ESC European Society of Cardiology

European Heart Journal - Case Reports (2025) **9**, ytaf071
https://doi.org/10.1093/ehjcr/ytaf071

CASE REPORT
Structural intervention

EchoNavigator®-guided transcatheter mitral valve-in-valve procedure to treat a degenerated radiolucent surgical bioprosthetic valve: a case report

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Received 5 July 2024; revised 3 October 2024; accepted 6 February 2025; online publish-ahead-of-print 14 February 2025

Background Radiolucent valves present unique clinical challenges since interventions often depend on multiple imaging modalities to perform such procedures successfully. EchoNavigator® is novel imaging software that specializes in real-time merging ultrasound and fluoroscopy images. It addresses these limitations by simultaneously integrating the benefits of two imaging modalities.

Case summary An 85-year-old man with a history of bioprosthetic valve disease developed life-limiting symptoms. Transesophageal echocardiogram (TEE) showed severe bioprosthetic mitral stenosis, prompting plans to perform a transcatheter mitral valve-in-valve (TMVIV) replacement. Using EchoNavigator® to mark the annulus on TEE, we were able to successfully deploy the valve using fluoroscopy to guide the successful deployment of the valve.

Discussion The treatment of degenerated valves using transcatheter valve-in-valve procedures has increased in frequency recently due to increasing age and comorbidities associated with patients. Identifying the true annulus plays an integral role in ensuring the valve is deployed in the ideal location. However, the radiolucent nature of the valve prohibits performing a TMVIV under conventional methods. Utilization of fusion imaging, such as EchoNavigator®, provides an opportunity to visualize such valves using the strengths of both modalities simultaneously, simplifying such procedures. To our knowledge, this is the first report of using such fusion technology to facilitate the placement of a bioprosthesis within a failed radiolucent surgical valve. Application of such technologies can help improve the performance and outcomes of such procedures by allowing operators to use the advantages of both imaging for improved outcomes.

Keywords EchoNavigator® • Bioprosthetic mitral valve • Structural cardiology • Emerging technology and innovation • Case report

ESC curriculum 2.2 Echocardiography • 4.10 Prosthetic valves • 7.4 Percutaneous cardiovascular post-procedure • 2.1 Imaging modalities • 4.4 Mitral stenosis

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Handling Editor: Julio Echarte
Peer-reviewers: Poonam Velagapudi; Matteo Sturla
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Tweet: Check out our paper describing our use of EchoNavigator® to help guide a TMVIV in a degenerated radiolucent surgical valve. #UABCVI, #FIT, #UABStructural

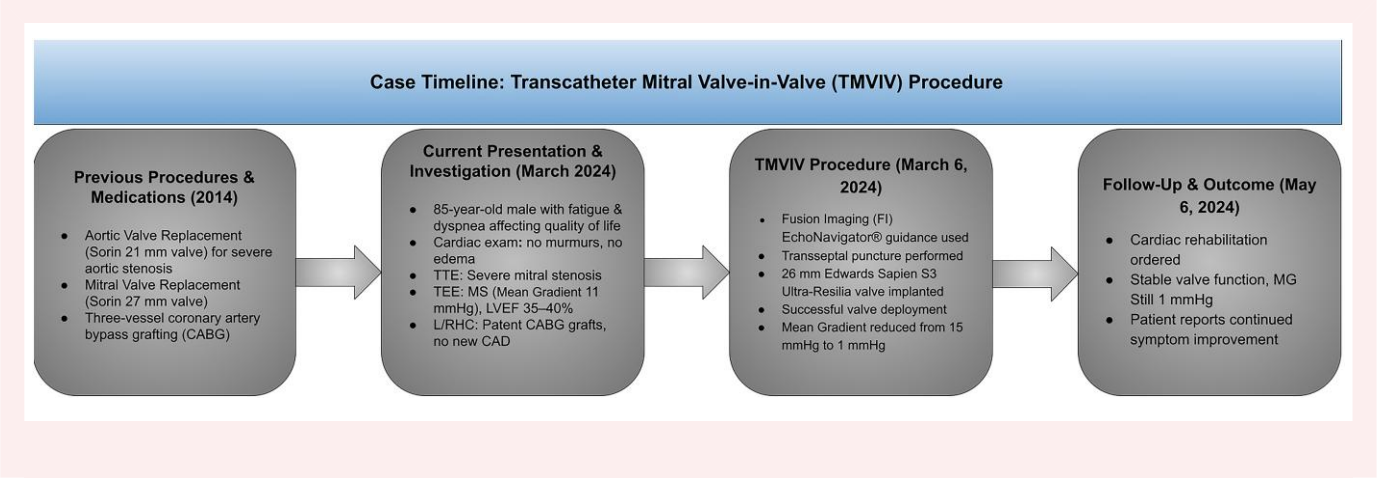
Learning points

- EchoNavigator® is an innovative fusion technology that can help guide complex structural procedures.
- Using and integrating such emerging technologies can help improve workflow and improve procedural success.
- Completing complex valvular interventions with current technology helps lay the groundwork for future artificial intelligence–based software.

Introduction

Bioprosthetic mitral valve degeneration can lead to the development of symptoms and poor outcomes if not addressed.[1] Transcatheter mitral valve-in-valve (TMVIV) replacement has emerged as an excellent treatment strategy, particularly in patients with elevated or prohibitive surgical risk.[2] Typically, the valve frame is easily visible on fluoroscopy and is used to guide valve implantation. In this case, the absence of an easily visible valve frame on fluoroscopy leads to increased technical complexity. In the case of radiolucent valves, the absence of fluoroscopic landmarks necessitates the integration of echocardiographic guidance to successfully complete the procedure. Currently, the use of echocardiography, however, is limited as these images are seen as entirely separate from fluoroscopic standard views. In such complex cases, the use of EchoNavigator® (EchoNav, Philips Medical System, Best, The Netherlands) can play a crucial role in guiding complex structural procedures. EchoNavigator® is a fusion imaging (FI) technology that combines real-time fluoroscopic and transesophageal echocardiogram (TEE) imaging, simultaneously gating imaging based on the patient's heart rhythm and standard landmarks identified at the beginning of the procedure. In this case, EchoNavigator® was invaluable in visualizing and marking crucial integral landmarks of the surgical bioprosthetic valve, allowing for precise valve positioning before deployment.[3] Here, we present a case of a complex TMVIV procedure successfully deployed within a degenerated radiolucent surgical valve using EchoNavigator® guidance.

Summary figure



Case presentation

An 85-year-old man presented with quality of life-limiting fatigue and dyspnoea. History was significant for aortic valve replacement in 2014 with a Sorin 21 mm (Sorin Group, LivaNova PLC, London, UK) for severe aortic stenosis, concomitant mitral valve replacement (MVR) with a Sorin 27 mm porcine valve, and three-vessel coronary artery bypass surgery. On examination, he was haemodynamically stable with regular rhythm, no murmurs, clear lungs, and intact peripheral pulses.

Medications included aspirin 81 mg, apixaban 5 mg, and furosemide 40 mg daily. Labs revealed mild anaemia (haemoglobin 12.0 g/dL), elevated B-type natriuretic peptide (258.0 pg/mL), and stable renal function (creatinine 1.1 mg/dL, estimated glomerular filtration rate 65 mL/min/1.73 m^2). After the presentation, transthoracic echocardiography (TTE) was done for initial evaluation, which showed the presence of severe bioprosthetic mitral stenosis (MS) depicted in (*Figure 1A*). Transesophageal echocardiogram confirmed severe MS with a mean gradient (MG) of 11 mmHg. The left ventricular ejection fraction (LVEF) was 35–40%, with a 3D EF of 36% (*Figure 1B*). The prosthetic aortic valve appeared to have moderate stenosis, with an MG of 30 mmHg.

To complete his evaluation, he had right heart catheterization prior to his procedure, which showed a pulmonary artery pressure of 55/20 (31) mmHg and a pulmonary wedge pressure of 24 mmHg. His pulmonary vascular resistance was 1.34 Woods units. Left heart catheterization revealed patent grafts and no new obstructive coronary artery disease. A cardiac computed tomography (CT) scan (*Figure 2*) was performed for valve sizing and case planning. The estimated neo-left ventricular outflow tract (Neo-LVOT) was roughly 625 mm^2. Based on the CT-guided area and dimensions of the previous valve, a 26-mm Edwards Sapien S3 Ultra Resilia (Edwards Lifesciences, Irvine, CA, USA) valve was chosen for the procedure. After a heart team discussion, it was decided that a valve-in-valve procedure was the most reasonable approach due to the patient's age and comorbidities, as reflected in his Society of Thoracic Surgeons scores [operative mortality 26%, morbidity and mortality 38.3%, prolonged ventilation 31.7%, and long hospital stay (>14 days) 32.7%] and risks of re-do sternotomy.

Due to the absence of radio-opaque landmarks and the patient's prohibitive surgical risk, it lent itself well to the application of FI to guide the implantation of the mitral prosthesis.

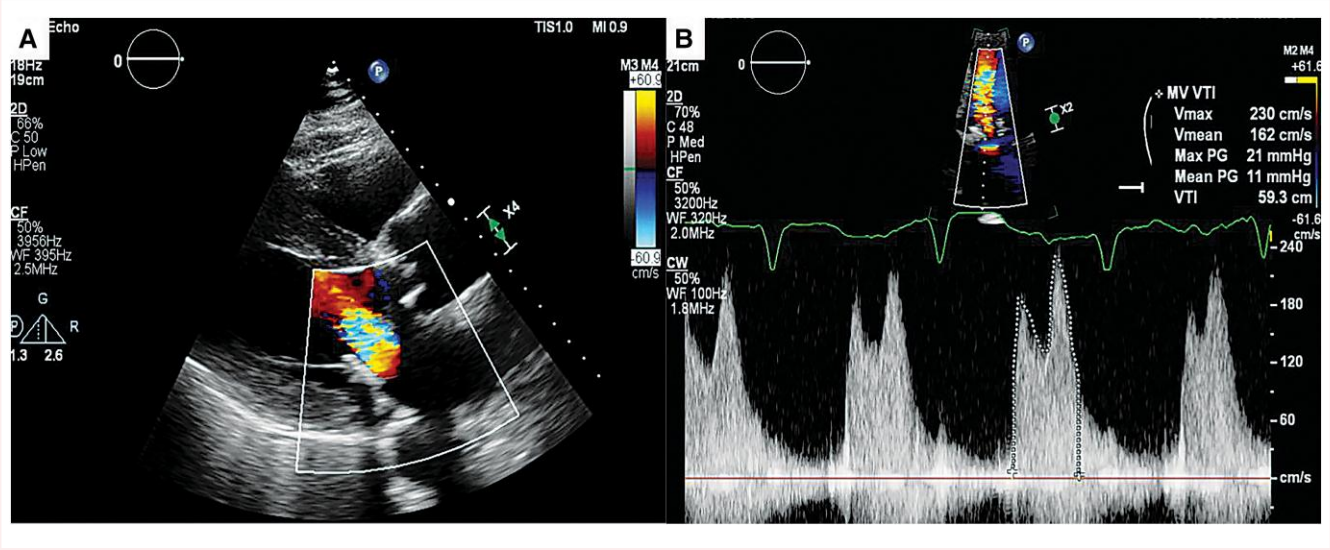


Figure 1 (*A*) 2D transthoracic echocardiography image showing the bioprosthetic mitral valve with severe mitral stenosis. (*B*) Transthoracic echocardiography continuous wave Doppler displaying severe bioprosthetic stenosis.

After being brought to the cardiac catheterization lab, the patient was placed under general anaesthesia. A TEE probe was placed to guide the trans-septal puncture and valve implantation. Pre-imaging and co-registration of fluoroscopic and echocardiographic landmarks were performed before access was obtained. Next, we placed an arterial line in the left proximal radial artery so that our anaesthesia team could monitor the patient's haemodynamics. Next, right femoral venous access was obtained, and two percloses were placed before dilating up to a 14 F Edwards E sheath (Edwards Lifesciences, Irvine, CA, USA) to deliver the valve. After registering our FI system to anatomic landmarks to identify the valve's relationship to the left ventricular (LV) apex, aorta, and mitral annulus, we then placed echo-guided markers to outline the mitral annular border. Since FI is typically gated by the cardiac cycle using electrocardiogram, we were able to simulate annular plane movement and variation throughout the cardiac cycle. We then used the Baylis VersaCross radiofrequency system (Baylis Medical, Mississauga, Ontario, Canada) and an SL1 sheath (Abbott Laboratories, Abbott Park, IL, USA) to cross the septum. Once across the septum, we advanced our wire into the left upper pulmonary vein. After removal of the sheath and dilator, we used a 14 mm Atlas Gold balloon (Bard Peripheral Vascular, Tempe, AZ, USA) to perform the septostomy to assist in delivering our valve delivery system. We then advanced an Agilis catheter (Abbott, Abbott Park, IL, USA) into the left atrium. With the aid of a Wholey wire (Covidien, Dublin, Ireland), the valve was crossed (*Figure 3A* and *B*). Next, we placed a pigtail catheter in the LV, and simultaneous pressures were obtained. We then exchanged the pigtail for a Confida wire (Medtronic, Minneapolis, MN, USA), and a 26 mm Edwards S3 Ultra Resilia prosthesis was advanced across the septum (*Figure 3C*). During positioning the valve, we also placed the 3 mm marker in the middle of the Commander delivery system (Edwards Lifesciences, Irvine, CA, USA), approximately one to two markers past the surgical ring, which is the ideal location for deployment (*Figure 4A* and *B*; *Video 1*). For most TMVIV procedures, we aim to deploy the prosthesis with a 90/10 bias towards the ventricle to prevent paravalvular leak (PVL) and minimize embolization risk. During valve deployment, rapid pacing at 180 b.p.m. was performed to stabilize the heart and ensure accurate placement (*Video 2*), resulting in the successful deployment of the valve (*Figure 4C* and *D*; *Videos 3* and *4*). The valve delivery system was successfully removed, resulting in an immediate reduction of the MG from 15 to 1 mmHg, as observed on TEE (*Figure 5*). The Perclose sutures were then deployed without complications. The patient was extubated and transferred to the ICU for post-procedure monitoring. Afterward, the patient was discharged home and returned to cardiac rehab. At discharge, his post-operative medications included aspirin, apixaban, and furosemide daily. He reported improvements in his heart failure symptoms, and his post-valve gradient was 1 mmHg at his first outpatient follow-up on 6 May 2024. His gradient has remained stable since March 2024, when his bioprosthesis was implanted.

Discussion

Transcatheter mitral valve-in-valve offers a minimally invasive alternative to traditional surgical MVR and has increased in frequency over the years as data demonstrate this to be a safe and effective option, particularly in the setting of elevated surgical risk.[4]

Data from the Valve-in-Valve International Data registry showed an overall technical success rate of 91%, with a relatively low rate of complications such as malpositioning (3.3%) or LV outflow tract obstruction, which occurred in 2.6% of cases.[5] The patient was not a candidate for more novel transcatheter treatments such as

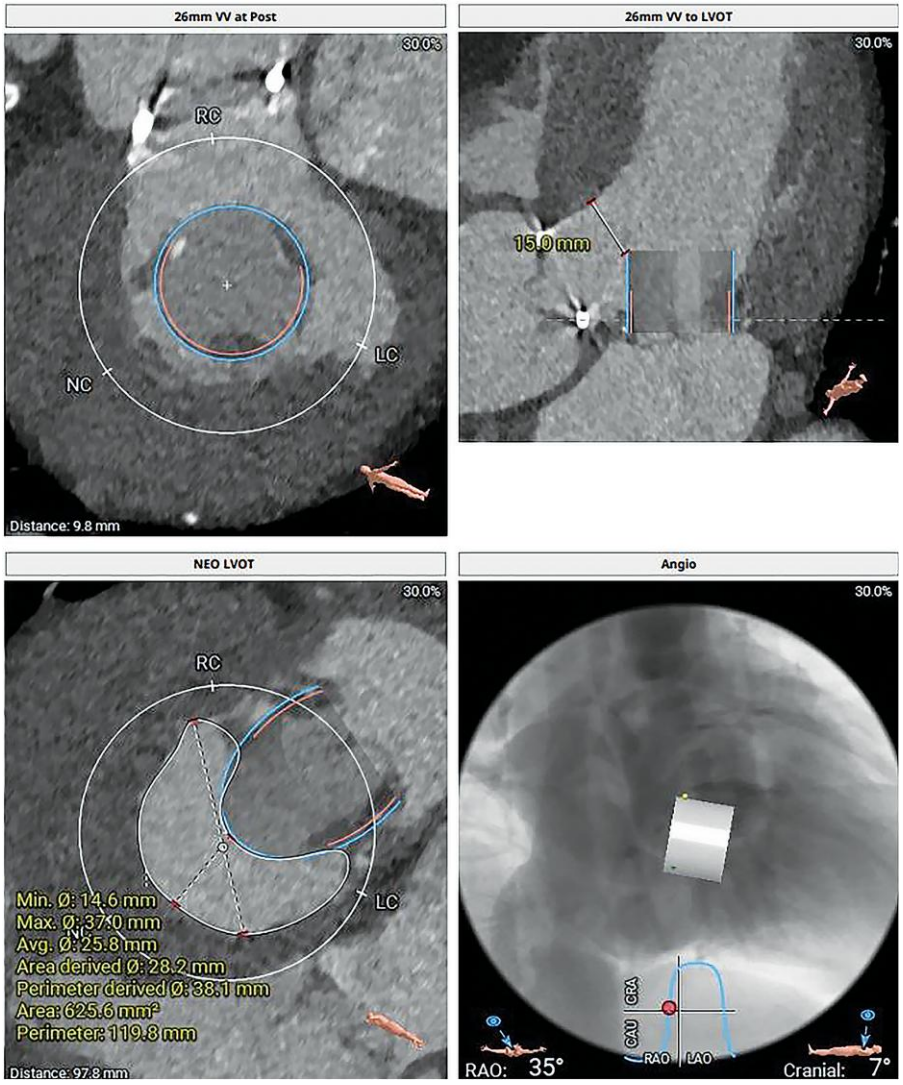


Figure 2 Pre-procedural computed tomography imaging for transcatheter mitral valve-in-valve planning. (*A*) Cross-sectional view showing the measurement of the valve-to-valve distance at 9.8 mm. (*B*) Longitudinal view illustrating the valve-to-left ventricular outflow tract distance, measuring 15.0 mm. (*C*) Neo-left ventricular outflow tract view showing the calculated area of the left ventricular outflow tract (625.6 mm^2) and perimeter-derived dimensions (38.1 mm). (*D*) Angiographic view was taken at a 35° right anterior oblique angle and 7° cranial orientation to assess the alignment and position of the new valve within the bioprosthetic annulus.

Tendyne or Intrepid, which are available at our institution under research circumstances but were not able to be utilized in this patient due to the presence of a previous surgical valve, as well as the research designation attached to both alternative valve options.[6]

We performed a CT scan and calculated the Neo-LVOT based on the appropriate Sapien valve relative to the previous valve area. In this case, a 26 mm S3 was chosen based on the true internal diameter and area of the previous valve. The estimated Neo-LVOT was 625 mm^2, far higher than our 190–200 mm^2 institutional cut-off. In our experience, due to the cylindrical structure of the S3, exceptional attention to obstruction of the LVOT by the anterior leaflet is more of a concern in the TMVIV procedure.

In routine cases, the mitral valve can be visualized by the frame to which its leaflets are sewn which are easily seen on fluoroscopy. However, in this case, no fluoroscopic landmarks were easily identifiable,

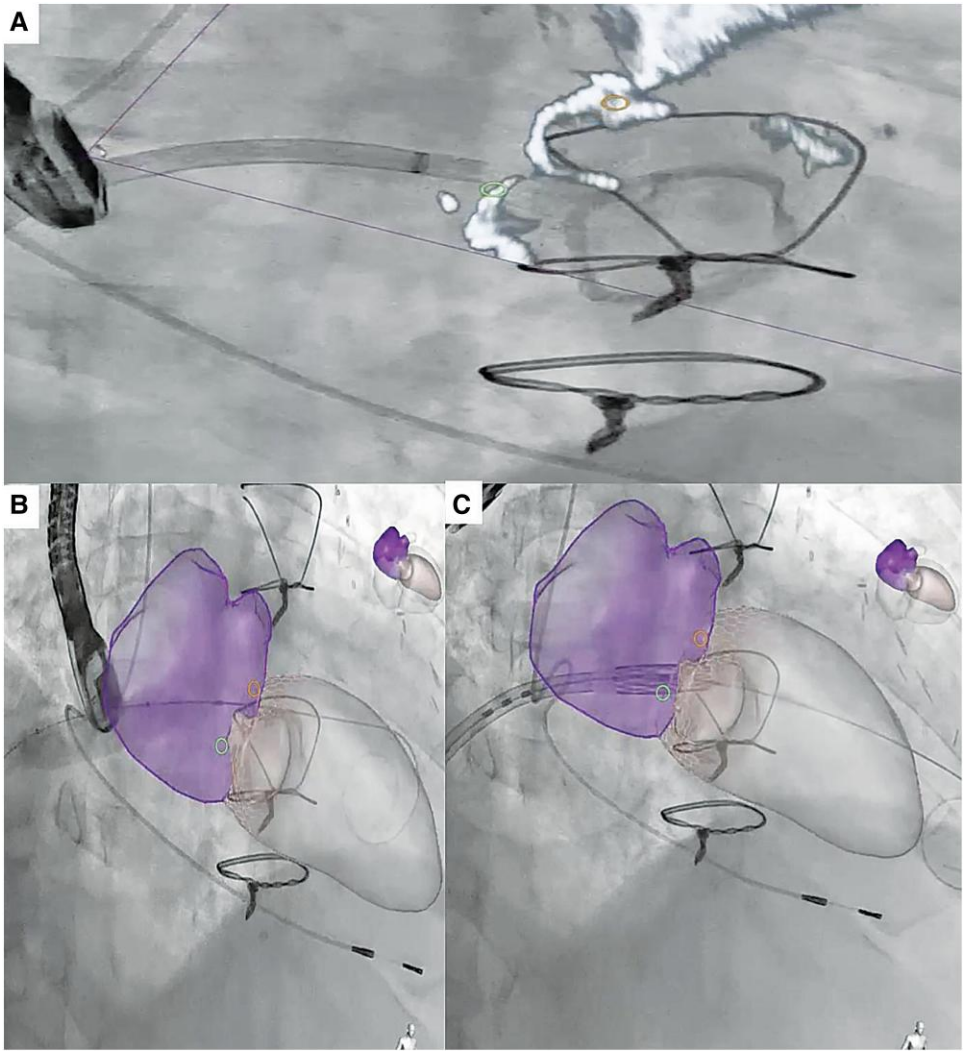


Figure 3 (*A*) Fluoroscopic image showing the septostomy procedure using EchoNavigator® fusion imaging. A 14-mm Atlas Gold balloon was utilized to perform the septostomy after using the Agilis and a pigtail catheter to cross the bioprosthetic. (*B*) EchoNavigator® fusion imaging is used to guide the transcatheter mitral valve-in-valve procedure. The highlighted overlay represents the mitral annulus, aiding in precisely positioning the valve within the annulus. (*C*) Fluoroscopic image using the EchoNavigator® system to guide the advancement of the 26 mm Edwards S3 valve across the septum and crossing the mitral valve.

making the positioning of the prosthesis challenging. Identification of the annular sewing ring can also be challenging. However, its identification is critical in successfully treating such valves, since valve deployment depth can impact LVOT interaction and the development of PVLs if the skirt does not fully encapsulate the previous valve. In order to address these limitations, this case presented itself well as an ideal situation to utilize FI to visualize the annulus using live echocardiographic markings overlaid on fluoroscopy to guide the procedure. EchoNavigator® enables real-time visualization of TEE imaging and allows users to place anatomical landmarks critical for the implantation of intracardiac devices or structures, resulting in more precise device positioning and enhanced procedural outcomes.[7] The EchoNavigator® system provides real-time synchronous views by displaying TEE and fluoroscopy on one screen. After identifying the mitral annulus, the software automatically identifies the TEE probe tip during active fluoroscopy to co-register the two imaging modalities. The tip's X-ray signature is continuously detected and followed

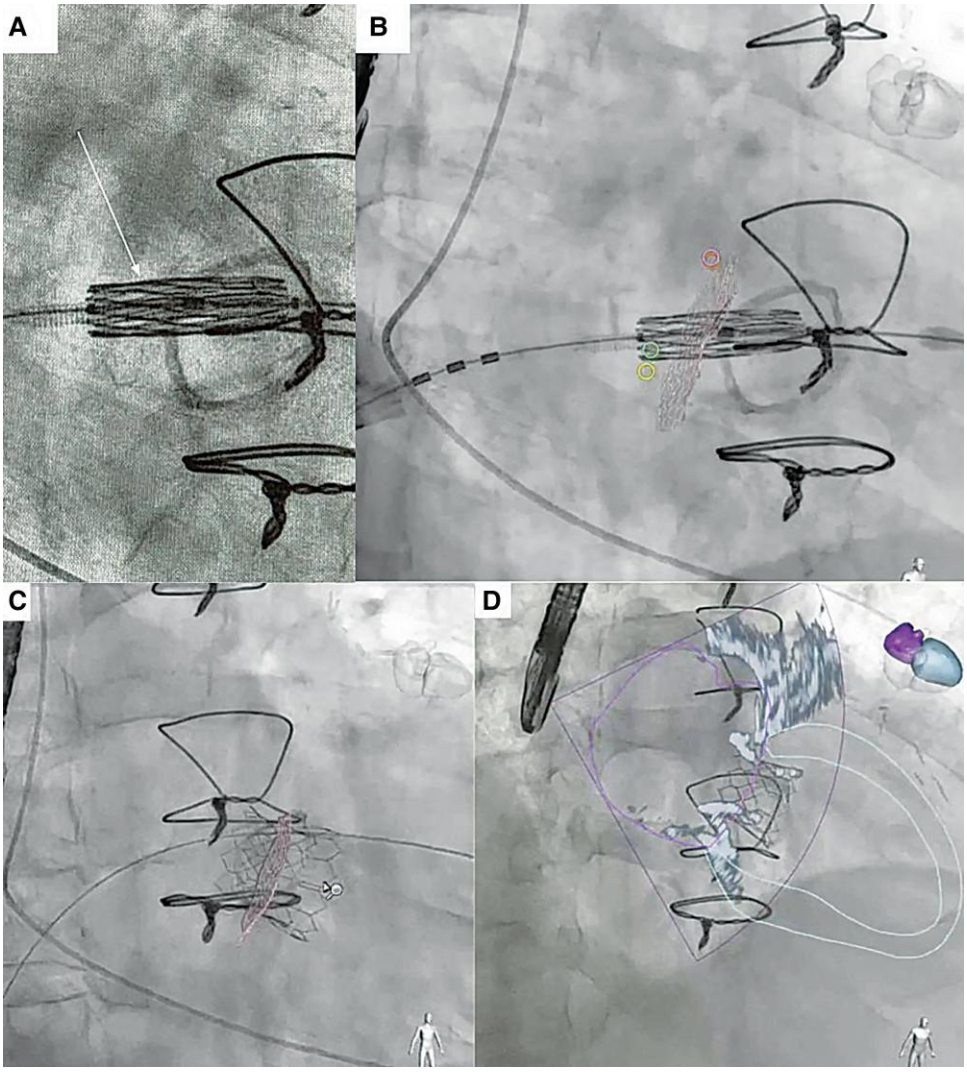
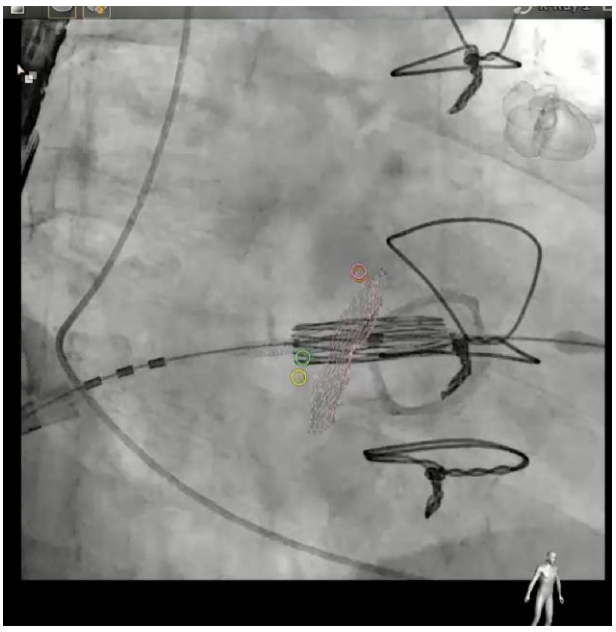
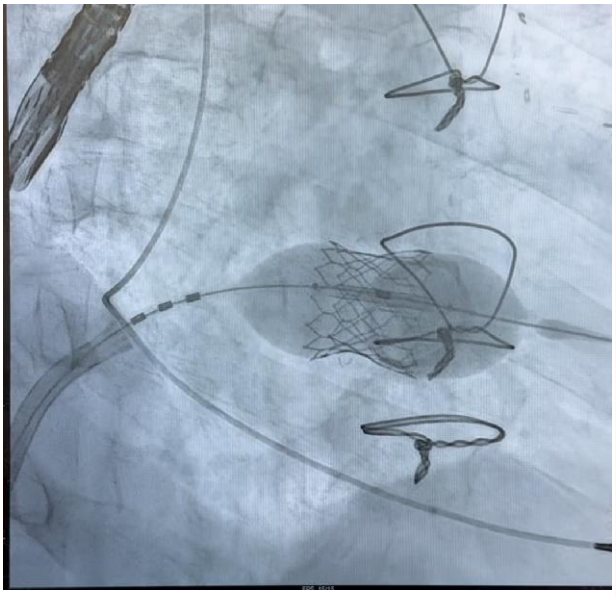


Figure 4 (*A*) Fluoroscopic image depicting the annulus seen on fluoroscopy without fusion enhancement. The arrow indicates the ring of the pre-existing bioprosthetic valve. (*B*) EchoNavigator®-guided image enhancing the visualization of the bioprosthetic mitral valve ring. (*C* and *D*) Fusion imaging view with EchoNavigator® guidance demonstrating the successful deployment of the 26 mm Edwards S3 Ultra Resilia prosthesis in the mitral position.

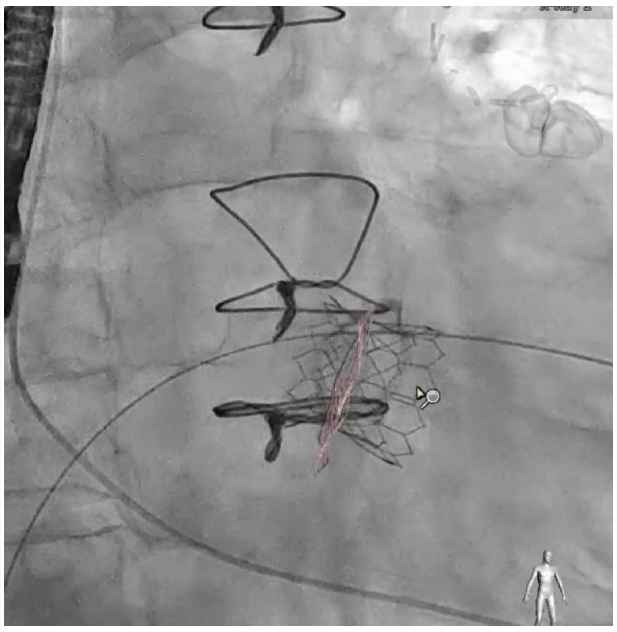
by the software's algorithm. The system displays a small window with the TEE head logo indicating the registration status and updates it on the fluoroscopy screen. C-arm orientation changes modify the orientation of TEE images live. If the probe leaves the fluoroscopy's field of view, it will be automatically resynchronized when it returns.[8] These features make the program ideal to perform real-time live guidance of structural heart procedures. When performing our trans-septal punctures, we aim to cross somewhat mid and posterior to ensure adequate height. We are biased towards the posterior of the septum in order to gain 'height' above the valve to assist in the crossing of the bioprosthesis. Our typical height goal is 4.0 cm above the valve to assist with positioning and crossing the valve in an in-line fashion. In this case, the trans-septal was about 4 cm above the valve. In TMVIV, we routinely perform a septostomy to aid in positioning the system across the septum. EchoNavigator® can assist in accurately detecting a puncture during crossing interatrial septum and help better optimize the punctures for several of our structural procedures, preventing the incidence of pericardial effusion, tamponade, or other catastrophic complications.[7] Despite its advantages, fusion



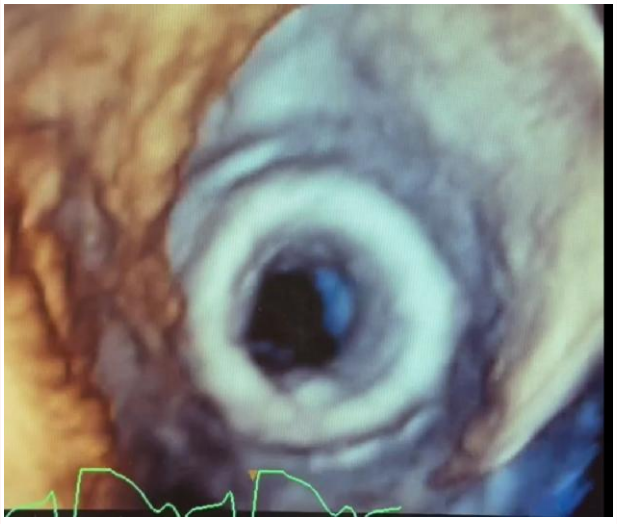
Video 1 This video demonstrates fluoroscopic imaging combined with EchoNavigator® system markers for accurate valve positioning. The 3 mm marker on the Commander DS system is positioned approximately one to two markers past the surgical ring, ensuring optimal alignment and preventing malpositioning.



Video 2 Fluoroscopic deployment of the Edwards Sapien 26 mm valve without fusion imaging enhancement.



Video 3 This video showcases the valve's final position across the enhanced 'virtual' valve.



Video 4 3D transesophageal echocardiography showing the Edwards S3 valve *in situ*, visualizing the valve's function during active cardiac cycles.

technology has several limitations. Firstly, the complexity of visual information and markers is limited by the gating obtained by the echocardiography and is usually limited to a small number of pre-programmed anatomic landmarks by the programmers. Specific structures are built

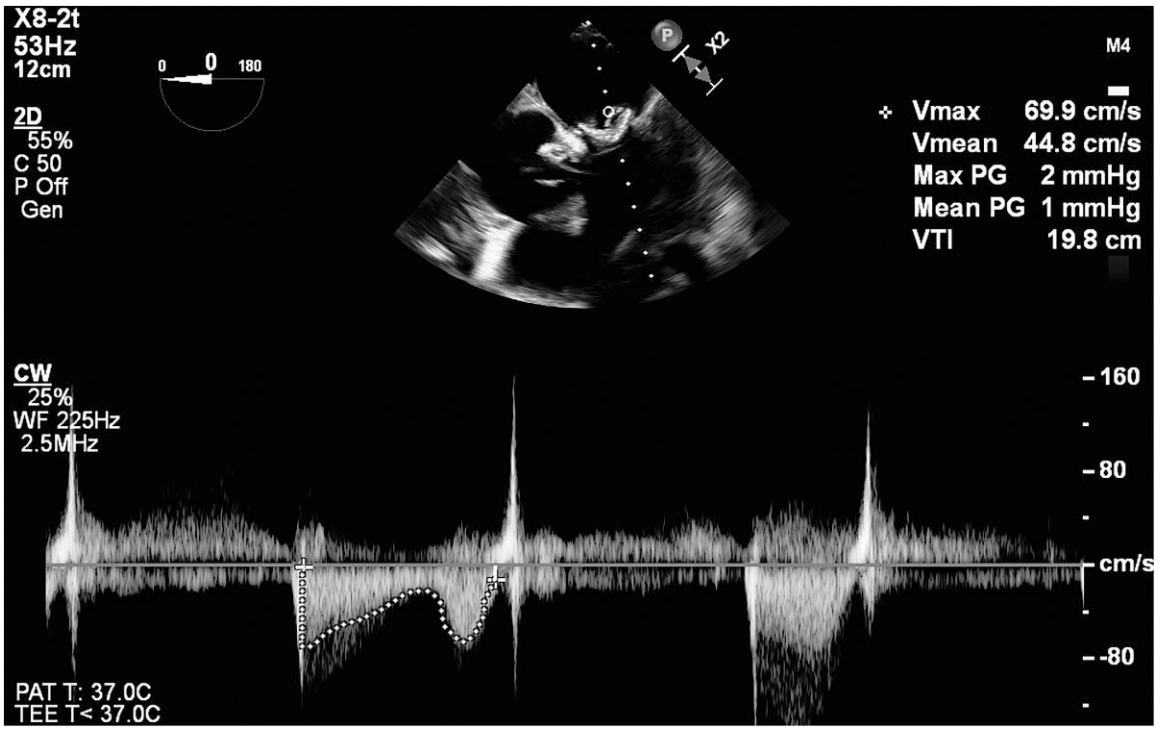


Figure 5 Post-deployment transesophageal echocardiogram image demonstrating the mean mitral valve gradient reduction from 11 to 1 mmHg, indicating successful valve function after the transcatheter valve implantation.

into the software and show cardiac/respiratory variation based on gating technology. Otherwise, other landmarks placed by the operator do not behave in a similar gated fashion. In most valvular procedures, this can be compensated by rapid pacing and correction of our annular markings pre-deployment to reflect better where the annulus will rest during rapid pacing and breath holding. Secondly, the investment in time and the learning curve to becoming adept at using the technology is the major barrier to its adoption. Initially, the technology recommended using steep angles such as a direct anterior–posterior (AP) view and a steep 45–60 degree left anterior oblique (LAO) view. However, we have found that replacing the AP view with a shallow right anterior oblique or LAO view of 20–25 degrees helps decrease the exaggerated angles initially suggested by the manufacturer and does not interfere with the accuracy of the technologies' gating. Furthermore, particular anatomic views, such as the short axis of the LV and mitral valve, are limited by the ability of the C-arm to travel to that location based on the patient's position and body habitus.[9]

In our case, EchoNavigator® was instrumental in advancing our valve to the LV and, under rapid pacing, pulled our valve back during slow deployment and rapid pacing to ensure adequate coverage of the previous valve. We landed our valve at a 90-10 ratio, with 90% of the valve resting in the LV and 10% in the atrium to prevent PVLs around the Sapien's skirt. In this case and other cases of radio-opaque surgical valves, the integration of FI is paramount to help identify accurate landmarks and reduce the complication rate. Post-procedure TEE confirmed that there was no evidence of PVL after the deployment.

In conclusion, this case emphasizes the use of innovative EchoNavigator® in guiding a TMVIV procedure with a Sapien S3 Ultra Resilia valve in a radiolucent surgical valve. The integration of FI technology proved critical in overcoming intracardiac structural challenges. Future investigations and research should explore the role of artificial intelligence–based enhancements to further optimize imaging and improve outcomes in structural heart interventions.

Lead author biography

Mustafa Ahmed, MD, is an interventional cardiologist who treats heart valve and structural heart disease, which are conditions involving defects or damage in the walls, muscles, or valves of the heart. Dr Ahmed is a leader in minimally invasive procedures to treat these conditions, specifically transcatheter aortic valve replacement, the MitraClip procedure, and paravalvular leak repair. He also is an expert in the use of 3D imaging to evaluate and treat complex structural heart disease, including accurate real-time guidance during structural heart procedures.

Acknowledgements

We would like to acknowledge the help of our other contributing fellows within the department.

Consent: The patient provided informed consent through our institution for the publication of this case report, including images and clinical details. All identifying information has been anonymized to protect privacy. The consent form is securely stored at our facility and is available to the journal upon request.

Conflict of interest. None declared.

Funding

None declared.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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