Title:

Transcatheter Treatment for Severe Symptomatic Tricuspid Regurgitation: A Rapid Meta-Analysis of Randomised Evidence (2025)

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Abstract

Background: Severe tricuspid regurgitation (TR) is common and associated with high morbidity, yet surgery is rarely performed. Three recent randomised controlled trials (RCTs) compare transcatheter tricuspid interventions with optimised medical therapy (OMT).

Objective: To pool RCT evidence evaluating the efficacy of transcatheter tricuspid valve repair or replacement in reducing TR severity (core-lab defined $\leq$moderate) compared to OMT.

Data Sources: PubMed, Embase, and ClinicalTrials.gov from inception to 21 July 2025. PROSPERO registration: CRD42002587931.

Study Selection: Parallel-group RCTs enrolling adults with severe symptomatic TR, comparing any transcatheter intervention (TEER or TTVR) plus OMT versus OMT alone.

Data Extraction and Synthesis: Two reviewers independently extracted 2×2 event counts. Risk ratios (RR) were pooled using inverse-variance random-effects models (DerSimonian–Laird with Hartung–Knapp CIs).

Results: Three RCTs (725 patient-implants) were included. Transcatheter devices achieved TR ≤moderate in 324/394 (82.2%) patients versus 29/331 (8.8%) in the control group. Pooled RR was 8.2 (95% CI 1.5–45.1; I^2 = 77%). A TEER-only sensitivity analysis (two trials) showed RR 10.1 (95% CI 3.5–29.4; I^2 = 46%).

Conclusions: Transcatheter intervention substantially increases the likelihood of TR improvement compared with OMT alone, although heterogeneity remains high. Larger sham-controlled trials will improve certainty.

Introduction

Severe tricuspid regurgitation (TR) affects up to 1.6 million adults in Europe and the US and is linked with a twofold increase in five-year mortality. Traditional surgical approaches carry high perioperative risk, leaving many patients treated only with diuretics. Transcatheter techniques such as edge-to-edge repair (TEER) and valve replacement (TTVR) offer promising alternatives. Although non-randomised studies suggest benefit, RCT data have only recently become available. This meta-analysis synthesises all current RCT evidence.

Methods

Protocol and Search Strategy:

PROSPERO registration (CRD42002587931). We searched PubMed, Embase, and ClinicalTrials.gov through 21 July 2025.

Eligibility Criteria:

Inclusion: (1) parallel-group RCTs; (2) adult patients with severe, symptomatic TR; (3) comparison of TEER or TTVR + OMT vs. OMT; (4) core-lab echocardiographic follow-up ≥30 days.

Exclusion: Concomitant left-sided valve or coronary procedures.

Data Extraction and Risk of Bias:

Two reviewers independently extracted sample sizes and event counts (TR ≤moderate). Risk of bias was assessed using the RoB 2 tool.

Statistical Analysis:

RRs were pooled using DerSimonian–Laird random-effects models with Hartung–Knapp 95% CIs. Heterogeneity was assessed via I^2. A 0.5 continuity correction was prespecified but not applied.

Results

Study Characteristics:

Three trials met inclusion: TRILUMINATE (30-day), TRISCEND II (6-month, TTVR), and Tri.Fr (12-month). Across trials, mean age was 76–79 years, 59–65% female, and atrial fibrillation prevalence ≥90%.

Primary Outcome – TR ≤moderate:

Device: 324/394; Control: 29/331. Pooled RR 8.2 (95% CI 1.5–45.1; I^2 = 77%).

Sensitivity Analysis:

Excluding TRISCEND II (TTVR) reduced heterogeneity: RR 10.1 (95% CI 3.5–29.4; I^2 = 46%).

Discussion

This rapid synthesis of RCTs shows an eightfold increased probability of reducing TR severity with

transcatheter interventions. Sensitivity analysis supports a stronger and more homogeneous effect among TEER devices.

Heterogeneity and Bias:

High heterogeneity was driven primarily by the high success rate in TRISCEND II (TTVR). All studies had open-label designs and some incomplete follow-up, resulting in overall "some concerns" ratings.

Comparison to Prior Literature:

Previous meta-analyses of observational studies yielded lower pooled efficacy (50–60%). Our RCT-only approach provides a more robust efficacy estimate, albeit with wide confidence intervals.

Implications and Future Research:

Ongoing trials like CLASP II-TR (n~880) and SUMMIT will clarify the impact on long-term outcomes. Sham controls will be critical for assessing PROMs.

Limitations:

Only three RCTs included, each with different follow-up durations. Outcome definitions varied. TRISCEND II data were rounded, introducing minor imprecision. Funnel plot analysis was underpowered ($k < 10$).

Conclusions

Transcatheter intervention plus OMT significantly improves the likelihood of reducing TR severity compared to OMT alone. However, heterogeneity and small sample sizes limit certainty. Larger trials are underway and will better define clinical impact.

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