinical scenario in patients with mitral valve disease, especially when stenosis and regurgitation coexist. Conventional surgical mitral valve replacement (MVR) in the presence of extensive MAC is associated with increased perioperative morbidity and mortality due to technical difficulties such as annular debridement, risk of atrioventricular disruption, and challenges in prosthesis anchoring.^{1,2} As a result, high-risk or inoperable patients with severe MAC have historically had limited treatment options.^{1,2}

Transcatheter mitral valve replacement in MAC ("valve-in-MAC") has emerged as a less invasive alternative for this high-risk group. However, the procedure itself remains technically complex, with unique risks such as left ventricular outflow tract obstruction, valve embolization, and paravalvular leak. Careful pre-procedural imaging is essential to assess annular dimensions, calcification

severity, aorto-mitral angle, and predicted neo-LVOT area.¹⁻⁴ In our patient, despite septal bulging and an acute aorto-mitral angle (36.2°) suggesting increased LVOT obstruction risk, the neo-LVOT area was above critical thresholds, suggesting safe device implantation. Thus, we proceeded with MAC without using the LAMPOON (Laceration of the Anterior Mitral leaflet to Prevent Outflow Obstruction) or BATMAN (Balloon Assisted Translocation of the Mitral Anterior leaflet) techniques, which have been proposed as a preventive strategies in anatomies with high LVOT obstruction risk.⁹⁻¹¹

Most previously reported valve-in-MAC procedures have used the Edwards Sapien 3 system.^{1,2,12} One of the key challenges of TMVR with the Edwards Sapien 3 system is the inability to retrieve the valve into the sheath when it cannot be advanced through the native valve or a previously stiffened interatrial septum despite adequate balloon dilatation. In such cases, the entire assembly—including the sheath and valve—must be removed from the body and cannot be reimplanted.^{5,6} In contrast, with the novel Myval THV system, if the valve cannot be advanced through the interatrial septum, it can be safely withdrawn into the 14F Python sheath, removed from the body, recrimped, and reimplanted.^{5,6} Another disadvantage of the Edwards system is its limited ability

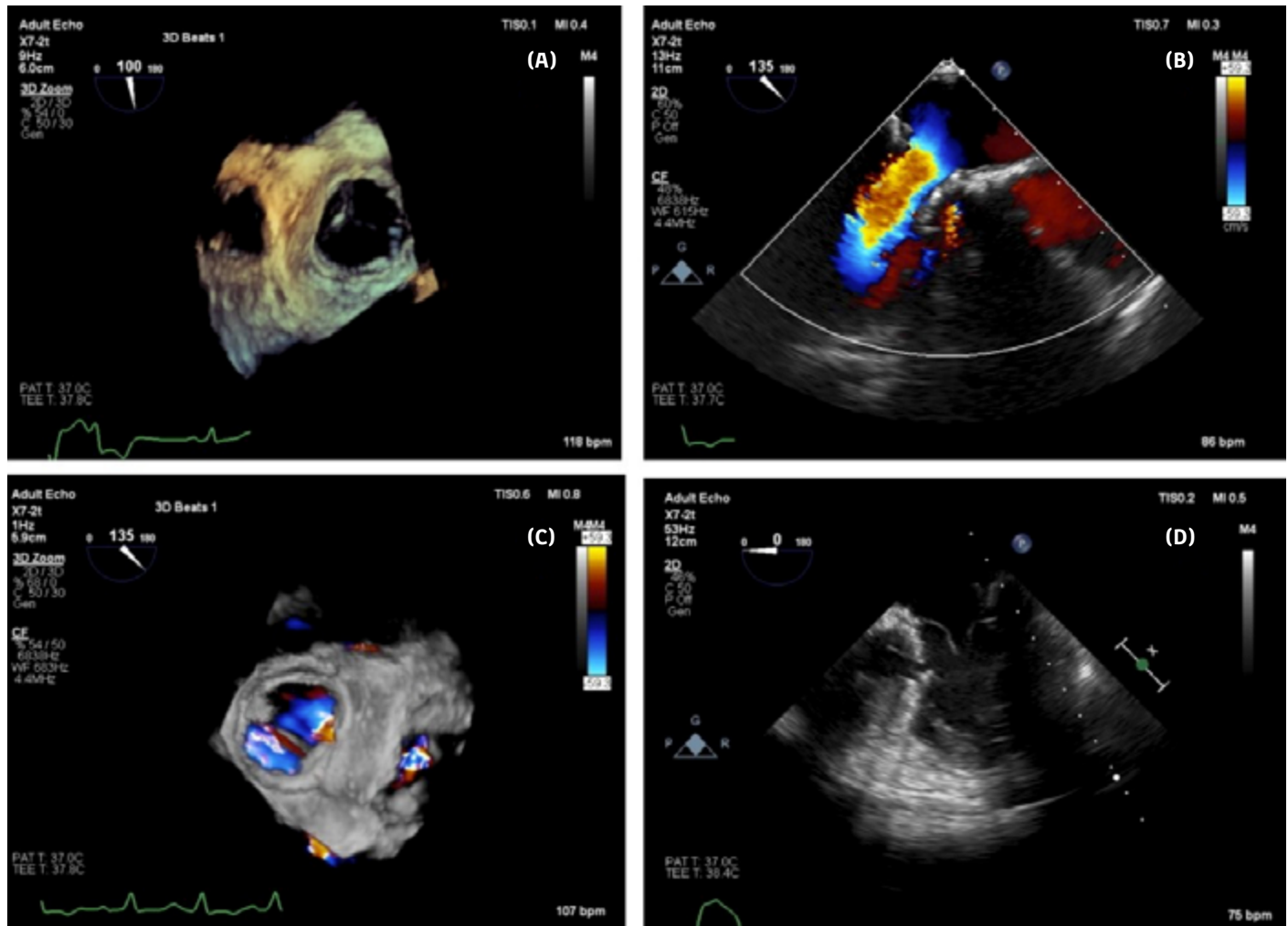


Figure 4. (A) Three-dimensional (3D) transesophageal echocardiography (TEE) image showing a well-functioning 30.5 mm Myval valve. (B) Color Doppler two-dimensional (2D) TEE image showing no paravalvular leak. (C) Color Doppler three-dimensional TEE image showing no paravalvular leak. (D) Two-dimensional TEE image showing a well-functioning 30.5 Myval valve.

to accommodate large annuli without overfilling, which may increase the risk of paravalvular leak and valve embolization.⁵ In comparison with the Edwards Sapien 3 system's largest 29-mm prosthesis, the Myval THV provides extra-large options (30.5 mm and 32 mm), which may improve annular fit and reduce procedural risks of valve-in-MAC cases. In our patient, implantation of a 30.5 mm prosthesis successfully demonstrated the feasibility of the Myval THV system in anatomically complex settings with a large annulus.

In this case, we used a planned buddy guidewire technique to improve device stability during deployment. Crossing the interatrial septum (IAS) with a balloon-expandable THV may fail despite preparatory balloon septostomy. The use of a planned buddy guidewire placed in the left ventricle can facilitate crossing of the IAS and positioning of the mitral bioprosthesis.⁸ We believe that this approach may facilitate the majority of TMVR and valve-in-MAC procedures.

Approximately 30%–40% of patients with severe MAC may be anatomically suitable for TMVR.^{12,13} Despite this, the steep learning curve and risk of complications such as LVOT obstruction,

valve migration, paravalvular leak, and valve thrombosis highlight the necessity of a multidisciplinary heart team approach. Our experience reinforces the value of collaborative decision-making, comprehensive imaging assessment, procedural planning, and the use of a novel Myval THV for successful outcomes during TMVR.

Conclusion

To the best of our knowledge, this report represents the first valve-in-MAC case in Türkiye using the Myval THV, contributing to the growing global experience. This case also highlights the successful application of a novel balloon-expandable Myval THV in a valve-in-MAC procedure, with favorable results achieved through meticulous imaging, accurate valve sizing, and the use of advanced procedural strategies. Further studies are required to confirm midterm and long-term results.

Ethics Committee Approval: This is a single case report; therefore, ethics committee approval was not required in accordance with institutional policies.

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

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