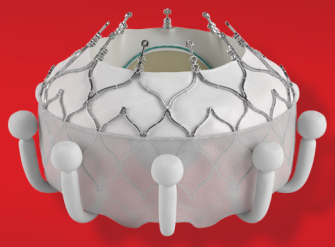
THE TRISCEND II PIVOTAL TRIAL

Data summary of first 150 patients at 6 months



The first randomised controlled trial for transcatheter tricuspid valve replacement therapy in patients with at least severe tricuspid regurgitation (TR)

The TRISCEND II pivotal trial is a prospective, global, multicentre randomised controlled clinical trial to evaluate the safety and effectiveness of the EVOQUE system with optimal medical therapy (EVOQUE + OMT) compared to OMT alone in patients with at least severe TR. These data relate to the first 150 patients randomised and treated in the TRISCEND II pivotal trial, which has completed its full enrollment of 400 patients and for which follow-up is ongoing.

STUDY FLOW

Patients with[1]
- TR graded as severe or greater
- Symptomatic TR despite medical therapy

2:1 Randomized
N=150

EVOQUE + OMT N=96

OMT Alone N=54

Primary endpoints (first 150 patients)

- Composite of major adverse events at 30 days
- TR reduction to ≤moderate at 6 months
- Hierarchical composite of KCCQ, NYHA, 6MWD improvement at 6 months

BASELINE CHARACTERISTICS & TR ETIOLOGY

Baseline Characteristics[2]	EVOQUE + OMT (N=96) % or Mean ± SD	OMT Alone (N=54) % or Mean ± SD
Age, years	79.4 ± 7.7	78.2 ± 8.3
Female	82.3%	75.9%
STS score, MVR, %	10.2 ± 5.7	9.4 ± 4.5
NYHA functional class III or IV	79.2%	70.4%
Atrial fibrillation	97.9%	96.3%
Prior valve surgery/intervention	31.3%	31.5%
Pacemaker or ICD	36.5%	42.6%
TR Etiology by Core Lab[2,a]		
Primary[b]	14.6%	13.0%
Secondary[c]	77.1%	70.4%
Mixed/Indeterminate	8.3%	16.7%

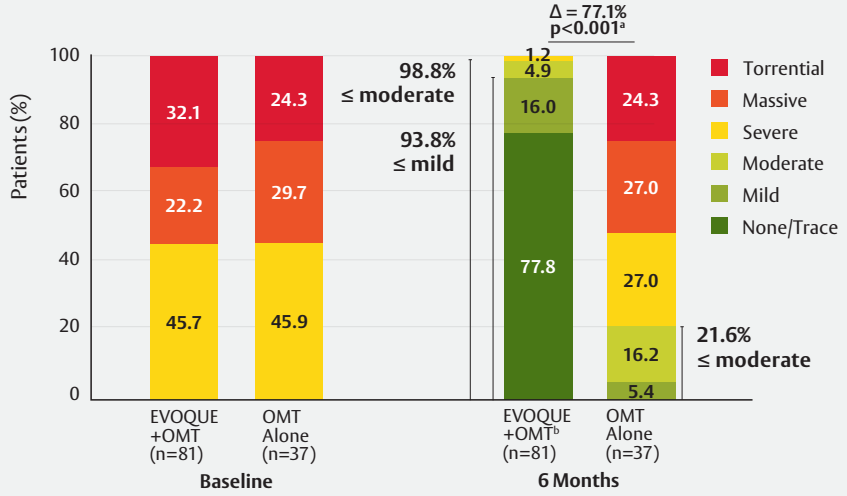
[a]Echocardiographic core lab: Baylor Scott & White The Heart Hospital Plano, Plano, TX, USA. [b]Degenerative, organic, structural or pacer-related. [c]Functional or nonstructural.

The EVOQUE system demonstrated an acceptable safety profile

The TRISCEND II pivotal trial met the primary safety endpoint at 30 days, with a composite major adverse event (MAE) rate in EVOQUE+OMT patients (N=95) of 27.4%.[a]

[a]Composite MAE rate includes cardiovascular mortality (3.2%), myocardial infarction (1.1%), stroke (0%), new need for renal replacement therapy (1.1%), severe bleeding (10.5%; fatal, life-threatening, extensive, or major bleeding, as defined by the Mitral Valve Academic Research Consortium), non-elective tricuspid valve re-intervention (0%), major access site and vascular complications (3.2%), major cardiac structural complications (2.1%), device-related pulmonary embolism (1.1%), and arrhythmia and conduction disorder requiring permanent pacing (14.7%) based on the first 150 patients enrolled.

98.8% of EVOQUE+OMT patients had moderate or less TR at 6 months[2]



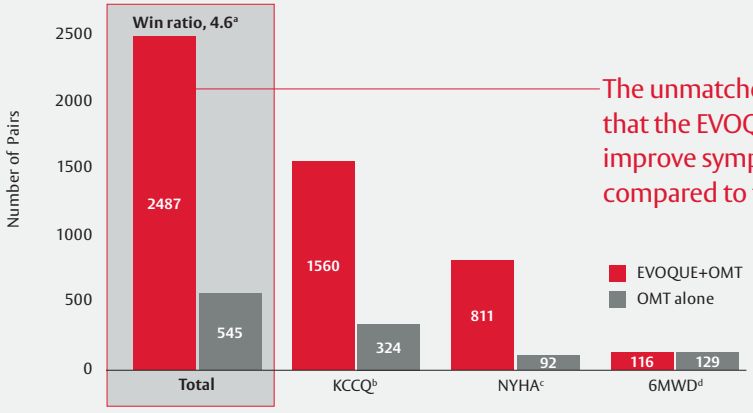
In the analysis of the first 150 patients, **the TRISCEND II pivotal trial met the first co-primary effectiveness endpoint** with TR grade reduction to ≤ moderate at 6 months.

Graph shows paired analysis. [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.

Significant improvement in functional status and quality of life outcomes in 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.

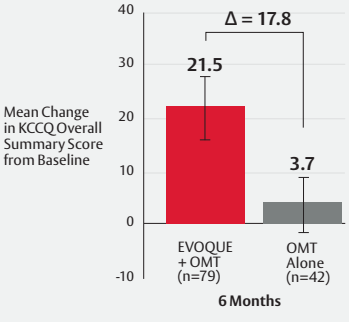
HIERARCHICAL COMPOSITE ENDPOINT



The unmatched win ratio analysis demonstrated that the EVOQUE system is 4.6 times more likely to improve symptomatic and functional outcomes compared to the medical therapy alone.[3]

[a]The lower bound of the one-sided 97.5% confidence interval is 2.6. [b]KCCQ overall summary score improvement of ≥ 10 points. [c]NYHA functional class improvement of ≥ 1 class. [d]6MWD improvement of ≥ 30 meters.

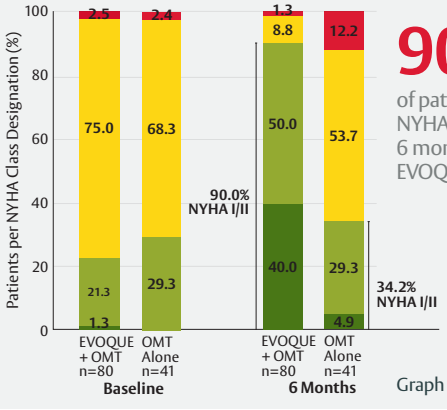
KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE (KCCQ)



21.5
point improvement on KCCQ analysis from baseline to 6 months in the EVOQUE + OMT group[2]

Graph shows paired analysis

NEW YORK HEART ASSOCIATION (NYHA) FUNCTIONAL CLASS



90.0%
of patients achieved NYHA Class I/II at 6 months in the EVOQUE + OMT group[2]

Graph shows paired analysis

SIX-MINUTE WALK DISTANCE (6MWD)

In paired analysis of 6MWD, the median distance for the EVOQUE+OMT group improved between baseline and 6 months (+18 m; n=73). The median distance for the OMT alone group worsened at 6 months (-16 m; n=34).[3]

34 meters difference in 6MWD between the EVOQUE+OMT and OMT alone groups

CONCLUSIONS FROM THE FIRST 150 PATIENTS AT 6 MONTHS

- The TRISCEND II pivotal trial met its primary safety endpoint at 30 days and its co-primary effectiveness endpoints at 6 months.
- The TRISCEND II pivotal trial demonstrated that, in the first 150 patients:
  - Transcatheter tricuspid valve replacement (TTVR) with the EVOQUE system is feasible with an acceptable 30-day safety profile in a highly comorbid population.
  - In a patient population in which more than 50% had massive or torrential TR at baseline, the EVOQUE system reduced TR to none/trace in 77.8% of EVOQUE + OMT patients at 6 months.
  - Treatment of severe TR with the EVOQUE system resulted in clinically meaningful improvements in functional status and quality of life at 6 months.

References: 1. TRISCEND II Pivotal Trial. ClinicalTrials.gov Identifier: NCT04482062. Accessed 14 November 2023. Last updated 02 November 2023. **2.** Kodali S. (26 October 2023). TRISCEND II Trial: A Randomized Trial of Transcatheter Tricuspid Valve Replacement in Patients with Severe Tricuspid Regurgitation. TCT 2023 Conference, San Francisco, CA, United States. **3.** Edwards EVOQUE system IFU.

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