Clinical summary

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

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

THE TRISCEND II PIVOTAL TRIAL

## Objective

This sub-analysis of the TRISCEND II randomized controlled trial assessed whether baseline tricuspid regurgitation (TR) severity influenced clinical outcomes following transcatheter tricuspid valve replacement (TTVR) with the Edwards EVOQUE system.

## Methods

Patients were stratified into two cohorts, severe TR and massive/torrential TR, based on baseline TR severity using a 5-grade echocardiographic classification system.

Outcomes, including primary safety and effectiveness endpoint (win ratio), TR grade, quality of life, functional status, and exercise capacity assessed at 1 year, and heart failure hospitalization (HFH) and all-cause mortality (ACM) evaluated at 18 months were compared.

**Patients with ≥ severe TR**
Symptomatic despite optimal medical therapy

↓

**Modified Intent-to-Treat (mITT) Population**
n=392

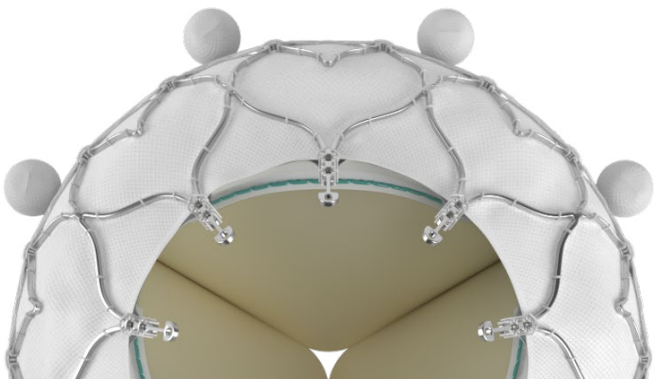
↓

**Severe TR**
n=172
(TTVR: 122; Control: 50)

**Massive/torrential TR**
n=220
(TTVR: 137; Control: 83)

## Key outcomes

- **Primary endpoint met:** At 1 year, **EVOQUE TTVR was superior to medical therapy alone regardless of baseline TR severity.** Win ratio: 1.64 (P=0.008) for severe TR patients; 2.20 (P<0.001) for massive/torrential TR patients.
- **TR elimination:** At 1 year, **95% of TTVR patients in both subgroups achieved TR ≤ mild**, compared to <3% of patients on medical therapy alone.
- **ACM & HFH benefit:** **EVOQUE TTVR patients with massive/torrential TR at baseline saw a reduction in ACM or HFH** (34.2% vs 48.4%, P=0.045) **and HFH** compared to medical therapy alone (23.6% vs 38.8%, P=0.030) at 18 months. Differences for severe TR patients were not statistically significant between the two groups.
- **Health status improvement:** **EVOQUE TTVR patients demonstrated meaningful improvements in health status for both severe and massive/torrential TR cohorts**, including KCCQ-OS scores, NYHA Class I/II achievement, and 6-minute walk distance.



Edwards

## Baseline characteristics

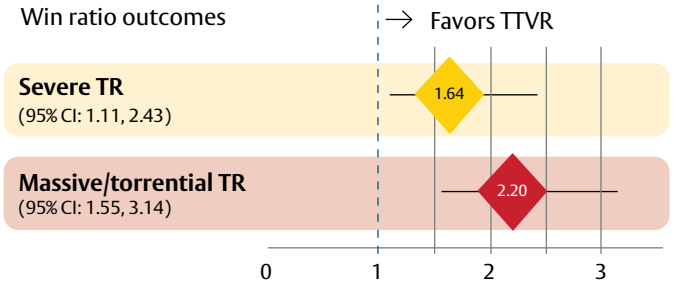
Patient demographics and comorbidities were balanced between TTVR and control groups and between TR severity cohorts.

| Baseline characteristics | Severe n=172 | Massive/torrential n=220 |
|---|---|---|
| **Age, years** | 80.0 | 78.6 |
| **Female** | 74.4 | 76.4 |
| **NYHA class III-IV** | 69.2 | 73.6 |
| **Atrial fibrillation** | 96.5 | 93.6 |
| **Renal disease** | 54.7 | 56.8 |
| **Pacemaker/ICD** | 37.8 | 39.5 |
| **Ascites** | 16.3 | 22.3 |
| **KCCQ-OS (mean)** | 53.1 | 51.2 |

## Primary endpoint

The TRISCEND II primary endpoint was a hierarchical composite that included death, durable right ventricular assist device/heart transplantation, tricuspid valve intervention, heart failure hospitalization, and improvements in quality of life, functional status, and exercise capacity.

In the sub-analysis, a win ratio demonstrated that EVOQUE TTVR provides a 1.64x greater likelihood of clinical benefit for severe TR and a 2.20x greater likelihood for massive/torrential TR at 1 year compared to medical therapy alone.

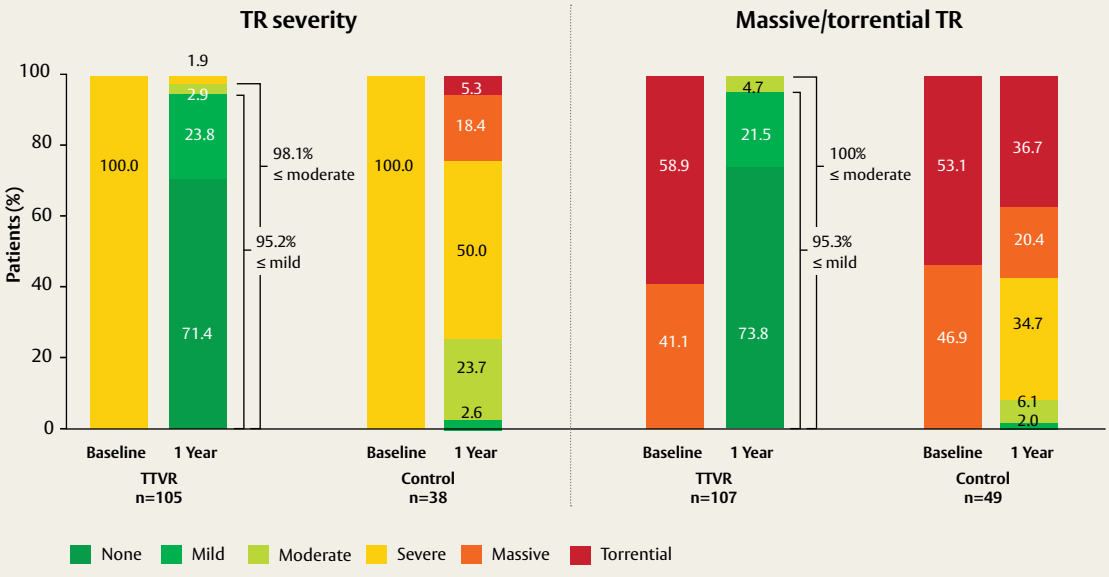



**A win ratio** shows how often patients using a certain therapy may have better clinical outcomes than those on standard treatment, based on a ranking of important events.

## Consistent TR elimination

At 1 year, **95.2% of TTVR patients with severe TR and 95.3% with massive/torrential TR at baseline achieved TR ≤ mild**, compared to 2.6% and 2.0% of control patients, respectively.

**Figure 1.** Changes in TR severity at 1 year stratified by baseline TR severity




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

**>95%**
EVOQUE TTVR

**<3%**
Control

## Clinical, functional, and quality-of-life improvements

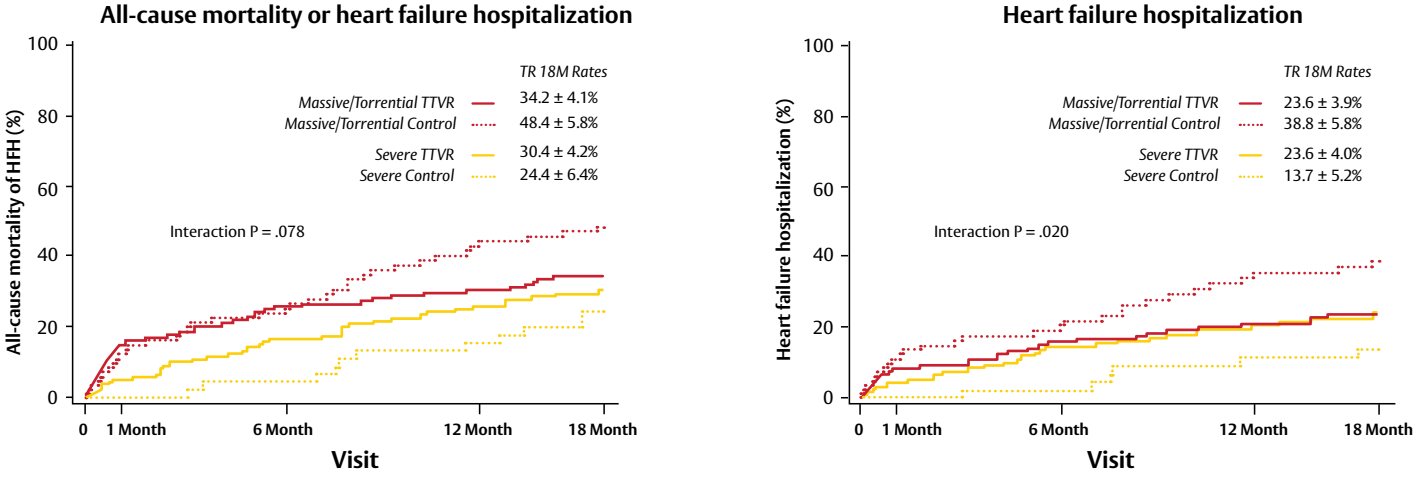
EVOQUE TTVR delivered **meaningful improvements in health status** compared to medical therapy alone **across both TR severity cohorts**.

| Better quality of life (KCCQ-OS Score, TTVR vs control) | | Improved functional class (NYHA Class I/II, TTVR vs control) | | Increased exercise capacity (6MWD, TTVR vs control) | |
|---|---|---|---|---|---|
| **+14.6 points** vs +7.4 points **Severe TR** | **+22.2 points** vs -0.7 points **Massive/ torrential TR** | **88.6%** vs 33.3% **Severe TR** | **93.5%** vs 35.2% **Massive/ torrential TR** | **+10.6 meters** vs -27.2 meters **Severe TR** | **+35.2 meters** vs -5.4 meters **Massive/ torrential TR** |

## All-cause mortality and heart failure hospitalization outcomes

Patients with massive/torrential TR at baseline experienced a **lower rate of ACM or HF hospitalization at 18 months**. These findings were primarily driven by a **lower rate of HF hospitalization**.

**Figure 2.** Kaplan-Meier estimates at 18 months stratified by baseline TR severity




## Conclusion

TTVR with the EVOQUE system demonstrated **significant clinical benefits and consistent TR elimination**, alongside improvements in quality of life, functional status, and exercise capacity, **regardless of baseline TR severity**.

**Patients with massive/torrential TR appeared to derive greater clinical benefits**, particularly in terms of a **lower heart failure hospitalization rate**, a potential signal for lower all-cause mortality, and improved health status.

# Important Safety Information

## Edwards EVOQUE Tricuspid Valve Replacement System

**Indications: The EVOQUE tricuspid valve replacement system is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite being treated optimally with medical therapy for whom tricuspid valve replacement is deemed appropriate by a Heart Team.**

**Contraindications:** The EVOQUE valve is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen, who have active bacterial endocarditis or other active infections, or who have untreatable hypersensitivity to nitinol alloys (nickel and titanium).

**Warnings:** The EVOQUE valve, delivery system, loading system, dilator kit, are designed, intended, and distributed as STERILE and for single use only. The positioning accessories are available in single use, nonsterile, disposable as well as reusable configurations, please refer to the device information and ensure the device is used as intended. Do not resterilize or reuse any of the single use devices. There are no data to support the sterility, nonpyrogenicity, or functionality of the single use devices after reprocessing. Ensure the correct valve size is selected. Implantation of the improper size (i.e., undersizing or oversizing) may lead to paravalvular leak (PVL), migration, embolization, and/or annular damage.

Patients with previously-implanted devices (e.g., IVC filter) should be carefully assessed prior to insertion of the delivery system to avoid potential damage to vasculature or a previously-implanted device. Patients with pre-existing cardiac leads should be carefully assessed prior to implantation to avoid potential adverse interaction between devices. Care should be taken when implanting cardiac leads after EVOQUE valve implantation to avoid potential adverse interaction between the devices. Patients implanted with the EVOQUE valve should be maintained on anticoagulant/antiplatelet therapy as determined by their physicians in accordance with current guidelines, to minimize the risk of valve thrombosis or thromboembolic events.

There are no data to support device safety and performance if the patient has: echocardiographic evidence of severe right ventricular dysfunction; pulmonary arterial systolic pressure (PASP) > 70 mmHg by echo Doppler; a trans-tricuspid pacemaker or defibrillator lead that has been implanted in the RV within the last 3 months; or dependency on a trans-tricuspid pacemaker without alternative pacing options.

**Precautions:** Prior to use, the patient's eligibility depends on the anatomic conditions based on CT scan. It is advised that a multi-disciplinary heart team be of the opinion that EVOQUE valve implantation is preferable to alternative percutaneous device solutions, including minimally-invasive open heart surgery. It is advised that a multi-disciplinary heart team takes into consideration the severity of disease and the chances of reversibility of right heart failure based on a complete hemodynamic assessment.

The EVOQUE valve is to be used only with the EVOQUE delivery system and EVOQUE loading system. The procedure should be conducted under appropriate imaging modalities, such as transesophageal echocardiography (TEE), fluoroscopy, and/or intracardiac echocardiography (ICE). Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. Conduction disturbances may occur before, during, or following implantation of the EVOQUE valve, which may require continuous ECG monitoring before hospital discharge. The risk of conduction disturbances may increase with the 56mm valve size. If a patient has confirmed or suspected conduction disturbances, consider patient monitoring and/or electrophysiology evaluation. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Long-term durability has not been established for the EVOQUE valve. Regular medical follow-up is advised to evaluate EVOQUE valve performance. Implantation of the EVOQUE valve should be postponed in patients with (1) a history of myocardial infarction within one month (30 days) of planned intervention, (2) pulmonary emboli within 3 months (90 days) of planned intervention, (3) cerebrovascular accident (stroke or TIA) within 3 months (90 days) of planned intervention, (4) active upper GI bleeding within 3 months (90 days) prior to procedure requiring transfusion.

**Potential Adverse Events:** Potential adverse events related to standard cardiac catheterization, use of anesthesia, the EVOQUE valve, and the implantation procedure include: death; abnormal lab values; allergic reaction to anesthesia, contrast media, anti-coagulation medication, or device materials; anaphylactic shock; anemia or decreased hemoglobin (Hgb), may require transfusion; aneurysm or pseudoaneurysm; angina or chest pain; arrhythmia – atrial (i.e., atrial fibrillation, supraventricular tachycardia); arrhythmias – ventricular (i.e., ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; bleeding; cardiac arrest; cardiac (heart) failure; cardiac injury, including perforation; cardiac tamponade / pericardial effusion; cardiogenic shock; chordal entanglement or rupture that may require intervention; coagulopathy, coagulation disorder, bleeding diathesis; conduction system injury, which may require implantation of a pacemaker (temporary or permanent); conversion to open heart surgery; coronary artery occlusion; damage to or interference with function of pacemaker or implantable cardioverter defibrillator (ICD); edema; electrolyte imbalance; embolization including air, particulate, calcific material, or thrombus; emergent cardiac surgery; endocarditis; esophageal irritation; esophageal perforation or stricture; EVOQUE system component(s) embolization; failure to retrieve any EVOQUE system components; fever; gastrointestinal bleeding; hematoma; hemodynamic compromise; hemolysis / hemolytic anemia; hemorrhage requiring transfusion/surgery; hypertension; hypotension; inflammation; injury to the tricuspid apparatus including chordal damage, rupture, papillary muscle damage; local and systemic infection; mesenteric ischemia or bowel infarction; multi-system organ failure; myocardial infarction; nausea and/or vomiting; nerve injury; neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-emergent reoperation; pain; pannus formation; paralysis; percutaneous valve intervention; peripheral ischemia; permanent disability; pleural effusion; pneumonia; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; rehospitalization; renal failure; respiratory failure, atelectasis – may require prolonged intubation; retroperitoneal bleed; right ventricular outflow tract (RVOT) obstruction; septicemia, sepsis; skin burn, injury, or tissue changes due to exposure to ionizing radiation; stroke; structural deterioration (wear, fracture, calcification, leaflet tear, leaflet thickening, stenosis of implanted device, or new leaflet motion disorder); thromboembolism; transient ischemic attack (TIA); valve dislodgement/embolization; valve endocarditis; valve explant; valve leaflet entrapment; valve malposition; valve migration; valve paravalvular leak (PVL); valve regurgitation (new or worsening tricuspid, aortic, mitral, pulmonary); valve thrombosis; vascular injury or trauma, including dissection or occlusion; vessel spasm ; wound dehiscence, delayed or incomplete healing.

**CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.**

**References**

Lurz P, Hahn RT, Kodali S, et al. Tricuspid valve replacement outcomes by baseline tricuspid regurgitation severity: The TRISCEND II Trial. Eur Heart J. 2025.



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