Tricuspid valve replacement outcomes by baseline tricuspid regurgitation severity: the TRISCEND II trial

THE TRISCEND II PIVOTAL TRIAL

Lurz P. et al., Eur Heart J. 2025

Study Design & Aim

A sub-analysis[1] of the TRISCEND II pivotal trial

The TRISCEND II pivotal trial is the first prospective, multicenter, randomized controlled trial to evaluate transcatheter tricuspid valve replacement (TTVR) with the Edwards EVOQUE system in conjunction with optimal medical therapy (OMT) against OMT alone (control group) in a 2:1 randomization in patients with ≥ severe symptomatic tricuspid regurgitation (TR).[2]

The aim of this sub-analysis is to assess whether baseline TR severity influenced treatment outcomes following TTVR.

Methods

Patient stratification by baseline TR severity

Patients were stratified into two cohorts, severe TR and massive/torrential TR, based on TR severity at baseline using a 5-grade echocardiographic classification system[3]. Patient demographics and comorbidities were well balanced between TTVR and control groups and between TR severity cohorts.

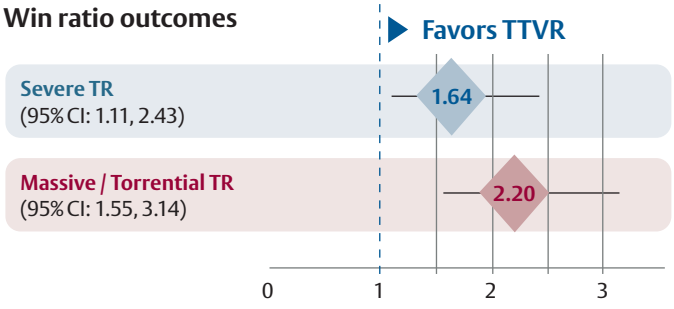
Outcomes assessed at 1 year
Primary safety and effectiveness endpoint, TR reduction, quality of life, functional status, and exercise capacity.

Outcomes assessed at 18 months*
Heart failure hospitalization (HFH) and all-cause mortality (ACM).

Primary Safety and Effectiveness Endpoint

At 1 year, EVOQUE TTVR was superior to medical therapy alone regardless of baseline TR severity.

Win ratio outcomes



The win ratio analysis demonstrated that **EVOQUE TTVR provides a greater likelihood of clinical benefit† at 1 year vs OMT alone** for both the Severe TR (P = 0.008) and Massive/Torrential TR (P<0.001) cohorts.

‡ 53 patients in the control group crossed over to TTVR after their 1-year visit (n=22 in the Severe TR group; n=31 in the Massive/Torrential TR group).

* Analyses of 18-month outcomes were not pre-specified in the trial protocol. ACM and HFH data were collected through routine adverse event reporting by the sites, and these events were CEC-adjudicated.

† The primary endpoint was a hierarchical composite that included death, durable right ventricular assist device/heart transplantation, tricuspid valve intervention, annualized HFH, and pre-specified improvements in quality of life, functional status, and exercise capacity.

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Tricuspid Regurgitation Reduction

Consistent TR elimination with EVOQUE TTVR, regardless of baseline TR severity.

Patients with **TR ≤ mild** at 1 year, for both TR severity groups

>95% EVOQUE TTVR

<3% Control

All-Cause Mortality and Heart Failure Hospitalization Outcomes

TTVR patients with the most severe TR at baseline experienced a lower rate of ACM or HFH at 18 months (Figure 1A). driven primarily by a **lower rate of HFH** (Figure 1B). ACM was similar in the Severe TR group for TTVR (13.6%) and control (13.5%; P = .980). In the Massive/Torrential TR group, ACM was 17.9% for TTVR and 23.6% for control (P = .338).

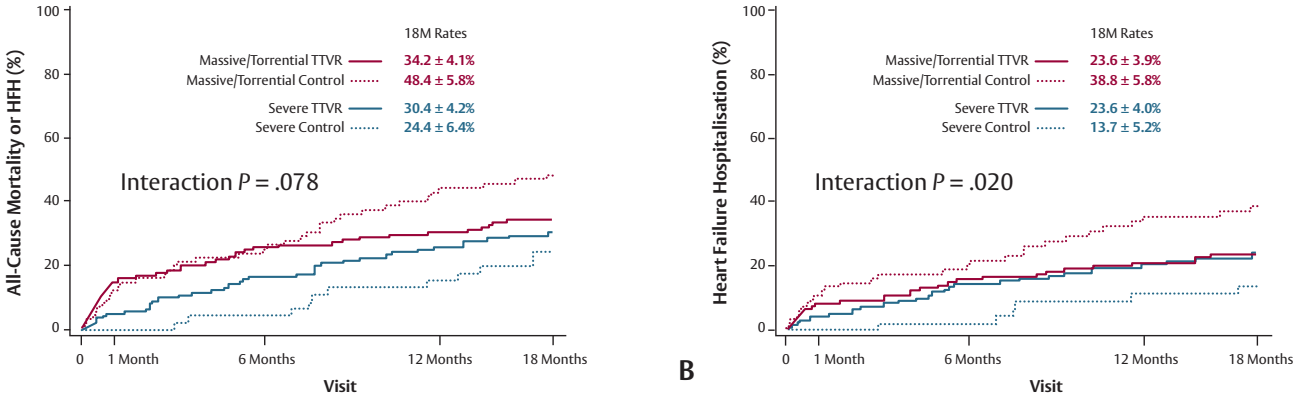

Figure 1: Kaplan-Meier estimates at 18 months stratified by baseline TR severity for (A) ACM or HFH (Massive/Torrential TR: TTVR 34.2 ± 4.1% vs. Control 48.4 ± 5.8%; P = .045; NNT 7; Severe TR: TTVR 30.4 ± 4.2% vs. Control 24.4 ± 6.4%; P = .438); **and (B) HFH alone** (Massive/Torrential TR: TTVR, 23.6 ± 3.9% vs. Control, 38.8 ± 5.8%, P = .030; NNT 7; Severe TR: TTVR 23.6 ± 4.0% vs. Control 13.7 ± 5.2, P = .134). For further details on statistical analyses please see reference 1.

Clinical, Functional, and Quality-of-Life Outcomes

Clinically meaningful improvements with EVOQUE TTVR at 1 year, with the magnitude of improvement consistently greater in patients with the most severe TR at baseline.

	Quality of Life KCCQ-OS Score	**Functional Class** NYHA Class I/II	**Exercise Capacity** 6MWT
Severe TR	+14.6 points vs 7.4	88.6% vs 33.3%	+10.6 meters vs -27.2
Massive / Torrential TR	+22.2 points vs -0.7	93.5% vs 35.2%	+35.2 meters vs -5.4

Reported values correspond to TTVR vs Control

Conclusion[1]

Treatment with the EVOQUE TTVR demonstrated:

Superior clinical benefits vs OMT alone **and consistent TR elimination regardless of baseline TR severity.**

Hard endpoint benefit vs OMT alone, with **a number needed to treat of 7** at 18 months, **for patients with the most severe TR.**

Acronyms: TTVR: transcatheter tricuspid valve replacement; OMT: optimal medical therapy; TR: tricuspid regurgitation; HFH: heart failure hospitalization; ACM: all-cause mortality; CI: confidence interval; CEC: clinical events committee; KCCQ-OS: Kansas city cardiomyopathy questionnaire overall summary; NYHA: New York heart association; 6MWT: 6-minute walk test. NNT: number needed to treat.

References: 1. Lurz P, et al. *Eur Heart J*. 2025. DOI: 10.1093/eurheartj/ehaf676; **2.** Hahn R.T et al., *N Engl J Med*. 2025;392(2):115-126; **3.** Hahn RT, Zamorano JL. *Eur Heart J Cardiovasc Imaging* 2017;18(12):1342-1343.

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