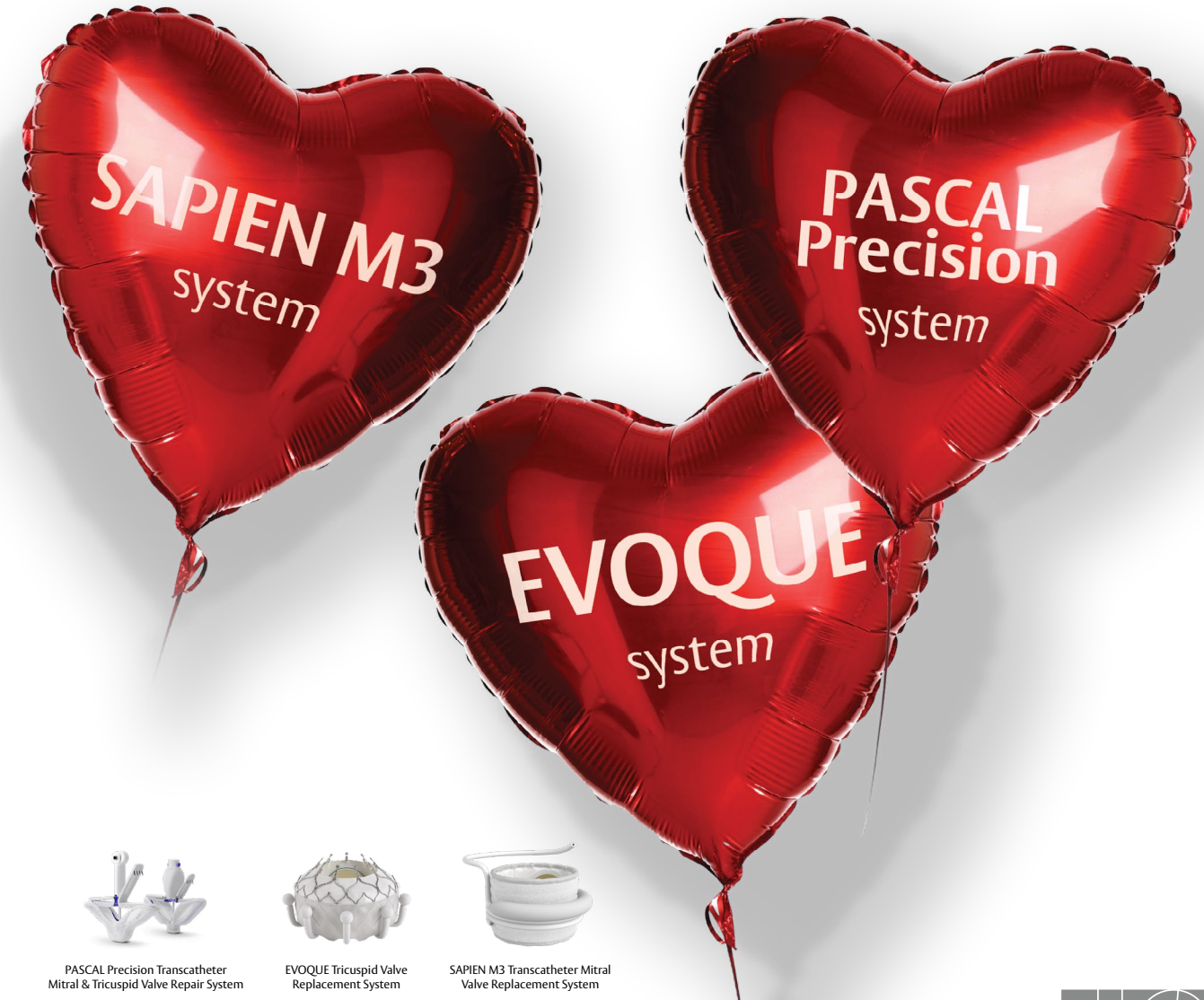
TMTT Today

Your source for information on Edwards' innovations in transcatheter mitral and tricuspid therapies

Issue #15 – May 2026

Repair and replace

Celebrating the most comprehensive portfolio for mitral and tricuspid regurgitation



PASCAL Precision Transcatheter Mitral & Tricuspid Valve Repair System

EVOQUE Tricuspid Valve Replacement System

SAPIEN M3 Transcatheter Mitral Valve Replacement System

In this issue

Edwards

Dear Reader,

Clinically relevant MR affects approximately 10% of individuals over 75 years old and, if left untreated, can lead to heart failure, reduced quality of life and increased mortality.[9] A growing body of evidence supports transcatheter edge-to-edge repair (TEER) for patients with clinically significant, symptomatic MR who are at high surgical risk.[3,5,6,10] TEER with the PASCAL Precision system, developed by Edwards Lifesciences, has shown significant and sustained MR reduction and durable patient benefits.[5,6]

Often patients are not candidates for surgery or TEER. To solve this problem, transcatheter mitral valve replacement (TMVR) has emerged, including the SAPIEN M3 system – the first and only approved fully transseptal TMVR system indicated for the treatment of patients with at least moderate-to-severe symptomatic MR.[1]

In this issue, Darshin Patel, Vice President of Engineering at Edwards Lifesciences, talks us through the key design features of the SAPIEN M3 system and the journey of its development. In discussion with Dr Michael Mullen, we report the 1-year outcomes from the ENCIRCLE trial,[1] the first pivotal trial evaluating outcomes of percutaneous, transseptal TMVR with the SAPIEN M3 system. Dr Adam Rdzanek also presents a real-world case of the SAPIEN M3 system being successfully used to treat secondary ventricular MR. We also report the recent updates to the ESC/EACTS guidelines and the latest data releases from studies on the PASCAL Precision system.[3–8]

Severe TR is a prevalent, often undertreated and life-threatening condition and transcatheter tricuspid valve replacement (TTVR) is an emerging treatment option for patients with severe or greater TR at high surgical risk, aiming to reduce symptoms and improve quality of life.[3,11–14] The EVOQUE system is the first-of-its-kind TTVR option for eligible patients.*

In this issue, we also showcase the latest research on TTVR with the EVOQUE system, including 2-year data from the TRISCEND II clinical trial.[2,15] Finally, we present three interesting case studies discussing the use of tricuspid TEER (T-TEER), mitral TEER (M-TEER) and TTVR to treat patients with MR and TR.

Enjoy reading!

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*First of its kind device commercially available (in the EU).

Contents

SAPIEN M3 transcatheter mitral valve replacement system

Design of the first and only approved fully transseptal, transcatheter mitral valve replacement system

For patients with at least moderate-to-severe symptomatic native mitral valve regurgitation, who are not candidates for surgery nor currently available transcatheter repair therapies, TMVR is an evolving and promising treatment option.[1] Initial TMVR systems utilise a transapical approach, which demonstrate feasibility but are associated with an increased risk of early mortality.[1,16] Edwards Lifesciences has since launched the SAPIEN M3 system, the first and only approved fully transseptal TMVR system.

Here, Darshin Patel talks us through the design of the SAPIEN M3 system and explains how it combines the trusted SAPIEN platform with an innovative dock to provide a new, minimally invasive option for patients with symptomatic moderate-to-severe or severe mitral regurgitation.

Darshin Patel
Vice President, Engineering, Edwards Lifesciences

Darshin Patel is Vice President of Engineering within the Transcatheter Mitral Valve Replacement team at Edwards Lifesciences. He is responsible for developing innovative TMVR technologies, including the SAPIEN M3 system.

Figure 1: The SAPIEN M3 system facilitates an innovative two-phase procedure with the SAPIEN M3 dock encircling the native mitral anatomy creating a stable and standardised landing zone for the SAPIEN M3 valve.

At Edwards Lifesciences, we are committed to developing patient-focused innovative technologies. Due to the complexity and nature of mitral valve disease, there is currently a significant unmet need for patients who are unsuitable for TEER or surgical approaches.[1,17] This motivated us to pursue an effective option for these patients – a challenge that spanned multiple years of development, with multiple iterations to optimise the therapy for physicians and patients. We are proud to have brought the SAPIEN M3 system to the market – the first and only approved fully transseptal TMVR system.

A two-phase procedure

The SAPIEN M3 system is designed as an innovative two-phase procedure – dock delivery and valve delivery – developed to overcome the complex anatomy of the mitral valve (Figure 1).[17] The dock provides a stable and standardised landing zone for the SAPIEN M3 valve – optimised to treat mitral regurgitation. This approach enables a balance between secure anchoring and maintaining the integrity of surrounding structures.[17]

'SAPIEN M3 was designed specifically for the native mitral valve. An encircling dock creates a stable landing zone and the valve—built on proven SAPIEN technology—is optimised to seal within it. It's a very intentional design, meant to bring structure and predictability to an incredibly complex space'

Darshin Patel

The dock: An innovative anchor

The unique nitinol dock encircles the native mitral leaflets to create a stable anchor for the SAPIEN M3 valve.[17]

'The main goal of the dock is to provide an anchoring site for the valve in an atraumatic manner, to optimise sealing and durability'

Darshin Patel

The dock has four key features (Figure 2).[17]

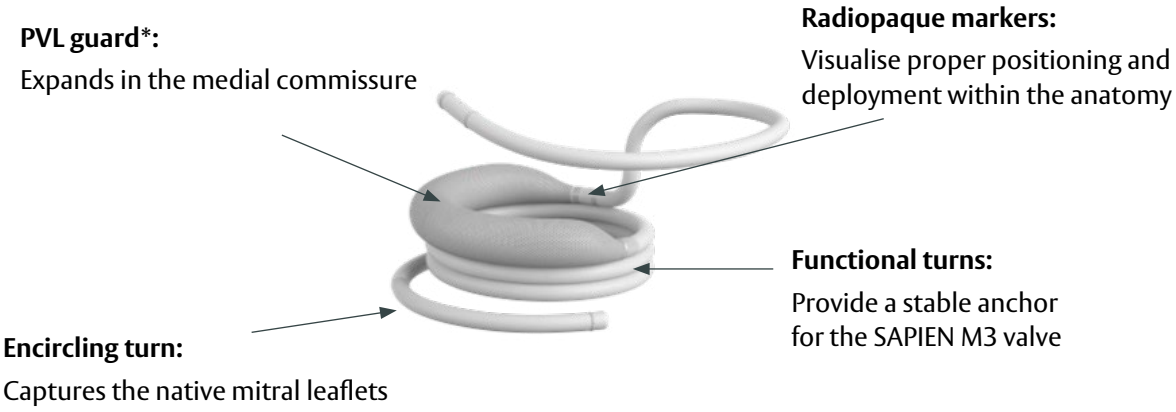


Figure 2: The nitinol dock is fully repositionable and retrievable prior to dock release.
*Paravalvular leak guard

The dock encircles the native mitral leaflets which applies an inward force to the mitral apparatus, pulling leaflets and chordae towards the centre of the dock, and approximating the papillary muscles (Figure 3). This allows the SAPIEN M3 system to treat multiple patients with a single 29 mm valve size.[17]

The dock is designed to minimise protrusion into the left ventricular outflow tract (LVOT) and eliminates the need for outward radial force on the annulus during anchoring.[17] The dock captures the anterior leaflet and pulls it away from the outflow tract, reducing LVOT obstruction. In addition, the dock allows for intraprocedural adjustment; the dock is fully repositionable and retrievable prior to dock release, enabling real-time imaging feedback to refine capturing, positioning and orientation.[17]

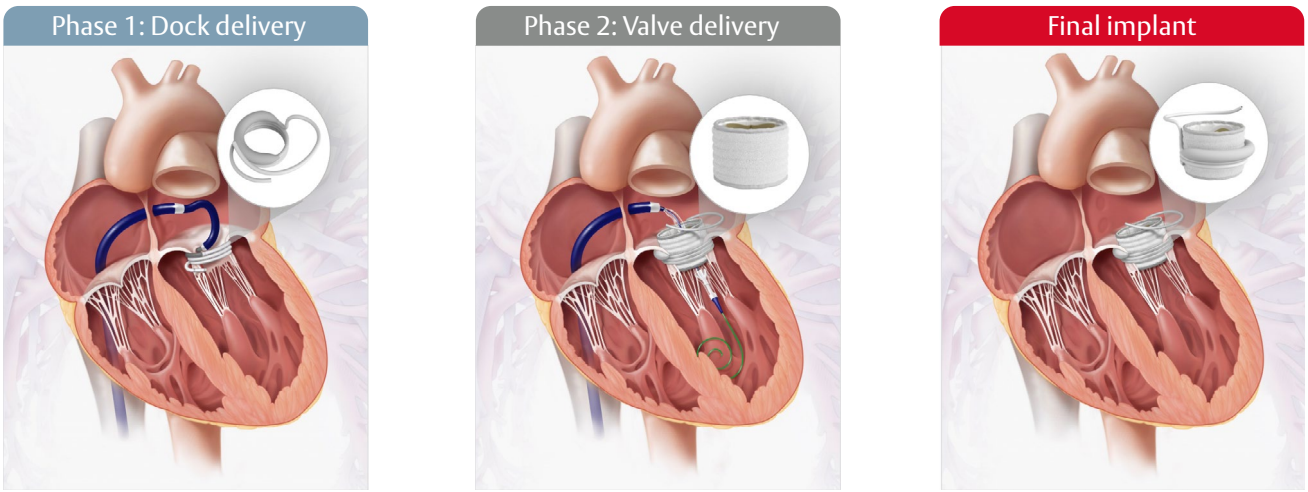


Figure 3: The innovative SAPIEN M3 dock encircles the native mitral anatomy, creating a stable and standardised landing zone for the SAPIEN M3 valve.

'The dock is not a simple helical coil. The encircling turn is larger than the functional turns and captures the mitral leaflets, while the functional turns provide a stable anchor for the SAPIEN M3 valve. The atrial turn maintains transient positioning, with a proximal end oriented away from the anatomy to prevent injury'

Darshin Patel

The valve: Built on a proven platform

The SAPIEN M3 valve design utilises the trusted and proven SAPIEN platform, which has been used in over 1 million procedures globally.* The valve is largely the same as the SAPIEN 3 valve, with a few modifications. Its balloon-expandable design is familiar to physicians and helps place and anchor the valve accurately and consistently.[17]

Therefore, the SAPIEN M3 valve uses the same frame and leaflet design as a 29 mm balloon-expandable SAPIEN 3 valve, but with the addition of a key mitral deployment adaptation – a full-length, textured polyethylene terephthalate (PET) skirt to respect the native anatomy, enhance sealing within the dock and reduce risk of paravalvular leak (Figure 4). When deployed, the SAPIEN M3 valve is angled away from the anterior native mitral leaflet and towards the posterior leaflet thereby decreasing the risk of LVOT obstruction.[17]

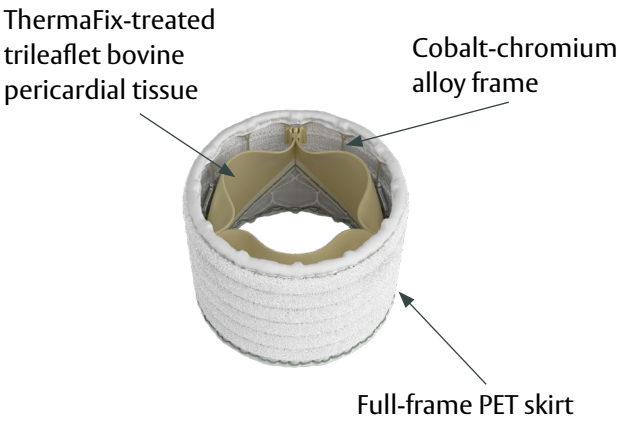


Figure 4: Structure of the SAPIEN M3 valve, optimised to treat mitral regurgitation.

The catheters

The SAPIEN M3 system uses a low-profile 23F inner diameter hydrophilic guide sheath, which provides left atrium access throughout the procedure. Following femoral vein access and a transseptal puncture, the dock is positioned through a deflectable sheath by the SAPIEN M3 dock steerable catheter, designed with a hydrophilic coating and flexible distal tip to respect mitral anatomy. Finally, the Edwards Commander M delivery system is used for controlled deployment of the balloon-inflatable SAPIEN M3 valve under rapid ventricular pacing.[17]

'The SAPIEN M3 system offers a fully transseptal, minimally invasive approach to TMVR. Transfemoral, transseptal delivery via the left atrium is designed to support a simpler procedure and improved patient recovery'

Darshin Patel

Conclusion

The SAPIEN M3 system represents the first and only approved fully transseptal TMVR system. Designed to offer a minimally invasive alternative for patients with native mitral valve regurgitation, the SAPIEN M3 system leverages the proven technology of the SAPIEN 3 platform, anchored within an innovative dock. This innovative two-phase procedure provides a viable option for patients with at least moderate-to-severe symptomatic mitral regurgitation, who are deemed unsuitable for surgery or transcatheter edge-to-edge therapy by a Heart Team.[17]

'We want to set an example to ensure that the future is bright for TMVR'

Darshin Patel

Scan the QR code to watch the full animation of the innovative two-phase procedure for SAPIEN M3 system implantation.

*As of Q1 2024.

One-year outcomes from the ENCIRCLE trial[1]

Many patients with severe MR are not eligible for surgery or TEER. TMVR has emerged as a promising alternative for these patients. However, early TMVR systems require a surgical transapical approach which carries substantial procedural risk and increased morbidity and mortality.[1] The SAPIEN M3 system offers a less invasive, transseptal TMVR treatment option built on the trusted SAPIEN 3 platform, which has been used in over 8,000 mitral procedures globally.* The ENCIRCLE trial is the first clinical trial designed to evaluate outcomes following percutaneous transseptal TMVR using the SAPIEN M3 System.

Dr Michael J Mullen
Barts Heart Centre, London, UK

Dr Mullen is a consultant cardiologist with expertise in structural heart disease, valvular heart disease and transcatheter therapies.

'Having a TMVR option is really important for the subgroup of patients who are at high-risk for surgery or unsuitable for repair technologies'

Dr Michael Mullen

'A key advantage of the SAPIEN M3 valve is that it is built on the SAPIEN platform, which has a long track record of being used in both the aortic and mitral position. The two-phase procedure allows us to deliver a low-profile valve, lowering the risk of LVOT obstruction'

Dr Michael Mullen

The ENCIRCLE trial (NCT04153292) is an ongoing, prospective, single-arm, multicentre pivotal study designed to evaluate the safety and effectiveness of percutaneous TMVR with the SAPIEN M3 system in patients with symptomatic (New York Heart Association [NYHA] class ≥II) moderate-to-severe or severe MR (≥3+) who were unsuitable for surgery or commercially available transcatheter treatment due to anatomical criteria or comorbid conditions.[1,18]

Guerrero *et al*. report the 1-year outcomes from the main cohort of 299 treated patients, recruited at 56 centres across the USA, Canada, the UK, the Netherlands, Israel and Australia. The implant success rate was 96% and no patients required implantation of a second valve or conversion to surgery during the initial procedure.[1]

Baseline characteristics

Age:
77 years†

NYHA class III or IV:
71%

Severe MR grade 4:
48%

MR, mitral regurgitation; NYHA, New York Heart Association.

The primary endpoint was a non-hierarchical composite of all-cause mortality and heart failure rehospitalisation (HFH) at 1 year, compared with a prespecified performance goal of 45%, which was determined in consultation with the U.S. Food and Drug Administration and derived from event rates from the optimal medical therapy (OMT) arm of M-TEER randomised controlled trials available at the time of trial design (COAPT and MITRA-FR trials).[19,20] Prespecified secondary endpoints included improvement in MR grade, NYHA class, Kansas City Cardiomyopathy Questionnaire overall summary score (KCCQ-OS), and left ventricular end diastolic volume index (LVEDVi) compared with baseline at 1 year.[1,18]

*As of Q1 2024; †Median age.

'The learning curve through the ENCIRCLE trial has been really positive and shorter than expected, I have been surprised at how quickly we have been able to become competent with the procedure'

Dr Michael Mullen

Safety outcomes

The trial's primary endpoint was met, the composite 1-year Kaplan–Meier estimate for all-cause death or HFH was 25.2% (95% confidence interval [CI] 20.6–30.6; 13.9% [10.4–18.5] for death and 16.7% [12.8–21.6] for HFH), which was significantly lower than the prespecified performance goal of 45% (p<0.0001).[1]

The procedure was associated with a low complication rate; 30-day all-cause mortality was 0.7%, which was lower than expected in this complex patient population.* One-year adverse events are shown in Table 1.[1] Dr Mullen considers this a positive and expected safety profile, which can help 'advise patients about the risks and benefits of this treatment'.

Table 1. Adverse events at 1 year.

	Kaplan–Meier estimate, % (95% CI)
Stroke	9.3 (6.4–13.4)
Mitral valve reintervention	6.4 (4.1–10.1)
Clinically significant valve thrombosis*	6.7 (4.3–10.3)
Haemolysis requiring intervention†	7.1 (4.7–10.8)
New permanent pacemaker	5.5 (3.0–10.1)

CI, confidence interval.
*Includes leaflet thickening with impaired leaflet motion with mitral valve stenosis (increase in mean mitral valve gradient ≥5 mmHg) and clinical signs or symptoms of mitral valve stenosis.
†Haemolysis requiring blood transfusion or mitral valve reintervention.

Sustained reduction in MR and LVEDVi

TMVR with the SAPIEN M3 system resulted in significant and sustained reduction of MR as determined by paired evaluation of MR severity. Residual MR was reduced to mild or less in 95.7% of patients and to none or trace in 79.3% of patients at 1 year (Figure 5).[1] This reduction in MR was associated with beneficial left ventricular remodelling, evidenced by a significant decrease in LVEDVi at 1 year (mean [standard error, SE] −4.7 [1.4]%, p<0.0001)[18] and improved haemodynamics, including increased stroke volume and cardiac index.[1,18]

'The SAPIEN M3 valve is very effective in reducing MR. The reduction in MR was both highly significant, with most patients having none or trace MR, and sustained to 1 year'

Dr Michael Mullen

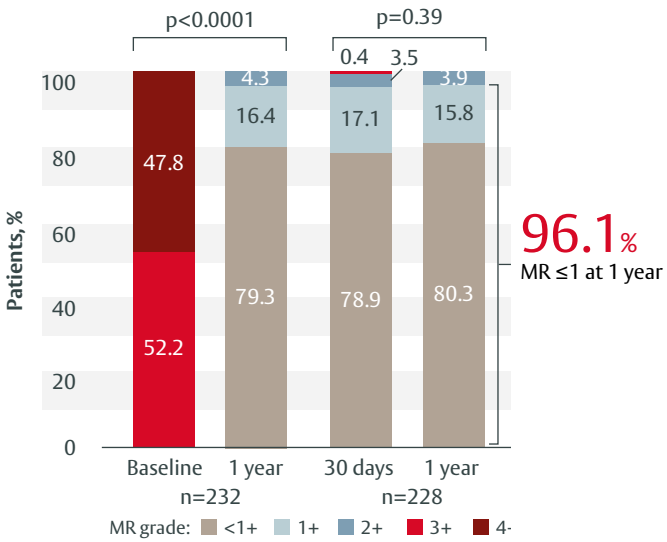


Figure 5. MR reduction with the SAPIEN M3 system at 1 year in the ENCIRCLE trial.

Paired comparisons between baseline and 1 year and between 30 days and 1 year are shown.

MR, mitral regurgitation.

*The Society of Thoracic surgeons predicted risk of mortality was 6.6%; observed-to-expected ratio: 0.1.

Meaningful health status improvements for patients

Reduction in all-cause death and HFH was accompanied by clinically relevant improvements in function and quality of life at 1 year. An improvement in NYHA class was observed in 73% of patients (171/233, p<0.0001); 88% of patients were in class I or II at 1 year compared with 29% at baseline (Figure 6). In addition, mean KCCQ-OS increased by 18.4 points from baseline (SE 1.7; p<0.0001).[1]

'I think the SAPIEN M3 valve is going to have a huge impact on clinical practice, because it is the first fully transseptal TMVR valve that is commercially available. It really sets the scene for a new type of technology that can be widely applied to a significant number of patients'

Dr Michael Mullen

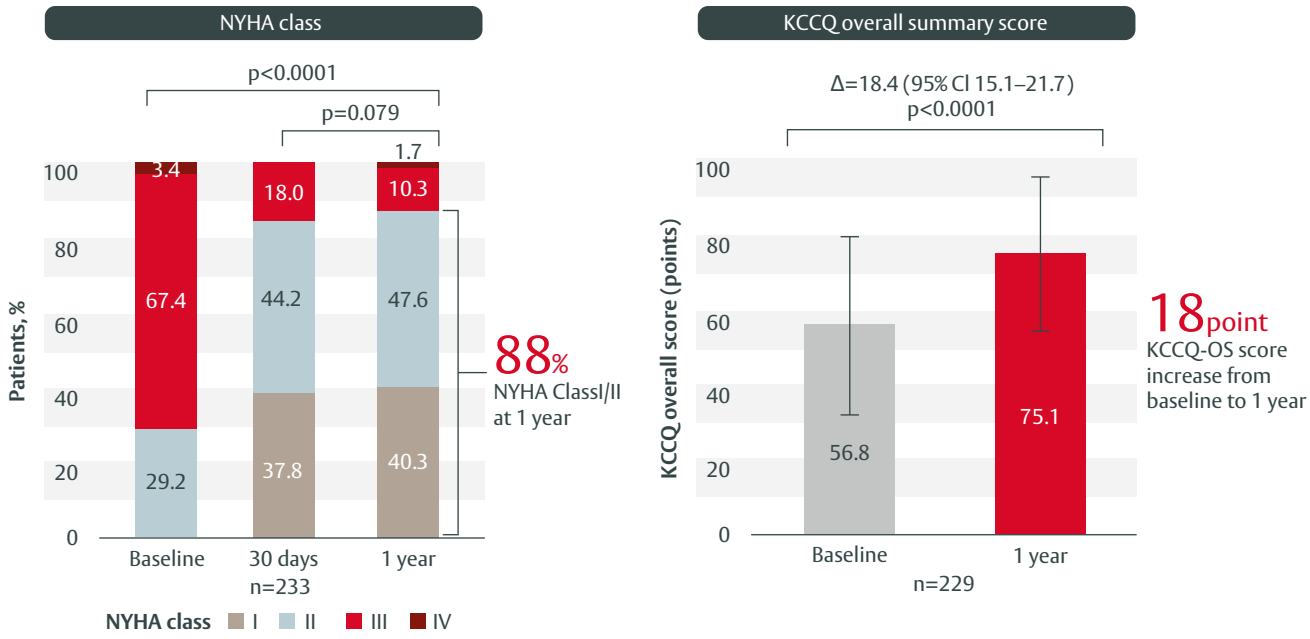


Figure 6. Functional and quality-of-life improvements with the SAPIEN M3 system at 1 year in the ENCIRCLE trial.

Graphs show paired comparisons. Error bars show 95% CI.
CI, confidence interval; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire overall score; NYHA, New York Heart Association.

Conclusion

The ENCIRCLE pivotal trial 1-year results demonstrate that percutaneous transseptal TMVR with the SAPIEN M3 system in patients with symptomatic MR who are unsuitable for surgery or TEER is associated with mortality and HFH rates significantly lower than the performance goal. The observed low 30-day and 1-year mortality rates, sustained reduction in MR severity and meaningful improvements in functional status and quality of life support percutaneous TMVR as a novel therapeutic option for patients with symptomatic MR who are unsuitable for surgery or TEER.[1]

'This technology is going to work really well for those patients who are unlikely to achieve the desired outcomes with TEER. With the SAPIEN M3 system, we can get a predictably good result'

Dr Michael Mullen

Case study: The SAPIEN M3 system for treating secondary ventricular MR

Dr Adam Rdzanek is an interventional cardiologist at the Medical University of Warsaw. He specialises in coronary artery procedures, percutaneous mitral valve repair and replacement procedures and tricuspid regurgitation therapies.

The patient

The patient was an 80-year-old male with chronic heart failure due to non-ischaemic cardiomyopathy. He was on optimised medical therapy and had received a cardiac resynchronisation therapy defibrillator in 2023. Despite this, he presented to our clinic with dyspnoea on exertion, a left ventricular ejection fraction (LVEF) of 45% and an elevated N-terminal-pro-B-type natriuretic peptide level of 3,109 pg/mL. Therefore, we decided that this patient required further intervention.

Baseline echocardiography showed severe MR, with a regurgitant jet from the medial commissural region and a short and tethered posterior mitral valve leaflet (Figure 7).

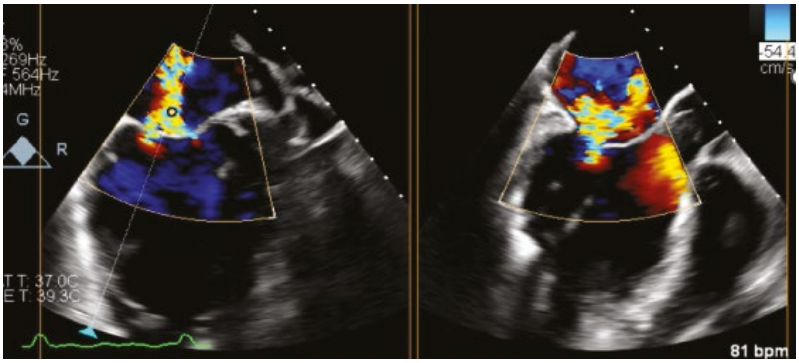


Figure 7. Baseline TOE showing severe MR, with the main regurgitant jet originating from the medial commissural region and a short and tethered posterior mitral valve leaflet.

Courtesy of Dr Piotr Ścisło.
MR, mitral regurgitation; TOE, transoesophageal echocardiography.

The challenge

Mitral valve surgery was not considered suitable for this patient as he was elderly with no concomitant coronary artery disease; the ESC/EACTS guidelines for the management of valvular heart disease recommend TEER as a Class I indication for severe ventricular secondary MR over surgery (Class IIb).[3] However, the patient had several anatomical features that made him unsuitable for TEER.[9] Firstly, the posterior leaflet was very short (about 6–7 mm) and tethered, which increases the risk of single leaflet device attachment following implantation. Secondly, considering the mitral valve area of 3.8 cm^2, TEER may have put the patient at risk of mitral valve stenosis. Therefore, we decided that this patient was unsuitable for TEER and a candidate for TMVR.

Patient key facts

80 years old

Male

Severe MR

NYHA class III

The strategy

Using computed tomography (CT) screening, the Heart Team determined that the patient was suitable for SAPIEN M3 system implantation; however, there was a risk of a low dock position due to the anatomy. As a team, we thoroughly reviewed the bailout procedure to make sure we all were aware of the risks and the solutions in case of any problems.

'Work as a team to review the screening and discuss the potential risks of every case. You need to be aware of tricky situations that may occur and know the solutions – this is crucial for a successful procedure'

Dr Adam Rdzanek

'You can't achieve success individually. It's teamwork, not a solo game. Talk to your echocardiographers and learn from them'

Dr Adam Rdzanek

The procedure

The TMVR procedure with the SAPIEN M3 system begins with dock delivery.[21] We introduced the dock delivery system through the left atrium and advanced it beneath the mitral valve into the LVOT. After several attempts to encircle and capture the native mitral leaflets, we determined that the initial entry site was too far from the medial commissure, providing an important procedural learning on the value of optimising the entry location.

The dock is fully repositionable and retrievable prior to dock release, so, starting afresh, we withdrew the dock delivery system to the left atrium and entered the left ventricle closer to the medial commissure. This time, with careful positioning, we successfully encircled the subvalvular apparatus within the dock, with no system height issues (Figures 8A and B). The dock was released, and we proceeded with the second phase of the procedure, in which the SAPIEN M3 valve was deployed successfully (Figure 8C). Valve deployment is carried out through the same guide sheath as dock deployment, simplifying the procedure and reducing the risk of damage to the surrounding structures.

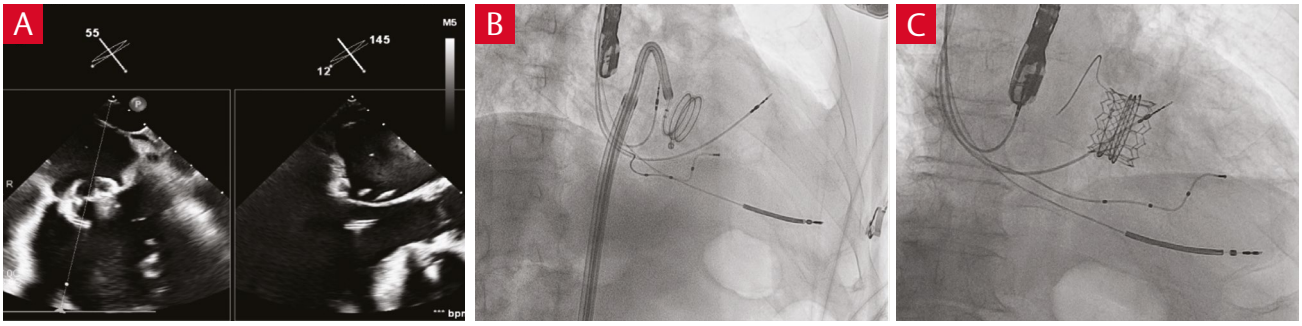


Figure 8. Echocardiography and cardiac angiography images showing successful encirclement (A/B) and valve deployment (C).

Courtesy of Dr Piotr Ścisło.

'The docking system is well designed and intuitive, enabling you to monitor and navigate every step of your encircling manoeuvre'

Dr Adam Rdzanek

Postprocedurally, the mean gradient across the mitral valve was 4 mmHg, with no residual MR or significant paravalvular leak (Figure 9). The ejection fraction dropped by approximately 8%; however, the stroke volume increased, indicating a positive haemodynamic effect. The patient was discharged on Day 3 post procedure, and at 3-month follow-up, we saw symptomatic improvement, a stabilised ejection fraction of ~40% and excellent echocardiographic results.

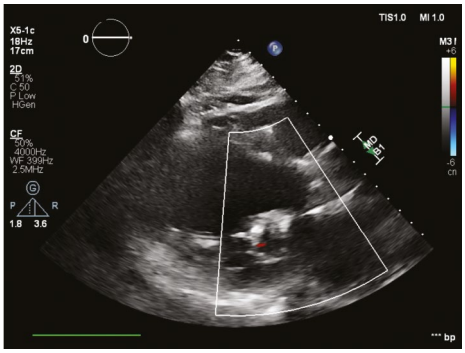


Figure 9. TOE showing the final result, with no MR.

Courtesy of Dr Piotr Ścisło. MR, mitral regurgitation; TOE, transoesophageal echocardiography.

Key tips

- Excellent teamwork and collaboration with the echocardiographers is essential: you are all team members and can learn from each other
- The team should thoroughly review and discuss each case to prepare for any eventuality
- Be ready to adapt to challenges in imaging – intraprocedural echocardiography may vary from screening
- Make use of the training, experience and advice from the Edwards team

Prediction of new pacemaker requirement after transcatheter tricuspid valve replacement

TTVR is an innovative therapy for patients with symptomatic TR despite medical therapy, with recent positive results in clinical trials and real-world studies.[22-25] However, the need for new permanent pacemaker implantation following TTVR has been observed in clinical practice, with a real-world rate of 14.9–18.9% in pacemaker-naive patients at 30 days.[22,25] This analysis, presented at PCR London Valves 2025, aimed to identify predictors of new pacemaker requirements following TTVR with the EVOQUE system.[15]

Dr Christian Besler
United Heart Centre Freiburg, Bad Krozingen, Germany

Dr Besler is an interventional cardiologist and Head of the Structural Heart Disease programme at the University Heart Centre Freiburg Bad Krozingen.

'The close proximity between the tricuspid annulus and atrioventricular conduction system axis is well known, as is the finding of new conduction disturbances following TR therapies. However, we lack proper risk estimation models for new conduction disturbances, which would be of great help for patient management'

Dr Christian Besler

'We analysed the routine pre-procedural CTA for each patient to delineate the configuration of the atrioventricular conduction system axis and illustrate its geometric relationship to the tricuspid valve annulus'

Dr Christian Besler

The EVOQUE system has demonstrated safety and efficacy in the TRISCEND clinical trial, however permanent pacemaker implantation is increasingly recognised as a prevalent postoperative complication[22,23,25,26] – most likely resulting from atrioventricular node and the His-bundle adjacent to the anteroseptal portion of tricuspid annulus being vulnerable to mechanical stress associated with the prosthesis deployment and positioning.[27,28]

In this multicentre, single-arm observational study, Dr Besler and his colleagues used simulation of the atrioventricular conduction axis and tricuspid annulus on pre-procedural CT, to identify predictors of new permanent pacemaker requirement (PPR) after TTVR.[15,29]

Patient population and methods

We included consecutive patients (n=178, median age 80.0 years [interquartile range: 11.0 years]) who were treated with the EVOQUE system between September 2020 and December 2024, and were either pacemaker-naive or had had a prior pacemaker implantation with a low right ventricular (RV) pacing burden (<5%).[15,29]

The primary endpoint was PPR within 30 days post TTVR, including permanent pacemaker implantation for complete heart block, advanced second-degree atrioventricular block or slow atrial fibrillation, or increase in RV pacing rates to >80% in participants with pre-existing pacemakers.

Pre-procedural computed tomography angiography (CTA) was used to provide a 3-dimensional visualisation of the conduction axis, and estimate the course of the conduction axis from atrioventricular node to left bundle branch.[15]

Permanent pacemaker requirement

A total of 21% of patients (n=38, median age 80 years [IQR: 9.5 years]) had new PPR. There were no significant differences in baseline variables such as pre-operative electrocardiogram findings (except for atrial fibrillation and left anterior fascicular block, Table 2), history of heart valve procedures or implanted device size between those patients with and without PPR.[15,29]

Table 2: Pre-operative electrocardiogram results for patients with and without PPR post TTVR.[15,29]

Pre-operative findings, %	No PPR	PPR	p value
Atrial fibrillation	79	87	0.04
Right bundle branch block	20	21	0.89
Left bundle branch block	2	8	0.08
Left anterior fascicular block	16	11	0.03
Left posterior fascicular block	1	8	0.18

PPR, permanent pacemaker requirement.

Predictors of PPR

Several anatomic measurements from the pre-procedural CTA were significantly associated with PPR following the procedure (Figure 10). A higher lateral offset distance was associated with a reduction in the probability of PPR following TTVR. However, the probability of PPR increased with increasing conduction system exposure angle and perimeter-derived diameter. Of patients with a lateral offset distance ≤5.5 mm and a conduction exposure angle of ≥42° (n=13), 62% had new PPR.[15]

In addition, pre-procedural left posterior fascicular block was a significant electrocardiographic predictor of PPR (adjusted odds ratio: 8.79 [95% CI 1.29–74.6; p=0.027]).[15]

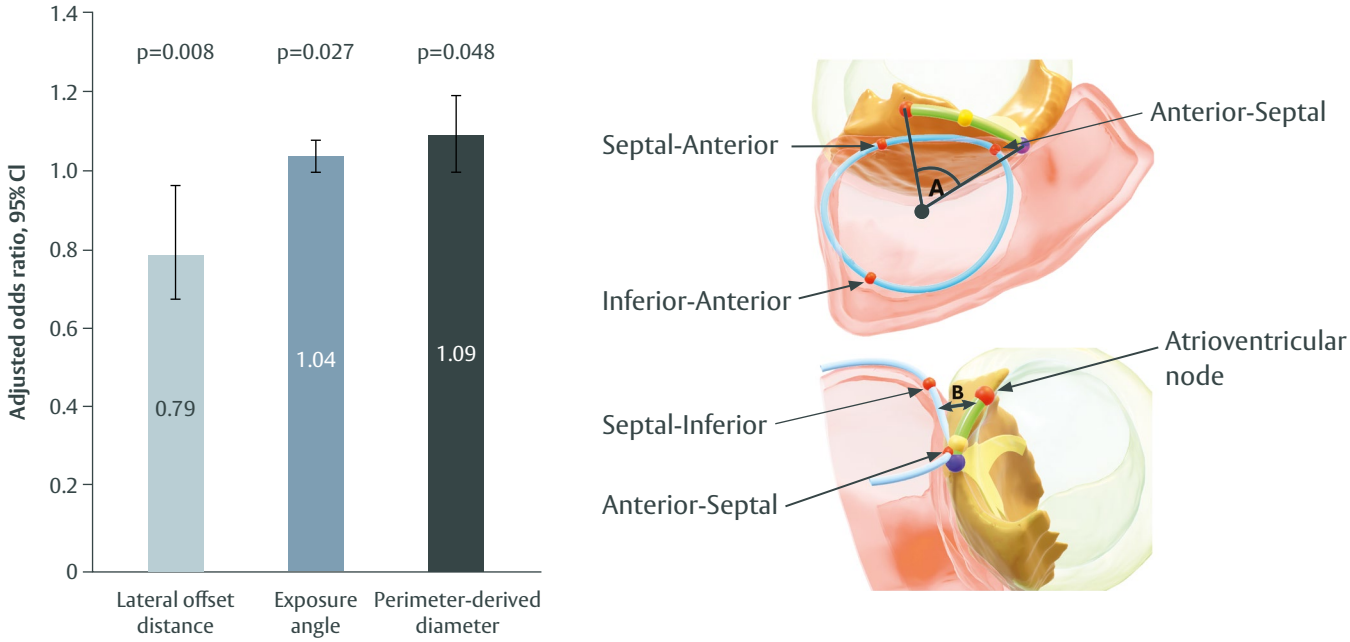


Figure 10. Anatomical predictors of new PPR, with schematic detailing. A and B refer to the angle of exposure and lateral offset distance, respectively.

CI, confidence interval; PPR, permanent pacemaker requirement.

Courtesy of Dr Christian Besler

'The exposure angle describes how exposed to injury the conduction system is on the annular plane, while the lateral offset distance describes how far away the conduction system runs from the tricuspid annulus laterally. These features are unique to each patient: an anatomic fingerprint'

Dr Christian Besler

Clinical impact

Predicting the risk of PPR after TTVR may be improved by defining the lateral offset distance and conduction system exposure angle on pre-procedural CTA. This study highlights the potential of conduction system-guided planning to reduce complications after TTVR and further enhance patient management and outcomes.

Conclusion

Conduction system-guided planning has the potential to improve patient management following TTVR by highlighting the risk of potential complications. This exploratory study provides initial evidence that defining certain anatomical features with pre-procedural CTA may improve post-TTVR PPR risk prediction. Future studies should focus on validating this strategy in TTVR.[15]

'If we can validate these findings, they may individualise the post-procedural monitoring of our patients and streamline decision making on permanent pacemaker implantation'

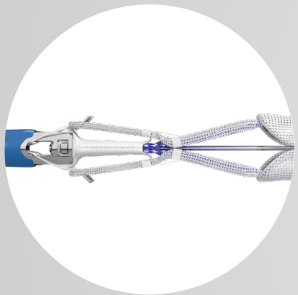
Dr Christian Besler

PASCAL Precision System

Innovating in mitral and tricuspid TEER

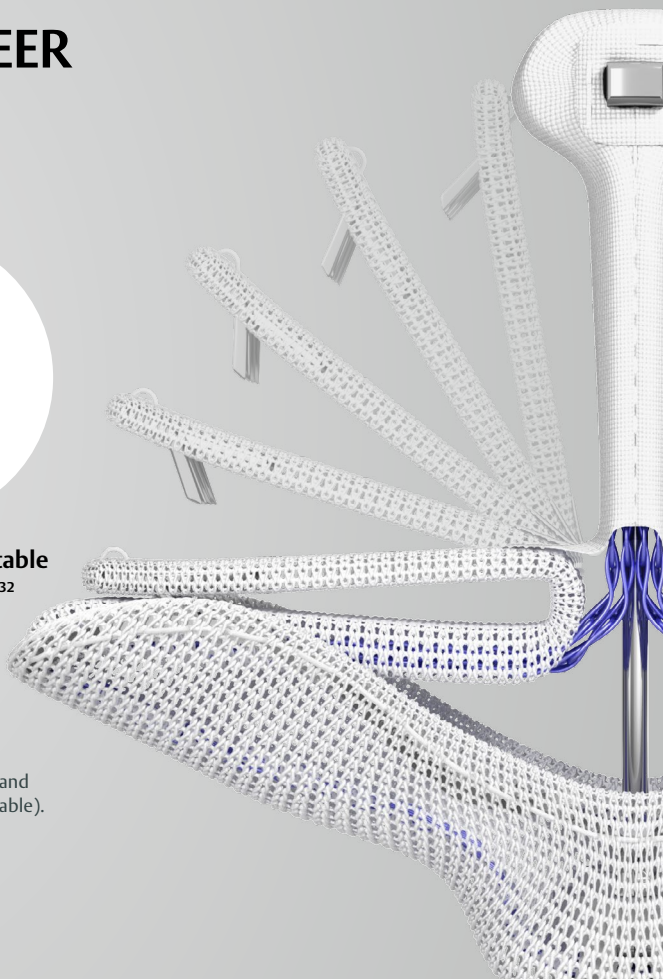
The only TEER system

Designed for precise control[30*]



With elongation capability

With over 90% predictable implant release[5,31,32]



*Due to unkeyed catheters, 3-plane maneuvering and atraumatic leaflet capture.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

TEER, transcatheter edge-to-edge repair
Simulation data on file.

2025 ESC/EACTS valvular heart disease guidelines: Implications on clinical practice

The 2025 ESC/EACTS guidelines for valvular heart disease highlight updated recommendations based on the latest clinical data.[3] The guidelines reflect a shift towards earlier diagnosis, clearer phenotyping of valve disease and broader integration of transcatheter therapies into routine care pathways, reinforcing the need for timely referral and multidisciplinary decision making.

Learn more about the ESC/EACTS guideline updates

The expert heart valve centre

The importance of early referral to heart valve centres for diagnosing and treating patients with mitral and/or tricuspid valve disease is emphasised in the updated guidelines.[3,33]

Transcatheter-focused updates for MR and mitral stenosis

Severe primary MR

The indication for TEER has been strengthened to a Class IIa recommendation in symptomatic patients who are anatomically suitable and at high surgical risk according to the Heart Team.[3,33] This recommendation is supported by registry data that show the low rates of HFH and 1-year mortality after this procedure.[33,34]

Atrial and ventricular secondary MR

For the first time, atrial and ventricular secondary MR have been defined and distinguished to highlight the significant differences between patients, allowing for more specific treatment pathways.[3,33]

Severe atrial secondary MR: Class IIb recommendation for TEER in symptomatic patients unsuitable for surgery after optimisation of medical therapy including rhythm control, when appropriate.

Severe ventricular secondary MR: Class I recommendation for TEER in certain haemodynamically stable, symptomatic patients with impaired LVEF, despite OMT.

'The updates are based on growing evidence supporting the favourable effects of transcatheter therapies in certain mitral and tricuspid valve pathologies, with appropriate patient selection'

Dr Christian Besler

Mitral stenosis

A Class IIb recommendation for transcatheter mitral valve implantation in symptomatic patients with extensive mitral annular calcification and severe mitral valve dysfunction in experienced and specialist heart valve centres, increasing treatment options.[3,33]

Transcatheter-focused updates for TR

For severe TR, prior to intervention, there is now a Class I indication for careful evaluation of TR aetiology, disease stage, patient operative risk and recovery likelihood by a multidisciplinary Heart Team.[3]

Severe TR without left-sided valvular heart disease requiring surgery[3]

As evidenced by randomised clinical trials of T-TEER and TTVR showing improvements in quality of life and right ventricle remodelling,[23,33,35] a Class IIa recommendation is given for transcatheter TV treatment to improve these outcomes in patients with symptomatic severe TR despite OMT without severe right ventricle dysfunction or pre-capillary pulmonary hypertension.[3]

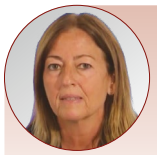
Conclusion

The 2025 ESC/EACTS guidelines include stronger recommendations for transcatheter therapies for both mitral and tricuspid valve disease, depending on aetiology and patient-specific considerations.[3] Implementation of these recommendations in routine practice is expected to drive earlier referral, broader adoption of transcatheter solutions and more consistent patient selection, potentially improving outcomes for patients with valve disease.

Recent evidence on TEER with the PASCAL Precision system

Mitral TEER

In 2025, long-term data from the CLASP study and a sub-analysis of the MiCLASP study investigating the predictability of the PASCAL Precision system were released.



Dr Caterina Gandolfo
IRCCS-ISMETT-UPMC

These data position the PASCAL Presicion system as a predictable TEER solution that is likely to drive earlier intervention, broader adoption and more consistent outcomes, translating into meaningful and sustained benefits for patients

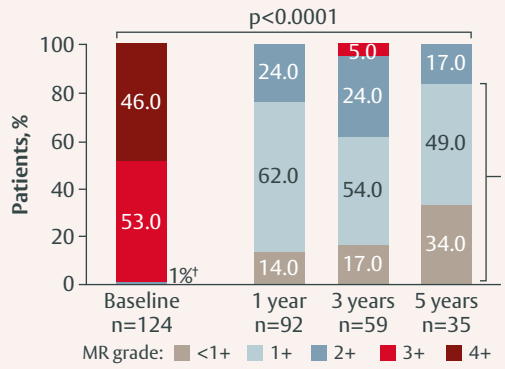
THE CLASP STUDY

Prospective, multicentre, single-arm, study[6]

124 patients*

5 years*

Long-term significant improvements in MR and functional status with sustained left ventricular reverse remodelling at 5 years in patients with clinically significant MR.[6]



83%

87% in FMR patients

75% in DMR patients

52% freedom from mortality

62% freedom from HFH

91% NYHA class II/II

−30 mL LVEDV volume

Adapted from Ng M. 2025. For details on statistical analyses, please see reference 6.
*Based on reported follow-up. †TOE was used for baseline qualification of one patient due to discordance of MR severity between TTE and TOE.
DMR, degenerative MR; FMR, functional MR; HFH, heart failure hospitalisation; LVEDV, left ventricular end diastolic volume; NYHA, New York Heart Association TOE, transoesophageal echocardiography; TTE, transthoracic echocardiography.

THE MiCLASP STUDY

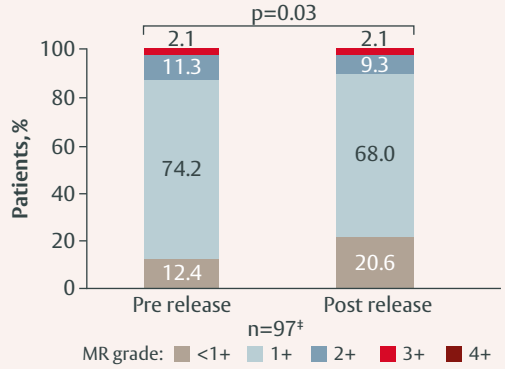
Sub-analysis of a prospective, multicentre, single-arm, post-market clinical follow-up study[5]

100 patients

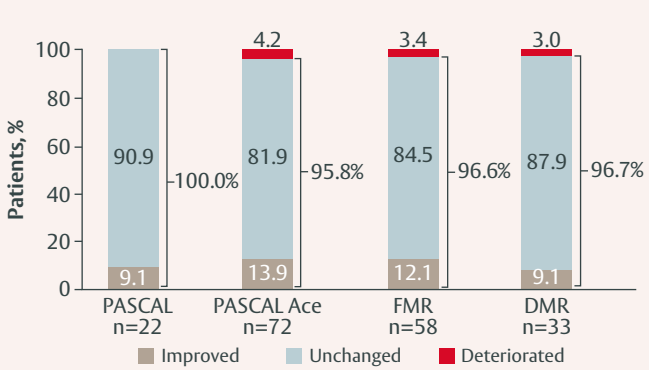
30 days

Predictable intraprocedural MR outcomes after implant release in >95% of patients, regardless of aetiology or implant type.[5]

Significant improvement in MR grade following implant release, sustained to 30 days



Most patients showed no MR deterioration following implant release, independent of implant type or aetiology



Adapted from Kister T. 2025. Figures show paired analysis, for details on statistical analyses, please see reference 5.
In patients with >1 implant, MR grade for the last device implanted was used.
‡In three patients, MR grade for last device implanted was not assessable by the echocardiographic core laboratory. DMR, degenerative MR; FMR, functional MR.

Tricuspid TEER

Also in 2025, 2-year outcomes from the TriCLASP study investigating T-TEER with the PASCAL Precision system were published.[4] The benefits of T-TEER in reducing tricuspid annulus dimensions were also highlighted in a 3D echocardiography single-centre study.[8]

Dr Christos Iliadis
University of Cologne

T-TEER emerges as a therapy with beneficial effects on tricuspid valve dimensions and right heart remodelling. As TR is most frequently induced by annular dilatation and begets further adverse right heart remodelling, raising awareness for timely intervention is warranted

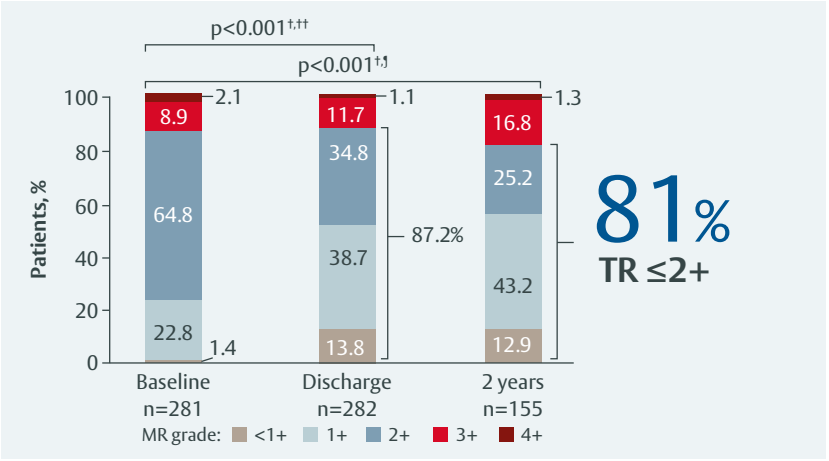
THE TriCLASP STUDY

Prospective, multicentre, single-arm, post-market clinical follow-up[4]

300 patients*

2 years*

Significant and sustained improvements in TR, functional status and quality of life at 2 years in patients with clinically significant TR in a post-market setting.[4]



81% TR ≤2+

78% freedom from ACM

72% freedom from HFH

73% NYHA class I/II

+7 pts KCCQ-OS

Adapted from Geisler T. 2025. Figures show unpaired analysis, for details of statistical analysis, please see reference 4. *Based on reported follow-up. †Wilcoxon signed-rank test for moderate or less TR, paired analysis; ††n=269; baseline=23.8%, discharge=87.3%; ǂn=149; baseline=26.9%, 2 years=81.2%. ACM, all cause mortality; HFH, heart failure hospitalisation; KCCQ-OS: Kansas City Cardiomyopathy Questionnaire Overall Summary Score; NYHA, New York Heart Association TR, tricuspid regurgitation

University of Cologne[8,36]

Retrospective, single-centre, consecutive patient study[8,36]

103 patients

2 years

Significant reduction in tricuspid annular (TA) dimensions after T-TEER, with the clover strategy independently associated with greater TA area reduction and first exploratory evidence linking TA remodelling to residual TR and 2-year survival. [8,36]

6.2% Reduction in TA area following T-TEER

Clover strategy showed greater TA area reduction *vs* zipping technique† (**7.9 *vs* 3.8%**, p=0.026)

TA area reduction correlated with ≥1 grade TR improvement (p=0.034)

†clover technique defined as placement of ≥1 in both anteroseptal and posteroseptal commissures; zipping technique defined as implantation of ≥2 devices in a single commissure. A, anterior; P, posterior; S, septal.

T-TEER with the PASCAL and TriClip systems – a single-centre study[7]

A separate study, also based at the University Hospital Cologne (n=53), investigated the PASCAL and TriClip systems and showed similar and significant TA reductions for both. Independent leaflet capture was performed in **96%** of PASCAL Precision system and **9%** of TriClip system cases (p<0.001)

Two-year outcomes from the TRISCEND II trial

The TRISCEND II pivotal trial is the first randomised trial for TTVR, assessing the safety and effectiveness of the EVOQUE system.[2,23] At 1-year follow-up, EVOQUE TTVR combined with optimal medical therapy (OMT) demonstrated superiority to OMT alone in terms of the primary hierarchical composite safety and effectiveness endpoint in patients with at least symptomatic severe TR.[23] Post 1-year follow-up visit, patients receiving OMT alone were eligible for crossover to TTVR.[2,23] At ACC 2026, the 2-year trial outcomes and 1-year crossover follow-up were presented.[2]

Dr Anna Sannino
Charité, University Medicine Berlin, Berlin, Germany

Dr Sannino specialises in echocardiographic diagnostics and has a particular interest in imaging techniques in heart valve disease.

'The TRISCEND II trial is the first randomised trial demonstrating the clinical impact of TTVR – a major milestone in the field. The 2-year outcomes reinforce the potential durability of this treatment, with sustained clinical benefits and consistent performance'

Dr Anna Sannino

Study design and crossover cohort

In this multicentre, prospective trial, patients were randomised to undergo TTVR with the EVOQUE system plus OMT (TTVR) or OMT alone (Control) in a 2:1 ratio (Figure 11).[2,23] After 1 year, 60% of patients with complete 1-year follow-up in the Control group attempted to crossover and undergo treatment with TTVR. Of the attempted crossover procedures, 94% were successful.[2]

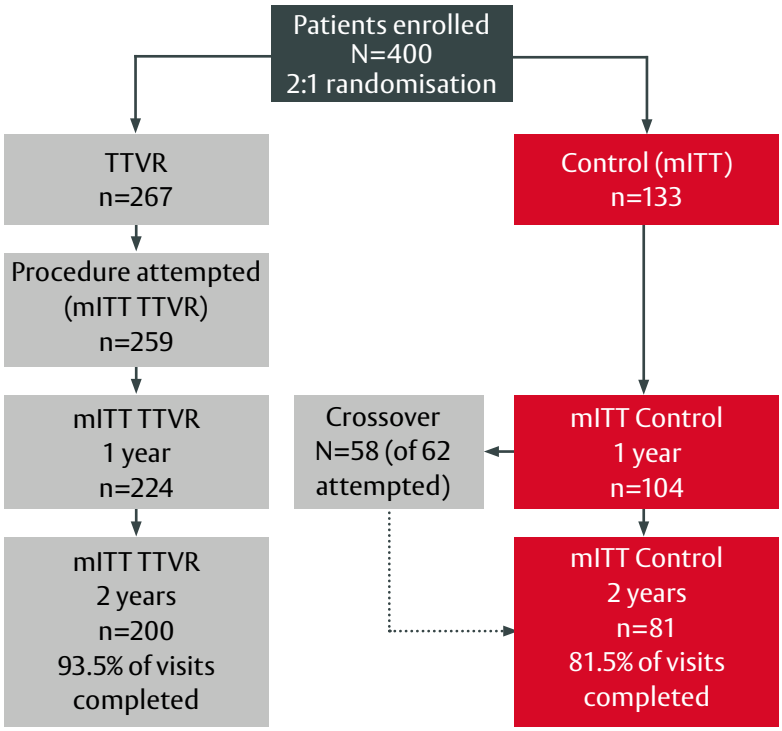


Figure 11. Schematic of the TRISCEND II study design.[a]

[a]Of the N=259 TTVR procedures attempted, 258 had the device attempted and 247 had the device implanted.[23] **mITT TTVR:** 29 deaths, 6 withdrawals prior to 1-year follow-up; 19 deaths, 5 withdrawals prior to 2-year follow-up. **mITT Control:** 13 deaths, 16 withdrawals prior to 1-year follow-up; 15 deaths (9 from non-crossover attempted group, 6 from crossover attempted group), 8 withdrawals prior to 2-year follow-up.

mITT, modified intent-to-treat; TTVR, transcatheter tricuspid valve replacement.

EVOQUE TTVR significantly lowers all-cause mortality at 2 years when accounting for patient crossover*

At 2-year follow-up, no statistically significant difference in all-cause mortality (ACM) was observed between groups (25.3% mITT Control *vs* 19.1% mITT TTVR, p=0.192). However, this comparison is confounded by substantial crossover to TTVR (n=62),† which markedly reduced the number of non-crossover patients in the Control group at 2-year follow-up, likely attenuating the ability to detect a treatment effect. Therefore, to address the impact of patient withdrawal and crossover in the mITT Control group, a post-hoc sensitivity analysis using Bayesian multiple imputation modelling was performed to estimate outcomes under a preserved control arm. In this analysis, ACM at 2 years was significantly lower in the imputed TTVR group compared with the imputed Control group (p=0.03).[2]

*Significance observed in Bayesian sensitivity analysis adjusted for withdrawal and crossover. †Crossover patients were included in the mITT Control group per intent-to-treat principle.

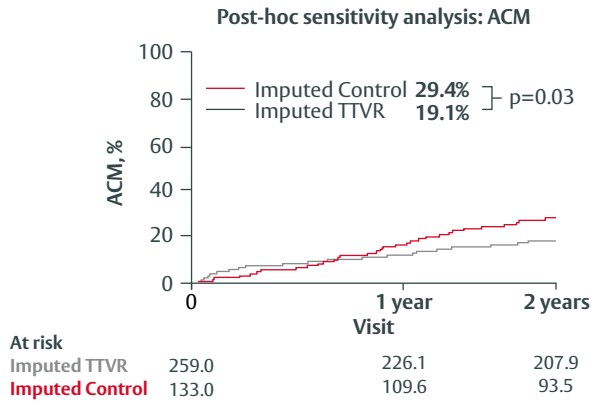


Figure 12. ACM in imputed TTVR and Control groups following post-hoc sensitivity analysis with Bayesian multiple imputation modelling.

Kaplan–Meier rates reported at 410 and 730 days, decimals in Kaplan–Meier imputed patient values are a result of averaging patient numbers across >1,000 simulated results, p values calculated using Wald-type test. ACM, all cause mortality; TTVR, transcatheter tricuspid valve replacement.

'Reduced ACM at 2 years in the imputed TTVR group (when accounting for patient crossover) is exciting and suggests TTVR's potential to improve mortality in patients with advanced TR'*

Dr Anna Sannino

EVOQUE TTVR consistently delivers significant and sustained TR elimination to ≤mild and improvements in quality of life through 2 years

TTVR with the EVOQUE system in combination with OMT resulted in significant and sustained improvement in TR severity through 2-year follow-up, with TR ≤mild in 95% of patients in both the as-treated (AT) TTVR and Crossover groups, whereas only 15% of OMT only patients had ≤mild TR (Figure 13).

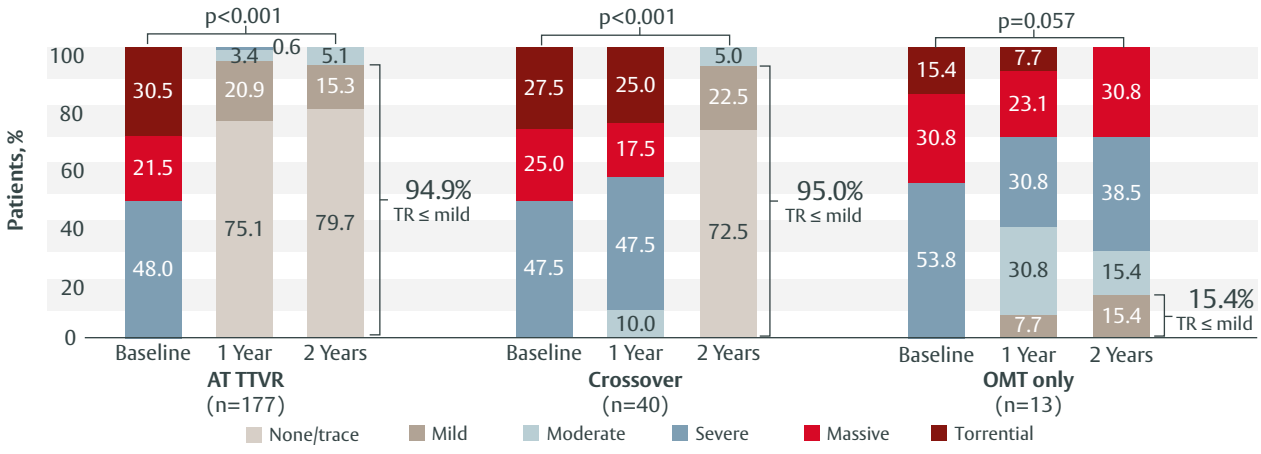


Figure 13. TR grade through 2 years, according to the received treatment.

Graph shows paired data, Wilcoxon signed rank test performed to compare paired TR grades at baseline and at 2-year follow-up. AT, as-treated; OMT, optimal medical therapy; TR, tricuspid regurgitation; TTVR, transcatheter tricuspid valve replacement.

Patients treated with EVOQUE TTVR also showed improvements in quality of life from baseline, with an increase of 18 points on the KCCQ-OS score in the AT TTVR group (n=177). Crossover patients showed an improvement of 20 points (n=47), whereas OMT only patients (n=13) showed a 14-point increase.[2]

'These data highlight that TTVR is not only effective in reducing TR but also translates into meaningful improvements in patient-centred outcomes: improved quality of life, functional capacity and symptom relief, areas where TR has a profound negative impact'

Dr Anna Sannino

EVOQUE TTVR has an established safety profile with continued confidence through 2 years

At 2-year follow-up, EVOQUE TTVR demonstrated a favourable safety profile, with significantly lower rates of non-elective tricuspid valve reintervention (0.8% *vs* 3.8%, p=0.047, Table 3), with no added device-related risk.[2]

Table 3: Selection of cumulative safety outcomes in mITT TTVR and mITT Control patients at 2 years.

	TTVR (N=259)	Control (N=133)[a]	p value
Cardiovascular mortality, %	13.9	15.0	0.762
Stroke, %	2.3	1.5	0.722
Severe bleeding,[b] %	19.7	15.8	0.409
Non-elective TV intervention, %	0.8	3.8	0.047
New pacemaker or ICD in pacemaker-naïve patients, %	30.2	15.0	0.012

[a]The mITT Control group includes patients who underwent crossover to TTVR. [b]Fatal, life-threatening, extensive or major bleeding, as defined by MVARC. p values calculated using Fisher's exact test.
ICD, implantable cardioverter defibrillator; TTVR, transcatheter tricuspid valve replacement; TV, tricuspid valve.

'The nuances of the trial, particularly the impact of crossover, highlight the importance of careful patient selection and continued data generation as the field evolves. This will likely encourage earlier intervention and promote a more structured, multidisciplinary approach to TR management'

Dr Anna Sannino

Limitations

The study had several limitations: it was powered for the 1-year composite primary endpoint rather than individual components like ACM. Secondly, the 2:1 randomisation and substantial crossover reduced the number of Control patients at 2 years. Finally, the post-hoc Bayesian analyses were not prespecified, making the findings hypothesis-generating.

Conclusion

The 2-year outcomes from the TRISCEND II trial demonstrate significant and sustained TR elimination to ≤mild following EVOQUE TTVR and, when accounting for withdrawals and patient crossover, a significant reduction in ACM compared with OMT alone. The safety profile extends confidence in the performance of EVOQUE TTVR for treatment in TR patients who remain symptomatic despite OMT.[2]

'The TRISCEND II trial supports a paradigm shift in the management of severe TR – from a historically undertreated condition to one where effective transcatheter therapies are available'

Dr Anna Sannino

Tips and tricks for your patients with MR and TR

Case study 1: Indirect annuloplasty effect when treating severe functional MR (FMR) with the PASCAL implant

Dr Sebastian Rosch is a cardiologist at the University Medical Centre of the Johannes Gutenberg University, Mainz.

Dr Thilo Noack is a senior consultant for cardiac surgery and a heart valve interventionalist in the University Department of Cardiac Surgery at the Heart Center Leipzig.

The patient

A 66-year-old man in NYHA class III had severe ischaemic cardiomyopathy resulting from advanced coronary disease. The patient's medical history consisted of multiple percutaneous coronary interventions and a cardiac resynchronisation as part of a multimodal heart failure therapy. His LVEF was severely reduced at 18%. Due to severe ventricular and annular dilatation, we observed a ventricular functional eccentric MR. Considering the patient's severely elevated perioperative risk, the joint decision of our interdisciplinary Heart Team was for M-TEER.

Patient key facts*

66 years old

Male

Severe MR

NYHA class III

The challenge

Major challenges in this case were the severely reduced left ventricular function, the massively dilated ventricle and the resulting restriction of both the anterior and posterior mitral valve leaflets. M-TEER in these anatomies may result in elevated postinterventional mean transmitral pressure gradients, which are associated with mortality and therefore need to be prevented.

The strategy

We opted for a two-device strategy to achieve residual mild MR. To obtain this optimal outcome, we hypothesised that the flexible nitinol scaffold of the PASCAL implant would minimise the risk of elevated transmitral pressure gradients.

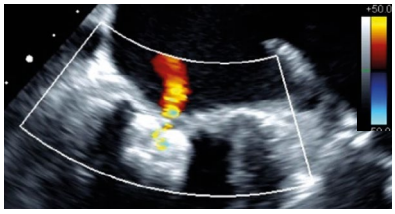


Figure 14. Peri-procedural TOE after implantation of the second PASCAL implant.

TOE, transoesophageal echocardiography.

Courtesy of Dr Sebastian Rosch

The procedure

After transseptal puncture, we inserted and released the first PASCAL implant within the mitral valve. We placed the second implant medial to the first device, further optimising the M-TEER result by using the implant's independent leaflet capture mechanism to optimise leaflet clasping (Figure 14).

The procedure resulted in significant MR reduction (to mild MR) and a mean transmitral pressure gradient of 2.1 mmHg at discharge. We also observed a reduction in acute intraprocedural anterior–posterior diameter (from 4.13 cm to 3.95 cm), and in annular circumference and area.

Key tips

- In patients with FMR, TEER is useful for both leaflet approximation and for indirect annuloplasty, and both should be considered when planning your strategy
- In 2023, a study investigating the PASCAL repair system and MitraClip showed a significant and comparable reduction in anterior–posterior diameter, annular circumference and annular area, with evidence of left ventricular reverse remodelling at 1 year with the PASCAL repair system[37]

Rosch S *et al.* 2023

*TRI-SCORE and GLIDE-SCORE not reported in this case

Case study 2. T-TEER using the clover technique with two PASCAL Ace implants

Dr Jaqueline Da Rocha E Silva is an interventional echocardiologist and cardiologist at Ludwig Maximilians University, Munich. She is also a consultant at the Echo Core Lab at the Cardiovascular Research Foundation, New York.

The patient

The patient was an 89-year-old man, who presented with dyspnoea (NYHA class III), preserved LVEF and peripheral oedema. He had permanent atrial fibrillation, hypertension, hyperlipidaemia and stage 3 chronic kidney disease. In 2018, he had a dual chamber permanent pacemaker implanted.

In the clinic, echocardiography revealed severe TR (Figure 15) without leaflet impingement, making the patient a candidate for T-TEER.[38] Tricuspid valve morphology was type IIIb (4 leaflets) and effective regurgitant orifice area was 0.47 cm^2. A low GLIDE score of 1 was calculated.

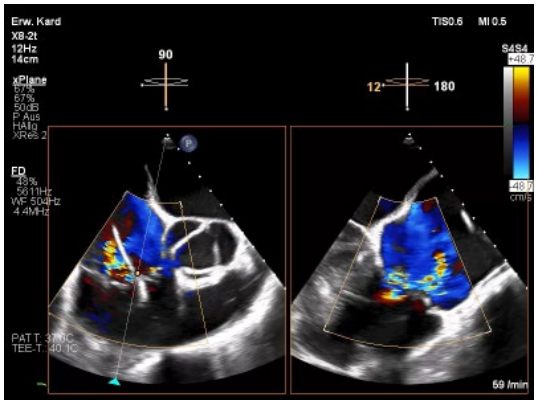


Figure 15. Baseline TOE, showing severe TR.

Courtesy of Dr J Da Rocha E Silva. TR, tricuspid regurgitation.

The challenge

The patient required a minimally invasive approach due to his advanced age and multiple comorbidities. He also had a history of gastrointestinal bleeding, making anticoagulation a contraindication and TTVR unsuitable. We therefore carefully evaluated his anatomy to determine whether a repair strategy would be feasible.

The previously implanted pacemaker had a lead positioned in the anteroseptal coaptation zone instead of the more typical commissural location, which could have made T-TEER challenging. However, transthoracic echocardiography (TTE) and transoesophageal echocardiography (TOE) revealed that the lead was free in the subvalvular apparatus, and there was good leaflet movement; therefore, we decided the valve could be repaired without removing the pacemaker lead.

Patient key facts

- 89 years old
- Male
- Severe TR
- NYHA class III
- GLIDE score 1
- TRI-SCORE 4

The strategy

We decided to perform T-TEER with the PASCAL Precision system, as our previous experience suggested that it would ensure gentle leaflet grasping of the frail leaflets and the maneuverability of the system would allow us to approach the valve safely. We utilised the '**clover technique**',[8] which involved placing a PASCAL Ace implant in both the anteroseptal and posteroseptal commissures. Previous studies have shown that T-TEER may exert an indirect annuloplasty effect, with the clover technique providing more pronounced tricuspid annulus remodelling compared with the 'zipping technique'.[8] Exploratory evidence suggests that tricuspid annulus remodelling is associated with decreased residual TR and increased 2-year survival.[8]

'When the anatomy allows, the clover technique is often our first approach. Based on our experience, it enables treatment of the posteroseptal commissure, with the aim of limiting future remodelling and supporting durable results'

Dr Jaqueline Da Rocha E Silva

The procedure

Our technique for the clover approach in T-TEER is to place the initial implant in the anteroseptal commissure to stabilise and reduce the annulus and then move to the posteroseptal commissure, which is often more challenging. In our experience, this is another advantage of using the PASCAL Precision system; we find that the independent leaflet capture and optimisation allow for a better annuloplasty effect while using this technique.[7]

Avoiding the pacemaker lead was the most important challenge during this procedure. We used TOE and fluoroscopy guiding to facilitate leaflet capture while avoiding dislodgement. The lead was located anteroseptally; therefore, the initial PASCAL Ace implant was placed behind it, using the maneuverability of the PASCAL Precision system to avoid grasping the lead during leaflet capture. When this was successful, a second PASCAL Ace implant was then placed in the posteroseptal commissure.

T-TEER was successful, with the discharge echocardiogram showing mild TR in the anteroseptal commissure and a tricuspid valve mean pressure of 2 mmHg with no stenosis (Figure 17). T-TEER also induced an indirect annuloplasty effect with a septolateral diameter reduction of 9 mm, a perimeter reduction of 3 mm and an overall area reduction of 2.8 cm^2 (Figure 16).

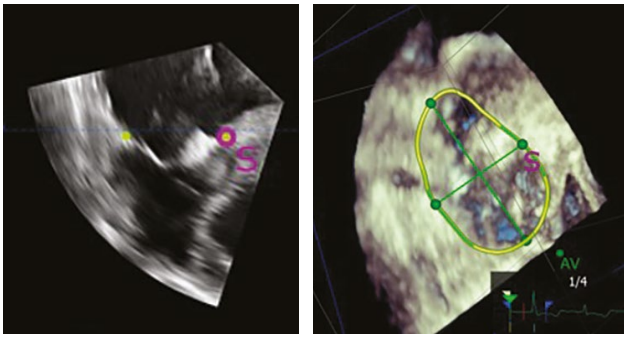


Figure 16. TOE post T-TEER procedure showing induced annuloplasty effect, with an overall area reduction of 2.8 cm^2.

Courtesy of Dr J Da Rocha E Silva. TOE, transoesophageal echocardiography; T-TEER, tricuspid transcatheter edge-to-edge repair.

'Our standard approach is to use two devices with the clover technique; in our experience, you can get a good annuloplasty effect and reduction of annular dimensions with two devices'

Dr Jaqueline Da Rocha E Silva

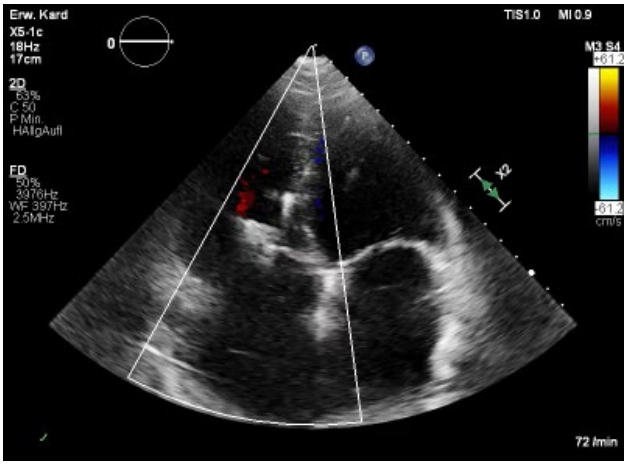


Figure 17. 30-day TTE follow-up revealing a successful annuloplasty with only mild residual TR.

Courtesy of Dr J Da Rocha E Silva. TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

'This case shows that it is feasible to perform and achieve good results with T-TEER in patients with a suboptimal lead position'

Dr Jaqueline Da Rocha E Silva

Key tips

- The clover technique is a good strategy for reducing annular dimensions and potentially increasing durability
- When performing T-TEER in a patient with pacemaker leads, the maneuverability of the PASCAL Precision system is essential to avoid interacting with the leads during the procedure

Case study 3. EVOQUE TTVR in a patient with a basal septal lead for physiological pacing

Dr Ángel Sánchez Recalde is the Director of the Interventional Cardiology Service at the Ramón y Cajal University Hospital, Sanitas La Zarzuela University Hospital, Sanitas La Moraleja University Hospital and Hospital Blua Sanitas Valdebebas.

The patient

An 81-year-old man presented with permanent atrial fibrillation, dyspnoea (NYHA class III) and right-sided heart failure with jugular venous distension and lower-limb oedema. Two years prior, he had received a single-chamber ventricular pacemaker with a septal ventricular lead for physiological pacing.

TTE revealed severe-to-massive TR, RV dilatation and mild mitral and aortic regurgitation. Cardiac CT and TOE confirmed a mixed TR aetiology with restricted posterior motion caused by the RV lead and a functional component due to annular dilatation.

The patient needed intervention for his persistent symptoms, but we anticipated that the impingement of the posterior leaflet, the TR severity and the 8 mm coaptation gap would make TEER difficult. Hence, we evaluated the patient for TTVR with the EVOQUE system.

Patient key facts

- 81 years old
- Male
- Severe-to-massive TR
- NYHA class III
- GLIDE score 2
- TRI-SCORE 6

The challenge

The patient was pacemaker-dependent, with a RV lead crossing the tricuspid valve and an electrode implanted in the basal septum less than 10 mm from the tricuspid valve annulus (Figure 18). Therefore, there was a substantial risk of lead–prosthesis interaction, which can damage or dislodge leads or elevate the pacing thresholds, leading to a requirement for alternative pacing strategies and, therefore, a loss of physiological pacing and clinical deterioration.

The strategy

We planned to deploy the anchors as high as possible. During the first ventricular deployment phase, we wanted all nine prosthetic anchors to be positioned at the leaflet hinge points; only limited repositioning would be possible during full ventricular or first atrial expansion because of the RV lead. A Safari guidewire in the RV apex, posterior to the anterior papillary muscle, was prepared to provide pacing support, if needed, during the procedure.

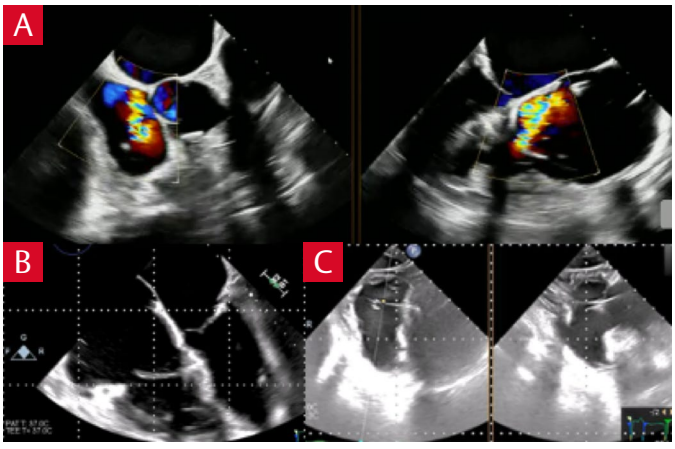


Figure 18. Baseline TOE showing severe TR (A); TOE four-chamber view showing the pacemaker lead anchored in the basal septum (B); transgastric view showing the pacemaker lead crossing the tricuspid valve and directed towards the basal septum (C).

Courtesy of Dr Á Sánchez Recalde. TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

The procedure

Based on CT screening measures, re-confirmed pre-procedurally via TOE, we selected a 52 mm EVOQUE valve. The procedure began with achieving the optimal position of the delivery system, using a slight secondary flex to obtain a more lateral orientation and optimal height just below the leaflet tips. After the positioning was confirmed, the valve anchors were exposed.

Intracardiac echocardiography (ICE), including TOE multiplanar reconstruction assessments (MPR), guided staged anchor release, with positional adjustments to ensure optimal leaflet capture. The first ventricular portion of the prosthesis was expanded until it gained enough height for leaflet engagement at all nine anchors, leaving the pacemaker lead positioned between two anchors (Figure 19). Once this was confirmed, the ventricular portion was fully expanded. Atrial expansion followed, maintaining anchor alignment.

The procedure was successful: TR was resolved and pacing thresholds remained unchanged despite jailing of the pacing lead (Figure 20). The patient was discharged without complications after 5 days. This case demonstrates that, with careful planning, EVOQUE valve implantation is feasible in patients with a pacemaker lead in the basal septum without adverse effects at short-term follow-up.

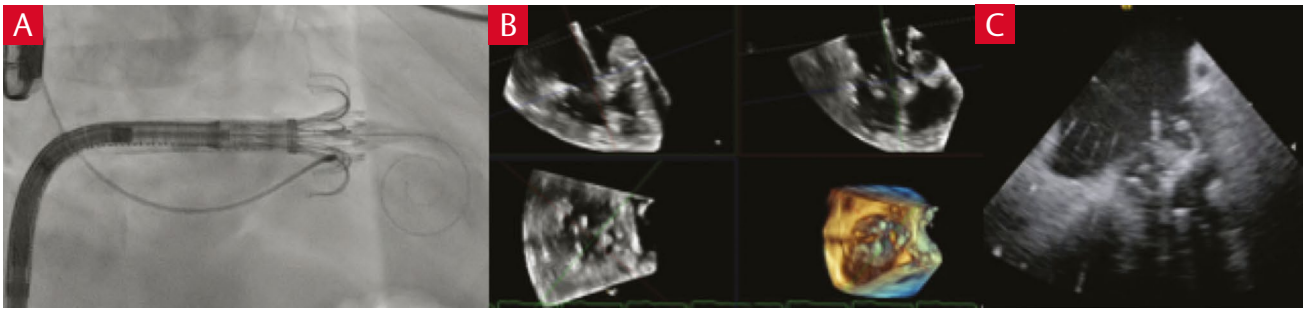


Figure 19. Initial ventricular expansion using fluoroscopy (A); early ventricular expansion using TOE MPR demonstrating appropriate prosthesis positioning with anchors located at the hinge points in the anteroposterior and septolateral planes (B); and ICE confirming appropriate prosthesis positioning (C).

Courtesy of Dr Á Sánchez Recalde. ICE, intracardiac echocardiography; MPR, multiplanar reconstruction; TOE, transoesophageal echocardiography.

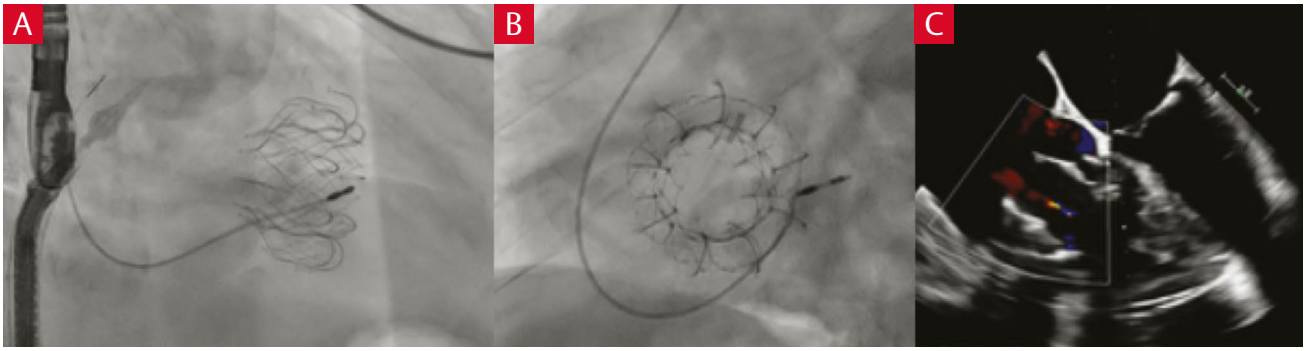


Figure 20. Fluoroscopy following release of the EVOQUE valve, showing pacemaker lead–prosthesis interaction (A and B); post-release TOE showing centrally positioned prosthesis with trivial residual TR (C).

Courtesy of Dr Á Sánchez Recalde. TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

Key tips

- During the initial ventricular deployment phase, ensure that the valve reaches the leaflet hinge points, positioning the pacemaker lead between two anchors
- Make sure you have an alternative strategy for ventricular pacing during the procedure, and reassess pacing thresholds at end of the implantation

Conclusion

At Edwards, we are committed to advancing transcatheter mitral and tricuspid therapies. As demonstrated by the 1-year results from the ENCIRCLE trial[1] and real-world cases, the SAPIEN M3 system represents an innovative solution for the treatment of patients with symptomatic MR who are unable to undergo surgery or TEER. The two-phase and fully transseptal approach, alongside the familiar valve platform, mark the SAPIEN M3 system procedure as a significant advancement in the field of TMVR.

The SAPIEN M3 system joins the PASCAL Precision system in our range of options for treating patients with symptomatic MR, providing solutions for a range of patients based on their specific needs.

Ask your questions...

We can be reached at TMTT-Today@edwards.com to answer your questions about the portfolio of therapies for transcatheter mitral and tricuspid valve therapies.

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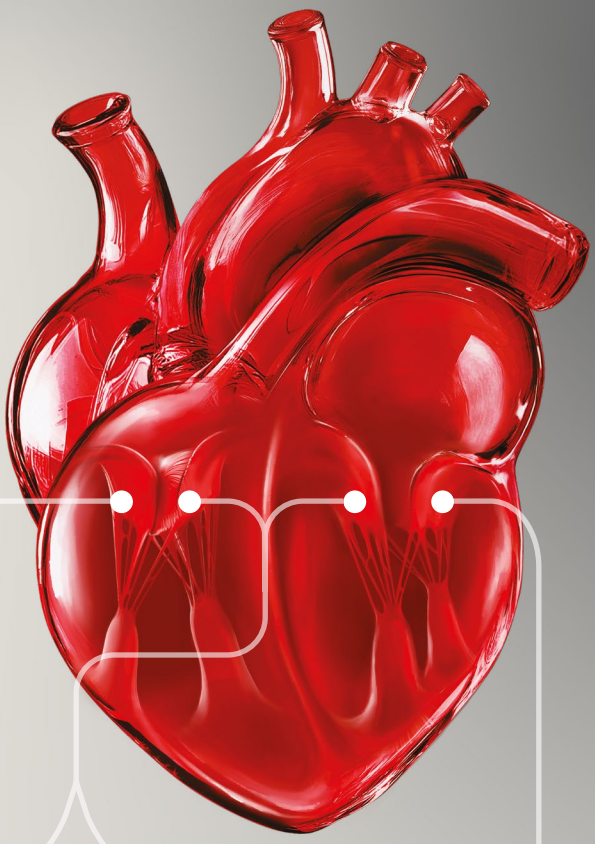

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