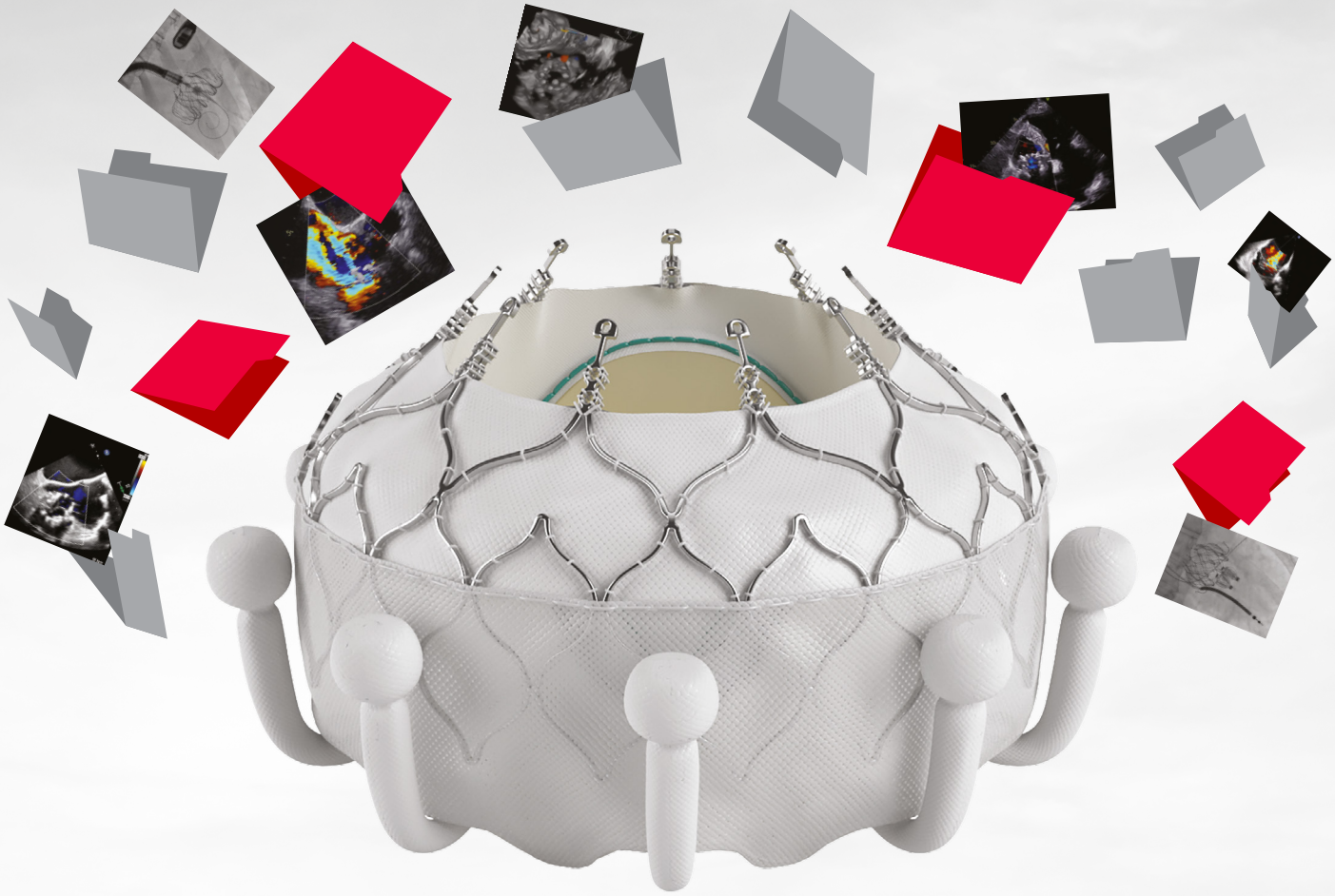
TMTT*Today* CASE SERIES

Issue #14 – November 2025

Real-world patients. Real-world impact with the EVOQUE system.



Inside this issue:

- From pivotal trial to real-world impact: The EVOQUE system's evidence journey
- Explore four cases where EVOQUE transcatheter tricuspid valve replacement made the difference

Edwards

Dear Reader,

In 2025, the ESC/EACTS Guidelines for the management of valvular heart disease introduced two important recommendations for tricuspid regurgitation (TR) that firmly position transcatheter therapies as an integral part of clinical decision-making. The new guidelines recommend multidisciplinary Heart Team evaluation for patients with TR (Class I/C), and suggest considering transcatheter tricuspid valve intervention in selected high-risk patients without left-sided valvular disease (Class IIa/A), aiming to improve quality of life and promote right ventricular (RV) remodelling.[1]

Learn more about the ESC/EACTS guideline updates

Additionally, transcatheter solutions were further validated in new data presented at three major cardiology congresses, which confirmed the safety and effectiveness of transcatheter tricuspid valve replacement (TTVR).[2–4] A summary of these studies is provided below, followed by four commercial cases with the EVOQUE system that display the translation of emerging evidence into real-world clinical practice.

Contents

The EVOQUE system's evidence journey: From pivotal trial to real-world impact

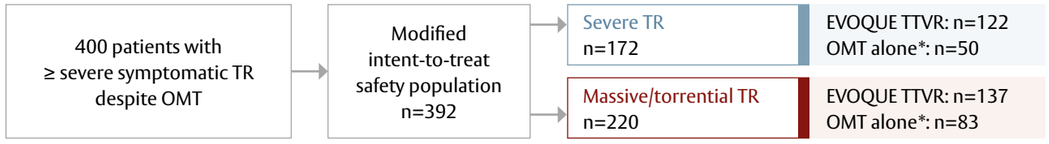
Presented at ESC Congress 2025

TRISCEND II pivotal trial: EVOQUE TTVR led to a hard endpoint benefit at 18 months for patients with the most severe TR

Results from a sub-analysis of the TRISCEND II pivotal trial, which included patients with at least severe TR, were presented at the ESC Congress 2025[2] and simultaneously published in the *European Heart Journal*.[5]

Aim: To evaluate whether baseline TR severity influenced TTVR outcomes with the EVOQUE system plus optimal medical therapy (OMT) versus OMT alone.[5]

Patients were stratified into two cohorts:[5]



Study outomes:[5]

12-month follow-up

Outcomes assessed: primary safety and effectiveness endpoint, TR reduction, quality of life, functional status and exercise capacity

Regardless of TR severity, EVOQUE TTVR showed:[5]

- **Superior clinical benefits *versus* OMT alone** (p<0.001) ✓
- **Consistent TR elimination** 95% TR ≤1+
- **Meaningful improvements in functional and quality-of-life outcomes**

18-month follow-up

Outcomes assessed: heart failure hospitalisation (HFH) and all-cause mortality (ACM)

In patients with massive/torrential TR, EVOQUE TTVR showed:[5]

- **Lower composite rate of ACM or HFH *versus* OMT alone** (p=0.045) –14%
- **Lower rate of HFH *versus* OMT alone** (p=0.030) –15%
- **Number needed to treat** to prevent 1 additional ACM or HFH 7

Conclusions

In this study, EVOQUE TTVR demonstrated:[5]

- Superior clinical benefits *versus* OMT alone and consistent TR elimination, regardless of baseline TR severity
- A hard endpoint benefit at 18 months *versus* OMT alone for patients with the most severe TR

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*53 patients in the control group crossed over to TTVR after their 1-year visit (n=22 in the severe TR group; n=31 in the massive/torrential TR group).

Presented at New York Valves 2025

Real-world EU data: At 30 days, EVOQUE TTVR showed safety and effectiveness in commercial use

The results of the first real-world analysis of the EVOQUE system were presented at New York Valves 2025[3] and published in *JACC: Cardiovascular Interventions*.[6]

Aim: To evaluate the safety and effectiveness of the EVOQUE system in consecutive patients enrolled in 12 European centres.[6]

Study outcomes at 30 days: clinical success,[a] ACM, HFH, permanent pacemaker implantation, bleeding and vascular complications, post-procedural cardiac decompensation, reintervention, acute kidney injury, device leaflet thickening and valve thrombosis.[6]

Baseline characteristics (n=176):[6]

- Mean age: 78 years
- Massive or torrential TR: 72%
- Pacemaker: 37%
- Conduction disturbances in pacemaker-naive patients: 32%
- Prevalent comorbidities

Plus, **more clinically complex patients** than in previous clinical trials,[7,8] including:[6]

- Moderate/severe RV dysfunction: 21%
- RV dilatation: 59%
- Pulmonary hypertension: 46%
- Prior tricuspid intervention/surgery: 8%

At 30 days, EVOQUE TTVR showed:

Consistent TR elimination[6] — **98%** TR ≤1+

Improvement in heart failure symptoms[6] — **80%** NYHA class I/II

Lower rate of complications[6] *versus* previous studies[7,8]

Predictors of clinical outcomes:[6]

Baseline massive/torrential TR was a predictor of improvement in NYHA class

Pre-existing conduction disturbance was a predictor for new pacemaker implantation

Baseline moderate/severe RV dysfunction was a predictor of 30-day clinical failure

NYHA, New York Heart Association.

Conclusions[6]

- 98% of patients achieved consistent TR elimination to ≤1+, associated with excellent clinical improvements, in terms of NYHA class, signs of right heart failure and hepatorenal congestion
- Patients with massive or torrential TR were more likely to experience functional improvement
- Patients had lower rates of complications than previously described,[7,8] with a 19% new pacemaker implantation rate in pacemaker-naive patients

View the publication

[a]Clinical success defined as proper position of the device with adequate performance (TR reduction to moderate or less, mean gradient <5 mmHg) and absence of mortality, stroke, unplanned reintervention, life-threatening bleeding, major vascular or cardiac complications, stage 2 or 3 acute kidney injury, myocardial infarction and major valve thrombosis.

Presented at TCT 2025

Real-world US data: At 30 days, EVOQUE TTVR showed favourable safety and effectiveness in the largest TTVR dataset to date

The results of the largest real-world analysis of the EVOQUE system were presented in the Late-Breaking Clinical Science session at TCT 2025.[4]

Aim: To characterise early clinical, echocardiographic and patient-reported outcomes of EVOQUE TTVR in real-world use in the USA, using the data collected from the STS/ACC TVT Registry on 1,034 consecutive patients.[4]

Study outcomes and measures at 30 days:[4]

- Effectiveness endpoint was residual TR grade
- Safety endpoints included all-cause and cardiovascular death, stroke, life-threatening/major bleeding, new pacemaker and hospitalisations
- Health status outcomes included change in NYHA class and Kansas City Cardiomyopathy Questionnaire overall summary score (KCCQ-OS)

Baseline characteristics (n=1,034):[4]

- Mean age: 77 years
- Severe TR: 97%*
- NYHA class III/IV: 73%
- HFH within past year: 48%
- Pacemaker/cardiac implantable electronic device: 34%
- Prevalent comorbidities

Procedural characteristics and key 30-day safety outcomes:[4]

- Successful device implantation: 98%
- Conversion to surgery: 0.8%†
- ACM: 3.1%
- HFH: 3.1%
- New pacemaker in pacemaker-naive patients: 15%
- Major or life-threatening bleeding: 1.3%‡

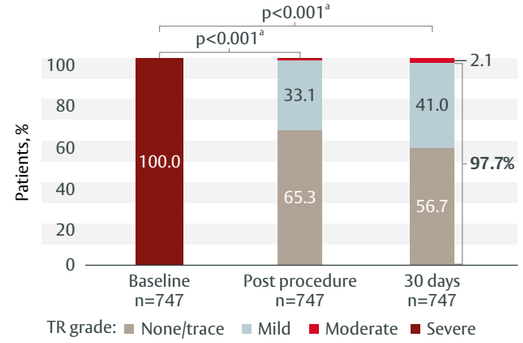
*TR was quantified as none/trace, mild, moderate, severe. †4 cardiac tamponade, 2 ventricular rupture, 1 device embolisation and 1 other.
‡Valve Academic Research Consortium-2 definitions.

At 30 days, EVOQUE TTVR showed:

Consistent TR elimination[4] — **98%** TR ≤1+

Lower pacemaker and bleeding rates[4††] *versus* previous studies[6–8]

Significant improvements in functional capacity (83% NYHA I/II) and **quality of life** (+22 points in KCCQ-OS)[4]



Graph shows paired analysis. [a]Wilcoxon signed-rank test.

Conclusions

- 98% of patients achieved consistent TR elimination to ≤1+, associated with clinical and quality-of-life benefits[4] in a broader patient population *versus* previous studies[6–8]
- Lower reported rates of complications *versus* previous studies,[6–8§] with a 15% new pacemaker implantation rate in pacemaker-naive patients** and a 1.3% life-threatening and major bleeding rate[4 ††]

View the publication

§The TVT Registry is an observational registry subject to incomplete reporting. Events and echocardiographic assessments were site-reported without a centralised clinical events committee review or core lab adjudication. **n=685. ††Valve Academic Research Consortium-2 definitions.

Case study 1: EVOQUE valve implantation in a young patient with a pacemaker

Hygeia Hospital, Athens, Greece

Dr Konstantinos Spargias

Dr Konstantinos Spargias is an interventional cardiologist and Director of the Transcatheter Heart Valves department at Hygeia Hospital in Athens, Greece.

The patient

The patient was a 59-year-old woman with dilated cardiomyopathy related to the autoimmune disease myositis. She was fitted with a cardiac resynchronisation therapy defibrillator (CRT-D) in 2017 and treated with two different immune suppression medications. In 2018, she presented at our centre with HF, a low ejection fraction, severe mitral regurgitation and moderate TR.
We performed mitral transcatheter edge-to-edge repair (M-TEER) with two PASCAL implants, which enabled the patient to return to a good quality of life. However, gradually her symptoms relapsed – fatigue was the main symptom – and despite maximal tolerated diuretic treatment, her TR deteriorated to torrential (Figure 1). Her referral was delayed because the patient's physician felt treatment options were lacking.

Patient key facts

- 59 years old
- Female
- Torrential TR
- NYHA class III

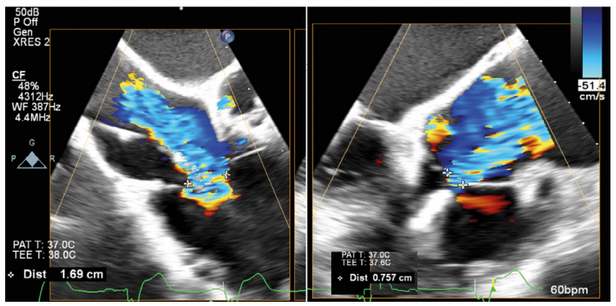


Figure 1. Echocardiography at baseline, with the CRT-D lead visible.

CRT-D, cardiac resynchronisation therapy defibrillator.

The challenge

The CRT-D lead was interacting with the posterior side of the septal leaflet, affecting the TR. Since the septal leaflet was partially impinged, we suspected that TEER would be suboptimal for this patient, so we did not offer this option.

The approach

We identified TTVR as the optimal solution for this patient and, following the launch of the EVOQUE system, we reached out to the patient, and she was delighted with this opportunity to improve her quality of life. Initially, we were concerned that the CRT-D lead might affect the valve replacement, but fortunately there was sufficient slack in the lead to allow successful implantation (Figure 2A).

Not all patients with TR have shortness of breath. Some present with fatigue; they feel tired walking but are not breathless.

Dr Konstantinos Spargias

The procedure

This was our fourth case with the EVOQUE system, and we were supported by Edwards clinical experts, who have extensive knowledge and experience with the procedure. We found the delivery system easy to use, and valve implantation was straightforward, with the CRT-D causing no problems. The PASCAL implants on the mitral side did not interfere with the imaging. Considering that the patient had torrential TR at baseline, the achieved result was optimal (Figure 2): TR was reduced to none to mild (Figures 2C and 2D), and the patient is feeling so much better.

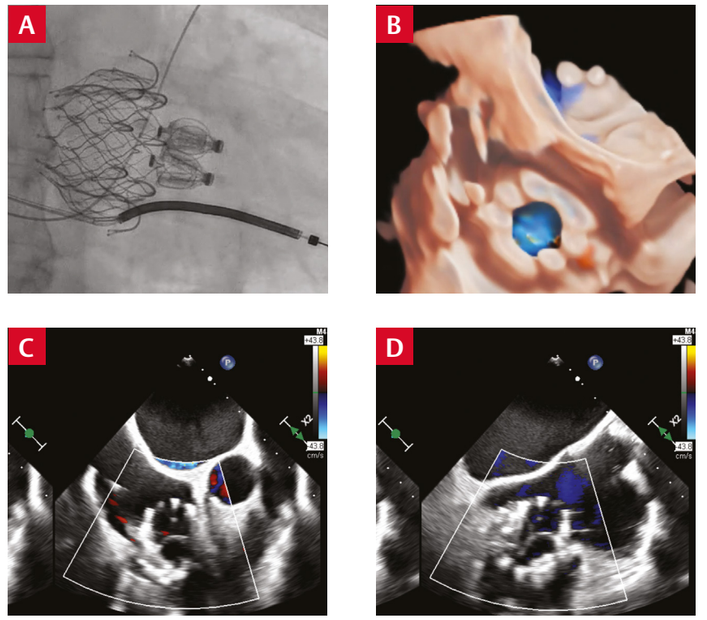


Figure 2. Post-procedural imaging: fluoroscopic imaging showing the deployed EVOQUE valve (A); 3D echocardiography with colour showing the deployed EVOQUE valve viewed from the right atrium (B); 2D echocardiography with colour showing the deployed EVOQUE valve during systole in intercommissural (C) and mid-oesophageal (D) views.

The patient's symptoms were so bad that she had a very poor quality of life. I am pleased to report that she has improved after the procedure and is feeling much better.

Dr Konstantinos Spargias

Key tips

- The procedural success of TTVR relies heavily on the collaboration between the interventional cardiologist and the echocardiographer; they must work together to achieve optimal patient outcomes. While this relationship is also important for TEER, it is even more so for TTVR, where there is little room for optimisation and repositioning.
- Accurate guidewire positioning in the right ventricle is crucial to success. Take your time to carefully guide the wire, ensuring it crosses the tricuspid valve with the entire curve, and direct it to the best apical spot you can.
- Achieve coaxiality from the beginning when the capsule is advanced into the tricuspid valve, before starting to deploy. For guidance on this critical step and other aspects of the procedure, review Edwards training materials.

Case study 2: EVOQUE transcatheter replacement system for treating massive multi-leaflet TR

Monzino Heart Centre, Milan, Italy

Dr Federico De Marco

Dr Federico De Marco is an interventional cardiologist and Director of the Structural Heart programme at Monzino Heart Centre in Milan, Italy.

The patient

An 88-year-old woman with massive functional TR was first seen in our practice over a year ago. She had previously been hospitalised three times for right heart failure. Despite being elderly, she was very fit for her age but was unable to enjoy her usual activities, like walking, and maintain her independence due to the effects of her TR, particularly breathlessness. Unfortunately, she was not a suitable candidate for tricuspid TEER (T-TEER) due to her complex anatomy and was medically managed with high dose diuretics to help with her symptoms.

Patient key facts

- 88 years old
- Female
- Massive TR
- NYHA class II

The challenge

The patient's tricuspid valve was multi-leaflet Type IV,[9] consisting of five leaflets (essentially star-shaped with five points), with a large coaptation gap (12–15 mm) and complex regurgitation jet morphology (Figure 3); therefore, achieving a good outcome with T-TEER was very unlikely.

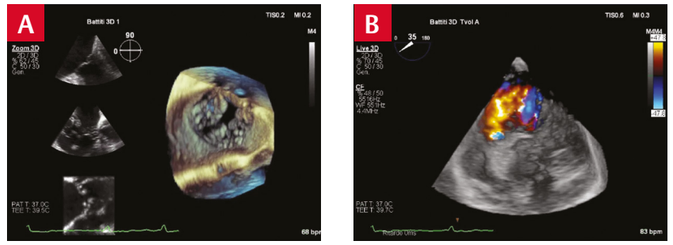


Figure 3. Baseline TOE shows multi-leaflet valve and wide coaptation defect (A) and massive TR (B).

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

The strategy

When the EVOQUE system became available to us, following patient selection discussions with Edwards, we identified this patient as a good candidate for TTVR. This was the first patient we treated with the EVOQUE system, and the whole team received very good training and support from Edwards. A thorough understanding of echocardiography and computed tomography imaging is essential, and the training gave us the confidence to undertake the procedure.

The procedure

Two days before the procedure, the patient was given intravenous diuretics, as a pre-conditioning treatment to optimise the volume status. The patient was being treated with a direct oral anticoagulant for chronic atrial fibrillation; these were stopped prior to the procedure and restarted the day after the procedure.

The patient received a 52 mm EVOQUE valve, and the procedure went well without any specific challenges. We found the EVOQUE system very user-friendly, due to the size of the delivery system (diameter 28F) and the intuitive knob system.

The patient felt better immediately after the procedure. As this was our first case with the EVOQUE system, she was admitted to the intensive care unit for a night (note, we haven't done this with subsequent patients). She was discharged from hospital 4 days after the procedure on a reduced diuretic dose. TR was reduced to mild (Figure 4) and there was a very minor trace paravalvular leak, which was clinically insignificant. At her 6-month follow-up, the patient's clinical improvement was maintained. Most importantly, the patient was well and able to enjoy her usual activities, including walking.

The patient felt well immediately after the procedure, and clinical improvement was maintained at the 6-month follow-up.

Dr Federico De Marco

Patient selection criteria

T-TEER is a good treatment option for patients with TR with suitable anatomies, and we can achieve good outcomes in these patients. However, prior to the launch of the EVOQUE system, treatment options were limited for the 40–50% of patients referred to us with TR whose anatomies deemed them unsuitable for T-TEER. Annuloplasty is not part of our routine practice currently, and caval valve implantation is regarded as a compassionate use therapy, reserved for more advanced disease.

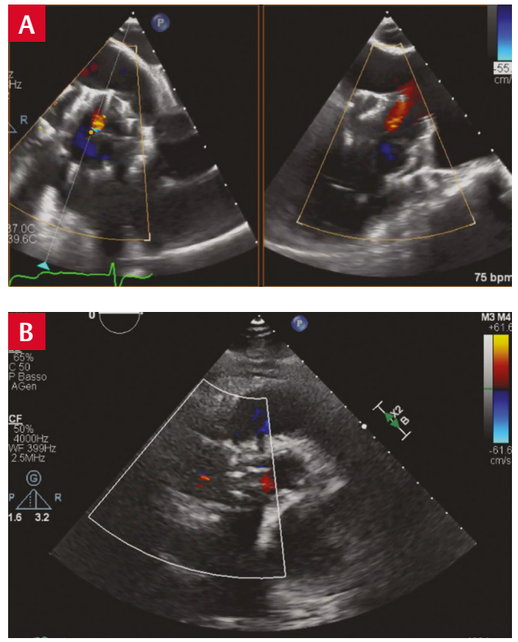


Figure 4. TOE immediately after the procedure (A) and 6 months post procedure (B) showing TR has been reduced to mild.

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

Patients that present with complex anatomies, such as tricuspid valves with multi-leaflet anatomy, complex regurgitation jets and wide coaptation gaps, are now considered for TTVR. Approximately half of the patients deemed unsuitable for T-TEER are good candidates for TTVR. The EVOQUE system provides a treatment option which can effectively reduce TR in these patients, contributing to the best possible clinical outcomes. With the recent launch of the 56 mm EVOQUE valve, we should hopefully be able to treat some of the patients previously rejected for TTVR because their annulus was too large, allowing more patients to benefit from effective treatment for their TR.

Half of patients with TR unsuitable for T-TEER may be good candidates for TTVR.

Dr Federico De Marco

Case study 3: Implantation of a 56 mm EVOQUE valve in a patient with a large coaptation defect and large tricuspid annulus

Vienna General Hospital, Austria

Professor Philipp Bartko

Professor Philipp Bartko is an interventional cardiologist and the Director of the Structural Heart Intervention programme at the Medical University of Vienna, Vienna General Hospital, Austria.

The patient

A 70-year-old patient presented with severe dyspnoea (NYHA III) and marked leg oedema. His medical history included hypertrophic cardiomyopathy, isolated post-capillary pulmonary hypertension, liver fibrosis and permanent atrial fibrillation, and his N-terminal pro-B-type natriuretic peptide (NT-pro-BNP) level was 1,280 pg/L. The patient was taking a variety of medications, including diuretics and apixaban. Transthoracic echocardiography revealed torrential TR and moderate mitral regurgitation (MR), with mildly reduced left ventricular and right ventricular function.

Patient key facts

- 70 years old
- Male
- Torrential TR
- NYHA class III

The challenge

The patient had a high TRI-SCORE risk (48%),[10] so the Heart Team agreed upon an interventional approach. However, there was a large coaptation defect, which was distributed over all the commissures, and a prolapse of the septal tricuspid valve leaflet (Figure 5). The GLIDE score was 3, indicating advanced anatomical complexity and a relatively low likelihood of procedural success with T-TEER.[11]

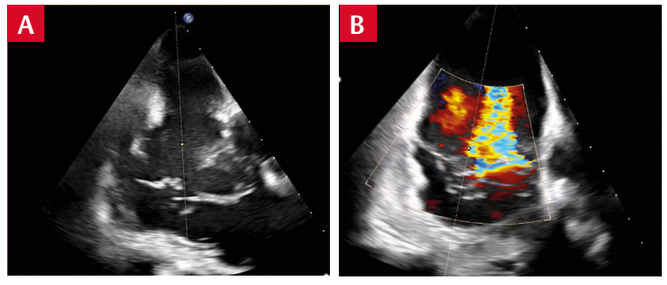


Figure 5. TOE showing the septal prolapse (A) and torrential TR (B).

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

The strategy

Using computed tomography (CT) screening, the Heart Team identified the patient as a good candidate for TTVR with the EVOQUE system. The patient had a large tricuspid annulus; therefore, a 56 mm EVOQUE valve was planned for implantation, based on detailed CT sizing. Since the patient's MR was not severe, the Heart Team decided against directly treating it concomitantly.

View this case and additional insights on PCRonline*

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The procedure

After confirming the adequate sizing by transoesophageal echocardiography (TOE) multiplanar reconstruction (MPR) of the native annulus, we thoroughly positioned the guidewire in the RV apex in the predefined fluoroscopic right anterior oblique view and under TOE guidance. The delivery system was carefully advanced after sheath retraction with the use of primary flex. After valve crossing and capsule-gap formation, the height was confirmed and trajectory adapted for optimal alignment. The anchors were exposed after checking adequate depth, a central position and coaxial trajectory. Anchor release was performed in a staged manner with multiple MPR spins and adjustments of depth trajectory and position as needed to ensure capture ready or captured leaflets. The ventricular part of the prosthesis was slowly expanded, and, after confirmation of leaflet engagement, the valve was atrialised towards the annular plane. No tilting maneuvers were necessary. The atrial expansion was performed ensuring anchor position at the hinge points of the leaflets.

Final release of the prosthesis was performed and the delivery system was fully disengaged (Figures 6A and 6B). The final result, as expected, showed TR resolution for the patient (Figure 6C). The patient was haemodynamically stable during the entire procedure. As with smaller EVOQUE valve sizes, the procedure was controlled, and prosthesis positioning and deployment was precise.

The patient was discharged 3 days after the procedure. After 1 month, his symptoms had improved to NYHA class II, with a reduction in peripheral oedema, and NT-pro-BNP halved to 570 pg/mL. However, echocardiography showed an increase in MR, which we suspected because of an increase in cardiac output. As a result, the patient underwent mitral TEER, which led to a reduction in MR grade from severe to mild.

The major advantages of TTVR are a short treatment period in hospital and rapid symptom improvement, enhancing patients' quality of life

Professor Philipp Bartko

Figure 6. Peri- and post-procedural imaging: 3D TOE showing the deployed EVOQUE valve (A); fluoroscopic imaging showing EVOQUE valve release (B); 2D TOE showing the final result, with TR resolution (C).

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

Key tips

- Use risk score calculators to assess the suitability of a particular intervention for your patients with TR. TRI-SCORE can help you determine their peri-operative risk of in-hospital mortality,[10] and GLIDE score can help you evaluate the probability of procedural success with T-TEER.[11]
- Both staged TTVR and M-TEER, as well as TTVR and M-TEER in one procedure can be considered and should be discussed during Heart Team meetings.[12]
- Close follow-up ensures adequate monitoring of MR progression after TTVR.

Case study 4: EVOQUE valve implantation after failed TEER[13]

Cologne University, Germany

Dr Matti Adam

Dr Adam is an interventional cardiologist and Director of the Structural Heart program at Cologne University. He specialises in transcatheter valve therapies and is dedicated to advancing innovative and patient centred solutions in both clinical practice and research.

The patient[13]

A 69-year-old woman presented with dyspnoea at rest (NYHA functional class IV) and acute heart failure 1 year after undergoing successful T-TEER with two PASCAL Ace implants. Both implants were located in the anteroseptal commissure, one centrally placed, with good leaflet insertion. The patient was diagnosed with recurrent severe TR due to disease progression. Her previously implanted surgical aortic valve and transapical mitral bioprosthesis were functioning well.

Patient key facts

- 69 years old
- Female
- Severe TR
- NYHA class IV

The challenge[13]

Recurrent TR after T-TEER (Figure 7) posed a significant symptomatic burden with limited treatment options. Here, the central placement of one of the PASCAL Ace implants complicated the possibility of TTVR, as central devices impede straightforward anchoring and positioning.

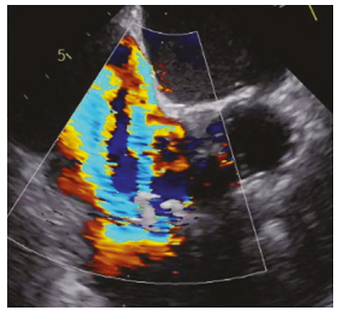

Figure 7. Baseline echocardiography, showing two PASCAL Ace implants and residual significant TR.

TR, tricuspid regurgitation.

Adapted from 'ELASTA-T: Electrosurgical laceration of a T-TEER device and subsequent TTVR' by Curio J *et al*. 2025[13] reused under CC BY 4.0.

The strategy

Despite the presence of the PASCAL Ace implants, the patient was evaluated for TTVR with a 52 mm EVOQUE valve. However, to enable TTVR, electrosurgical laceration and stabilisation (ELASTA) of the central T-TEER device was planned (Figure 8).[13]

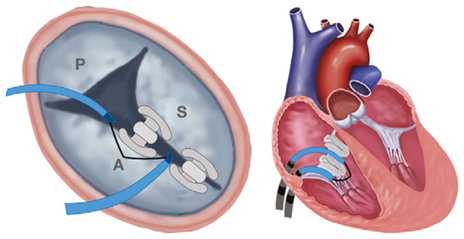

Figure 8. Schematic of the ELASTA-T technique, showing a 'flying V'-shaped wire positioned under the central PASCAL Ace implant at the anterior tricuspid leaflet. During the technique, a continuous 70 W electrosurgical current, with light catheter traction, was applied.

Adapted from 'ELASTA-T: Electrosurgical laceration of a T-TEER device and subsequent TTVR' by Curio J *et al*. 2025[13] reused under CC BY 4.0.

Make sure you capture the TEER implants within the EVOQUE valve anchors – they won't come out again, and they are terrific fluoroscopy markers.

Dr Matti Adam

The procedure

Following the ELASTA method, the anterior leaflet was lacerated, leading to single-leaflet attachment to the septal leaflet. The EVOQUE valve was then successfully implanted, stabilising the PASCAL Ace implants, which acted as positioning landmarks and anchor points.[13] Post-procedural echocardiography confirmed TR elimination with no relevant paravalvular leakage (Figure 9),[13] and the result was sustained at 6-month follow-up (Figure 10).

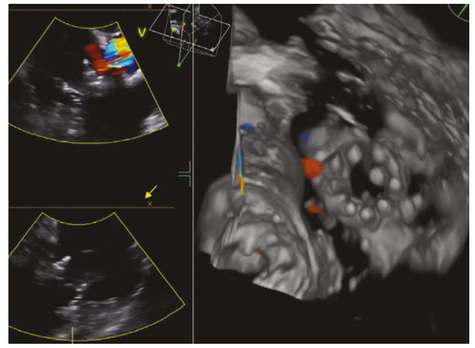

Figure 9. Post-procedural TOE, showing TR elimination and no relevant PVL.

PVL, paravalvular leakage; TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

Adapted from 'ELASTA-T: Electrosurgical laceration of a T-TEER device and subsequent TTVR' by Curio J *et al*. 2025[13] reused under CC BY 4.0.

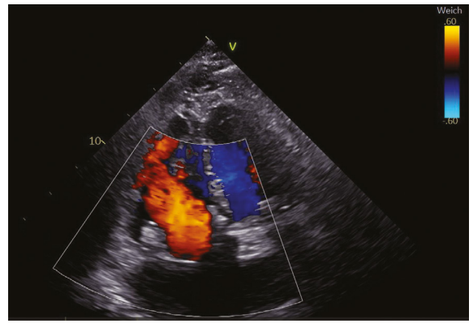

Figure 10. TTE 6 months post procedure.

TTE, transthoracic echocardiography.

We see from the data that with TTVR, we really improve patients' symptoms, their functional capacities and rehospitalisations – that's what these elderly, often high-risk, patients need.

Dr Matti Adam

Read more about this case in *JACC: Cardiovascular Interventions*[13]

Key tips

- As per the new Class I recommendation in the ESC/EACTS guidelines,[1] evaluate all patients with TR as part of an interdisciplinary Heart Team. As a Heart Team, together you should find the right treatment for each patient.
- If you are inexperienced at TR interventions, or if you have a particularly difficult case, consider proctoring or reverse proctoring.
- Ensure you plan for a potential increase in annular size after laceration, because you will lose the cinching effect of the TEER implant.

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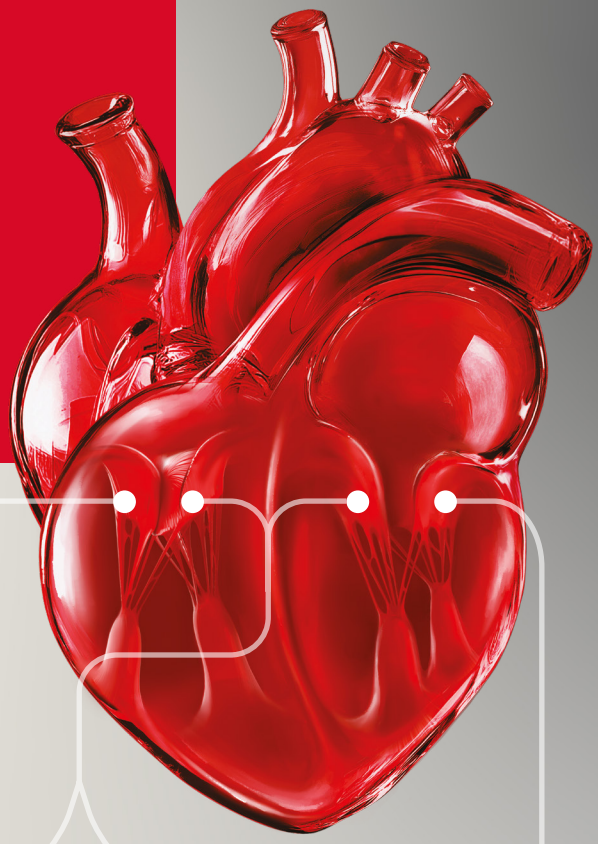

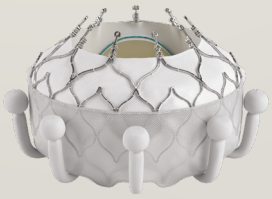

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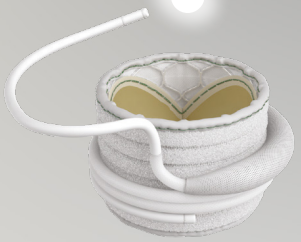

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