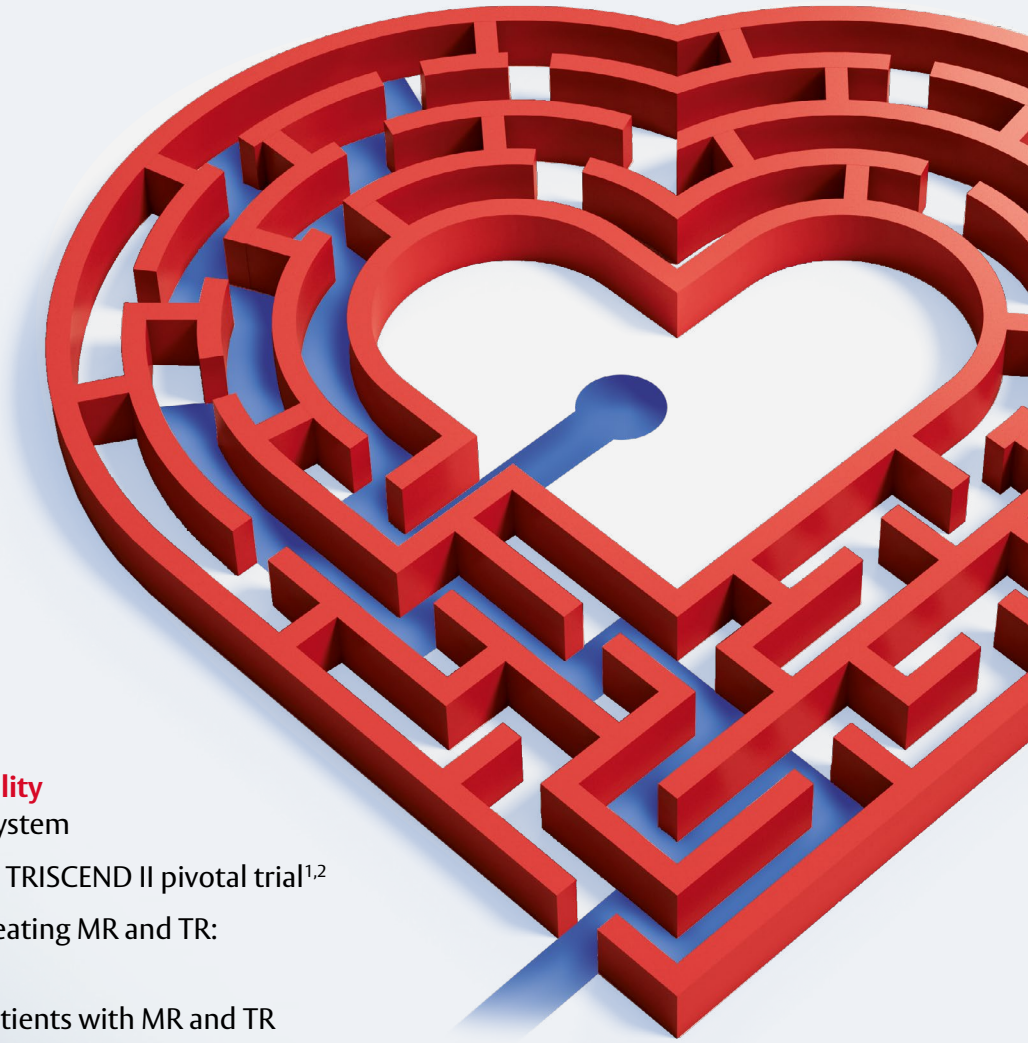
TMTT Today

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

Issue #13 – May 2025

Find your way
with the PASCAL Precision System



Inside this issue:

- Explore the **maneuverability** of the PASCAL Precision system
- One-year results from the TRISCEND II pivotal trial[1,2]
- The PASCAL system for treating MR and TR: Recent updates
- Tips and tricks for your patients with MR and TR

Edwards

Dear Reader,

Patients come in all shapes and sizes, and a one-size-fits-all strategy is not possible when it comes to treating mitral and tricuspid regurgitation (MR and TR).[3,4] A thorough evaluation of the patient's valvular anatomy is vital when deciding on the best approach.[3] Complex anatomies may increase the procedural difficulty of transcatheter edge-to-edge repair (TEER),[3] so you need to feel confident that you can navigate within the heart in a smooth, controlled manner and handle any unexpected challenges.

In this issue, Dr Antonio Mangieri describes how the advanced maneuverability of the PASCAL Precision system provides advantages when dealing with challenging anatomies. He gives step-by-step tips on correcting implant trajectories after sub-optimal transseptal puncture (TSP).[5] In addition, Professor Dr med. Tobias Geisler and Dr med. Mirjam Wild summarise recent updates to the clinical evidence for the PASCAL system in mitral and tricuspid TEER.[6–9]

Some patients, however, may be unsuitable for TEER.[3,4] For those with severe, symptomatic TR, the EVOQUE tricuspid valve replacement system now offers another option, as discussed in *TMTT Today* issue 12. In this issue, Professor Philipp Lurz shares the encouraging 1-year results from the TRISCEND II pivotal trial evaluating the safety and effectiveness of the EVOQUE system with optimal medical therapy (OMT) compared with OMT alone in the treatment of patients with severe or greater TR.[1]

Finally, we share four anatomically complex cases that together illustrate the strength of Edwards' unique portfolio of repair and replacement technologies for the mitral and tricuspid valves.

Enjoy reading!

Luciana Soares

Senior Vice President

Transcatheter Mitral and Tricuspid Therapies (TMTT) Europe

Edwards Lifesciences

Neal Uren

Vice President, Medical Affairs & New Therapies

Transcatheter Mitral and Tricuspid Therapies (TMTT) Europe

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Contents

Explore the maneuverability of the PASCAL Precision System

Navigating the challenges of sub-optimal transseptal puncture: R&D insights and a real-life case example

The patient population treated for MR in an interventional cardiologist's daily practice often presents more challenging anatomies than those seen in clinical trials. Complex anatomies include a floppy septum with patent foramen ovale, which may lead to a sub-optimal TSP.[5] This increases the anatomical difficulty of a TEER procedure; therefore, Heart Teams need to understand how best to overcome these challenges to be able to achieve the optimal result for the patient.[10,11] Here, Dr Antonio Mangieri describes how the advanced maneuverability of the PASCAL Precision system provides advantages when dealing with sub-optimal TSP, as illustrated by the case of a patient with a medial paracommissural lesion.

Dr Antonio Mangieri
Humanitas Research Hospital, Milan, Italy

Dr Antonio Mangieri is an interventional cardiologist at Humanitas Research Hospital in Milan. His dedication to the latest advances in the field has positioned him as a key figure in the hospital's cardiology team, and he has played a pivotal role in shaping the cardiovascular care landscape in Milan and beyond.

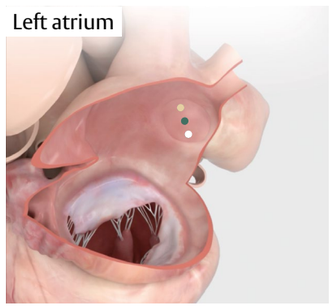


Figure 1. The optimal puncture location (green dot) is around 4.5 cm above the mitral valve coaptation line.[11,13]

High (yellow dot) and low (white dot) puncture locations are indicated above and below the optimal location.

TSP is a crucial step in mitral TEER (M-TEER). When performed precisely, it can reduce the risk of complications and optimise the trajectory of the delivery system for device implantation.[12] The optimal puncture site is mid-fossa and posterior, with a transseptal height of around 4.5 cm above mitral leaflet coaptation (Figure 1).[11,13] However, certain anatomical conditions, such as a small fossa, a floppy septum or aortic tubular tract dilatation, may hinder an optimal puncture,[5] leading to an implant trajectory that is too high or low and/or too anterior or posterior.[11]

To achieve an optimal mitral valve repair, correcting the consequences of a sub-optimal TSP is important before attempting to clasp the mitral valve leaflets. The PASCAL Precision system (Figure 2) is designed for precise placement with accurate, intuitive control* and has several features that are advantageous when correcting a sub-optimal trajectory.

The guide sheath and steerable catheter are unkeyed. They advance, retract, rotate and flex independently from each other, and, together with the implant catheter handle, enable operators to maneuver the implant in eight degrees of freedom. The guide sheath is used to position the implant over the mitral valve line of coaptation; flexing the guide sheath moves the implant posteriorly (Figure 2), which can help correct an aorta hugger trajectory (Box 1).
The steerable catheter moves the implant in the medial/lateral plane (Figure 2) and, along with the guide sheath, enables operators to gain or lose height from the mitral valve plane (Box 1).[11] In addition, the system benefits from a responsive catheter design with optimised torque transfer to facilitate implant placement,† and a balanced catheter with built in stability and flexibility. Overall, the PASCAL Precision system offers refined control that may facilitate precise maneuvers.[14]

*Performance data on file and marketing evaluation.
†Design and performance data on file and marketing evaluation.

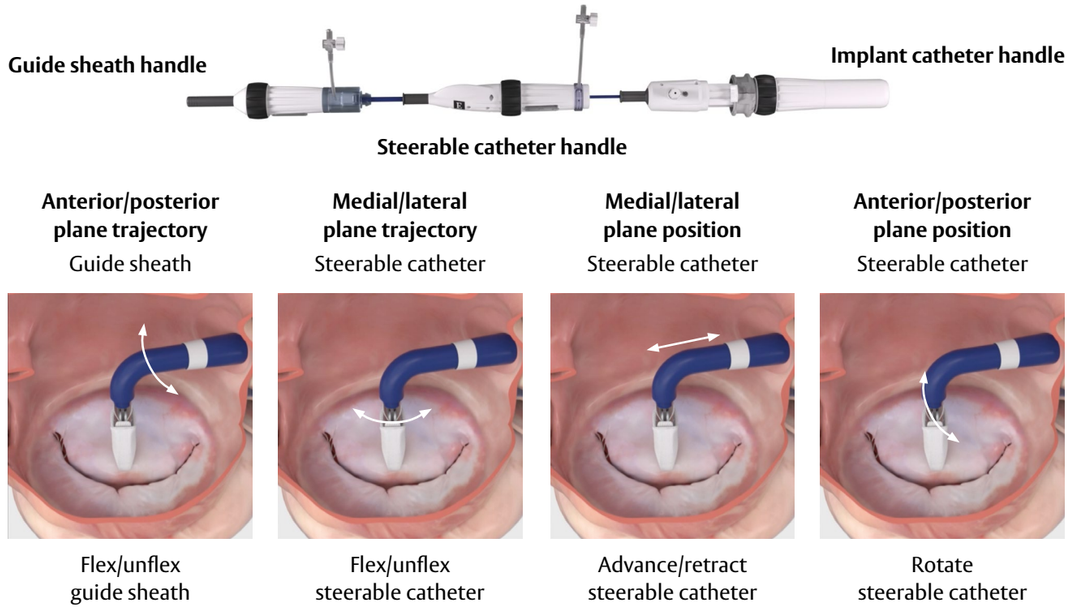


Figure 2. The PASCAL Precision system has independent catheters that enable maneuverability in three planes.

Case study: Using the PASCAL Precision system to gain height and correct an aorta hugger after a low TSP

To illustrate these beneficial features of the PASCAL Precision system, I present the case of an elderly man with severe MR, whose small atrium and floppy septum led to a low and anterior TSP.

The patient

An 83-year-old male with hypertension and diabetes presented with shortness of breath and peripheral oedema. He had a history of heart failure with preserved ejection fraction, atrial fibrillation and previous percutaneous coronary intervention. The patient had a chronic increase of B-type natriuretic peptide (748 pg/dL) despite medication, including diuretics, and was in New York Heart Association (NYHA) class IIIa.

Baseline transoesophageal echocardiography (TOE) showed severe MR due to a medial paracommissural lesion involving the P3 and A3 segments, with a prolapse flail (Figure 3). Additionally, there was a cleft in the middle of the valve at P2.

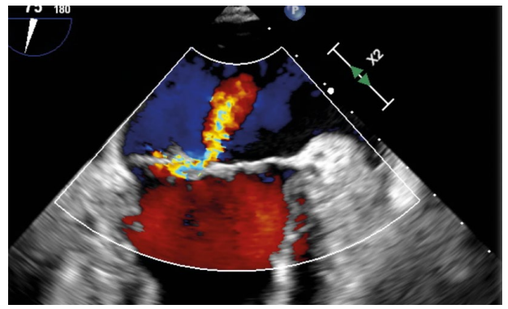


Figure 3. Baseline TOE showing severe MR.

MR, mitral regurgitation; TOE, transoesophageal echocardiography.

The challenge

A medial paracommissural lesion like this tends to require a high puncture; however, the patient had a small atrium, which increases the risk of having a low TSP and insufficient height from the mitral valve. This type of lesion also increases the risk of chordal entanglement. In addition, the aortic tubular tract was dilated, resulting in a posterior shift of the left atrium and a risk of an aorta hugger. Finally, we anticipated a challenging puncture because of the floppy fossa with a patent foramen ovale.

The approach

The patient's age and comorbidities rendered him high risk for surgery; therefore, the Heart Team agreed on M-TEER. We selected the PASCAL Precision system because it allows for gaining height in the case of a low TSP,[11] which we anticipated. We chose the PASCAL Ace implant because we believed its narrower profile relative to the PASCAL implant would be beneficial for this patient's anatomy.

The procedure

As anticipated, the floppy septum made the TSP challenging. The proximity to the left atrium wall meant a high risk of adverse events, such as perforation or pericardial effusion. As such, we used a SafeSept® guidewire to enable a precise, controlled puncture. We managed to achieve a TSP height of 3.41 cm above the level of mitral leaflet coaptation (Figure 4A).

We successfully followed the recommended steps to gain height (Box 1); however, the catheter was in an anterior–posterior trajectory, tilting away from the aorta as it approached the mitral valve plane (Figure 4B). This trajectory is known as an aorta hugger, and it prevented us from being able to clasp both leaflets symmetrically and to clasp enough of the posterior leaflet during our first attempt (Figure 4C). Therefore, before reattempting clasping, we first corrected the aorta hugger, using the straightforward steps shown in Box 1.

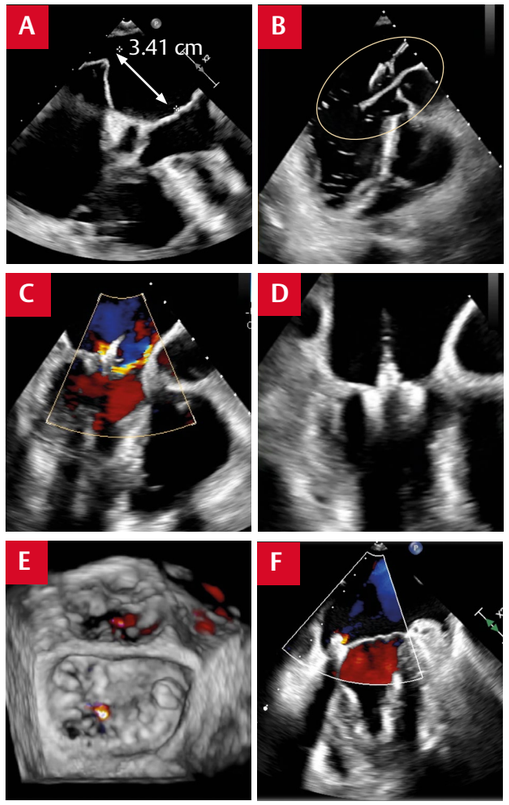


Figure 4. TOE showing the low TSP (A); aorta hugger (B); asymmetric leaflet clasping (C); symmetric clasping (D); post-procedural result (E, F).
TOE, transoesophageal echocardiography; TSP, transseptal puncture.

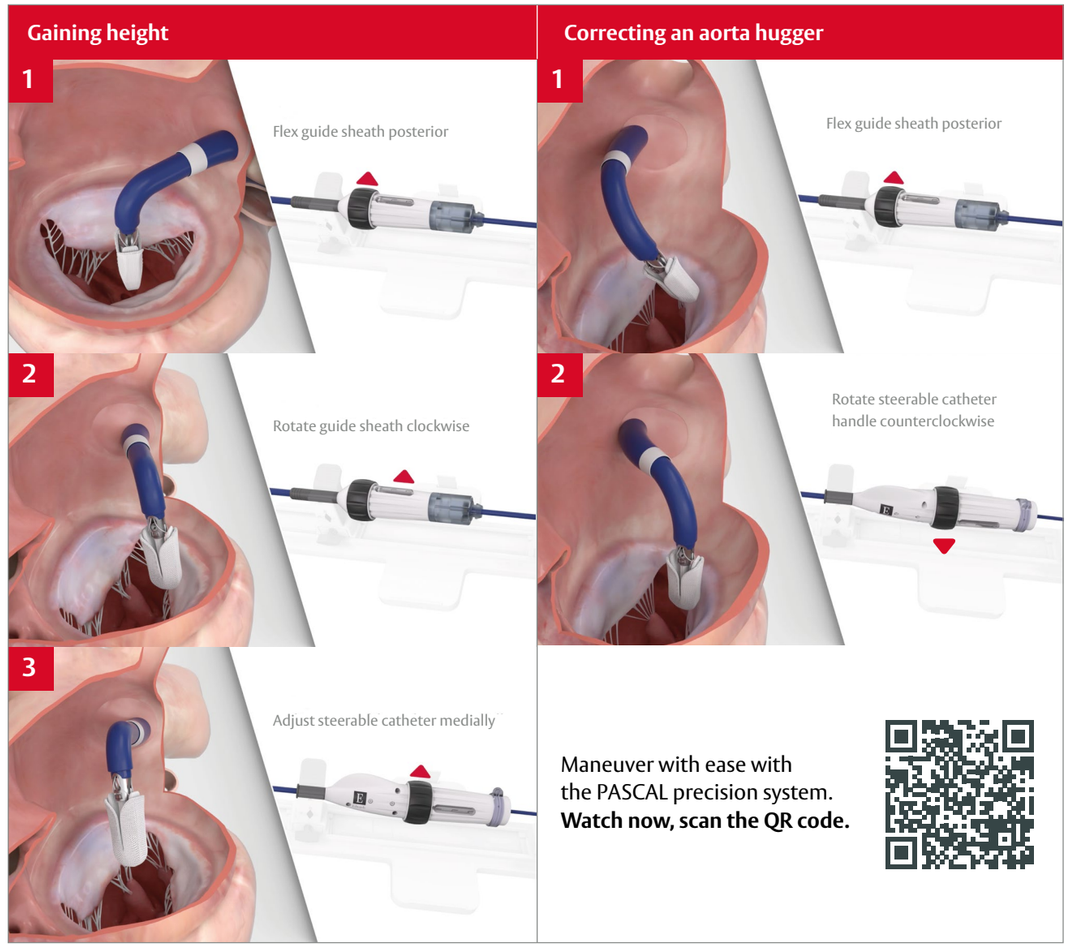
After trajectory correction, we were able to achieve symmetrical clasping (Figure 4D), reducing the MR to trace without significant gradient (mean gradient 2 mmHg) with a single PASCAL Ace implant (Figures 4E and 4F). The patient was safely discharged the day after the procedure.

If you try to fix a mitral valve lesion without correcting an aorta hugger, you have a very low chance of achieving a good result, because you are not respecting the geometry of the valve.

Dr Antonio Mangieri

This case highlights the performance of the PASCAL Precision system that allows one to easily correct the trajectory of the device even in complex clinical scenarios.

Dr Antonio Mangieri



Box 1. Corrective maneuvers to gain height and to correct an aorta hugger.

Conclusion

Complex anatomies are a common feature of daily practice for Heart Teams and can hinder an optimal TSP. This case illustrates how the PASCAL Precision system can adapt to specific procedural and anatomical needs, successfully overcoming the challenges of a low TSP and an aorta hugger trajectory. By optimising the implant trajectory before positioning the implant, the likelihood of a successful mitral valve repair and hence a positive outcome for the patient increases.

EVOQUE Transcatheter Tricuspid Valve Replacement System

One-year results from the TRISCEND II pivotal trial

The TRISCEND II pivotal trial is the first randomised controlled trial of a transcatheter tricuspid valve replacement (TTVR) therapy in patients with at least severe TR. In *TMTT Today* issue 12, we reported encouraging 6-month data related to the first 150 patients randomised and treated in the trial.[15] Now, Professor Philipp Lurz discusses the 1-year primary endpoint as well as clinical and quality-of-life outcomes for the randomised full cohort.[1]

Professor Dr med. Philipp Lurz

Mainz University Medical Center, Germany

Professor Philipp Lurz, an interventional cardiologist, is the Director of the Center for Cardiology at the Mainz University Medical Center. He is a principal investigator of the TRISCEND II pivotal trial and the MiCLASP registry and an investigator in the CLASP IID/IIF randomised controlled trial, as well as in multiple trials for other therapies.

The TRISCEND II pivotal trial (NCT04482062) is a prospective, multicentre, randomised controlled trial evaluating the safety and effectiveness of the EVOQUE system with optimal medical therapy (OMT) compared with OMT alone in the treatment of patients with symptomatic, severe or greater TR. A total of 400 patients were randomised in a 2:1 ratio to either the EVOQUE + OMT group (n=267) or the OMT alone group (n=133).[1]

EVOQUE + OMT[1] (n=259*)		OMT alone[1] (n=133)
79.3 years		79.1 years
74.9% female		76.7% female
73.0% NYHA class III/IV		69.2% NYHA class III/IV
5.4% EuroSCORE II		5.6% EuroSCORE II
96.1% atrial fibrillation		92.5% atrial fibrillation

*Of the 267 patients randomised to EVOQUE system TTVR, 8 exited prior to procedure.
EuroSCORE, European System for Cardiac Operative Risk Evaluation; NYHA, New York Heart Association; OMT, optimal medical therapy.

Safety and effectiveness outcomes

The primary outcome was a hierarchical composite consisting of seven events (Figure 5). A win ratio was calculated for the primary outcome by comparing all possible patient pairs, starting with the first event in the hierarchy. The primary endpoint was met, demonstrating that EVOQUE TTVR + OMT was superior to OMT alone, with a win ratio of 2.02 (95% confidence interval 1.56–2.62, p<0.001).[1]

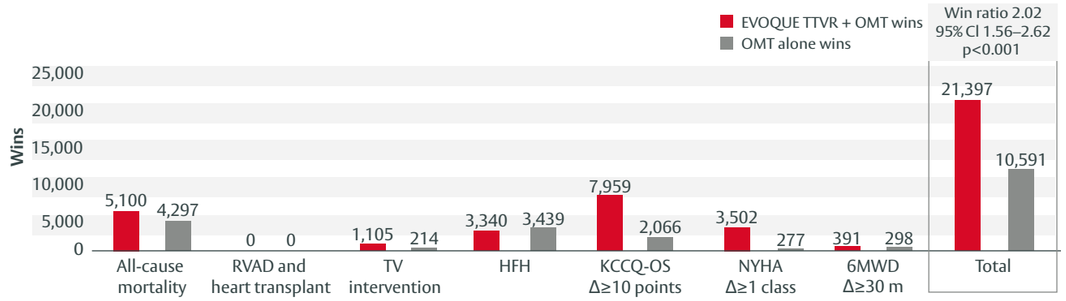


Figure 5. Primary safety and effectiveness composite endpoint win ratio analysis.[1]

Events are shown in rank order, left to right.
6MWD, 6-minute walk distance; CI, confidence interval; HFH, heart failure hospitalisation; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire overall summary; NYHA, New York Heart Association; OMT, optimal medical therapy; RVAD, right ventricular assist device; TTVR, transcatheter tricuspid valve replacement; TV, tricuspid valve.

The win ratio of 2.02 means that patients randomised into the TTVR group were twice as likely to win (i.e. have a clinical benefit) than those treated with medical therapy alone.

Professor Philipp Lurz

Adverse clinical events were mostly periprocedural, mainly driven by severe bleeding and new permanent pacemaker implantation rates (Table 1).[1]
Professor Lurz is optimistic that periprocedural complications will become less frequent in the future, thanks to increasing procedural experience and improvements in periprocedural management, including anticoagulation. 'During the trial, most patients on direct oral anticoagulants (DOAC) were switched to warfarin. However, based on a recent publication,[16] it may be reasonable to maintain the preprocedural anticoagulation strategy after TTVR also ("no change strategy"). This appears to reduce the risk of bleeding without increasing the thrombosis risk. In case of relevant valve dysfunction under DOAC, a switch to a vitamin K antagonist may be considered,' he explains.

Table 1. Selected early and late safety events in the TRISCEND II pivotal trial.[1]

CEC-adjudicated event	Early events (≤30 days)[a]		Late events (31–365 days)[b]	
	EVOQUE + OMT (n=259), %	OMT alone (n=133), %	EVOQUE + OMT (n=247), %	OMT alone (n=128), %
Cardiovascular mortality	3.1	0.0	5.7	7.8
Myocardial infarction	0.8	0.0	1.2	0.8
Stroke	0.4	0.0	1.2	0.0
Severe bleeding[c,d]	10.4	1.5	5.3	4.7
Non-elective TV reintervention	0.8	0.8	0.0	2.3
CIED implant in pacemaker-naive patients[d,e]	24.7	0.0	4.2[f]	3.9[f]

[a]Includes patients from day of procedure in the EVOQUE + OMT group and from randomisation in the control group.
[b]Patients must have been enrolled for ≥31 days to be included in this category.
[c]Fatal, life-threatening, extensive or major bleeding, as defined by the Mitral Valve Academic Research Consortium.[17]
[d]Beyond 30 days, the severe bleeding and CIED implantation rates were similar for EVOQUE + OMT and OMT alone.
[e]Excludes patients with pre-existing CIED. Percentages calculated using the number of patients without a pre-existing CIED at baseline as the denominator (early events: EVOQUE + OMT n=162; OMT alone n=80; late events: EVOQUE + OMT alone n=118; OMT alone n=76).
[f]Patients who had a pacemaker implanted in the first 30 days are excluded.
CEC, clinical events committee; CIED, cardiac implantable electronic device; OMT, optimal medical therapy; TV, tricuspid valve.

Kaplan–Meier estimates for all-cause mortality at 1 year were a mean (±SE) of 12.6 ± 2.1% in the EVOQUE + OMT group and 15.2 ± 3.3% in the OMT alone group showing a numerical trend favouring TTVR, despite the initially higher rate of periprocedural adverse events. A 30-day landmark analysis of 1-year all-cause mortality demonstrated even lower mortality in the EVOQUE + OMT group once past this initial procedural risk (Kaplan–Meier estimate mean [SE] 9.4 [1.9]%). A similar favourable trend for EVOQUE TTVR was also seen in Kaplan–Meier estimates for heart failure hospitalisation (HFH) at 1 year (EVOQUE + OMT group: 20.9 ± 2.6% *vs* OMT alone group: 26.1 ± 4.1%).[1]

Consistent TR reduction

TTVR with the EVOQUE system enabled consistent reduction of TR, reducing residual TR to mild or less in 95.3% of patients at 1 year and eliminating TR in 72.6% of patients (Figure 6).[1]

Figure 6. TR reduction with the EVOQUE system at 1 year in the TRISCEND II pivotal trial.

Graphs show paired data.
OMT, optimal medical therapy.
Figure adapted from Hahn *et al*. 2024.[1]

In the vast majority of patients, TTVR with the EVOQUE system resolved TR to mild or less, which separates it from TEER.

Professor Philipp Lurz

Meaningful health status improvements for patients

TR reduction was accompanied by clinically relevant improvements in symptoms, function and quality of life at 1 year. Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS) increased by 18.4 points *versus* baseline (compared with +2.8 points *versus* baseline for OMT alone[18]), and 6-minute walk distance increased by 23.2 m *versus* baseline (compared with −14.8 m *versus* baseline for OMT alone; Figure 7[18]).[1] In addition, 91.0% of patients were in NYHA class I or II at 1 year *versus* 34.4% with OMT alone (Figure 8).[18]

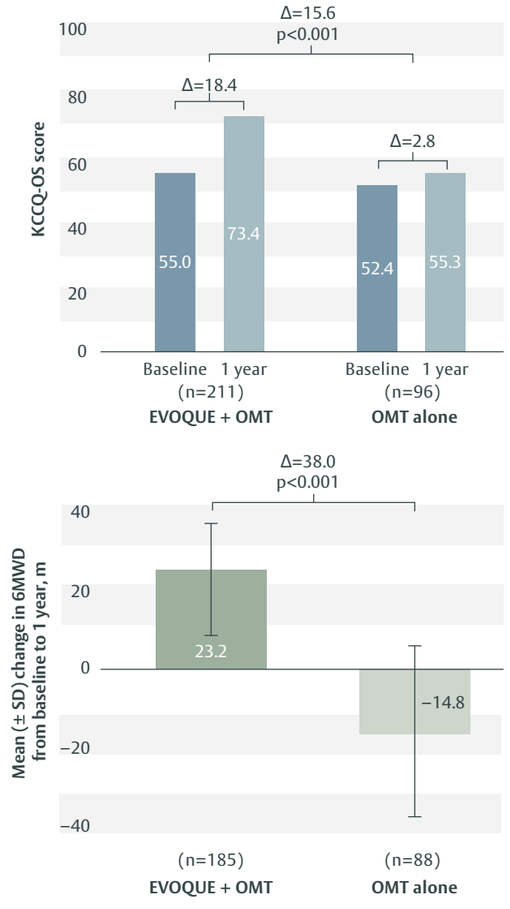


Figure 7. Functional and quality-of-life improvements with the EVOQUE system at 1 year in the TRISCEND II pivotal trial.[1,2,18]

KCCQ-OS chart shows paired analysis.
6MWD, 6-minute walk distance; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire overall summary; OMT, optimal medical therapy.

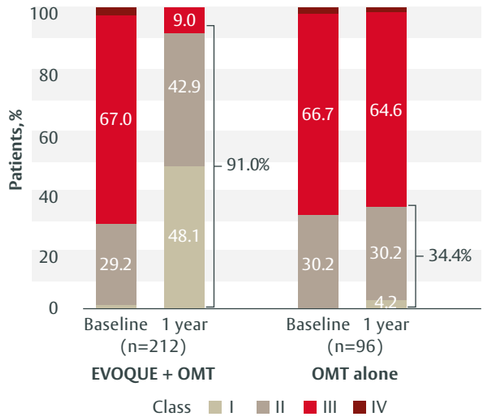


Figure 8. NYHA functional class improvement with the EVOQUE system at 1 year in the TRISCEND II pivotal trial.[18]

Graph shows paired analysis.
NYHA, New York Heart Association; OMT, optimal medical therapy.

The most striking finding was the extent of improvement in quality of life for the TTVR group, which, at over 18 points, was much higher than for medical therapy alone. In my mind, this can't be explained by anything other than the treatment itself.

Professor Philipp Lurz

Conclusions

These results from the TRISCEND II pivotal trial demonstrate TTVR as an effective therapy with a proven safety profile for patients with at least severe TR. Consistent TR reduction was accompanied by meaningful health status benefits and favourable numerical trends in all-cause mortality and HFH at 1 year.[1] 'It is clear that resolving TR by TTVR improves patient symptoms dramatically. That will clearly impact decision making and, hopefully, boost referrals for treatment,' says Professor Lurz.

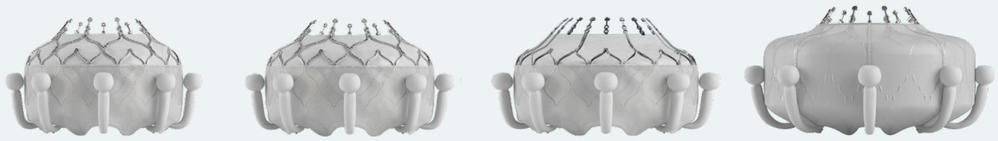
Additional size now available: 56 mm EVOQUE valve

"The 56 mm EVOQUE valve expands the cohort of severe TR patients who can benefit from TTVR."
Professor Philipp Lurz

4	1	
valve sizes	delivery system	Ability to treat more patients

The new EVOQUE 56 mm valve treats patients with larger tricuspid annuli.

All four EVOQUE valve sizes are compatible with the same low profile 28F delivery system.



44 mm | 48 mm | 52 mm | 56 mm

Now available

Recent updates on mitral and tricuspid valve repair with the PASCAL System

Mitral TEER

Professor Dr med. Tobias Geisler
University Hospital Tübingen, Germany

In 2024, 2-year data were released for the MiCLASP study, the CLASP IID trial and the CLASP IID registry.[6,7] These consistent results demonstrated the long-term durability of TEER with the PASCAL system across different MR aetiologies and anatomical complexities and settings. Taken together, these findings are very assuring for us interventional cardiologists, for our referring colleagues and for our patients. These results will hopefully contribute to increased confidence and acceptance for transcatheter mitral valve repair in a broad spectrum of MR.

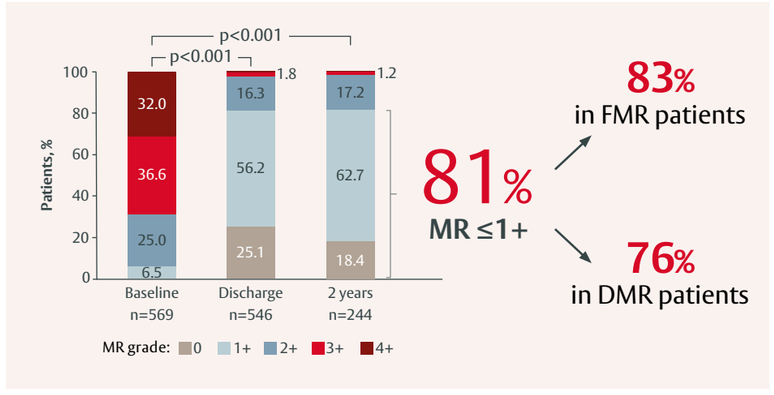
- Significant, sustained MR reduction[6,7]
- Favourable survival and low HFH[6,7]
- Meaningful improvements in functional capacity and quality of life[6,7]

THE MiCLASP STUDY

Prospective, multicentre, single-arm, post-market clinical follow-up study[6]

600 patients* | **2** years*

Confirmed safety and significant, sustained effectiveness at 2 years in patients with significant, symptomatic MR in a post-market setting.[6]



88% freedom from CV mortality

74% freedom from HFH

74% NYHA class I/II

+13 pts KCCQ-OS

Figure shows unpaired analysis. Adapted from Geisler T. 2024. For details on statistical analyses, please see reference 6.

The MR reduction was accompanied by a durable effect on quality of life and a substantial reduction in HFH, even in patients with functional MR (FMR), who were sicker than those with degenerative MR (DMR).
Professor Tobias Geisler

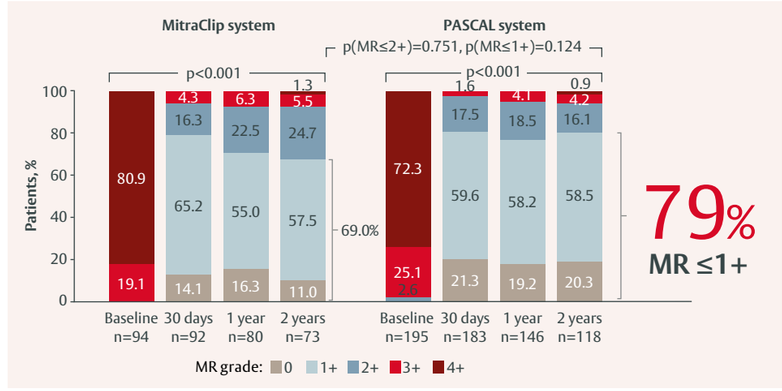
*Based on reported follow-up.

THE CLASP IID TRIAL

Prospective, multicentre, randomised controlled pivotal trial[14]

204 patients treated with the PASCAL system* | **2** years*

Confirmed safety and significant, sustained effectiveness at 2 years in patients with significant, symptomatic DMR.[7]



89% freedom from CV mortality

86% freedom from HFH

88% NYHA class I/II

+17 pts KCCQ-OS

with the PASCAL system

Figure shows unpaired analysis. Adapted from Zahr F. 2024. For details on statistical analyses, please see reference 7.

The sustained MR reduction with the PASCAL system after 2 years was a standout result for me. Numerically, more patients achieved MR ≤1+ with the PASCAL system than with the MitraClip device (79% *vs* 69%; **p=0.124**).
Professor Tobias Geisler

THE CLASP IID REGISTRY

Prospective, multicentre, single-arm study[7]

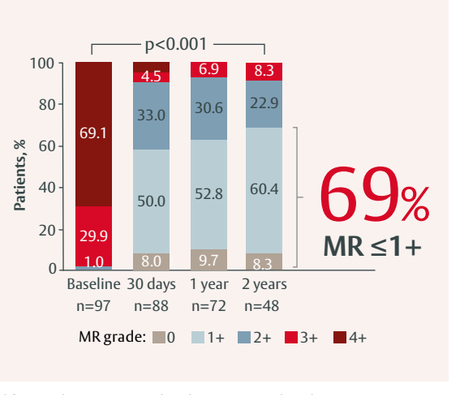
98 patients* | **2** years*

Significant and sustained MR reduction at 2 years in patients with significant, symptomatic DMR and complex mitral valve anatomy.[7]

Baseline anatomical complexity distribution

- **37.2%** ≥2 independent significant jets
- **15.0%** Bileaflet/multi-scallop prolapse involvement
- **13.3%** Mitral valve orifice area <4.0 cm²
- **10.6%** Flail width >15 mm and/or flail gap >10 mm
- **9.7%** Significant jet in the commissural area
- **14.2%** Other[a]

[a]Please refer to reference 7 for details.



84% freedom from CV mortality

85% freedom from HFH

84% NYHA class I/II

+12 pts KCCQ-OS

MR figure shows unpaired analysis. Figures adapted from Zahr F. 2024. For details on statistical analyses, please see reference 7.

In patients with DMR and complex anatomy, we can achieve similar, sustained MR reduction rates to those with less complex anatomy. This does not come at the cost of increased gradient.
Professor Tobias Geisler

*Based on reported follow-up.

Tricuspid TEER

Dr med. Mirjam Wild
University Heart Center Freiburg Bad Krozingen, Germany

One-year data for the TriCLASP study and PASTE registry, investigating the PASCAL system in patients with TR, were recently reported.[8,9] The strong safety profile and very good results for a broad patient population in these studies are reassuring. The next step is to share these results with general practitioners and referring cardiologists, to encourage them to refer patients earlier for evaluation and possible treatment.

Significant, sustained TR reduction[8,9]

High survival and low HFH[8,9]

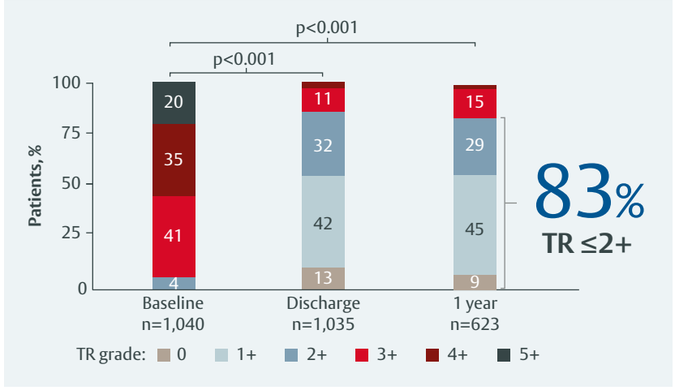
Meaningful improvements in functional capacity and quality of life[8,9]

PASTE registry

Investigator-initiated, multicentre, retrospective and prospective, observational cohort study[8] | **1,059** patients | **1** year

Significant and sustained TR reduction and clinical improvements at 1 year in a real-world, high-risk patient population with complex anatomy at baseline:[8]

Mean TRI-SCORE risk **23%** | Coaptation gap >8 mm **24%** | Transvalvular CIED lead **27%** | >3 leaflets **43%**



86% freedom from all-cause mortality

84% freedom from HFH

66% NYHA class I/II

−9 pts MLHFQ

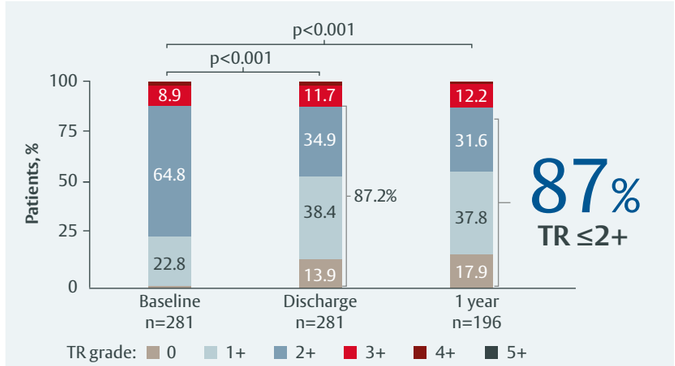
Figure shows unpaired analysis. Adapted from Wild MG *et al*. 2025. For details on statistical analyses, please see reference 8. MLHFQ, Minnesota Living with Heart Failure Questionnaire.

These results confirm the safety and efficacy of tricuspid TEER (T-TEER), even in these clinically and anatomically advanced patients.
Dr Mirjam Wild

THE TriCLASP STUDY

Prospective, multicentre, single-arm, post-market clinical follow-up[9] | **300** patients | **1** year*

Significant and sustained improvements in TR, functional status and quality of life at 1 year in patients with clinically significant TR in a post-market setting.[9]



88% freedom from all-cause mortality

83% freedom from HFH

75% NYHA class I/II

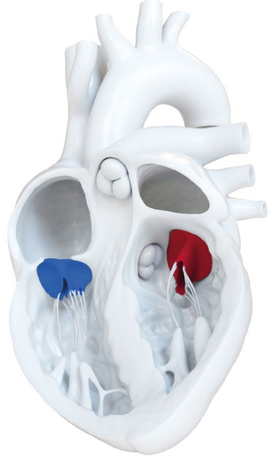
+8 pts KCCQ-OS

Figure shows unpaired analysis. Adapted from Hausleiter J. 2024. For details on statistical analyses, please see reference 9.

The TriCLASP study reinforces the safety and efficacy of T-TEER. It also underscores the clinical benefits for patients, offering another promising step forward in providing previously undertreated individuals with a viable treatment option and the potential for meaningful improvements in their daily lives.
Dr Mirjam Wild

PASCAL System body of evidence

THE CLASP TR STUDY
THE CLASP II TR TRIAL
THE TriCLASP STUDY
PASTE registry



THE CLASP STUDY
THE MiCLASP STUDY
THE CLASP IID TRIAL
THE CLASP IIF TRIAL

*Based on reported follow-up.

Tips and tricks for your patients with MR and TR

Case study 1: PASCAL Precision System for treating MR: Deploy the implant with procedural confidence*

Bielefeld Clinic, Germany

Dr med. Kristin Marx

Dr med. Kristin Marx is a senior physician for internal medicine and cardiology at Bielefeld Clinic in Germany.

Dr med. Ekaterina Stellbrink

Dr med. Ekaterina Stellbrink is a senior physician for internal medicine and cardiology, also at Bielefeld Clinic, where she specialises in echocardiography.

The patient

An 80-year-old woman presented to our hospital in early 2024 with cardiac decompensation, accompanied by dyspnoea, lower limb oedema and persistent atrial fibrillation. She was diagnosed with dilated cardiomyopathy characterised by severe left ventricular (LV) dysfunction, without coronary sclerosis, and severe FMR with leaflet thickening. After restoring sinus rhythm, we initiated heart failure therapy in accordance with the current guidelines. Two months later, the patient continued to exhibit symptoms of heart failure and persistent severe MR (Figure 9A), with no improvement in LV function. Right heart catheterisation revealed post-capillary pulmonary hypertension with a prominent v-wave. Following a multidisciplinary discussion within the Heart Team, we decided to proceed with M-TEER.

Patient key facts

- 80 years old
- Female
- Mixed MR
- NYHA class III–IV

The challenge

The patient exhibited LV dysfunction, severe atrial and ventricular dilatation and subsequent mitral ring dilatation. Additionally, the thickened, sclerotic leaflets resulted in severely reduced coaptation length and an overriding anterior mitral leaflet (AML) with central coaptation loss. The regurgitation orifice was crescent-shaped, with confluent central medial and central lateral parts. Those anatomical features contributed to a mixed aetiology of MR and, together with curling of the posterior mitral leaflet (PML) during the procedure (Figure 9B), presented procedural challenges.

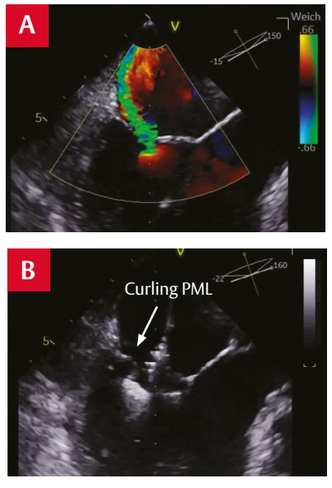


Figure 9. 2D echocardiography of the mitral valve at baseline.

PML, posterior mitral leaflet.

*Performance and design data on file.

The strategy

Our strategy was to address both the approximation of the leaflets and the annular dilatation. We recognised that we would need two implants for this patient because of the large mitral annulus. We opted for the PASCAL Precision system because it allows multiple repositionings of the implants without damage to the sclerotic leaflets; it is very well suited for delicate and precise grasping. We chose the PASCAL Ace implant for its narrow profile, which facilitates the placement of two devices close to each other.

The procedure

The initial grasping attempt was sub-optimal because of the curling of the PML, which resulted in the PML folding. Consequently, we decided to optimise the grasping technique, to capture the leaflet in full length and prevent folding. To achieve this, the PML was initially grasped at a deeper level, and the PASCAL Ace implant was positioned in a slight V-configuration (Figure 10A). We placed the first implant in the central medial position, using the independent clasping feature to first clasp the PML and then the AML. After the initial closure, we achieved a significant reduction in the MR; however, a substantial lateral jet persisted (Figure 10B). Our intention was to place the second implant adjacent to the first, but the outcome of our initial grasping attempt was unsatisfactory: the clips were in a V-shaped configuration, resulting in residual MR. We subsequently adjusted the angulation of the sheath using 3D visualisation and the FlexiSlice tool and simultaneously grasped both leaflets. This maneuver nearly eliminated the MR, leaving only a trace jet (Figures 10C and 10D). This result was confirmed to be sustained the following day during transthoracic echocardiography (TTE; Figure 10E).

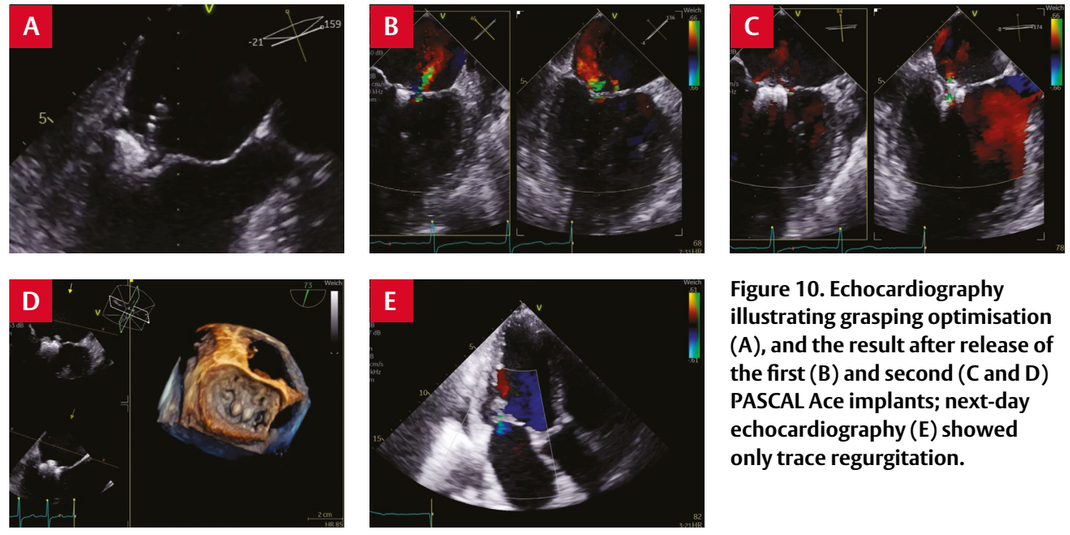


Figure 10. Echocardiography illustrating grasping optimisation (A), and the result after release of the first (B) and second (C and D) PASCAL Ace implants; next-day echocardiography (E) showed only trace regurgitation.

Key tips

Predictability is one of the advantages of the PASCAL Precision system. What you see after closure of the device is what you get after releasing the implant. In our opinion, the flexibility of the delivery system may contribute to the predictability. For new users, however, understanding how to steer the system can be challenging in the beginning. Take advantage of training that is offered to you, and take your time switching between 3D and X-plane views to ensure optimal angulation, rotation and clocking, as well as full insertion of the leaflets, which should enable you to achieve excellent results.

Case study 2: PASCAL Precision System for treating massive TR

Hospital Universitario Puerta de Hierro, Madrid, Spain

Dr Maria Del Trigo

Dr Maria Del Trigo is an interventional cardiologist and is responsible for the Mitral & Tricuspid Transcatheter Valves Program at Hospital Universitario Puerta de Hierro in Madrid.

Dr Vanessa Moñivas

Dr Vanessa Moñivas is an imaging specialist in structural interventions and coordinator of the valvulopathies in Puerta de Hierro Hospital.

The patient

A 68-year-old male patient presented with atrial fibrillation and ischaemic cardiomyopathy. He was receiving dialysis for urological pathology but reported abdominal distention, oedema and fatigue. TTE revealed massive TR, so he was referred to the Heart Team for tricuspid intervention.

Patient key facts

- 68 years old
- Male
- Massive TR
- NYHA class III

The challenge

The screening TOE revealed a very large coaptation gap. Additionally, the patient had two-scalloped septal leaflet and severe septal leaflet retraction (Figure 11), meaning he was not a good candidate for T-TEER.

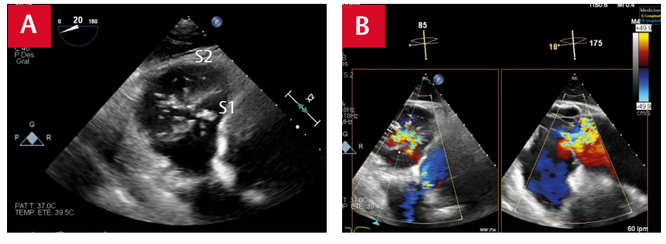


Figure 11. Screening TOE. Short-axis view showing the complexity of the valve with two septal leaflets (A) and with colour confirming massive TR (B).

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

We love the PASCAL Precision system for T-TEER because positioning the guiding catheter is easy.

Dr Maria Del Trigo

The strategy

T-TEER is our first choice for patients with severe TR, so we intensified dialysis to enable this approach. The patient underwent four dialysis sessions per week in the 3 months prior to intervention to reduce the coaptation gap. We had two initial strategies for the patient:

1. Zipping: position a PASCAL Ace implant between the anterior leaflet and scallop S1, and another between the anterior leaflet and scallop S2, or
2. Clover: position a PASCAL Ace implant between the anterior leaflet and scallop S1, and another between the posterior leaflet and scallop S2.

The procedure

Our initial strategy of clasping between scallop S1 and the anterior leaflet opened the cleft further and worsened the TR. Therefore, we elongated, returned to the right atrium and changed the position and orientation. The PASCAL Precision system allows us to perform this maneuver easily and safely. In addition, the independent clasping capability was a crucial feature for us in this case, allowing us to perform more confident clasping between the anterior leaflet and scallop S2 of the septal leaflet.

While we initially planned to use two implants, we were able to achieve an excellent result with just one, and the outcome improved even further after releasing the device (Figure 12).

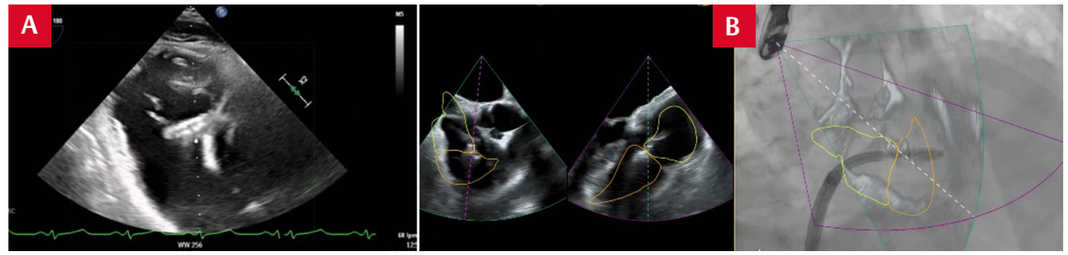


Figure 12. Peri-procedural TOE showing grasping of the septal leaflets (A) and more confident grasping of scallop S2 of the septal leaflet and the anterior leaflet (B).

TOE, transoesophageal echocardiography.

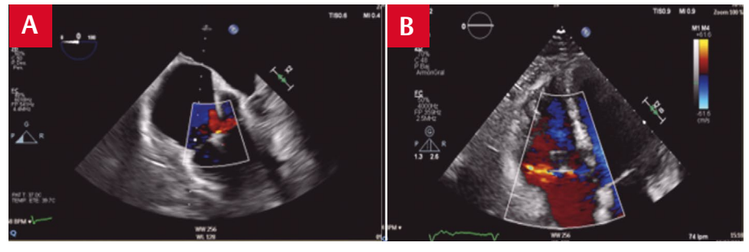


Figure 13. Intraprocedural TOE showing reduction in TR (A) and at 3-month follow-up (B).

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

We were very pleased with the result, as the patient's TR improved from torrential to grade I. At the 3-month follow-up, the reduction in TR was maintained (Figure 13), and the patient's clinical symptoms had improved significantly, with reduced abdominal distension and less fatigue.

Key tips

- Pre-procedural treatment optimisation is crucial and may allow the successful treatment of patients with difficult anatomies.
- Thorough evaluation of the tricuspid anatomy is vital to determine possible treatment strategies.
- Try to keep working frequently with the same team as this improves communication. For example, we are so in tune with each other that Dr Moñivas often has the required echo view on screen before it has been requested! Additionally, building experience working together with mitral procedures before undertaking tricuspid procedures is invaluable.

Case study 3: EVOQUE 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 (FTR) 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 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 FTR
- NYHA class II

The challenge

The patient's tricuspid valve was multi-leaflet Type IV,[19] consisting of five leaflets (essentially star-shaped with five points), with a large coaptation gap (12–15 mm) and complex regurgitation jet morphology (Figure 14); therefore, achieving a good outcome with T-TEER was very unlikely.

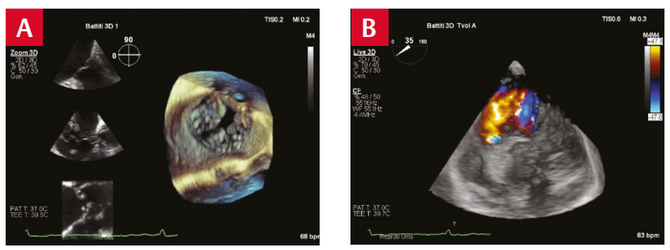


Figure 14. Baseline TOE shows multi-leaflet valve and wide coaptation defect (A) and massive TR (B).

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 (CT) 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 DOAC 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 15) 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.

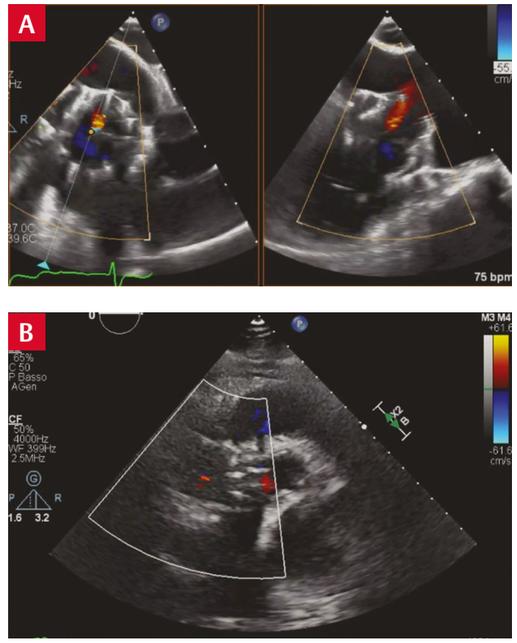


Figure 15. TOE immediately after the procedure (A) and 6 months post procedure (B) showing TR has been reduced to mild.

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 4: Implantation of a 56 mm EVOQUE valve treating large tricuspid annulus and coaptation gap

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. TTE revealed torrential TR and moderate 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%),[20] 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 16). The GLIDE score was 3, indicating advanced anatomical complexity and a relatively low likelihood of procedural success with T-TEER.[21]

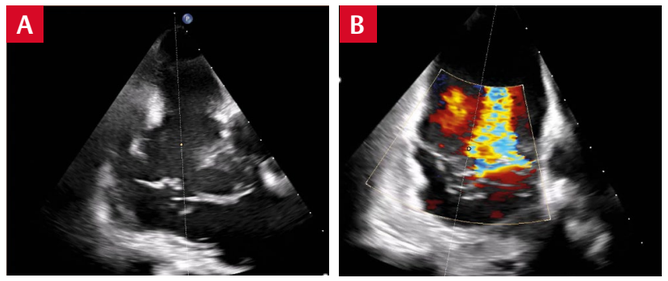


Figure 16. TOE showing the septal prolapse (A) and torrential TR (B).

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

The strategy

Using 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*

The procedure

After confirming the adequate sizing by TOE multiplanar reconstruction (MPR) of the native annulus, we precisely positioned the guidewire in the right ventricular 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 17A and 17B). The final result, as expected, showed TR resolution for the patient (Figure 17C). 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 level 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**

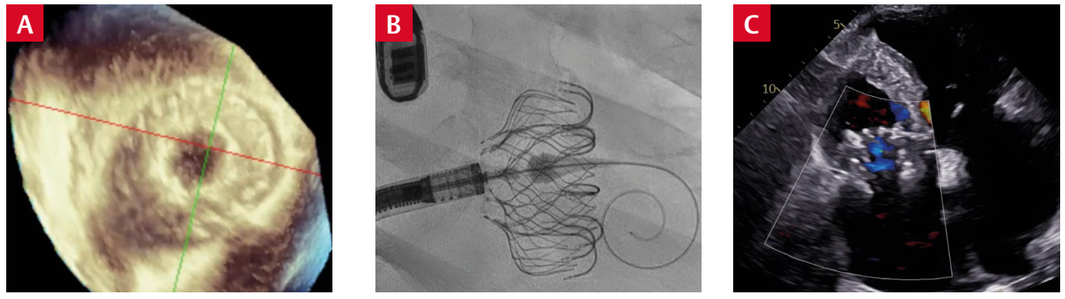


Figure 17. Peri- and post-procedural imaging: 3D TOE showing the deployed EVOQUE valve (A); fluoroscopic imaging showing EVOQUE valve release (B); 2D TOE showing the final result, with TR resolution (C).

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 perioperative risk of in-hospital mortality,[20] and GLIDE score can help you evaluate the probability of procedural success with T-TEER.[21]
- Both staged TTVR and M-TEER, and TTVR and M-TEER in one procedure can be considered and should be discussed during Heart Team meetings.[22]
- Close follow-up ensures adequate monitoring of MR progression after TTVR.

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Conclusion

Many people around the world suffer debilitating symptoms and poor quality of life because of MR and/or TR.[1,3,8,23] Edwards is committed to building a portfolio of transcatheter repair and replacement technologies for both the mitral and tricuspid valves that addresses the needs of these patients. The evidence from the clinical trials, real-world registries and cases presented in this issue support the safety and effectiveness of both the PASCAL Precision system and the EVOQUE system, increasing the treatment options for Heart Teams and their patients, including those with complex anatomies.[1,5–9]

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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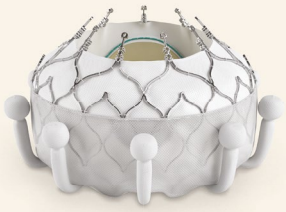

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