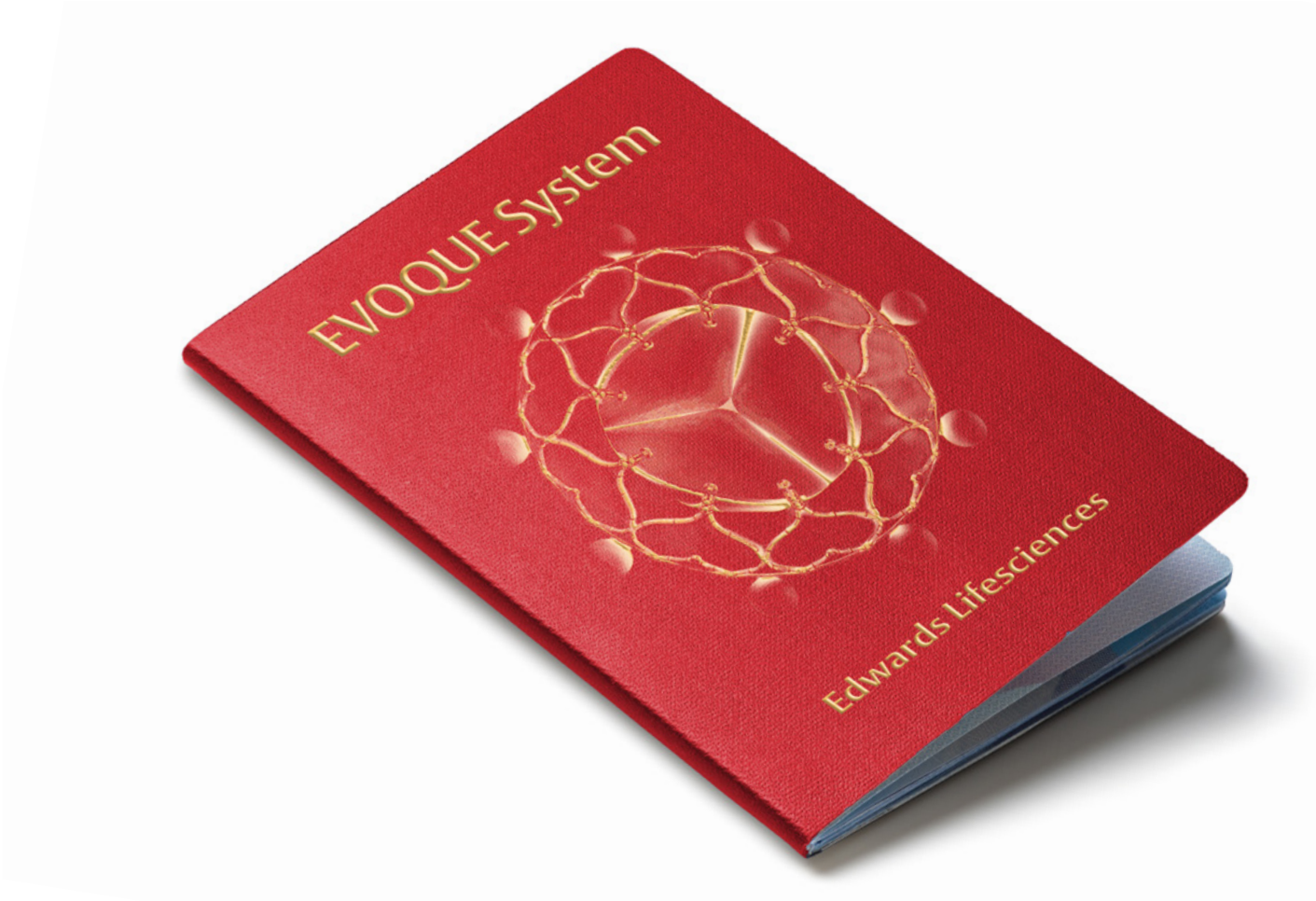
TMTT Today

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

Issue #12 – July 2024

Get ready for your journey with the EVOQUE System



Discover what's inside this issue:

- Perspectives from a heart failure specialist on transcatheter tricuspid intervention
- Insights into the development of the EVOQUE system
- Outcomes from the TRISCEND II pivotal trial and TRISCEND study[1,2]
- Tips and tricks from EVOQUE and PASCAL Precision system cases for your patients with tricuspid regurgitation

Edwards

Dear Reader,

Over 3 million people in Europe have clinically relevant tricuspid regurgitation (TR);[3] however, severe TR is largely undertreated,[4]* despite being associated with high 1-year mortality rates.[5] Patients with TR may experience debilitating symptoms, but their medical treatment options have been limited.[4] Therefore, we are delighted to introduce the EVOQUE system, the world's first transcatheter tricuspid valve replacement (TTVR) system.† Together with the PASCAL Precision system, the EVOQUE system increases the treatment options for people with severe or greater TR who are unsuitable for surgical intervention.

In this issue, heart failure (HF) specialist Dr Ali Vazir gives his perspective on transcatheter tricuspid valve intervention, highlighting how TTVR is an important part of the armamentarium for tackling the challenges of TR. Matt Becerra, Vice President of Research and Development at Edwards Lifesciences, describes the development process behind the EVOQUE system, including how its components are designed for anatomical compatibility with the tricuspid valve. Next, Professors Jörg Hausleiter and Philipp Lurz discuss the latest data from the TRISCEND study and TRISCEND II pivotal trial, which demonstrate the safety and effectiveness of the EVOQUE system for treating patients with severe TR.[1,2] Finally, we share three cases of transcatheter tricuspid valve interventions, including two implantations of the EVOQUE valve.

Enjoy reading!

Luciana Soares
Senior Vice President, Europe
Transcatheter Mitral
and Tricuspid Therapies
Edwards Lifesciences

Professor Neal Uren
Vice President, Professional
Education and Medical Affairs
Edwards Lifesciences

*Based on US data.
†First-of-its kind device commercially available (in the EU).

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Transcatheter tricuspid valve intervention: The heart failure specialist's perspective

TR and HF are often interconnected, with many patients experiencing both.[6,7] Here, we ask HF specialist Dr Ali Vazir his views on the challenges of treating TR and recent advances in transcatheter tricuspid valve interventions.

Dr Ali Vazir

Royal Brompton Hospital, London, UK

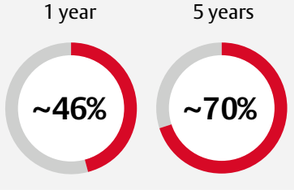
Dr Ali Vazir is a consultant cardiologist based at Royal Brompton Hospital. His areas of expertise include the management of acute and chronic HF, valvular heart disease and peri-procedural transoesophageal echocardiography.

Tricuspid regurgitation: Key facts

TR overlaps significantly with HF, especially in patients with HF with preserved ejection fraction[9]

Increase in TR severity is associated with **worse prognosis**[5]

Mortality rate for patients with severe TR: [5]



"Severe TR has often been undertreated,[4] and the tricuspid valve has received less attention than other heart valves. However, recent advances in transcatheter tricuspid valve interventions and evidence from the TRILUMINATE pivotal randomised controlled trial (RCT; NCT03904147; outlined in *TMTT Today* issue 10)[8] have ignited interest in the tricuspid valve. The community that cares for patients with HF is beginning to understand more about this valve and the clinical implications of TR. However, healthcare professionals are waiting for guideline endorsement of transcatheter tricuspid valve interventions – based on strong evidence – before referring their patients.

TMTT Today issue 10

What are the challenges when treating patients with TR?

1) Complex pathophysiology

There are many reasons why secondary TR develops. These include pulmonary hypertension, left-sided heart disease and atrial fibrillation.[10] Around 90% of patients have severe secondary TR,[11] and, for appropriate treatment, we need to identify the underlying cause.[9] For example, an overlap exists between HF syndromes and severe TR (Figure 1).[9,10] In patients with both an HF syndrome and TR, I suggest treating the HF syndrome first, before considering whether the patient requires tricuspid valve intervention. Often, if you treat the left side of the heart effectively, the TR reduces over time,[12] so a tricuspid valve intervention may be unnecessary. However, some patients will still have significant residual TR despite left-sided (mitral) valve interventions;[13] these patients are candidates for tricuspid valve intervention.

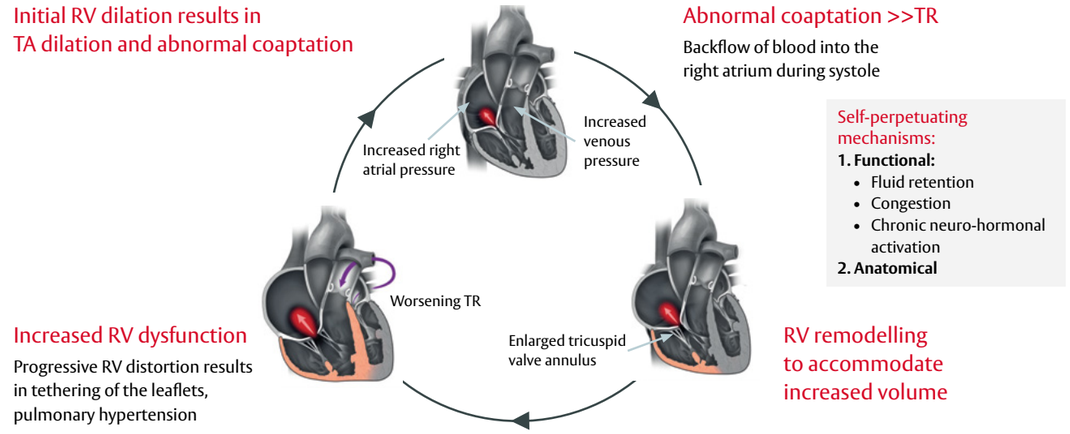


Figure 1. The vicious cycle of TR and right ventricle (RV) remodelling.

An HF syndrome can lead to changes in the heart structure and pulmonary circulation that can lead to severe TR. On the other hand, progressive TR and subsequent RV remodelling can lead to an HF syndrome.[10]

RV, right ventricle; TA, tricuspid annulus; TR, tricuspid regurgitation.
Adapted from Latib *et al*. 2018.[14]

2) Late referral

By the time many patients are referred to our centre for evaluation, their severe TR has resulted in damage to other organs, such as the liver or kidneys (Figure 2). Previous studies have shown that real-world patients have a pre-intervention HF hospitalisation (HFH) rate of around 1.2 HFH/patient-year.[15] In addition, almost 80% of them have kidney disease,[15] and around 45% have liver disease.[16] The right side of their heart is often in poor condition, and the patients are too weak to undergo surgical intervention. This scenario is in contrast with the patient cohort participating in the TRILUMINATE pivotal RCT, where only 25.1% of patients had been hospitalised for HF in the preceding year, 35.4% had kidney disease and less than 10% had liver disease,[8] as outlined in *TMTT Today* issue 10.

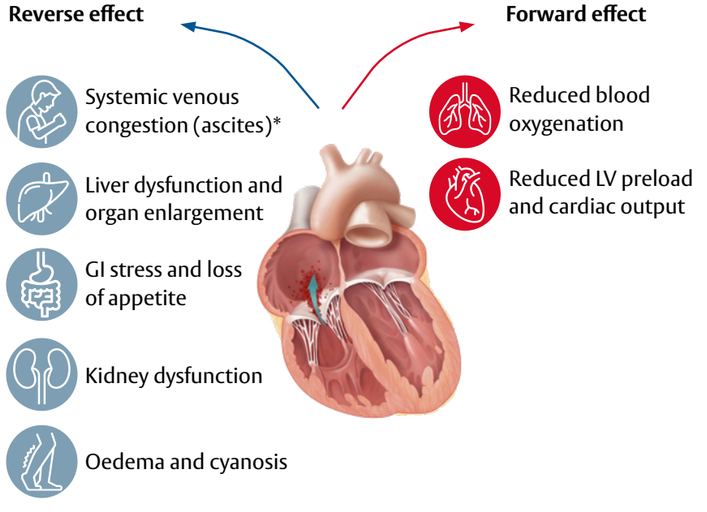


Figure 2. The impact of significant TR and the relevance of the right heart in the circulatory system.[17–21]

*Moderate-to-severe TR is one of the key predictors of congestion at discharge in patients with acute HF.[19]
GI, gastrointestinal; HF, heart failure; LV, left ventricle; TR, tricuspid regurgitation.

What are the solutions to these challenges?

An awareness programme is part of the solution.[22] We need to educate the wide range of healthcare professionals who look after these patients – from electrophysiologists to geriatricians to respiratory physicians – so they better understand the importance of early referral to appropriate treatment for tricuspid valve disease. But, of course, beneficial treatments supported by a physicians' experience and meaningful evidence are crucial to convincing our colleagues to refer their patients.

> Medical therapy alone shows little benefit in terms of long-term prognosis for patients with significant TR.[23]
>
> **Dr Ali Vazir**

Medical therapy alone shows little benefit in terms of long-term prognosis for patients with significant TR.[23] It can improve symptoms for a period of time,[4] but TR, like most valve lesions, is a mechanical problem that requires a mechanical intervention to try to correct the problem.

Various tricuspid valve interventions are available, including surgery.[24] However, by the time many patients present to centres that perform tricuspid valve surgery, they are considered high risk for surgery – with a mortality risk of 8.8%[11] – because of advanced age and comorbidities. The TRI-SCORE system, published by Dreyfus *et al*., can help us to identify these high-risk patients with isolated TR.[25] Being able to offer at least some of them an alternative to surgery, in the form of a transcatheter tricuspid valve intervention, is fantastic. Thanks to the wide availability of devices such as the PASCAL Precision system, tricuspid transcatheter edge-to-edge repair (T-TEER) is currently the most common transcatheter tricuspid therapy.[26] Indeed, the PASCAL platform recently demonstrated good safety and efficacy for the treatment of TR in a real-world population (see *TMTT Today* issue 10).[27]

However, not all patients are suitable for T-TEER (for example, those with a wide leaflet gap),[26] so I am excited that we now have another transcatheter option: the Edwards EVOQUE tricuspid valve replacement system. I am particularly impressed by the 6-month data on the EVOQUE system from the TRISCEND II pivotal trial, where EVOQUE valve implantation plus optimal medical therapy (OMT) was compared with OMT alone in the first 150 randomised and treated patients with at least severe TR (see page 12 for a summary of the results). The EVOQUE system significantly reduced TR: 93.8% of patients treated with the EVOQUE system and OMT had mild or less TR at 6 months.* This reduction in TR translated into improved symptoms and, crucially, quality of life for patients.[1] So far, we have achieved similar results with EVOQUE valves implanted at our centre.

For many patients, it is quality of life, rather than length of life, that really matters.[28] Obviously, this is a very personal preference, but, nevertheless, data suggest that better quality of life is associated with improved survival,[28] so the two are not mutually exclusive. I'm pleased to see that most HF and interventional studies now use the Kansas City Cardiomyopathy Questionnaire (KCCQ), together with New York Heart Association (NYHA) functional class, to demonstrate that interventions really do improve people's day-to-day living. In my opinion, the hope of a better quality of life motivates patients to seek treatment.

> I am particularly impressed by the 6-month data on the EVOQUE system from the TRISCEND II pivotal trial.
>
> **Dr Ali Vazir**

As we wait for more data, I am confident that we will see stronger support for transcatheter valve intervention within the guidelines and the community. This, combined with awareness programmes, should encourage earlier referral and treatment of patients with severe TR and, ultimately, lead to more patients benefitting from an improved quality of life.

*In a paired analysis of the first 150 patients in the TRISCEND II trial, EVOQUE + OMT patients (n=81).

EVOQUE Tricuspid Valve Replacement System

Development of the world's first transfemoral tricuspid valve replacement system*

The EVOQUE valve, developed by Edwards Lifesciences, is the first-of-its kind TTVR system.* Severe TR is largely undertreated,† and patients with this condition have limited medical treatment options.[4] Here, Matt Becerra explains the driving force behind the development of the EVOQUE valve and describes how the key components have been carefully designed for anatomical compatibility with the tricuspid valve.

Matt Becerra
Vice President, Research and Development, Edwards Lifesciences

Matt Becerra is a Vice President of Research and Development at Edwards Lifesciences. He is responsible for developing new technologies in transcatheter mitral and tricuspid therapies, including the EVOQUE tricuspid valve replacement system.

A handful of us with backgrounds in tricuspid valve therapies knew there was a large unmet need in the treatment of TR.

Matt Becerra

Edwards has been investing in the development of a portfolio of repair and replacement therapy options designed to treat mitral and tricuspid valve disease. On the repair side, we have the PASCAL Precision system for treating mitral and tricuspid regurgitation; however, for a number of years, our replacement programme focused only on the mitral side of the heart. Therefore, back in 2018, a small but passionate group within product development at Edwards Lifesciences began investigating whether the technology used in transcatheter mitral valve replacement could be applied to tricuspid valve replacement. Looking at the technology – the delivery system, imaging, valve frame design – we believed we had all the building blocks we needed to help the many patients with at least moderate-to-severe TR in need of additional treatment options.[4] However, with no prior tricuspid valve replacement precedent to guide us, the initial development heavily relied on our internal expertise. First, we worked on redesigning and reconfiguring existing delivery system technology to create a transcatheter valve system that could treat patients with TR. We also worked closely with physicians in the field to develop the procedure for tricuspid valve replacement. When the time came to perform the stress test on the valve, our usual machines did not have the settings required to simulate a tricuspid valve, further emphasising the innovation behind this valve. After all this hard work, we were delighted to introduce the EVOQUE tricuspid valve replacement system to the market (Figure 3).

Through collaboration with physicians and finding the right patients, we have now built the platform and the exciting device that we have today.

Matt Becerra

*First-of-its kind device commercially available (in the EU).
†Based on US data.

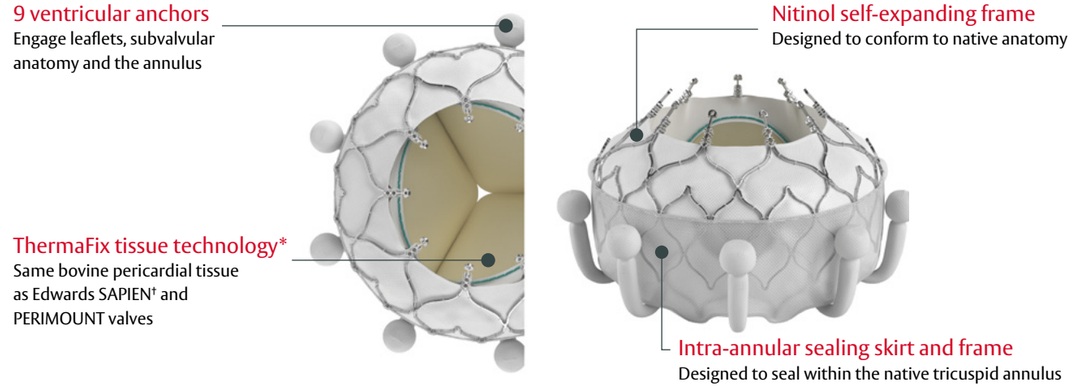


Figure 3. The EVOQUE tricuspid valve.

*No clinical data are available that evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients.
†Excluding Edwards SAPIEN 3 Ultra RESILIA valve.

The EVOQUE valve has four key design features (shown in Figure 3). The nitinol self-expanding frame comprises an inner structural frame, to which the leaflets and anchors are attached, and an outer frame, which is softer and designed to conform to the native valve anatomy. The inner frame diameter is fixed with a 28 mm valve design, whereas the outer frame varies to produce three different valve sizes (44, 48 and 52 mm), enabling treatment of a wide range of tricuspid anatomies.[29]

One of the key design decisions was to have one frame that is stronger for structure, and another one softer for conformability, which allows us to scale this valve design to treat more patients.

Matt Becerra

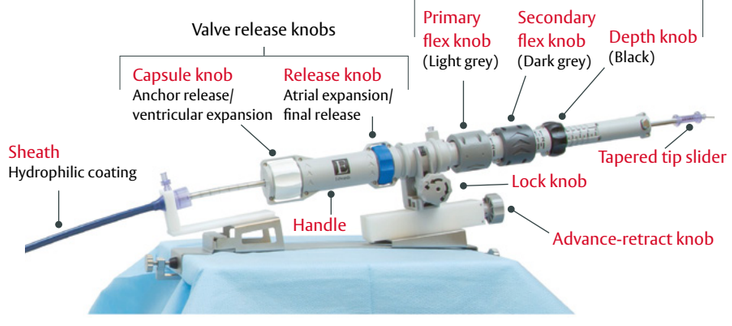


Figure 4. The EVOQUE valve delivery system.

All three valve sizes crimp down into the same low profile (28F outer diameter) delivery system (Figure 4). Tricuspid valve leaflet anatomy varies considerably; fewer than 55% of patients have the classic three-leaflet conformation.[30] Therefore, an important feature of the delivery system is its ability to manoeuvre in three different planes, including a unique depth feature that allows for controlled positioning and orientation towards and across the tricuspid valve (Figure 5A). Once the delivery system has accessed the tricuspid valve and has been correctly positioned, the outer capsule can be retracted until the ventricular anchors are exposed to engage with the native leaflet anatomy (Figure 5B). The EVOQUE valve is then deployed by allowing it to expand and gradually releasing the system (Figure 5C).

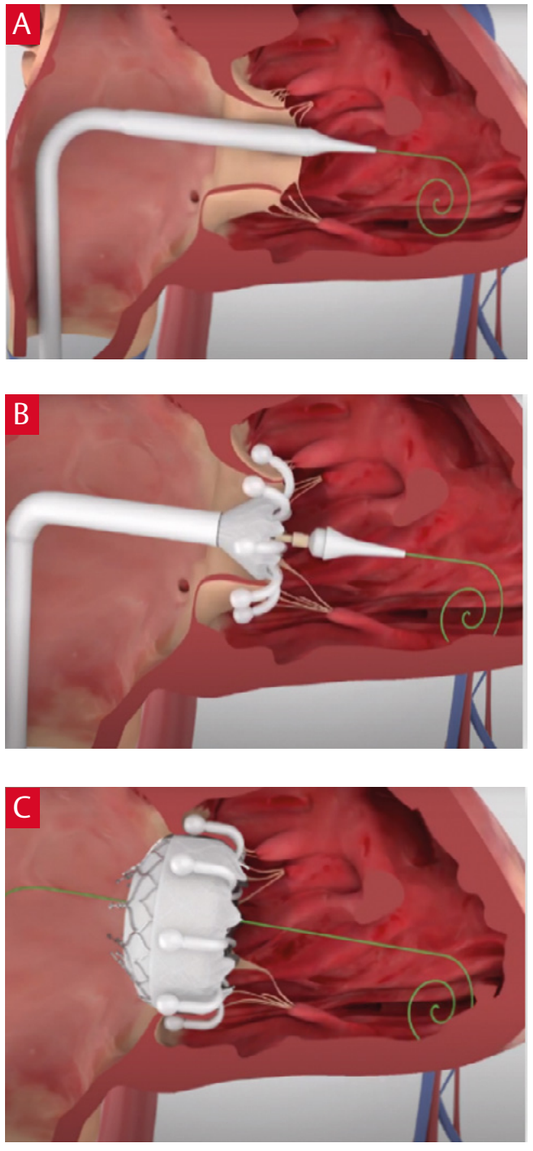


Figure 5. Access (A), position (B), and deployment (C) of the EVOQUE valve.

Conclusion

The EVOQUE tricuspid valve replacement system has been designed with TR patients in mind, with the intention for a controlled and reproducible transcatheter procedure optimised for the tricuspid anatomy. With over 1,000 patients treated with the EVOQUE valve,* Edwards is pleased to contribute an additional treatment option for patients with TR. The safety and performance of the EVOQUE system in patients with symptomatic, moderate or greater TR is being evaluated in the TRISCEND study (NCT04221490). Two-year outcomes confirm the safety and performance of the EVOQUE system, along with meaningful and sustained improvement in clinical, functional and quality-of-life outcomes (see page 16).[2] In addition, the TRISCEND II pivotal trial (NCT04482062) evaluating the safety and effectiveness of the EVOQUE system with OMT compared with OMT alone in patients with at least severe TR demonstrated, in the first 150 patients, an acceptable 30-day safety profile, and clinically meaningful improvements in functional status and quality of life at 6 months (see page 12).[1]

The EVOQUE tricuspid valve is helping many patients. We will continue to learn more over the coming years so that we can further innovate and improve the treatment of patients with TR.

Matt Becerra

*Data on file, including patients from compassionate use and those enrolled in the TRISCEND study and TRISCEND II pivotal clinical trial.

EVOQUE Transcatheter Tricuspid Valve Replacement System

Outcomes from the TRISCEND II pivotal trial and TRISCEND study

Medical professionals are increasingly recognising that severe TR leads to debilitating symptoms and poor outcomes.[4,31] More than 90% of patients with clinically relevant TR are currently not treated[32] as they have limited treatment options;[4] the surgical mortality is high* and medications may treat symptoms but not the tricuspid regurgitation.[4,33] Here, Professor Philipp Lurz discusses early data from the TRISCEND II pivotal trial comparing the EVOQUE transcatheter tricuspid valve replacement system and OMT with OMT alone in patients with at least severe TR.[31] In addition, Professor Jörg Hausleiter highlights the 2-year data from the TRISCEND study of the EVOQUE system.[2]

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 Principal Investigator of the TRISCEND II pivotal trial and the MiCLASP registry and an investigator in the CLASP IID/IIF RCT, as well as in multiple trials for other therapies.

Data related to the first 150 patients randomised and treated in the TRISCEND II pivotal trial

The TRISCEND II pivotal trial (NCT04482062) is a prospective, multicentre randomised controlled pivotal trial evaluating the safety and effectiveness of the EVOQUE system with OMT compared with OMT alone in patients with severe or greater TR.[34]

The TRISCEND II pivotal trial has a two-part study design based on the FDA breakthrough designation, with 30-day safety and 6-month effectiveness assessed in the first 150 patients randomised and treated, followed by the analysis of the full cohort. In both phases, 30-day safety will be assessed by a composite major adverse event (MAE) rate, with effectiveness endpoints at 6 months of TR grade reduction to moderate or less and a hierarchical composite of KCCQ score, NYHA functional class and 6-minute walk distance (6MWD).

*Overall operative mortality was 7.3% in a retrospective analysis of 6,507 adult patients who underwent isolated tricuspid valve surgery.[35]

At 1 year, the composite primary endpoint of all-cause mortality, right ventricular assist device implant or heart transplant, tricuspid valve surgery or intervention, annualised HFH, KCCQ score, NYHA functional class and 6MWD will be assessed in the full cohort of 392 patients. Inclusion and exclusion criteria are listed in Table 1.[1] In this article, we report the results for the first 150 patients at 6 months.

Table 1. Inclusion and exclusion criteria for the TRISCEND II pivotal trial.

Inclusion criteria	Exclusion criteria
• Age ≥18 years • Signs/symptoms of TR or prior HFH • Receiving OMT at the time of TR assessment • Functional and/or degenerative TR graded as at least severe by TTE • Local Heart Team determines patient is appropriate for tricuspid valve replacement	• Anatomy precluding proper implantation • Life expectancy <365 days • LVEF <25% • Evidence of severe right ventricular dysfunction • Any of the following pulmonary pressure parameters: – PASP >60 mmHg by echo Doppler – PASP >70 mmHg by RHC – PVR >5 Wood units by RHC • Previous tricuspid surgery or intervention • Trans-tricuspid pacemaker or defibrillator lead – Implanted in RV within last 90 days – Pacemaker dependent without alternative option – Secondary prevention ICD with therapy delivered • Severe aortic, mitral and/or pulmonic valve stenosis and/or regurgitation • Unable to walk ≥100 m in 6MW test

6MW, 6-minute walk; HFH, heart failure hospitalisation; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; OMT, optimal medical therapy; PASP, pulmonary artery systolic pressure; PVR, pulmonary vascular resistance; RHC, right heart catheterisation; RV, right ventricle; TR, tricuspid regurgitation; TTE, transthoracic echocardiogram.
Adapted from Lurz P. 2023.[1]

The first 150 patients were predominantly female (82.3% in the EVOQUE + OMT group and 75.9% in the OMT group) with a mean age of 79.4 ± 7.7 years in the EVOQUE + OMT group and 78.2 ± 8.3 years in the OMT group. They were highly symptomatic, with 79.2% of patients in the EVOQUE + OMT group and 70.4% in the OMT group in NYHA functional class III/IV. Surgical risk was high, with mean Society of Thoracic Surgeons (STS) scores of 10.2 ± 5.7% in the EVOQUE + OMT group and 9.4 ± 4.5% in the OMT group.[1]

Key procedural characteristics for patients undergoing EVOQUE valve implantation[1]

95.8% of patients were implanted with study valve*

90.6% of patients discharged home

4.0 days in hospital†

*Four procedures aborted due to challenging imaging or anatomy.
†Median.

Safety outcomes

The TRISCEND II pivotal trial met the primary safety endpoint at 30 days, with a composite MAE rate of 27.4% in the EVOQUE + OMT group (Table 2).[1]

Table 2. Primary safety endpoint at 30 days: composite MAE rate.

CEC-adjudicated MAEs	EVOQUE + OMT (N=95) % (n)
Cardiovascular mortality	3.2 (3)
Myocardial infarction	1.1 (1)
Stroke	0.0 (0)
New need for renal replacement therapy	1.1 (1)
Severe bleeding[a]	10.5 (10)
Non-elective tricuspid valve re-intervention	0.0 (0)
Major access site and vascular complication	3.2 (3)
Major cardiac structural complication	2.1 (2)
Device-related pulmonary embolism	1.1 (1)
Arrhythmia and conduction disorder requiring permanent pacing	14.7 (14)
Composite MAE rate[b]	**27.4 (26)**

[a]Severe bleeding as defined by the Mitral Valve Academic Research Consortium. [b]Patients may have had more than one event.
CEC, clinical events committee; MAE, major adverse event; OMT, optimal medical therapy.

Adapted from Lurz P. 2023.[1]

The MAE rate was lower than what would have been expected from isolated tricuspid valve replacement surgery. So, in other words, it was safer than surgery.

Professor Philipp Lurz

TR reduction

TTVR with the EVOQUE valve effectively eliminated TR in the majority of patients, despite the presence of massive or torrential TR in more than 50% of the patient population at baseline. In the analysis of the first 150 patients, the TRISCEND II pivotal trial with the EVOQUE system + OMT demonstrated significant TR reduction to moderate or less in 98.8% of patients, with reduction to none/trace in 77.8% of patients at 6 months (p<0.001; Figure 6).[1] The degree of TR reduction is related to all-cause mortality and HFH,[36] explains Professor Lurz, so minimising residual TR – as seen here[1] – is important.

Tricuspid valve replacement has the potential to eliminate TR.

Professor Philipp Lurz

Functional and quality-of-life outcomes in the EVOQUE + OMT patients

In the analysis of the first 150 patients, the TRISCEND II pivotal trial met the second co-primary effectiveness composite endpoint consisting of clinically meaningful functional and quality-of-life outcomes at 6 months (Figure 7).[1]

Overall, these results in the first 150 patients from the TRISCEND II pivotal trial provide early evidence of EVOQUE system safety and effectiveness for patients with at least severe TR. 93.8% of EVOQUE + OMT patients achieved mild or less TR at 6 months,* with clinically meaningful improvements in functional status and quality of life at 6 months.[1] Edwards expects to present the full cohort of 392 TRISCEND II pivotal trial patients at TCT 2024.

*In a paired analysis of the first 150 patients in the TRISCEND II trial, EVOQUE + OMT patients (n=81).

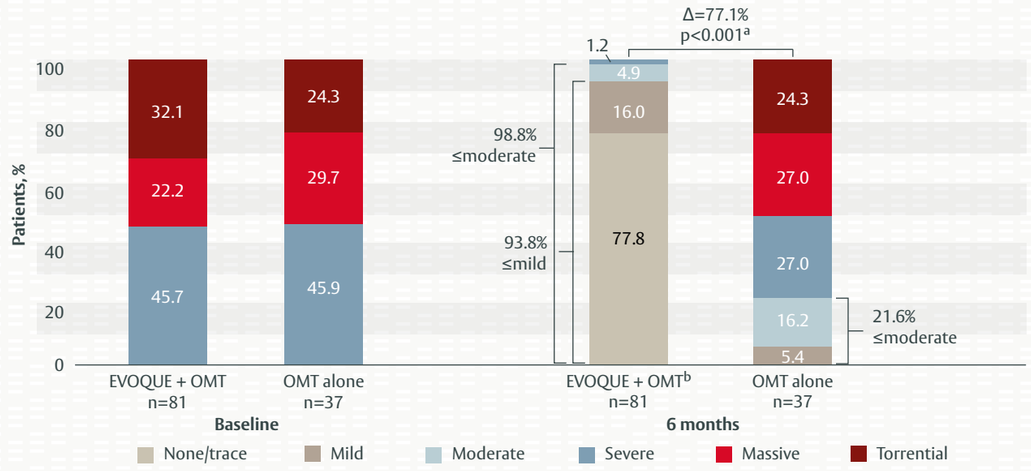


Figure 6. Significant reductions in TR grade with the EVOQUE system at 6 months in the TRISCEND II pivotal trial.

Graphs show paired data.
[a]Pooled Z-Test with continuity correction to be compared with one-sided significance level of 0.025.
[b]Cumulative valvular TR rates shown above. Over 85% of patients in the EVOQUE + OMT group had none/trace PVL at 6 months. Mild PVL was reported to be 8.8% at 6 months, with moderate PVL reported to be 2.5% at 6 months. No patients were reported to have severe or greater PVL at 6 months.
OMT, optimal medical therapy; PVL, paravalvular leak; TR, tricuspid regurgitation.
Adapted from Lurz P. 2023.[1]

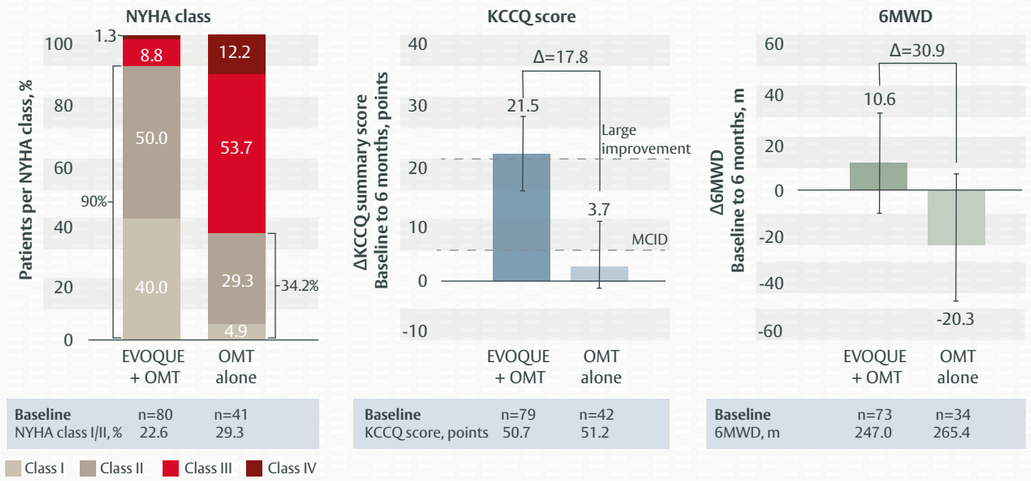


Figure 7. Clinically meaningful functional and quality-of-life improvements with the EVOQUE system at 6 months in the TRISCEND II pivotal trial.

Graphs show paired analysis. Error bars show 95% CI.
6MWD, six-minute walk distance; CI, confidence interval; KCCQ, Kansas City Cardiomyopathy Questionnaire; MCID, minimal clinically important difference; NYHA, New York Heart Association; OMT, optimal medical therapy.
Adapted from Lurz P. 2023.[1]

Professor Dr med. Jörg Hausleiter

Medical Clinic and Polyclinic I, Ludwig-Maximilians University (LMU), Munich,Germany

Professor Jörg Hausleiter is Professor of Medicine and the Deputy Clinic Director at LMU in Munich. His primary research interest is the development of new percutaneous treatments for patients with coronary and valvular diseases. Professor Hausleiter has been Principal Investigator in several clinical trials, including TRICI-HF, MiCLASP, TRILUMINATE, CLASP IID/IIF and PASTE.

Compared with surgery, TTVR may be a low-risk procedure we can offer to patients.

Professor Jörg Hausleiter

Two-year outcomes from the TRISCEND study

The TRISCEND study (NCT04221490) is a prospective, multicentre, single-arm study evaluating the safety and performance of the EVOQUE system in patients with at least moderate functional or degenerative TR who are symptomatic despite medical therapy or have previously been hospitalised for HF due to TR.[2] The safety endpoint is a composite of MAEs at 30 days, and the echocardiographic endpoint is TR grade reduction at discharge. Annual follow-up appointments to 5 years will assess clinical endpoints of all cause mortality, HFH and non-elective tricuspid valve reintervention. Functional endpoints assessed annually are NYHA functional class, 6MWD and KCCQ score.[2]

Patients were predominantly female (71.2%) with an average age of 78.6 ± 7.4 years. They were highly symptomatic, with 73.1% in NYHA functional class III/IV, and had a high rate of comorbidities, including atrial fibrillation in 90.4% of patients. Almost a third (32.7%) had a pacemaker or implantable cardioverter defibrillator. Surgical risk was high, with a mean STS score of 10.0 ± 5.5%.[2]

Key procedural characteristics[2]

94.7%
device success rate*

90.3%
of patients discharged home

4.0
days in hospital†

*Device deployed and delivery system retrieved as intended by patient's exit from cardiac catheterisation laboratory. Data from patients with available assessments.
†Median.

Safety outcomes

Isolated surgical tricuspid valve replacement has an overall mortality risk of around 10%.[37] For TTVR, the TRISCEND study demonstrated 30-day cardiovascular mortality of 2.5%. Favourable survival (82.5%) and freedom from HFH (84.8%) were reported at 2 years, with a 78.2% reduction in annualised HFH 2 years post procedure *versus* 1 year pre procedure.[2] The composite MAE rate at 2 years was 38.3%. The most common MAE was severe bleeding* (16.2% at 30 days, 30.5% at 2 years),[2] which Professor Hausleiter explains may be because tricuspid valve replacement tends to require continuous anticoagulation, and also because the patients had a high comorbidity burden.

*Defined per Mitral Valve Academic Research Consortium.

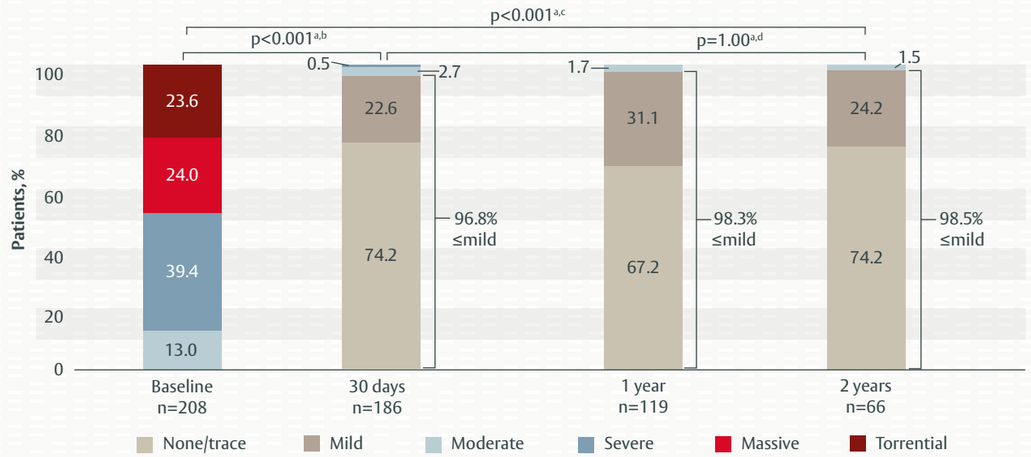


Figure 8. TR severity before and after tricuspid valve replacement with the EVOQUE valve in the TRISCEND study.*

Graph shows unpaired analysis.
*Over 83% of patients had none/trace PVL, 10–14% had mild PVL, 0–4% had moderate PVL and no patients had severe or greater PVL through 2 years' follow-up.
[a]Wilcoxon signed-rank test for moderate or less TR, paired analysis. [b]n=186; baseline=12.4%; 30 days=99.5%. [c]n=66; baseline=12.1%; 2 years=100%.
[d]n=66; 30 days=100%; 2 years=100%.
PVL, paravalvular leak; TR, tricuspid regurgitation.
Adapted from Makkar R. 2023.[2]

TR reduction

A significant and sustained reduction in TR was seen at 2 years: 98.5% of patients had mild or less TR, and 74.2% had no or trace TR (Figure 8). TR was reduced by at least one grade in all patients, by at least two grades in 98.5% of patients and by at least three grades in 78.8% of patients. Post-procedural tricuspid valve gradients were low, with a mean of 3.2 mmHg at 2 years. Additionally, there was echocardiographic evidence of favourable right heart remodelling, including significant decreases in right ventricular end-diastolic mid diameter (−10.3 mm) and right ventricular fractional area (−8.3%) *versus* baseline (p<0.001*).[2]

Clinical, functional and quality-of-life outcomes

One of the most important parts of this study, according to Professor Hausleiter, are the significant and sustained improvements in functional and quality-of-life outcomes (Figure 9). At 2 years, 86.5% of patients were in NYHA functional class I/II compared with 26.9% at baseline (p<0.001), and 58% of patients reported an improvement in KCCQ score of at least 20 points,[2] which is considered a large-to-very large clinical change.[38]

The percentage of patients in NYHA functional class I/II is high, and this goes along with improved quality of life and with an improvement in 6MWD of nearly 20% compared with baseline.

Professor Jörg Hausleiter

Overall, the TRISCEND study continues to demonstrate safety outcomes for the EVOQUE system, with a sustained reduction in TR, echocardiographic evidence of favourable right heart remodelling, and functional and symptomatic improvements for patients at 2 years.[2]

*Student's t-test.

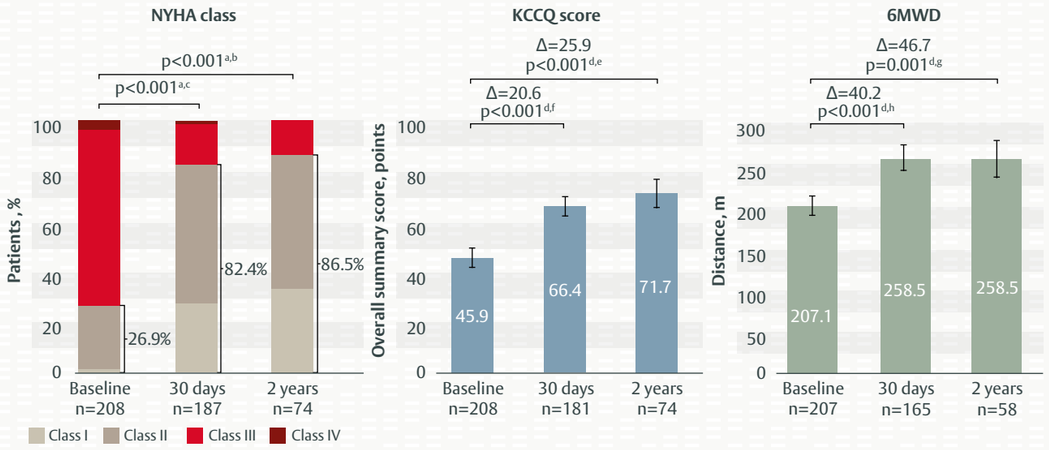


Figure 9. Significant and sustained clinical, functional and quality-of-life outcomes to 2 years in the TRISCEND study.

Graphs show unpaired analysis. Error bars show 95% CI. [a]Wilcoxon Signed Rank test for NYHA functional class I/II, paired analysis. [b]n=74; baseline=24%; 2 years=86%. [c]n=187; baseline=28%; 30 days=82%. [d]Student's t-test, paired analysis. [e]n=74; baseline=45.8 points; 2 years=71.7 points. [f]n=181; baseline=45.8 points; 30 days=66.4 points. [g]n=58; baseline=211.8 metres; 2 years=258.5 metres. [h]n=165; baseline=218.3 metres; 30 days=258.5 metres.
6MWD, six-minute walk distance; CI, confidence interval; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association.
Adapted from Makkar R. 2023.[2]

Conclusion

Together, the data from the TRISCEND study and TRISCEND II pivotal trial show that the EVOQUE system is a promising option for patients with symptomatic severe TR. Its strong safety profile combined with significant, sustained reduction in TR severity and meaningful functional and quality of-life outcomes[1,2] demonstrate that the valve has the opportunity to improve quality of life* for patients with this undertreated disease.[4,39†]

*Based on analysis of the first 150 patients on 6-month KCCQ results in the EVOQUE + OMT group of the TRISCEND II pivotal trial (n=79).
†Based on US data.

Tips and tricks for your patient with TR

The first UK implantation of the EVOQUE valve

Case study 1

Dr Jim Newton is a consultant cardiologist at John Radcliffe Hospital in Oxford, specialising in echocardiography and valvular heart disease. He is involved in assessing patients before, during and after structural heart procedures, bringing expertise in all aspects of procedural imaging.

Dr Sam Dawkins is a consultant cardiologist at John Radcliffe Hospital in Oxford. He specialises in general cardiology, interventional cardiology and structural intervention, including TEER.

The patient

A 79-year-old woman was referred to us in November 2023 with severe HF. She experienced breathlessness on exertion and had recently been hospitalised for extreme fluid retention. She was keen to be active and independent but was profoundly limited by these unpleasant symptoms.

The challenge

The patient's tricuspid valve had a type I (three-leaflet) configuration with tethering, leading to massive TR with an extensive regurgitant jet all the way along the coaptation line (Figure 10). Given the large coaptation gap, we anticipated that T-TEER might reduce the TR by a grade or two, but it was unlikely to achieve a reduction to moderate or less. Therefore, we hoped the patient would be suitable for TTVR with the EVOQUE system.

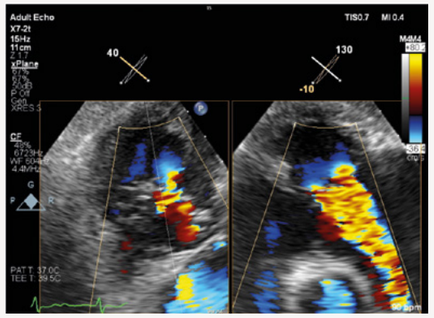


Figure 10. Baseline TOE confirming a type I tricuspid valve and massive TR, with a vena contracta of 15 mm.

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

The approach

We had never implanted an EVOQUE valve before, so we ensured that we prepared well.

Screening

We had already scheduled a screening day for five other patients who had previously been deemed unsuitable for TEER but appeared potentially suitable for the EVOQUE system based on their recent transthoracic echocardiograms. After discussing this particular patient's case at our multidisciplinary team meeting, we decided that her severe symptoms and presentation warranted expedited screening for suitability for the EVOQUE system. We invited her to join the screening day, where all patients underwent transoesophageal echocardiography (TOE) and computed tomography (CT). We then uploaded their images to the Edwards platform, and, within 24 hours, three patients were deemed suitable for TTVR with the EVOQUE system, including the case we present here.

Training

We underwent hands-on, simulator-based training with Edwards, which really helped us to understand the device and the procedure. We then had several meetings with our cath lab team to describe the procedure, share our knowledge and answer any questions. On the morning of this case, we had a detailed briefing meeting to clarify the procedural steps, the timeline and everyone's roles. We also had on-site support from the Edwards team, if needed.

The procedure

The technical and imaging aspects of the procedure were straightforward. We found the EVOQUE system to be intuitive to use, and its unique ability to manoeuvre in three planes independently allowed for extreme precision. Once we had the valve correctly oriented (Figure 11), we were confident of a great outcome – in our experience, TTVR with the EVOQUE system is predictable.

We were delighted with the result. Within about 90 minutes, the patient went from having massive TR to none at all (Figure 12) – remarkable! Her fluid retention and breathlessness are much improved since the procedure, and she is back to leading a normal life again.

Key tips

1. Make use of the training, experience and advice from the Edwards team – they are on hand to support you to achieve the best results with the EVOQUE system.
2. Optimise your cath lab layout so the interventional cardiologist and echocardiographer are facing each other, facilitating effective communication and collaboration. Additionally, establish a shared terminology for procedural descriptions to ensure rapid understanding between team members.
3. Consider implementing regular patient screening days like we do at our centre, where you bring in a group of patients who are potentially suitable for TTVR for same-day TOE and CT scans. Review the images in your multidisciplinary team meeting and upload them to the Edwards platform. Typically, you can expect a response the next day, enabling you to move forward with procedures.

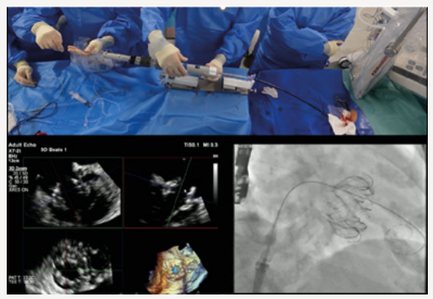


Figure 11. Photograph of the procedure, with echocardiographic and fluoroscopic images of the EVOQUE valve released in position.

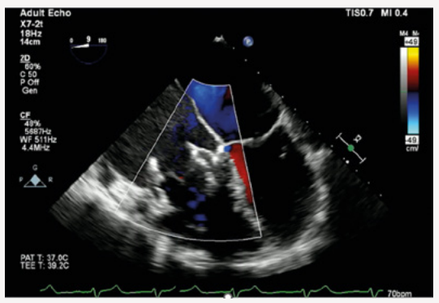


Figure 12. TOE showing the final result, with no TR.

TOE, transoesophageal echocardiography; TR, tricuspid regurgitation.

EVOQUE valve implantation in a young patient with a pacemaker

Case study 2

Dr Konstantinos Spargias is an interventional cardiologist and Director of the Transcatheter Heart Valves department at Hygeia Hospital in Athens, Greece. He has been involved in the PASCAL platform development programme and has participated in most of the related clinical trials (CLASP, MiCLASP, TriCLASP). He specialises in percutaneous valve therapies and has been an investigator in many other clinical trials, including SPACER, RESHAPE-II and the Intrepid pilot study.

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 TEER (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 13). Her referral was delayed because the patient's physician felt treatment options were lacking.

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 14A).

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 14): TR was reduced to none to mild (Figures 14C and 14D), and the patient is feeling so much better.

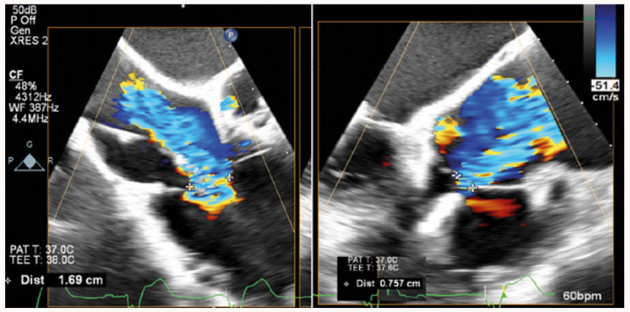
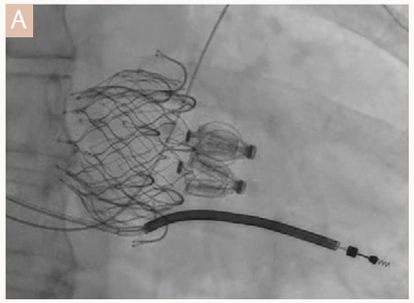
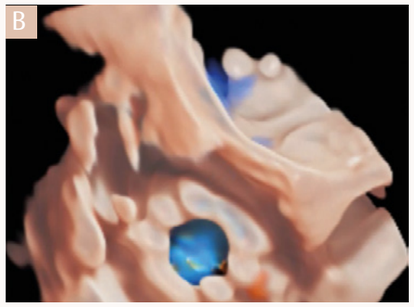
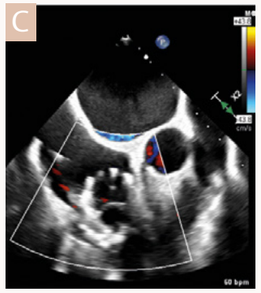


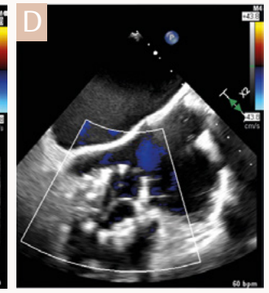
Figure 13. Echocardiography at baseline, with the CRT-D lead visible.

CRT-D, cardiac resynchronisation therapy defibrillator.









> 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**

Figure 14. 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.

CRT-D, cardiac resynchronisation therapy defibrillator.

Key tips

1. 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.
2. Accurate guide-wire 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.
3. 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.

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

Tricuspid transcatheter edge-to-edge repair with the PASCAL Precision System in an elderly patient with comorbidities

Dr Nedy Brambilla is Head of Structural Heart Disease Interventions at the Policlinico San Donato Research Hospital in Milan, Italy. She supervises clinical activity in the cardiology ward and coronary care unit and practical activity in the catheterisation laboratory, including transcatheter aortic valve implantation and TEER.

The patient

An 81-year-old woman with numerous comorbidities, including hypertension, hypothyroidism and atrial fibrillation, for which she had undergone catheter ablation and permanent pacemaker implantation. She presented with exertional dyspnoea (NYHA functional class II/III), and transthoracic echocardiography revealed massive functional TR (Figure 15) with normal right ventricular function, preserved left ventricular ejection fraction, moderate mitral regurgitation and severe biatrial dilation.

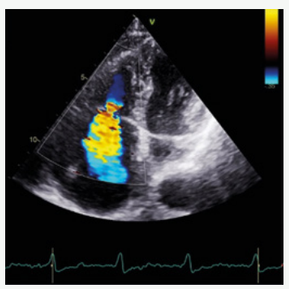


Figure 15. Pre-procedural TTE showing massive TR.

TR, tricuspid regurgitation; TTE, transthoracic echocardiography.

The challenge

The patient was high risk, with a EuroSCORE II of 4% and a TRI-SCORE of 3%. In addition, the TR jet was broad.

The approach

Based on the high risk, the patient was not a suitable candidate for surgical repair. With a growing body of evidence for TEER supporting the safety and efficacy of this treatment in clinical, post-market and real-world settings,[8,27,40,41] the Heart Team decided to treat the patient with T-TEER using the PASCAL Precision system. The system's guide sheath and steerable catheter move independently to each other, enabling manoeuvring within three planes to facilitate navigation and implant positioning (Figure 16).[42,43] To tackle the broad regurgitant jet, we planned to use two adjacent PASCAL Ace implants. The elongation feature of the PASCAL implants is particularly valuable in tricuspid repair as it facilitates manoeuvring in the ventricle and atrium, as well as disengaging from the chordal apparatus when needed.

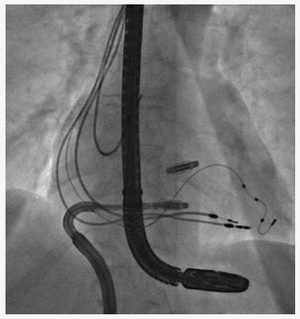


Figure 16. Fluoroscopy showing how the flexibility of the PASCAL Precision system may facilitate implant positioning.

The procedure

The flexibility unique to the PASCAL Precision system made gaining height easy (Figure 16). We deployed two PASCAL Ace implants, the first in an antero-septal position and the second in a postero-septal position (Figure 17). We performed leaflet optimisation to ensure the best possible result. We were extremely happy with the result: TR was reduced to mild (Figure 18), and the patient's symptoms improved immediately at discharge. In the 6 months following the procedure, she has not been hospitalised for right HF.

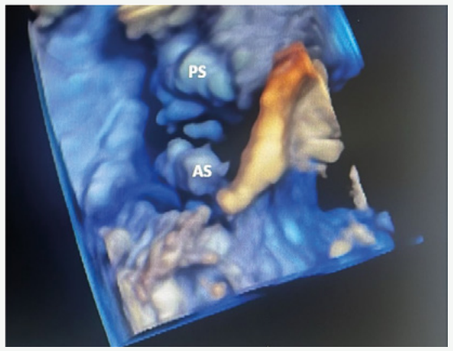


Figure 17. 3D echocardiogram showing the antero-septal and postero-septal positioning of the two PASCAL Ace implants.

AS, antero-septal; PS, postero-septal.

> Severe TR used to be undertreated because the only intervention was surgery, which wasn't an option for patients with comorbidities. Now, thanks to TEER, more patients are being referred and treated.
>
> Dr Nedy Brambilla

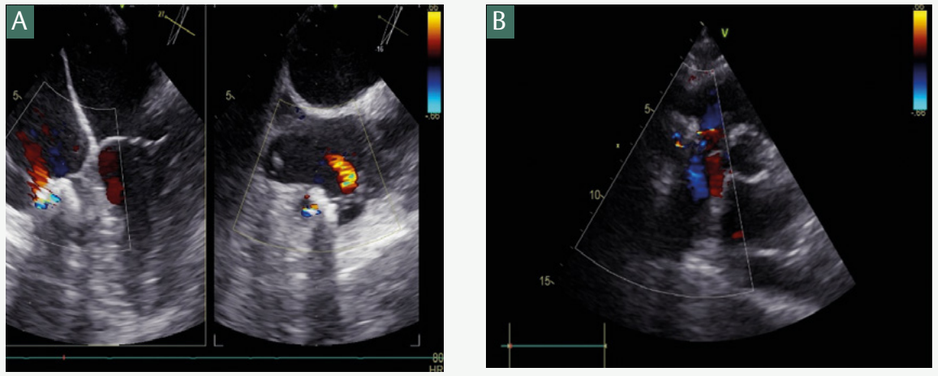


Figure 18. TTE post procedure (A) and at 6-month follow-up (B).

TTE, transthoracic echocardiography.

Key tips

If you are new to using the PASCAL Precision system, start with uncomplicated anatomies. It may take you a few cases to fully understand the system and take advantage of its features. After the initial learning curve, you will be able to treat more challenging anatomies.

Conclusion

Innovating to address unmet healthcare needs is at the heart of everything we do at Edwards. We recognised that a life-threatening condition like symptomatic severe TR deserved a revolutionary approach,[39]* which is why we developed the EVOQUE valve, the world's first TTVR system.† The cases and data presented in this issue demonstrate the valve's potential to significantly reduce – and potentially eliminate – TR.[1,2] ‡

The EVOQUE system, in addition to the PASCAL Precision system, means that we are able to provide a range of much needed treatment options[4] for eligible patients. We look forward to supporting them – and you – on that journey.

*Based on US data.
†First-of-its-kind device commercially available (in the EU).
‡In a paired analysis of the first 150 patients in the TRISCEND II trial, 77.8% of EVOQUE + OMT patients achieved TR reduction to none/trace at 6-month follow-up (n=81).

Ask your questions...

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

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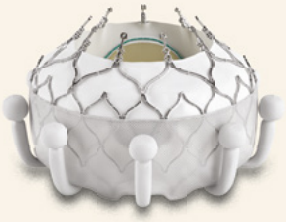

EVOQUE
Tricuspid Valve Replacement System

PASCAL Precision
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