Short-term outcomes of commercial transcatheter tricuspid valve intervention: a systematic review and meta-analysis

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Background: Severe tricuspid regurgitation (TR) is associated with increased all-cause mortality and morbidity. Isolated tricuspid valve surgery is uncommon due to high perioperative mortality and typically co-morbid patients. Transcatheter tricuspid interventions are an increasingly common therapeutic option becoming available for this high-risk patient cohort. This systematic review and meta-analysis sought to determine the short-term outcomes of these patients.

Methods: Four databases were searched from their inception to August 2025. All studies reporting 1-year mortality and New York Heart Association (NYHA) class pre- and post-intervention were identified. Studies utilizing non-commercially available devices were excluded. Relevant data were extracted, and meta-analysis was conducted using a random-effects model.

Results: Thirteen studies were included, encompassing a total of 1,589 patients. The aggregate mean age was 78.0 years. Thirty-day mortality was 1.8%, with 1-year mortality and heart failure hospitalization rates at 9.9% and 20.1%, respectively. At 1-year, TR was moderate or less in 66.5% of patients, and 81.1% of patients reported NYHA I or II status.

Conclusions: Transcatheter tricuspid interventions provide sustained symptomatic benefit and reduction in TR at one year.

Keywords: Transcatheter tricuspid intervention; edge-to-edge repair; tricuspid valve repair; short-term outcomes

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Introduction

Tricuspid regurgitation (TR) is associated with increased morbidity and mortality independent of ventricular dysfunction and pulmonary hypertension (1-3). TR is most commonly secondary to left-sided valvular or myocardial dysfunction, with primary causes such as rheumatic heart disease, infective endocarditis, and Ebstein's anomaly making up only 10–15% of residual cases (4). Patients with severe TR present with signs of right-sided heart failure, including peripheral edema and ascites, and decreased cardiac output resulting in exercise intolerance and end-organ dysfunction, all of which contribute to an overall poorer quality of life (5). Additionally, 1-year mortality in patients with severe TR has been previously reported as high as 42%, highlighting that survival and functional status are both significantly affected (6).

Optimal medical therapy (OMT) for TR principally involves diuretic therapy, with mineralocorticoid antagonists added in advanced disease to treat hepatic congestion (5,7). Underlying causes of secondary TR should also be addressed, including using guideline-directed medical therapy for heart failure with reduced ejection fraction, pulmonary vasodilators for pulmonary arterial hypertension, and achieving rhythm control for atrial fibrillation (5,7). Although medical therapy can improve symptom control, it is often insufficient to limit disease progression of TR (5,8,9). Meanwhile, tricuspid valve (TV) surgery provides definitive management of TR and has a Class I recommendation from US and European guidelines for patients with severe TR during concomitant left-sided cardiac surgery (7,10). However, isolated TV surgery remains uncommon due to high perioperative mortality rates, reported between 6.2% to 9%, and significant comorbidities in this patient population (11-13).

The recent introduction of transcatheter tricuspid valve interventions (TTVIs) has provided clinicians with a new therapeutic option for patients failing medical management and are of high surgical risk (14). A variety of transcatheter options have been introduced, including tricuspid edge-to-edge repair (TEER), tricuspid annuloplasty, orthotopic transcatheter tricuspid valve replacement (TTVR), and heterotopic caval valve placement (14,15). Metrics used to determine the safety and efficacy of these interventions include mortality, bleeding complications, device failure, reduced TR, and improved functional status (16,17). Validated tools such as the Bleeding Academic Research Consortium (BARC) scale for bleeding complications and New York Heart Association (NYHA) class classification for functional status are strong predictors of mortality and provide standardized metrics across clinical trials (18,19). NYHA classification is a well-established and the most widely used method to gauge symptom severity that can be easily utilized by a clinician based on history taking alone (20). Other tools for evaluating heart failure include the 6-minute walk test (6MWT) and the Kansas City Cardiomyopathy Questionnaire (KCCQ). Improvements in 6MWT scores have been demonstrated to be associated with increased survival (21). However, the requirement for a health practitioner to walk a patient for six minutes can reduce its ease of use and applicability. It may also not reflect a patient's usual activities at home, and other assessments of functional capacity such as continuous actigraphy have been suggested as alternatives (22). The KCCQ is a patient-reported outcome measure assessing the impact of heart failure on patient day-to-day activities. Whilst deterioration in this score has been associated with increased mortality in heart failure, an improvement in this score did not correspond to improved outcomes (23). Several reviews have previously reported the favorable peri-procedural safety and efficacy of TTVI (16,17,24). There is limited reporting on short-, medium- and long-term outcomes.

We therefore conducted a systematic review and meta-analysis to evaluate the peri-procedural and short-term clinical and safety outcomes of TTVI in patients with TR. We chose to evaluate NYHA as the clinical heart failure tool of choice given its ease of utilization and applicability. Endpoint timings of 30 days and 1-year post intervention were chosen based on the Tricuspid Valve Academic Research Consortium's definitions of peri-procedural and early outcome definitions (22).

Methods

Literature search strategy

The methods for this systematic review adhered to the guidelines outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Four electronic databases were interrogated to perform the literature searches, encompassing EMBASE, Ovid MEDLINE, PubMed, and SCOPUS. These databases were searched from dates of inception to August 2025. For the examination of the outcomes for TTVI, a search strategy was generated using the combination of keywords and Medical Subject Headings (MeSH) including ("tricuspid valve"[MeSH Terms] OR tricuspid*) AND (transcatheter* OR percutaneous* OR "catheter-based" OR "edge-to-edge" OR "valve repair" OR "valve replacement" OR "valve reconstruction" OR TTVR OR TTVI) AND (TriClip OR PASCAL OR EVOQUE* OR TricValve OR commercial*). Each study was independently assessed by at least two of the co-authors (D.N., D.D., Y.D., A.R.W.S.) with any conflicts resolved prior to progression through mutual agreement. Where the title and/or abstract provided insufficient detail to assess relevance for inclusion, a full text review was conducted in the first instance.

Eligibility criteria

Studies were included in the review if they examined a transcatheter tricuspid intervention method reporting 1-year mortality and the NYHA class pre- and 1-year post-intervention. We included both single-arm and multi-arm trials. We limited our inclusions to commercially available devices only. Studies were excluded from the review for the following criteria: (I) non-English reporting; (II) less than 10 cases included; (III) abstracts/conference presentations/editorials/reviews; (IV) inclusion of a pediatric population unless the data was segregated; (V) no mention of post-intervention results; (VI) aggregate data not split between subgroups, thereby preventing analysis; and (VII) full texts that were not available through general access, institutional access or contacting authors directly. Reference lists of the included studies were reviewed at the completion of the database search to identify any extra, as-of-yet included studies.

Primary and secondary endpoints

The primary endpoints assessed were all-cause mortality at 30 days, all-cause mortality at one year, heart failure hospitalizations at one year, reduction of TR grade at one year, and NYHA functional status at one year. Secondary endpoints assessed were rates of non-elective cardiovascular surgery or re-intervention, number of pacing devices implanted post-intervention, new-onset renal failure, myocardial infarction, stroke, infective endocarditis, and major bleeding secondary to intervention.

Data extraction, critical appraisal, risk of bias and quality assessment

Four reviewers (D.N., D.D., Y.D., K.P.) independently extracted data directly from publication texts, tables and figures. Two separate reviewers (A.R.W.S., R.G.) independently reviewed and confirmed all extracted data. Differing opinions between reviewers were resolved through discussion between all reviewers. Where data was insufficient or indistinct, attempts were made to contact the original authors of the study as required. Cochrane's Risk of Bias in Non-randomized Studies of Interventions, Version 2 (ROBINS-I V2) was used to assess the risk of bias for each study (25). The Canadian Institute of Health Economics Quality Appraisal score was used as the quality assessment tool (26). Studies were categorized as low quality (score <10/19), moderate quality (score ≥10/19), or high quality (score ≥15/19).

Statistics

A meta-analysis of proportions or means were performed for categorical and continuous variables, as appropriate, by an independent reviewer (D.D.). A random-effects model was used to account for inevitable between-study variance from sources such as differing regions, surgeon experience, surgical technique, equipment, and management protocols. Means and standard deviations (SDs) were calculated from the median, where reported, using the methods described by Wan and colleagues (27). Pooled data and SDs or standard error (SE) were presented as N (%) ± SD or SE with 95% confidence intervals (CIs).

Digitized Kaplan-Meier curves were aggregated using techniques developed by Guyot and colleagues for conducting secondary analysis of survival data (28). This method allows individual patient time-to-event data to be inferred from the Kaplan-Meier equations, taking into account patient numbers-at-risk and assuming constant censoring where that data is not provided. Hazard ratios are calculated from Kaplan-Meier data using the Cox proportional hazard model. Publication bias was examined with funnel plots and by Egger's tests. Heterogeneity amongst studies were assessed using the I^2 statistic. Thresholds for these values were considered as low, moderate, and high heterogeneity as 0–49%, 50–75%, and >75%, respectively. Potential sources of heterogeneity were explored through leave-one-out (LOO) sensitivity analysis conducted to identify studies which reclassified an outcome's heterogeneity threshold upon removal.

Two-tailed P values <0.05 were deemed as significant. All statistics were performed using Stata (version 17.0, StataCorp, Texas, USA), R (v4.5.1, R Core Team [2021] R Foundation for Statistical Computing, Vienna, Austria) or MedCalc (MedCalc Software Ltd., Version 23.09, Ostend, Belgium).

Results

Quantity of evidence

Application of the search terms identified a total of 1,859 records. After removal of duplicates, 1,030 records were identified for screening. Following use of the inclusion and exclusion criteria, 125 articles underwent full text review. No studies were excluded due to lack of access. Two additional studies were identified on review of bibliographies of included texts, screened and included in the review. A total of 13 studies were identified for inclusion, with detailed study characteristics provided in *Table 1* (29-41). The inclusion and exclusion process is visually presented by the PRISMA flow diagram (Figure S1). Four studies had overlapping patient populations, and data was filtered prior to analysis to account for this overlap (30-32,35). A total of 1,589 patients were included, consisting of 1,312 edge-to-edge repairs (TEER), 203 valve replacements (TTVR), 30 annuloplasties and 44 caval valve implantations (CAVIs).

Table 1 Study data

Primary author, year	Study period	Institution	Country or region	Type of study	Total patients	Median follow up time (months)	Type of device	Device name
Donal, 2025 (29)	2021–2023	Tri.fr Study	France and Belgium	Prospective	152	NR	TEER	TriClip (Abbott)
Naik, 2025 (30)	2019–2022	TRILUMINATE Pivotal Trial	United States, Europe and Canada	Prospective	469	NR	TEER	TriClip (Abbott)
Tang, 2025 (31)	2019–2022	TRILUMINATE Pivotal trial	United States, Europe and Canada	Prospective	285	NR	TEER	TriClip (Abbott)
Adams, 2024 (32)	2019–2021	TRILUMINATE Pivotal Trial	United States, Europe and Canada	Prospective	100	NR	TEER	TriClip (Abbott)
Lurz, 2024 (33)	2020–2022	bRIGHT Study	Europe	Prospective	511	NR	TEER	TriClip (Abbott)
Kodali, 2023 (March) (34)	NR	CLASP TR Early Feasibility Study	United States	Prospective	65	19.4	TEER	PASCAL and PASCAL Ace (Edwards)
Sorajja, 2023 (35)	2019–2021	TRILUMINATE Pivotal Trial	United States, Europe and Canada	Prospective	175	NR	TEER	TriClip (Abbott)
Kitamura, 2021 (36)	2017-2019	6 tertiary care centers (unnamed)	Germany and North America	Retrospective	30	NR	TEER	PASCAL (Edwards)
Lurz, 2021 (37)	2017–2018	TRILUMINATE Trial	Europe and United States	Prospective	85	NR	TEER	TriClip (Abbott)
Kodali, 2023 (December) (38)	NR	TRISCEND study	North America and Europe	Prospective	176	NR	TTVR	EVOQUE (Edwards)
Webb, 2022 (39)	2019–2020	7 centres (unnamed)	NR	Retrospective	27	12.5	TTVR	EVOQUE (Edwards)
Nickenig, 2021 (40)	2016–2017	TRI-REPAIR	Europe	Prospective	30	19.9	Annuloplasty	Cardioband (Edwards)
Blasco-Turrion, 2024 (41)	2018–2021	TRICUS Study and TRICUS EURO Study	Lithuania, Spain and Austria	Prospective	44	12.1	CAVI	TricValve (OrbusNeich P&F)

The cohort of Naik, 2025 was equal to Tang, 2025 and Adams, 2024, while Sorajja, 2023 also overlapped. CAVI, caval valve implantation; NR, not reported; TEER, transcatheter edge-to-edge repair; TTVR, transcatheter tricuspid valve replacement.

Quality of evidence

All included studies were assessed using a modified Canadian Institute of Health Quality Appraisal (26). All studies were deemed high-quality. All included studies were assessed using the Cochrane ROBINS-I V2 assessment for risk of bias and have been visually presented in Figure S2 (25). All were deemed at moderate risk of bias in the context of qualitative assessments for NYHA classifications being potentially biased by knowing the intervention. They were subsequently included in this review.

Basic demographics

Baseline patient demographic data and included procedural data are presented in *Tables 2,3*. For the total population, the mean age was 78.0 years with 34.7% males and a mean body mass index (BMI) of 26.3 kg/m^2. Comorbidities that were reported in a high proportion of the population included hypertension (81.3%), dyslipidemia (63.3%) and atrial fibrillation/flutter (90.4%). 19.7% of the population had a pre-existing pacemaker or implantable cardioverter defibrillator and 35.4% of the total population reported heart failure hospitalization in the past year. Across included studies, most patients presented with advanced symptomatic heart failure, with 76.0% classified as NYHA functional class III–IV. Similarly, average scoring through the KCCQ score (49.7) and 6MWT (253.9 m) indicated marked baseline functional limitation. The average Society of Thoracic Surgeons (STS) predicted risk score for isolated tricuspid valve repair was 6.1%, while the EuroSCORE II score averaged 5.7%, both reflecting an increased surgical risk profile.

Anatomically, baseline TR was equal or greater than severe in 91.6% of the total population, with a mean left ventricular ejection fraction (LVEF) of 57.8%. Mean tricuspid annular size was severely dilated at 44.8 mm with a moderate-to-severe coaptation gap of 6.5 mm. Right ventricular systolic performance, as assessed by tricuspid annular plane systolic excursion (TAPSE) and right-ventricular fractional area change (RV FAC), was borderline impaired on average (16.0 mm and 38.1%, respectively). 18.7% of total patients had a history of previous coronary artery bypass (CABG), 38.9% a history of any surgical valvular intervention, and 16.1% a history of previous percutaneous coronary intervention (PCI). Implantation was successful in a pooled mean of 94.4% of total patients, and 82.0% achieving a reduction in TR of 1 or more grades at the end of procedure. Where reported, there was a mean of 90.9 minutes from implant insertion to deployment, and mean fluoroscopy duration was 34.8 minutes. Overall, there was a high level of heterogeneity present in the majority of reported baseline and procedural characteristics.

Primary endpoints

Pooled 30-day mortality for the entire cohort was 1.8% (95% CI: 0.8–4.2%; Figure S3) with moderate heterogeneity (I^2=53.3%). Mortality rates between TEER and TTVR were similar at 1.2% and 2.0% respectively. One-year all-cause mortality was 9.9% (95% CI: 7.4–13.2%; Figure S4) across the entire cohort, with 9.6% for TEER and 8.3% for TTVR respectively. One-year heart failure hospitalization was 20.1% for the entire cohort (95% CI: 11.4–32.9%; Figure S5) with high heterogeneity (I^2=94.9%). The rate was 20.2% for the TEER cohort with high heterogeneity (I^2=96.5%), and 8.9% for the TTVR cohort. At 1-year follow-up, TR was moderate or less in 66.5% of the population (95% CI: 19.2–94.3%; Figure S6) with high heterogeneity (I^2=95.9%). This rate was 69.2% for the TEER population, with high heterogeneity (I^2=97.4) and 98.1% for the TTVR population. The proportion NYHA I or II status at one year follow up was 81.1% (95% CI: 73.4–86.9%; Figure S7) with moderate heterogeneity (I^2=70.6%), with similar rates for TEER and TTVR populations, 81.7% and 84.3% respectively. Results are summarized in *Table 4*.

Secondary endpoints

The pooled mean hospital length of stay was 2.4 days (95% CI: 1.2–3.7; I^2=97%; Figure S8) with 3.7% (95% CI: 0.5–24.6%; I^2=88.3%; Figure S9) requiring pacemaker implants post-intervention. TTVR had higher rates of pacemaker implants at 9.3% (95% CI: 1.5–41.6%, I^2=0%). Non-elective cardiovascular surgery or re-intervention was performed in 4.9% (95% CI: 3.9–6.2%; I^2=0%; Figure S10) of the population. The rate of new-onset renal failure, myocardial infarction and stroke was 3.8% (95% CI: 2.2–6.4%, I^2=21%; Figure S11), 0.3% (95% CI: 0.0–0.8%; I^2=0%; Figure S12), and 2.8% (95% CI: 1.3–6.1%; I^2=58.3%; Figure S13), respectively. There were no cases of infective endocarditis by 1-year and 13.6% (95% CI: 5.7–29.1%; I^2=91.3%; Figure S14) of patients experienced severe bleeding (defined as BARC type 3A or greater). Severe bleeding was higher in the TTVR group (23.8%, 95% CI: 1.8–83.8%; I^2=13.8%) compared to TEER (5.4%, 95% CI: 5.7–29.1%; I^2=84.1%). Results are summarized in *Table 5*.

Survival and freedom from heart-failure hospitalization curve analysis

Aggregation of overall survival was performed on 8 of the included studies, which included nine total curves. Overall survival for the entire cohort remained high, with Kaplan-Meier estimates of 98.5% at 1-month (95% CI: 97.5–99.1%), 96.3% at 3 months (95% CI: 94.9–97.3%), 93.3% at 6 months (95% CI: 91.6–94.7%), and 88.8% at

Table 2 Baseline patient demographic data

Characteristic	Total		The TEER cohort		The TTVR cohort	
	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)
Age, years	78.0 (77.3–78.7)	59.6% (1,589/10)	78.5 (78.1–79.0)	18.2% (1,312/6)	78.5 (70.9–86.0)	7.4% (203/2)
Males, %	34.7 (27.5–42.6)	71.8% (1,589/10)	40.6 (36.5–44.9)	17.3% (1,312/6)	23.5 (0–99.9)	78.8% (176/2)
BMI, kg/m^2	26.3 (25.2–27.4)†	63.6% (581/4)†	26.2 (24.4–28)†	73.3% (537/3)†	NR	NR
Hypertension, %	81.3 (77.4–84.6)	5.9% (831/6)	81.9 (45.7–96.1)	11.5% (554/2)	78.9 (2.2–99.8)	68.7% (203/2)
COPD, %	15.2 (9.0–24.3)†	50.9% (521/5)†	16.9 (8.0–32.1)†	58.2% (450/3)†	12.5 (4.5–30.5)	NA (27/1)
Dyslipidemia, %	63.3 (58.5–67.8)†	0.0% (591/4)†	63.0% (56.7–68.9)†	0.0% (385/2)†	65.3 (58.0–71.9)	NA (176/1)
Peripheral vascular disease, %	12.8 (6.8–23.0)†	83.7% (852/7)†	15.6% (6.7–32.2)†	86.4% (632/5)†	6.5 (3.7–11.2)	NA (176/1)
Ischaemic heart disease, %	22.5 (14.4–33.4)	70.6% (524/7)	20.3% (0.0–100.0)	92.8% (534/2)	22.8 (1.7–83.5)	24% (203/2)
Pre Intervention cerebrovascular accident or TIA, %	13.9 (10.7–17.8)†	11.6% (727/7)†	16.1% (6.7–34.0)†	65.8% (435/3)†	16.3 (0.5–88.9)	38% (203/2)
Diabetes, %	19.3 (16.5–22.3)†	0.0% (812/8)†	36.2% (14.2–66.0)†	93.4% (565/5)†	22.8 (1.7–83.5)	24% (203/2)
Renal insufficiency, %	50.2 (40.9–59.5)	84.5% (1,437/9)	44.2 (30.0–59.3)	75.6% (1,160/5)	58.0 (44.2–70.7)	0% (203/2)
Atrial fibrillation/flutter, %	90.4 (87.0–93.0)	42.6% (993/8)	90.1 (81.2–95.1)	61.5% (716/4)	89.6 (8.1–99.9)	41.7% (203/2)
Pre-existing pacemaker or ICD, %	19.7 (14.4–26.5)	70.3% (1,589/10)	17.4 (11.9–24.8)	64.1% (1,312/6)	32.7 (26.7–39.3)	0% (203/2)
HFH in past year, %	35.4 (27.4–44.3)	85.2% (1,373/5)	34.1 (23.9–45.9)	87.4% (1,197/4)	41.0 (34.0–48.3)	NA (176/1)
NYHA III–IV, %	76.0 (60.3–86.8)	93.3% (1,588/10)	69.6 (47.7–85.1)	95.6% (1,312/6)	79.4 (3.1–99.8)	48.4% (202/2)
KCCQ score	49.7 (44.5–54.8)	92.7% (1,241/5)	51.4 (46.8–56.1)	90.8% (1,197/4)	NR	NR
STS scoring (single valve repair), %	6.1 (3.8–8.3)	96.1% (326/5)	6 (-14.9–27)	93.3% (95/2)	7.6 (1.8–13.5)	8.8% (201/2)
EuroSCORE II, %	5.7 (4.7–6.7)	78.7% (457/7)	6.3 (1.6–11)	75.4% (180/3)	6.1 (-8.4–20.5)	80.1% (203/2)
Previous CABG, %	18.7 (14.0–24.4)†	36.7% (713/7)†	25.6% (10.7–49.8)†	86.3% (480/4)†	17.1 (7.6–34)	0% (203/2)
Previous surgical valvular intervention (any valve), %	38.9 (37.6–40.3)	0.0% (767/5)	39.2 (37.5–41.1)	0.0% (564/3)	38.1 (24.3–54)	0% (203/2)
Previous PCI, %	16.1 (14.1–18.4)†	0.0% (537/6)†	16.3% (12.4–21.0)†	0.0% (450/3)†	12.5 (4.5–30.5)	NA (27/1)
LVEF, %	57.8 (56.7–58.9)†	73.0% (1,292/10)†	58.1 (56.4–59.8)†	84.3% (1,035/6)†	56.3 (39.1–73.6)	57.1% (185/2)
Tricuspid annular size, mm	44.8 (42.8–46.8)	80.5% (608/4)	45.5 (43.0–48.1)	81.8% (564/3)	NR	NR
Tricuspid coaptation gap, mm	6.5 (5.0–8.0)†	96.3% (860/4)†	6.5 (5–8)†	96.3% (860/4)†	NR	NR
TAPSE, mm	16.0 (15.0–17.0)	94.6% (1,445/10)	16.1 (14.8–17.4)	96.5% (1,306/6)	15.5 (14.2–16.7)	0% (73/2)
RV FAC, %	38.1 (36.1–40.1)†	88.7% (644/7)†	38.8 (33.1–44.5)†	96.7% (529/4)†	38.4 (32.3–44.6)	0% (86/2)

†, data was available in Adams, 2024/Tang, 2025. CABG, coronary artery bypass grafting; CI, confidence interval; HFH, heart failure hospitalization; LVEF, left ventricle ejection fraction; NA, not available; NR, not reported; PCI, percutaneous coronary intervention; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; RV FAC, right-ventricular fractional area change.

Table 3 Procedural data

Characteristic	Total		The TEER cohort		The TTVR cohort	
	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)
Successful implant, %	94.4 (91.4–96.4)	0.6% (597/7)	94.8 (89.1–97.6)	22.8% (391/5)	94.1 (89.5–96.7)	NA (176/1)
Procedural success (≥1 grade TR reduction at end of procedure), %	82.0 (67.6–90.9)	0.9% (598/6)	78.3 (63.4–88.3)	0.8% (422/5)	92.9 (88.1–95.9)	NA (176/1)
Device time (implant insertion to deployment), minutes	90.9 (66.1–115.7)	98.2% (862/4)	98.1 (66.7–129.4)	97.8% (686/3)	71.6 (67–76.2)	NA (176/1)
Fluoroscopy duration, minutes	34.8 (25.2–44.4)[†]	76.4% (621/4)[†]	35.8 (16.6–55)[†]	83.8% (445/3)[†]	33.4 (31.2–35.7)	NA (176/1)

[†], data was available in Adams, 2024/Tang, 2025. CI, confidence interval; NA, not available; TEER, transcatheter edge-to-edge repair; TR, tricuspid regurgitation; TTVR, tricuspid valve replacement.

Table 4 Primary outcomes

Characteristic	Total		The TEER cohort		The TTVR cohort	
	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)
30-day or in-hospital mortality, %	1.8 (0.8–4.2)	53.3% (1,430/7)	1.2 (0.3–4.3)	41.5% (1,197/4)	2.0 (1.3–3.0)	0% (203/2)
1-year all cause mortality, %	9.9 (7.4–13.2)	48.0% (1,588/10)	9.6 (5.9–15.3)	62.9% (1,311/6)	8.3 (5.6–12.1)	0% (203/2)
1-year HFH, %	20.1 (11.4–32.9)	94.9% (1,298/7)	20.2 (9.3–38.4)	96.5% (1,227/5)	8.9 (2.6–26.4)	NA (27/1)
Tricuspid regurgitation ≤ moderate at 1 year, %	66.5 (19.2–94.3)	95.9% (852/6)	69.2 (23.1–94.4)	97.4% (716/3)	98.1 (90.9–99.6)	NA (76/1)
NYHA I–II at 1 year, %	81.1 (73.4–86.9)	70.6% (1,202/10)	81.7 (75.4–86.7)	62.2% (1,030/6)	84.3 (0.0–100.0)	88.4% (112/2)

CI, confidence interval; HFH, heart failure hospitalizations; NA, not available; NYHA, New York Heart Association; TEER, transcatheter edge-to-edge repair; TTVR, tricuspid valve replacement.

12 months (95% CI: 86.7–90.7%) (*Figure 1*). Aggregated survival curves grouped by intervention are presented in *Figure 2*. Aggregation of rates of freedom from heart failure hospitalization was performed on 5 of the included studies, which included 6 curves. Freedom from heart failure hospitalization was also high, with Kaplan-Meier estimates of 97.7% (95% CI: 96.4–98.5%), 93.5% (95% CI: 91.5–95.0%), 89.1% (95% CI: 86.7–91.1%), and 83.1% (95% CI: 80.2–85.6%) at 1-, 3-, 6- and 12-month respectively (*Figure 3*).

Heterogeneity and sensitivity analysis

Egger's test was performed for primary and secondary outcomes with ≥10 studies; however, the majority were underpowered (<10 studies), limiting interpretability. Visual inspection of funnel plots suggested no major asymmetry. Egger's test was significant for 1-year all-cause mortality (P=0.052) and thus trim-and-fill analysis was completed. Trim-and-fill analysis imputed four additional studies, resulting in a higher pooled mortality estimate of 11.6% (95% CI: 8.1–16.4%; Figure S15) compared

Table 5 Secondary outcomes

Characteristic	Total		The TEER cohort		The TTVR cohort	
	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)	Pooled weighted estimate (95% CI)	I^2 % (No. of patients/No. of studies)
Hospital LOS, days	3.0 (1.9–4.1)	95.7% (862/4)	2.6 (1.5–3.8)	95.1% (686/3)	4.0 (3.5–4.6)	NA (176/1)
Number of pacemaker implants post intervention, %	3.7 (0.5–24.6)	88.3% (866/4)	1.1 (0–33.5)	0% (663/2)	9.3 (1.5–41.6)	0% (203/2)
Non-elective cardiovascular surgery or re-intervention at 1 year, %	4.9 (3.9–6.2)	0.0% (1,409/9)	5.0 (3.4–7.2)	0.0% (1159/5)	4.1 (0.2–46.5)	0% (176/2)
New onset renal failure at 1 year, %	3.8 (2.2–6.4)[‡]	21.0% (1,041/7)[‡]	3.3 (1.1–9.4)[‡]	48.5% (835/4)[‡]	5.1 (0.0–94.5)	29.9% (176/2)
Myocardial infarction at 1 year, %	0.3 (0.0–0.8)[‡]	0.0% (574/7)[‡]	0.3 (0.0–3.4)[‡]	0.4% (324/3)[‡]	0.0 (0.0–8.4)	0.0% (176/2)
Stroke at 1 year, %	2.8 (1.3–6.1)	58.3% (898/8)	1.9 (0.4–8.0)	56.4% (648/4)	1.7 (1.2–2.3)	0.0% (176/2)
Severe bleeding (BARC type ≥3a), %	13.6 (5.7–29.1)	91.3% (784/6)	5.4 (0–99.3)	84.1% (534/2)	23.8 (1.8–83.8)	13.8 (176/2)

[‡], data was available in Sorajja, 2023. CI, confidence interval; LOS, length of stay; NA, not available; TEER, transcatheter edge-to-edge repair; TTVR, tricuspid valve replacement.

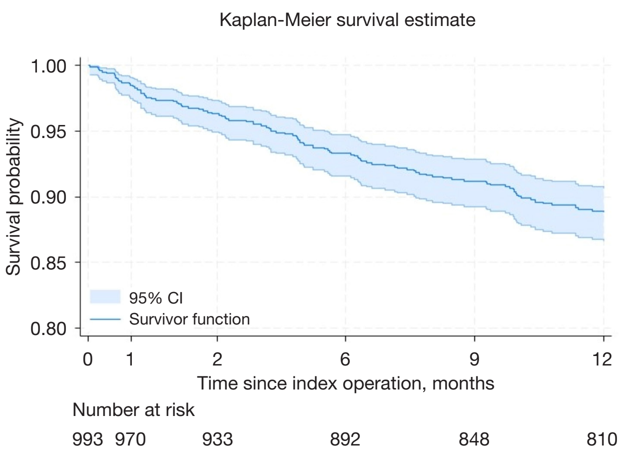

Figure 1 Kaplan-Meier curve for overall survival. CI, confidence interval.

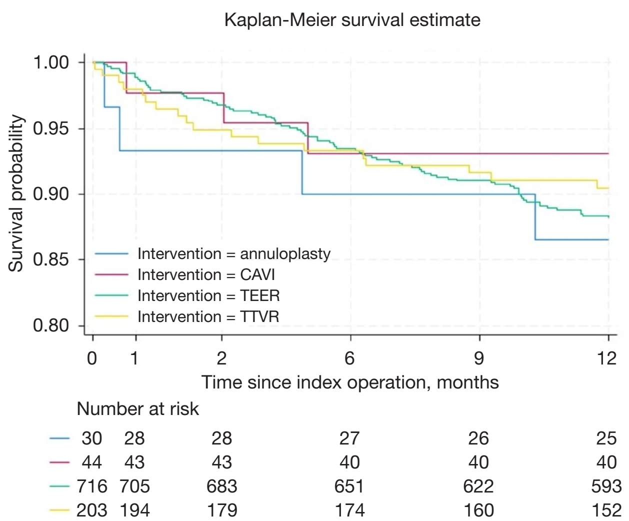

Figure 2 Kaplan-Meier curve for survival grouped by intervention type. CAVI, caval valve implantation; TEER, tricuspid edge-to-edge repair; TTVR, transcatheter tricuspid valve replacement.

with the observed estimate of 9.4% (95% CI: 6.9–12.8%). Heterogeneity increased following adjustment (I^2=60.3%). These findings suggest that the observed analysis may modestly underestimate mortality. However, these findings should be interpreted cautiously due to the limited number of included studies and the exploratory nature of single-arm meta-analyses.

LOO sensitivity analyses were performed for outcomes with significant heterogeneity (Figures S16-S24). Sequential

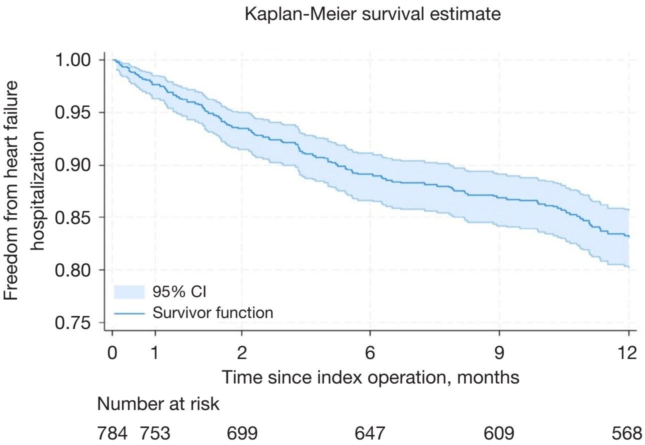

Figure 3 Kaplan-Meier curve for freedom from heart failure hospitalisation. CI, confidence interval.

removal of individual studies resulted in minimal changes to pooled estimates, with all iteration-specific CIs overlapping the primary random-effects models. No single study exerted disproportionate influence on 1-year moderate or lower TR rates, NYHA I–II classifications, and pacemaker implantation. For the remaining outcomes, despite omission of single studies substantially reducing heterogeneity, the pooled estimates remained within overlapping CIs, suggesting these studies as key contributors to between-study variability but not effect-defining. For 30-day all-cause mortality, exclusion of Nickenig *et al.* substantially reduced heterogeneity (I^2=15%), indicating that this study was a major contributor to between-study variability. For 1-year all-cause mortality, exclusion of Donal and Lurz [2024] substantially reduced heterogeneity (I^2=10.9% and 22.7% respectively), indicating these studies as key contributors to between-study variability, although pooled mortality estimates remained stable with overlapping CIs (29,33).

Discussion

Patients with severe TR suffer with a significant functional and quality of life impact, evidenced with high proportions of patients reporting NYHA III and IV symptoms. The advent of transcatheter interventions has presented a structural solution to a problem that has been mostly medically treated until recently.

Overall 1-year survival for the TTVI population was estimated to be approximately 90%. Data for the prognosis of severe TR presents a wide range of survival, ranging from 58% to 86% at one year (6,42). Given the large amounts of confounding variables in right-sided valvular disease that could contribute to mortality, such as concomitant left-sided disease, renal impairment or hepatic dysfunction, it is not appropriate to compare the outcomes of this meta-analysis directly to previously reported data about survival with tricuspid disease, highlighting the importance of two-armed comparative studies. The present systematic review identified only two two-armed studies meeting our criteria. The Tri.Fr study by Donal *et al.* demonstrated no statistically significant difference in mortality or cardiovascular hospitalization at 1-year between TEER and OMT (29). The TRILUMINATE Pivotal study by Tang *et al.* demonstrated no reduction in all-cause mortality, tricuspid valve surgery or heart failure hospitalizations through 1-year for the TEER population compared to OMT (31). The TRISCEND II pivotal study is another major two-armed study investigating TTVR which was not included in our systematic review as it did not directly report NYHA status of its patients (43). It, too, did not demonstrate any significant mortality difference between TTVR and OMT (43). To date, there has been limited evidence of longer-term outcomes beyond one year. A recent study presenting two-year data from the two-armed TRILUMINATE Pivotal study demonstrated no statistical significance in mortality between TEER and OMT (44). Even longer-term outcomes are being assessed in the currently enrolling CLASP II TR trial—a prospective, multicenter, randomized, controlled pivotal trial comparing the Edwards PASCAL TEER system to OMT alone (45).

Assessment of functional status over one year demonstrates the major benefit for TTVI. At baseline, 71% of patients had an NYHA class III or IV. At the 1-year mark, only 19% of patients were reported to have an NYHA class III or IV. The benefit was similar between TEER and TTVR. However, due to the qualitative and self-reported nature of the NYHA classification, there was a moderate risk of bias introduced from potential placebo effect. Nonetheless, there is a demonstrable improvement in functional status, providing a symptomatic improvement for patients undergoing TTVI.

There were objective improvements in tricuspid valve insufficiency. Severe or torrential TR was reported in almost all the included population, with 95% of patients falling into this category. The structural and functional benefit of TTVI was sustained at the 1-year mark, with 73% of patients demonstrating moderate or less TR, establishing the short term durability of TTVI.

Interestingly, despite functional improvement and objective improvement in TR, heart failure hospitalization rates remain a significant burden for patients, with 20% of patients requiring hospitalization for heart failure at one year. As death competes with heart failure hospitalization in this population, pooled hospitalization rates may be biased towards a lower rate and causal interpretation should be avoided. In the two-armed trials that were identified, there was no statistically significant improvement in heart failure hospitalization rates at one year compared to OMT, at around 10-13% for TEER (TRILUMINATE Pivotal, Tri. Fr) and no statistical significance for TTVR (TRISCEND II) (29,31,43). It is hypothesized that enrolment into a control group led to a more intense OMT regimen resulting in clinical improvement similar to TTVI (29).

The safety of TTVI has been demonstrated in the initial studies into TTVI and this is re-iterated in the present review (38,44). 30-day mortality was found to be 1.2%. In comparison, 30-day mortality for isolated tricuspid valve surgery can be up to 9% (11,12).

Surgical tricuspid intervention is associated with an increased need for pacemaker implantation, due to the proximity of the conduction system. A recent high-volume surgical center review demonstrated a pacemaker implant rate of 3.7% for isolated tricuspid repair, and 23% for isolated tricuspid replacement (46). In contrast, pacemaker requirements were lower in the TTVI populations, with our meta-analysis returning rates of 1.1% and 9.3% for TEER and TTVR respectively.

Endocarditis rates were only reported in three studies, all examining TEER, with no reported events of endocarditis (35-37). Severe bleeding occurred in 10% of all patients and was higher in the TTVR group at 23.8%. Data on concomitant and peri-procedural anticoagulation usage for these patients was not available. Hospital length of stay was also low, at an average of 2.4 days, demonstrating the ability for patients to recover quickly from their procedure and be discharged.

Limitations

Our systematic review has some notable limitations. Only two studies were multi-arm in nature, meaning that there is little information about the comparative population and results should be interpreted in isolation. This is an evolving field, with ongoing two-arm studies which are yet to be published. Our utilization of NYHA classification as our endpoint of interest regarding functional status excluded several studies examining this topic but presented other quantitative metrics such as KCCQ-OS and 6MWT, including the TRISCEND II pivotal study (43).

Conclusions

At a 1-year follow up, transcatheter tricuspid interventions provide a safe, effective way of managing the symptomatic burden of severe TR and reducing TR severity. Limited two-arm study data suggests no improvement in mortality or heart failure hospitalizations at 1-year. More two-armed, longer-term studies are required to establish the impact of transcatheter tricuspid interventions in comparison to OMT alone.

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Footnote

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