

'Minimalist approach' for transcatheter mitral valve replacement using intracardiac echocardiography and conscious sedation: a case series

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Background	Transcatheter aortic valve implantation operators have adapted to a less invasive technique by foregoing the use of general anaesthesia and transoesophageal echocardiography. This is known as a 'minimalist approach'. This approach has yet to be explored in transcatheter mitral valve replacement (TMVR). Two patients with high perioperative risk underwent TMVR using only monitored conscious sedation (CS) and intracardiac echocardiography (ICE).
Case summary	The patients were symptomatic and required treatment of severe mitral regurgitation and severe mitral stenosis in a mitral valve ring and prosthetic mitral valve, respectively. With the use of an antegrade transseptal approach, the procedure was conducted under CS using ICE only. After placement of the prosthetic mitral valve, the valve was assessed by advancing the ICE catheter through the interatrial septal defect and no significant paravalvular leak occurred. In one case, <i>ad hoc</i> treatment of right to left shunting was successfully pursued. Valve function was excellent immediately and at 24 h after implantation and resulted in significant haemodynamic improvement.
Conclusion	With more TMVR cases being conducted, the 'minimalist approach' with CS and ICE may be considered in selected cases.
Keywords	Transcatheter mitralvalve-in-valve • Valve-in-ring • Intracardiac echocardiography • Minimalist approach • Case report

Learning points

- Implementing a minimalist approach using only intracardiac echocardiography and conscious sedation for transcatheter mitral valve replacement is feasible.
- Intracardiac echocardiography is an effective and practical tool for atrial puncture, valve deployment, and valve interrogation.
- Using a minimalist approach for percutaneous mitral valve interventions allows adequate imaging, decreased invasiveness, patient safety, and operator independence.

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Introduction

The 'minimalist approach' using monitored conscious sedation (CS) has evolved to become the strategy of choice in most experienced transcatheter aortic valve implantation (TAVI) centres.¹ It is associated with improved procedural efficiency and reduced length of stay² without compromising procedural success or clinical outcomes.³ To our knowledge, this approach has not been evaluated in patients undergoing transcatheter mitral valve replacement (TMVR). We report the first two cases and demonstrate the feasibility of this approach, while highlighting the value of intracardiac echocardiography (ICE).

Timeline

assessment confirmed a large, anteriorly directed regurgitant jet from a relapsing posterior leaflet prolapse (*Figure 1A*; Supplementary material online, *Video S1*) with preserved biventricular function. Computed tomography (CT) revealed a 34-mm 3D CarboMedics Ring (Sorin SpA, Milan, Italy) with a measured inner area of 519 mm² and a calculated neo left ventricular outflow tract (LVOT) area of 418.9 mm².

Intervention

The procedure was performed in the hybrid operating suite using a 'minimalist approach' with ICE imaging and CS. Local anaesthesia was provided prior to bilateral femoral access. Neither central line nor Foley catheter were used. Transcatheter mitral ViR was pursed through a transseptal approach using a 29-mm Edwards Sapien S3

Case 1	
Six months prior to presentation	A 73-year-old woman with severe degenerative mitral valve regurgitation s/p surgical mitral valve repair w/ring
Upon presentation to clinic	Completed rehab but complaining of sob w/ exertion. New York Heart Association III, decompensated heart failure, and elevated BNP
	Transthoracic echocardiography: severe recurrent m itral regurgitation
	Evaluation by Heart Team including work up w/CTA and transoesophageal echocardiography (TOE); decision for percutaneous transcatheter mitral valve replacement (TMVR)
Operative procedure	Transcatheter mitral valve replacement, valve-in-ring; minimalist approach
	Discharged safely in 48 h on Aspirin and Plavix
12-week post-operative	After TMVR, symptomatically free and no evidence of paravalvular leak
Case 2	
Nine years prior to presentation	A 69-year-old woman with surgical bioprosthetic mitral valve implanted
Upon presentation to clinic	Subjectively, limited functional capacity, lower limb swelling, on exam diastolic murmur Grade III,
	volume overloaded, cardiac echo: severe mitral stenosis of bioprosthetic valve, severe pulmonary hyperten- sion, right ventricular systolic dysfunction
	Heart Team evaluation for severe symptomatic mitral stenosis: left right cath, TOE, CT imaging
	Prohibitive surgical risk due to frailty index and medical comorbidities
Operative procedure	Transcatheter mitral valve replacement, valve-in-valve; minimalist approach
	latrogenic ASD closure with occluder device
Postoperatively	After TMVR, no evidence of paravalvular leak
	Discharged in 48 h on Aspirin and Plavix
8-week post-operative	New York Heart Association functional Class II and reporting improved quality of life

Case presentation

Case 1

A 73-year-old woman was referred for management of severe symptomatic relapsing mitral valve regurgitation after a failed mitral valve repair 3 months prior. She presented to the clinic with dyspnoea on exertion, significant weight loss, and mild anaemia from low-grade haemolysis. Signs of decompensated heart failure and a loud precordial holosystolic murmur were appreciated on exam. Because of a previously complicated post-operative course with ensuing frailty and worsening heart failure, she was considered for transcatheter mitral valve-in-ring (ViR). Pre-procedural transoesophageal echocardiography (TOE) valve (Edwards Lifesciences, Irvine, CA, USA) from the right femoral vein (*Figure 1B*). A 9-Fr Viewflex ICE catheter (Abbott Vascular, Santa Clara, CA, USA) was inserted into the right atria from the contralateral femoral vein to guide the transseptal puncture and TMVR. Transseptal access was performed with an 8.5-Fr Agilis catheter and standard BRK needle (St. Jude Medical; St. Paul, MN, USA) (Supplementary material online, *Video S2*). Atrial septostomy was performed with a 12 mm \times 40 mm 0.035 'Mustang balloon (Marlborough, MA, USA) over a 0.035' Medtronic Confida wire (Minneapolis, MN, USA). Right ventricular (RV) burst pacing was employed at 180 b.p.m. to allow for a steady and gradual deployment of the balloon-expandable prosthesis within the 3D Carbomedics





ring. The valve delivery system was removed over a wire to maintain transseptal access. The tip of the ICE catheter was redirected into the left atrium (LA) chamber across the atrial septostomy to interrogate the bioprosthesis (Supplementary material online, *Video S3*). Intracardiac echocardiography examination showed clear visualization of a normal functioning mitral bioprosthesis in stable position with trivial paravalvular regurgitation (Supplementary material online, *Video S4*). The pressure gradient measured across the neo-LVOT was 3 mmHg. Colour Doppler interrogation of the atrial septostomy showed a small, non-clinically significant 8 mm left-toright shunt on colour Doppler that was left untreated. The patient's post-operative course was uneventful and characterized by prompt recovery with early discharge the next day on aspirin 81 mg and clopidogrel 75 mg daily. Remarkable clinical improvements with preserved valve function was appreciated during 12-week follow-up.

Case 2

A 69-year-old frail woman was referred for management of severe bioprosthetic mitral stenosis involving a 27-mm ThermaFix Carpentier-Edwards bovine pericardial valve implanted 9 years prior. Symptoms included progressive decline in functional capacity with dyspnoea on minimal exertion and her medical comorbidities included severe obstructive sleep apnoea and low-grade lymphoma. Physical exam was notable for moderate diastolic rumble with mechanical S1. Transthoracic echocardiography confirmed the presence of structural valve degeneration with mean transvalvular gradient of 13 mmHg. A transcatheter mitral valve-in-valve (ViV) procedure was recommended due to high frailty index, coupled with the presence of severe pulmonary hypertension with poor RV systolic function. Preprocedural CT imaging revealed a calculated neo LVOT area of 443 mm² and an inner bioprosthetic valve area of 462 mm².

Intervention

As with the previous case, a 'minimalist approach' was undertaken in the hybrid suite using CS and ICE imaging. Vascular access, transseptal

puncture, and atrial septostomy were completed using the same technique described earlier. A transcatheter 26-mm Edwards Sapien S3 valve was deployed under rapid burst pacing at 180 b.p.m. with an additional 1 mL of saline above nominal volume to flare the skirt of the S3 prosthesis. Fluoroscopic examination revealed adequate valve position and implant height (Figure 2A). The mean mitral valve gradient decreased from 14 to 2 mmHg following TMVR. A corresponding decrease in mean LA pressure was also observed from 34 to 14 mmHg, with a final LVOT gradient of 3 mmHg. Intracardiac echocardiography examination obtained from the LA chamber revealed a stable, normal functioning ViV bioprosthesis with no evidence of residual mitral regurgitation or mitral stenosis. Noticeably, the patient experienced significant hypoxaemia soon after the valve delivery system was removed. The finding was explained by the presence of right to left atrial shunting noted during ICE examination (Supplementary material online, Video S5) in a patient with severe residual tricuspid regurgitation and pulmonary HTN. Intracardiac echocardiographyguided percutaneous closure of the atrial septostomy was pursued ad hoc with a 14-mm Amplatzer Septal Occluder (AGA Medical, Golden Valley, MN, USA). The hypoxaemia resolved immediately following septal closure (Supplementary material online, Video S6; Figure 2B). The post-operative course was characterized by an uneventful recovery and early discharge 2 days later with aspirin 81 mg and clopidogrel 75 mg daily. At 30-day follow-up, the patient reported marked improvement in functional status and quality of life.

Discussion

Transcatheter aortic valve implantation was once uniformly performed using general anaesthesia and TOE, with central line placement, and Foley catheter insertion. It took over a decade to transform the practice of TAVI using a less invasive 'minimalist approach' with monitored CS and local anaesthesia.¹ As validated by multiple studies, this strategy has been associated with lower transfusion rates, procedural times and hospital length of stay, while reducing cost and



Figure 2 (A) Fluoroscopic exam showing left ventriculography with no evidence of mitral valvular regurgitation during left ventricular systole. (B) Fluoroscopic image showing final result: intracardiac echocardiography catheter (long arrow), Amplatz Septal Occluder (short arrow), and Edward Sapien S3 ViV.

improving procedural outcomes.¹⁻⁹ The adoption of a 'minimalist approach' in the contemporary era of TMVR has not yet been systematically evaluated. We, herein, report the first two cases whereby a 'minimalist approach' was successfully employed during TMVR using ICE imaging to safely execute and complete the procedure.

In the first case, a mitral ViR was performed in a frail and debilitated patient with refractory heart failure from severe degenerative mitral regurgitation despite previous surgical repair attempt. The second case involved a mitral ViV replacement in a patient with severe degenerative bioprosthetic mitral stenosis with concomitant RV systolic dysfunction, severe tricuspid regurgitation, and pulmonary HTN. Both patients were deemed high risk and poor surgical candidates for redo-surgery. Additionally, general anaesthesia with TOE was felt to add greater risk and concerns for prolonged recovery and post-operative complication. In both, the 'minimalist approach' (*Figure 1B*) resulted in prompt and uneventful recovery with early discharge within 48 h.

The feasibility of ICE-guided TMVR is also exemplified. In both cases, ICE imaging resulted in clear visualization of the interatrial septum during transseptal puncture, while providing an *ad hoc* solution for mitral valve assessment following TMVR. Furthermore, ICE provides clear visualization of the atrial septostomy post-TMVR and for percutaneous septal closure when clinically warranted as illustrated in Case 2. Although one may argue that TOE may be performed under conscious sedation, it is often cumbersome and therefore avoided in prolonged complex procedures. This too explains why in the contemporary era, ICE has evolved to become a resourceful tool for structural heart procedures such as atrial septal defect, patent foramen ovale, and LA appendage closure.^{10,11} In these cases ICE has been proven safe and effective,^{12,13} while evading the need for general anaesthesia, and reducing radiation exposure, contrast use, decreasing hospital length of stay and increasing operator independence.^{11,14,15}

Among the main limitations of ICE includes far-field interrogation of cardiac structures. This explains why, as in our case, transseptal access is required to interrogate the mitral valve or other left-sided structures. In the case of a TMVR, it is recommended that the distal ICE

catheter tip be advanced into the LA through the atrial septostomy (Supplementary material online, *Video S3*). Finally, although not specific to TMVR, a few studies have reported similar value to ICE and CS in patients undergoing Mitraclip or mitral balloon valvuloplasty.^{11,14,16} Until recently ICE imaging was only available in two-dimensional form, however, as three-dimensional ICE imaging becomes more available, it is likely that we will see a surge in its applicability. It is important to acknowledge that ICE imaging requires operator proficiency and technical expertise. Formal training is therefore encouraged to master the technique and assure its safety and applicability.

The present case series supports the strategy of a 'minimalist approach' using ICE imaging during TMVR and resulting in decreased invasiveness, adequate imaging, operator independence and early hospital discharge. Until further evaluation, this strategy should not replace the existing standard of care of general anaesthesia and TOE for TMVR. To our knowledge, however, this represents the first cases of mitral ViR and ViV performed using this approach—demonstrating its potential safety and feasibility.

Lead author biography



Robert J. Cubeddu, MD is a section head of structural heart disease, Chairman of Cardiology Heart and Vascular Institute Cleveland Clinic Florida. Post-graduate training in Interventional Cardiology and SHD at MGH, Harvard Medical School with vast experience in SHD interventions. National proctor for TAVR, Mitraclip, and Amplatzrelated products. Principal site investigator for several multicentre RCTs. Multiple publications in peer review journals. Member of the editorial board—Journal of CCI and Journal of SHD. Member of the national SHD council for SCAI. Interest in clinical research and innovations.

Supplementary material

Supplementary material is available at *European Heart Journal - Case* Reports online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patient in line with COPE guidance.

Conflict of interest: none declared.

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