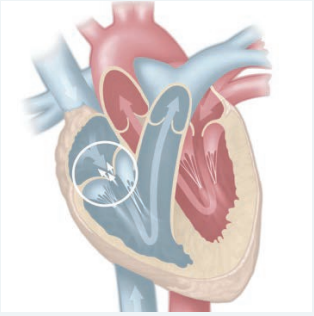
Quality of life improvements that matter to patients with the **EVOQUE Tricuspid Valve Replacement System**[15,17]

EVOQUE TTVR System Overview

Edwards

Severe tricuspid regurgitation (TR) is often an undertreated life-threatening condition[1,2*]

- TR occurs predominantly as a result of left-sided heart disease and increased left atrial pressure[3]
- Left-sided heart disease can lead to pulmonary hypertension, a subsequent rise in right ventricular (RV) pressure, and progressive RV dysfunction and dilatation[3]
- TR can be caused by atrial enlargement secondary to atrial fibrillation[3]



TR can progress in severity[1,8]

Prevalence	**2.6%** of adults aged 65 or older were found to have moderate or greater TR[9§] Over 3 million people in Europe have clinically relevant TR[10]
Severity	**19%** of patients with mild or trivial TR progressed to moderate or severe TR in about 3 years[11†]
Mortality	**>20%** of patients with severe TR are estimated to die within 1 year of diagnosis[12,13]

Medications, such as diuretics, may treat symptoms but not the TR itself, which can continue to progress[1,4]

TR and right heart failure may result in debilitating symptoms and poor outcomes when not adequately treated[1,5]

Progressive right ventricular (RV) dysfunction or right atrial dilatation can lead to the development of right heart failure, which can result in morbidities including:[1,6,7]

- Oedema
- Ascites
- Fatigue
- Dyspnoea

Reducing TR severity may improve patient quality of life[1,8]

*Based on US data. §Based on UK data. †Based on a retrospective echocardiographic analysis of Israeli patients.

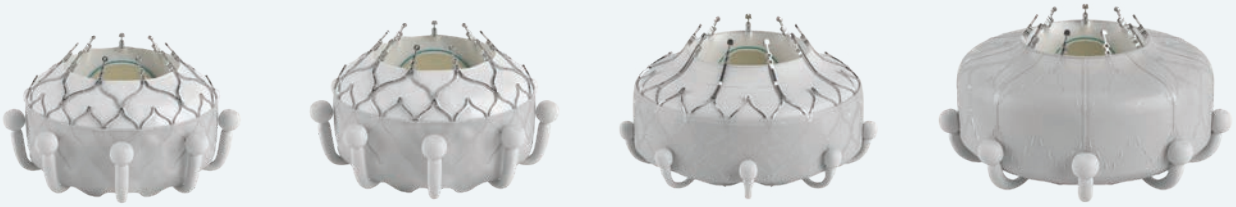
With the EVOQUE tricuspid valve replacement system, you may help Tricuspid Regurgitation (TR) patients return to a life they love.

Learn more about EVOQUE TTVR

The EVOQUE Transcatheter Tricuspid Valve Replacement (TTVR) system is designed to provide a controlled transcatheter procedure and to reduce severe TR.

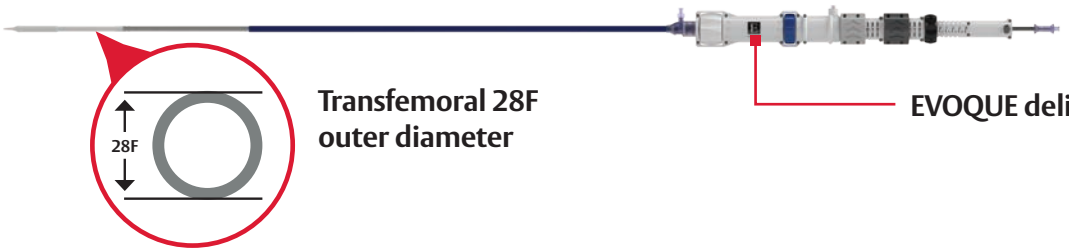
A system designed with your patients in mind

Multiple valve sizes designed to treat a wide range of tricuspid anatomies



44 mm | 48 mm | 52 mm | 56 mm

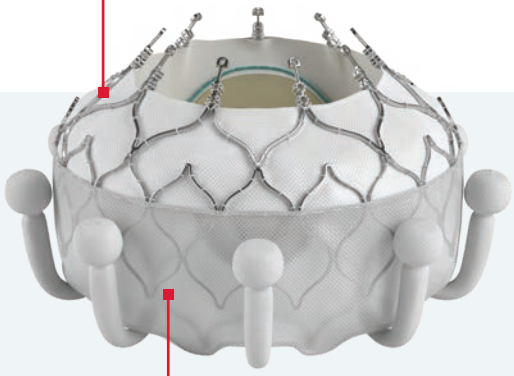
Transfemoral 28F outer diameter delivery system designed for maneuverability



Introducing the EVOQUE valve

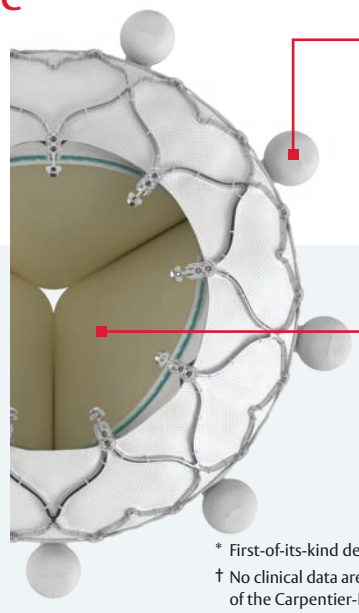
Designed for anatomical compatibility

Self-expanding, shape-memory nitinol frame designed to conform to native valve anatomy



Designed to seal within the native tricuspid annulus

Intra-annular sealing skirt and frame



Designed for a secure transcatheter implantation

Nine ventricular anchors engage leaflets, subvalvular anatomy and the annulus.

ThermaFix tissue technology†

Same bovine pericardial tissue as Edwards SAPIEN and PERIMOUNT valves‡

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

† 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

Clinical Summary:

TTVR Versus Optimal Medical Therapy[15]

THE TRISCEND II PIVOTAL TRIAL

Objectives

The TRISCEND II trial is a prospective, multi-center, randomized pivotal trial evaluating the safety and effectiveness of transcatheter tricuspid valve replacement using the Edwards EVOQUE system with optimal medical therapy compared to optimal medical therapy alone in patients with symptomatic ≥ severe tricupsid regurgitation (TR).

Methods

Patients with
- TR graded as ≥ severe
- Symptomatic despite optimal medical therapy

2:1 Randomized: **N=400**

EVOQUE TTVR n=267

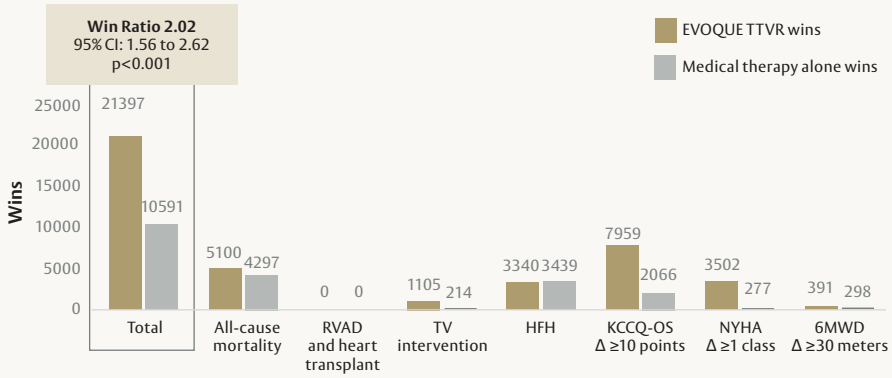
Medical therapy alone n=133

Results

Primary Endpoint

Based on 34447 possible pairs, there were 21397 wins for EVOQUE TTVR, 10591 wins for medical therapy alone, and 2459 ties, resulting in a win ratio of 2.02 (95% CI, 1.56 to 2.62; p<0.001). The primary safety and effectiveness endpoint was met, demonstrating EVOQUE TTVR was superior to medical therapy alone.

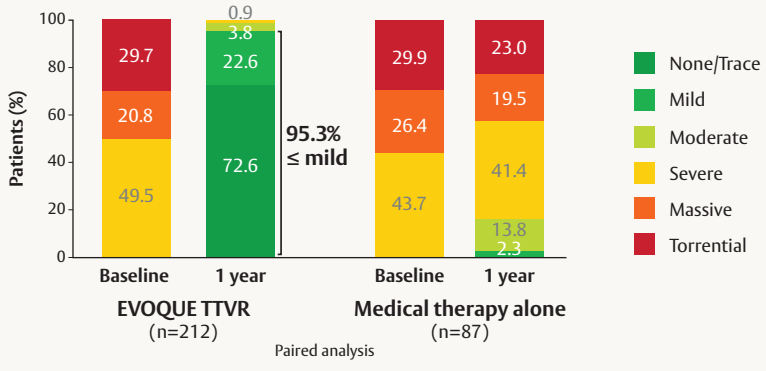
Primary Safety and Effectiveness Composite Endpoint Win Ratio Analysis



Echocardiographic Outcomes

EVOQUE TTVR achieved 95.3% ≤mild TR compared to 2.3% in medical therapy alone. TR was eliminated in 72.6% of patients who received EVOQUE TTVR.

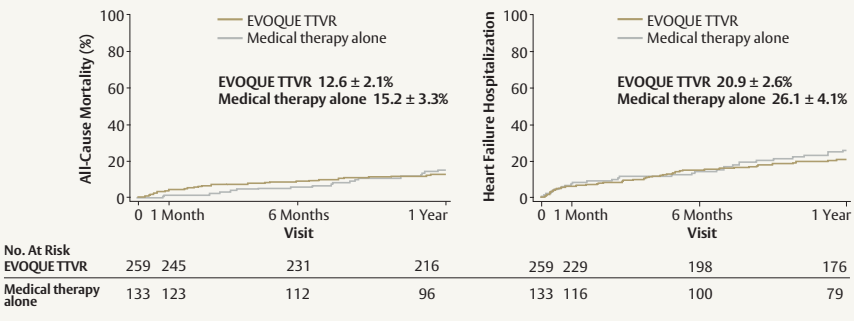
TR Reduction at 1 year



Conclusion

- Patients with severe TR experience significant symptom burden with diminished quality of life.
- TRISCEND II is the first randomized controlled trial studying tricuspid valve replacement compared to medical therapy alone.
- Results from the TRISCEND II trial establish TTVR as an effective therapy with a proven safety profile for patients with symptomatic ≥ severe TR, with consistent TR resolution accompanied by meaningful health status benefits.

Kaplan-Meier All-cause Mortality and HF Hospitalization



Clinical Summary:

Quality of life after TTVR[16]

THE TRISCEND II PIVOTAL TRIAL

Objectives

The TRISCEND II pivotal trial met its primary endpoint, and results have previously been reported. An objective of this study is to compare the health status outcomes of patients with symptomatic ≥ severe tricuspid regurgitation (TR) treated with transcatheter tricuspid valve replacement (TTVR) with the Edwards EVOQUE system plus optimal medical therapy compared to those who received optimal medical therapy alone.

TRISCEND II Trial Design — N=400 randomized (2:1) EVOQUE TTVR vs medical therapy alone

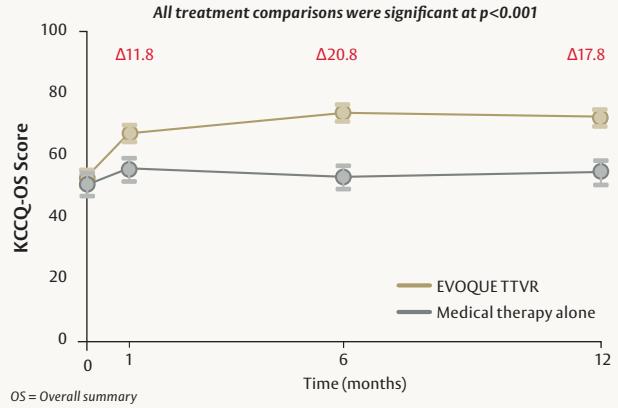
Health Status Assessment — Kansas City Cardiomyopathy Questionnaire (KCCQ) at baseline, 30 days, 6 months, 1 year

Baseline Characteristics* (*mITT (modified intention-to-treat population; n=392)*)

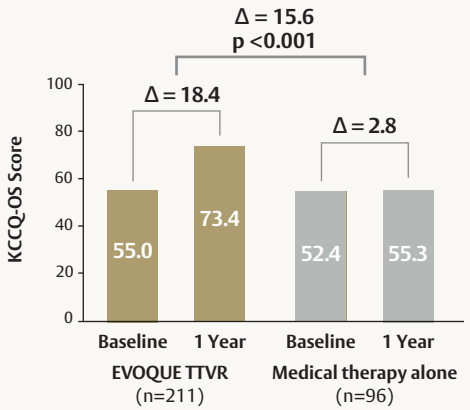
Mean Age	Sex
79.2 years	75.5% female
KCCQ-OS	**TR Grade**
52.1 points	56.1% massive/torrential

Significantly improved KCCQ-OS at 30 days, with further improvements at 6 months that were sustained to 1 year

KCCQ-OS over 1 year

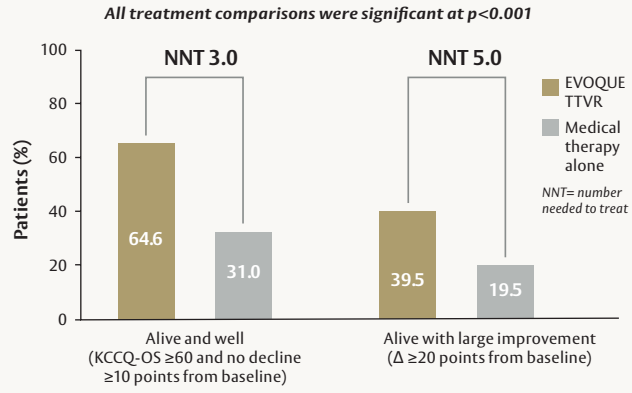


KCCQ-OS Improvement[14]

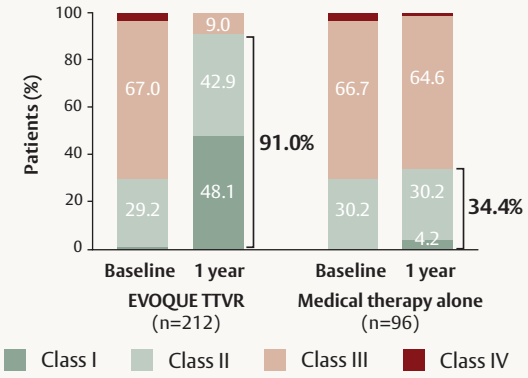


Twice as many patients were "alive and well" and "alive with large improvement" at 1 year after EVOQUE TTVR than with medical therapy alone

Survival and health status at 1 year



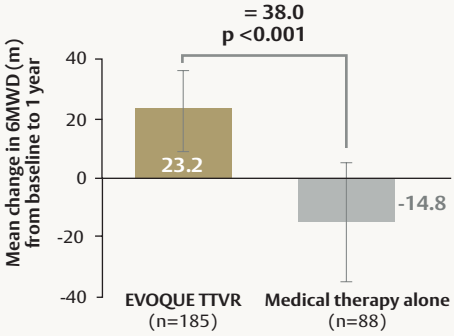
NYHA Functional Class Improvement[14]



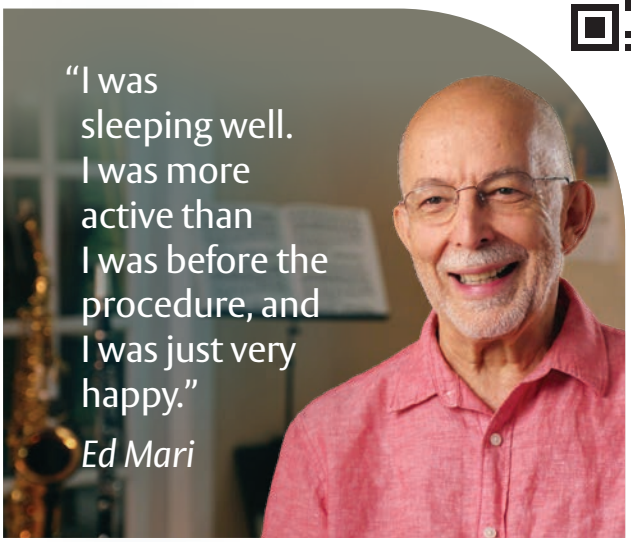
Conclusion

- Patients with symptomatic ≥ severe TR experience substantial impairment in health status.
- Compared with medical therapy alone, treatment of patients with symptomatic ≥ severe TR with EVOQUE TTVR resulted in significant and sustained improvements in patients' symptoms, function, and quality of life.
- Significant health status benefits were evident at 30 days after EVOQUE TTVR, continued to increase through 6 months, and remained durable through 1 year.

6MWD Improvement[14]



Hear more about these patient stories



6MWD = Six-minute walk distance, **HF** = Heart failure, **KCCQ-OS** = Kansas City Cardiomyopathy Questionnaire – Overall Summary, **LVOT** = Left ventricular outflow tract, **NYHA** = New York Heart Association, **TR** = Tricuspid regurgitation, **TTVR** = Transcatheter tricuspid valve replacement

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