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GLOBAL CARDIOLOGY
Global Cardiology 2026; **4**: 113-121
DOI: 10.4081/cardio.2026.104

ARTICLE

Transcatheter tricuspid valve repair for tricuspid regurgitation: a meta-analysis of MitraClip, TriClip, and PASCAL Systems

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Abstract

Tricuspid regurgitation (TR) is associated with significant morbidity and mortality, yet surgical intervention remains underutilized due to high operative risk. Transcatheter tricuspid valve repair (TTVr) has emerged as a less invasive alternative; however, comparative data across device platforms remain limited. We conducted a systematic review and meta-analysis in accordance with PRISMA guidelines, searching PubMed/MEDLINE, Embase, and Cochrane Library up to March 2026. Studies evaluating TTVr using MitraClip, TriClip, or PASCAL in adults with moderate-to-severe TR were included. Primary outcomes included changes in TR severity and echocardiographic parameters (TR volume, vena contracta, effective regurgitant orifice area, tricuspid annular plane systolic excursion). Secondary outcomes included 6-minute walk distance (6MWD) and New York Heart Association (NYHA) functional class. A random-effects model was used for pooled analyses. Fifty studies were included in the meta-analysis. TTVr significantly reduced TR volume (MD −21.53 mL; 95% CI −24.72 to −18.35) and vena contracta (MD −5.91 mm; 95% CI −7.62 to −4.19), with consistent improvements across devices. Severe TR was significantly reduced (RR 0.32; 95% CI 0.26-0.39). Functional outcomes improved, with increased 6MWD (MD 36.14 m; 95% CI 23.85-48.43) and a higher proportion of patients achieving NYHA class I/II. A modest decline in TAPSE was observed (MD −0.74 mm). Subgroup analyses showed no significant differences in most echocardiographic outcomes, though functional improvements varied among devices. We concluded that TTVr is associated with significant improvements in TR severity, echocardiographic parameters, and functional status. Comparable outcomes across MitraClip, TriClip, and PASCAL suggest a potential class effect, supporting TTVr as an effective treatment option for high-risk patients.

Key words: tricuspid regurgitation; transcatheter tricuspid valve repair; edge-to-edge repair; MitraClip; TriClip; PASCAL.

Received: 14 April 2026; Accepted: 19 May 2026.
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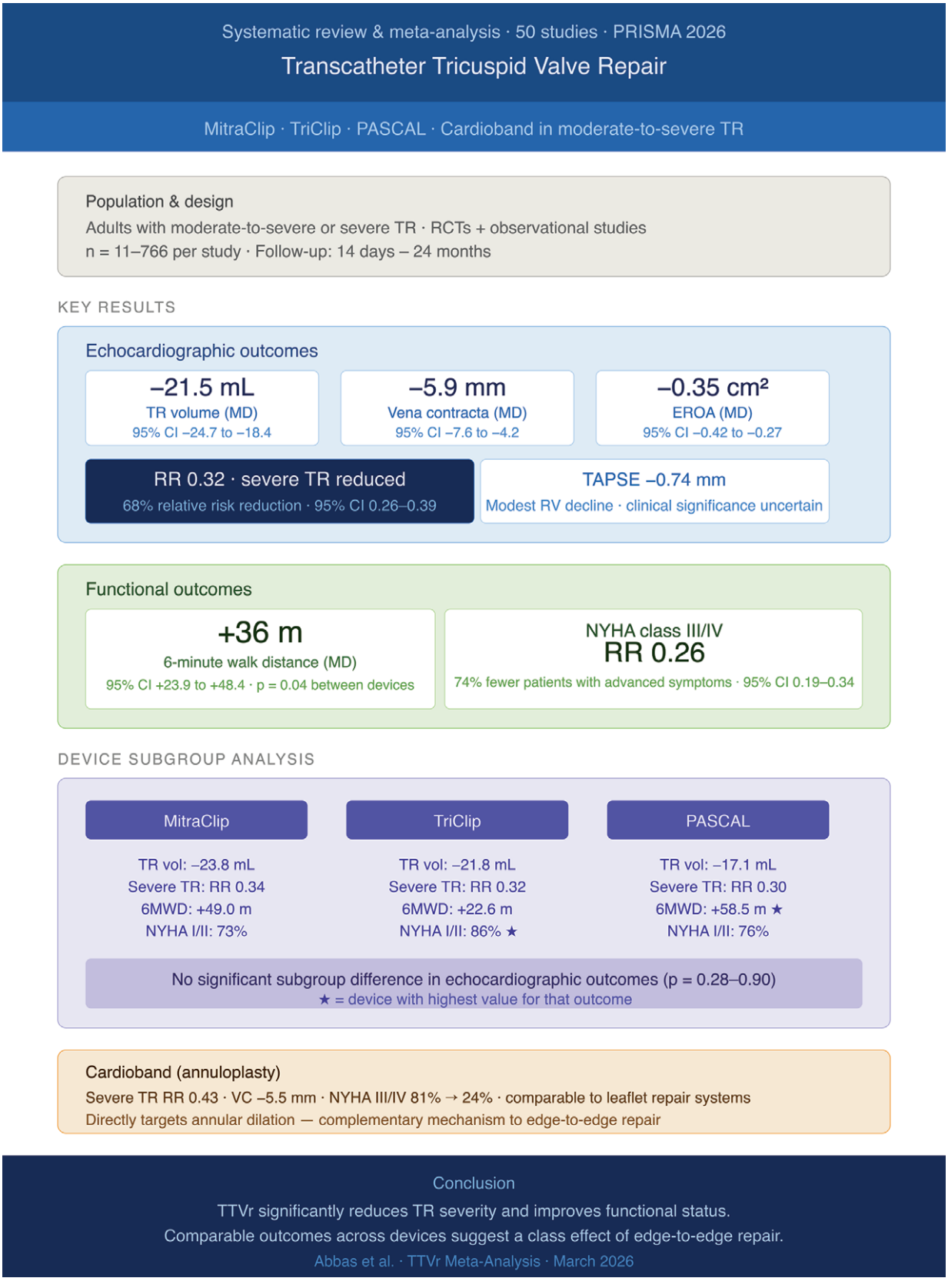
Graphical abstract



Introduction

Tricuspid regurgitation (TR) is a prevalent and clinically significant valvular heart disease associated with progressive right-sided heart failure, impaired functional capacity, and increased mortality. Once considered a benign condition, growing evidence has demonstrated that moderate-to-severe TR independently contributes to adverse outcomes, even after adjustment for comorbidities and left-sided heart disease.[1]

Surgical intervention for isolated TR remains underutilized due to high perioperative risk, advanced patient age, and frequent comorbid conditions at the time of presentation. Consequently, a large proportion of patients are managed conservatively, often with suboptimal symptomatic relief and continued disease progression.[2] These limitations have driven the development of transcatheter tricuspid valve repair (TTVr) therapies as less invasive alternatives.

Among these, edge-to-edge repair systems such as the MitraClip (Abbott Vascular, Santa Clara, CA, USA) – originally developed for mitral valve repair and used off-label in tricuspid regurgitation – the TriClip system (Abbott Structural Heart, Santa Clara, CA, USA), specifically designed for tricuspid valve intervention, and the PASCAL system (Edwards Lifesciences, Irvine, California, USA) have emerged as promising options. These devices have demonstrated feasibility, procedural safety, and early efficacy in reducing TR severity and improving clinical outcomes.[3-5] However, the available evidence remains heterogeneous, with variability in study design, patient populations, and outcome reporting. Moreover, direct comparative data across different device platforms are limited, and the relative effectiveness of these systems remains uncertain.

Therefore, we conducted a comprehensive systematic review and meta-analysis to evaluate the impact of transcatheter tricuspid valve repair on echocardiographic parameters, functional capacity, and clinical outcomes, with subgroup analyses comparing MitraClip, TriClip, and PASCAL systems.

Materials and Methods

Study design and reporting standards

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The study protocol was developed a priori, including predefined objectives, eligibility criteria, and outcomes of interest. This study is registered in the OSF database with DOI: 10.17605/OSF.IO/D4NWC.

Search strategy

A comprehensive literature search was performed across PubMed/MEDLINE, Embase, and Cochrane Library from database inception to March 2026. The search strategy combined controlled vocabulary (MeSH/Emtree terms) and free-text keywords related to "tricuspid regurgitation," "transcatheter tricuspid valve repair," "MitraClip," "TriClip," "PASCAL," and "edge-to-edge repair." No language restrictions were applied. Additionally, the reference lists of relevant articles and reviews were manually screened to identify further eligible studies.

Eligibility criteria

Studies were considered eligible if they fulfilled predefined inclusion criteria. The population comprised adult patients (≥18 years) diagnosed with moderate-to-severe or severe tricuspid regurgitation. Eligible interventions included TTVr performed using MitraClip, TriClip, or PASCAL systems. Studies were required to report at least one relevant outcome, including TR severity or quantitative parameters (regurgitant volume, effective regurgitant orifice area, or vena contracta), right ventricular function (*e.g.*, tricuspid annular plane systolic excursion), functional capacity (6-minute walk test), or clinical outcomes such as NYHA functional class. Both randomized controlled trials and observational studies (prospective or retrospective) were included. Exclusion criteria comprised case reports, small case series with fewer than 10 patients, reviews, editorials, and conference abstracts lacking full data. Studies without extractable quantitative data and those with overlapping populations were excluded, retaining the most comprehensive or recent dataset.

Data extraction

Two independent reviewers screened titles, abstracts, and full-text articles to determine eligibility. Data extraction was performed using a standardized form, capturing study characteristics (author, year, design, and sample size), patient demographics and baseline features, type of device used (MitraClip, TriClip, or PASCAL), and reported outcome measures including pre- and post-intervention values or event rates. Discrepancies between reviewers were resolved through discussion or consultation with a third reviewer.

Outcomes

Primary outcomes

The primary outcomes included changes in TR severity, assessed using both quantitative and categorical measures. Echocardiographic parameters were evaluated, including regurgitant volume, vena contracta width, effective regurgitant orifice area (EROA), and tricuspid annular plane systolic excursion (TAPSE).

Secondary outcomes

The secondary outcomes comprised functional and clinical measures. Functional capacity was assessed using the 6-minute walk test (6MWT), while clinical status was evaluated based on the New York Heart Association (NYHA) functional class.

Statistical analysis

Meta-analysis was conducted using a random-effects model based on the DerSimonian-Laird method to account for expected between-study variability. Continuous outcomes were pooled as mean differences (MD) with corresponding 95% confidence intervals (CI), while dichotomous outcomes were synthesized using risk ratios (RR) with 95% CI. Statistical heterogeneity across studies was evaluated using the I^2 statistic, with thresholds of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively. In the presence of substantial heterogeneity, potential sources were explored through subgroup and sensitivity analyses. A p-value of <0.05 was considered statistically significant for all analyses, and all statistical tests were two-sided.

Subgroup and sensitivity analyses

Prespecified subgroup analyses were performed according to the type of transcatheter device used, including MitraClip, TriClip, PASCAL, and other systems. Differences between subgroups were assessed using tests for subgroup interaction, with a p-value of less than 0.05 considered statistically significant. Sensitivity analyses were conducted where appropriate by sequentially excluding individual studies and reassessing pooled estimates. Publication bias was assessed using funnel plot visual inspection and Egger's regression test, provided that at least ten studies were available for a given outcome.

Risk of bias assessment

To evaluate the methodological quality of the included studies, we applied three validated risk of bias assessment tools according to study design. For observational cohort and single-arm studies, the Newcastle-Ottawa Scale (NOS) and the Methodological Index for Non-Randomized Studies (MINORS) were used. The NOS evaluates three domains − selection of study groups, comparability, and ascertainment of outcome − with a maximum score of 9 points. MINORS assesses eight domains with a maximum score of 16 points. For randomized controlled trials (RCTs), the Cochrane Risk of Bias 2 (RoB 2) tool was applied, assessing randomization, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting. All assessments were conducted independently by two reviewers, and discrepancies were resolved through discussion.

Results

Study selection

A comprehensive literature search of PubMed/MEDLINE, Embase, and the Cochrane Library up to 1 March 2026 identified a total of 527 records (PubMed: 191, Embase: 124, Cochrane Library: 212). After removal of 112 duplicate records, 415 unique studies remained for title and abstract screening.

Of these, 312 studies were excluded based on irrelevance to the study question, including non-human studies (n=28), review articles and editorials (n=96), conference abstracts without full data (n=74), and studies not involving transcatheter tricuspid valve repair or relevant devices (n=114).

The full texts of 103 articles were retrieved and assessed for eligibility. Following detailed evaluation, 53 studies were excluded for the following reasons: insufficient or non-extractable outcome data (n=18), absence of relevant clinical or echocardiographic endpoints (n=14), use of surgical rather than transcatheter interventions (n=11), or failure to report on edge-to-edge repair systems such as MitraClip, TriClip, and PASCAL.

Ultimately, 50 studies met the inclusion criteria and were included in the final qualitative and/or quantitative synthesis. The study selection process is illustrated in the PRISMA flow diagram (Supplementary Figure S1). Detailed results are shown in Supplementary Table S1.

Study characteristics

A total of 50 studies were included in the present analysis, comprising a mix of prospective cohorts, retrospective cohorts, observational studies, and randomized controlled trials (RCTs).[5-59]

The majority of studies were single-arm or observational in design, with several multicenter investigations and four major RCTs (Tri.Fr Trial, TRICAVAL, TRILUMINATE, and TRISCEND II Pivotal). Sample sizes varied substantially, ranging from 11 to 766 participants, reflecting both early feasibility studies and large registry-based analyses.

The interventions evaluated primarily included transcatheter tricuspid valve repair and replacement systems, most commonly MitraClip, TriClip, and PASCAL, with additional devices such as Cardioband and EVOQUE assessed in selected studies. Several studies also included comparative arms, such as guideline-directed medical therapy (GDMT) or optimal medical therapy (OMT).

Follow-up durations were heterogeneous, ranging from in-hospital or 14 days to up to 24 months, with many studies reporting short-term outcomes at 30 days and others extending to 6 months or 1 year. The most frequently reported outcomes included echocardiographic parameters such as TR severity, EROA, TAPSE, and regurgitant volume, as well as clinical outcomes including NYHA functional class, 6-minute walk distance (6MWD), all-cause and cardiovascular mortality, heart failure hospitalization, and major adverse cardiac and cerebrovascular events (MACCE). Details of study characteristics are given in Supplementary Table S2.

Tricuspid regurgitation severity and echocardiographic parameters

As shown in Supplementary Figure S2, there was a significant reduction in TR volume, with a pooled mean difference (MD) of −21.53 mL (95% CI: −24.72 to −18.35; I^2=80.5%). Subgroup analyses demonstrated consistent reductions across devices (P for subgroup difference = 0.33), including MitraClip (−23.84 mL), PASCAL (−17.10 mL), and TriClip (−21.81 mL).

In Supplementary Figure S8, vena contracta significantly decreased (MD: −5.91 mm; 95% CI: −7.62 to −4.19; I^2 = 97.9%), while EROA was also reduced (Figure S9; MD: −0.35 cm^2; 95% CI: −0.42 to −0.27; I^2 = 93.8%), with no significant subgroup differences (p=0.28 and p=0.34, respectively). All device groups demonstrated comparable improvements.

The pooled risk ratio (RR) for TR severity (Supplementary Figure S5) was 0.32 (95% CI: 0.26-0.39; I^2=85.8%), indicating a substantial reduction in severe TR following intervention. This effect was consistent across MitraClip (RR: 0.34), PASCAL (RR: 0.30), and TriClip (RR: 0.32), with no significant subgroup differences (p=0.90).

Right ventricular function

As illustrated in Supplementary Figure S3, a modest but statistically significant decline in TAPSE was observed (MD: −0.74 mm; 95% CI: −1.27 to −0.21; I^2=93.8%). Subgroup analysis revealed no significant differences among devices (p=0.50), although the effect was not statistically significant in the PASCAL and TriClip subgroups individually.

Functional capacity

Functional capacity, assessed by the 6-minute walk test (6MWT), improved significantly (Supplementary Figure S4), with a pooled increase of 36.14 meters (95% CI: 23.85 to 48.43; I^2=82.4%). Subgroup analysis demonstrated a statistically significant difference between devices (p=0.04), with the greatest improvement observed in the PASCAL group (58.52 m), followed by MitraClip (48.98 m) and TriClip (22.59 m).

New York Heart Association functional class

The proportion of patients in NYHA class III/IV post-intervention was significantly reduced (Supplementary Figure S6; RR: 0.26; 95% CI: 0.19-0.34; I^2=77.3%), with consistent effects across subgroups (p=0.23). Conversely, the proportion of patients achieving NYHA class I/II significantly increased (Supplementary Figure S10; RR: 0.78; 95% CI: 0.72.0.84; I^2=84.3%). Subgroup analysis revealed a significant difference (p=0.009), with the highest proportion observed in the TriClip group (0.86), compared to MitraClip (0.73) and PASCAL (0.76).

Risk of bias assessment

Across the included observational studies assessed using the NOS, the majority demonstrated high methodological quality, with most studies scoring 9/9 and only one study scoring 8/9, indicating low risk of bias across selection, comparability, and outcome assessment domains. MINORS assessment of single-arm studies similarly reflected overall good quality, with total scores ranging from 12 to 15 out of 16. Among the randomized trials, RoB 2 assessment revealed that most trials exhibited low risk of bias in the randomization process, missing outcome data, and measurement of outcomes. Some concerns were noted in deviations from intended interventions and selective reporting for certain trials, while a minority showed high risk of bias overall due to these deviations.

Discussion

In this comprehensive meta-analysis, we demonstrate that TTVr is associated with significant improvements in echocardiographic parameters, TR severity, and functional status across a broad patient population. Specifically, TTVr resulted in substantial reductions in TR volume, vena contracta, and EROA, along with marked improvements in NYHA functional class and 6-minute walk distance. These findings reinforce the growing role of transcatheter therapies as an effective treatment strategy for patients with moderate-to-severe TR who are often poor surgical candidates.

A key finding of our analysis is the consistent reduction in TR severity across all device platforms, with a pooled risk ratio of 0.32. This aligns with prior registry and trial data demonstrating the efficacy of edge-to-edge repair systems in reducing regurgitant burden. The TriValve registry and subsequent studies have similarly reported meaningful TR reduction and symptomatic improvement following TTVr.[34] Importantly, our subgroup analyses showed no significant differences between MitraClip, PASCAL, and TriClip systems for most echocardiographic outcomes, suggesting a potential class effect of edge-to-edge repair technologies.

Despite these consistent improvements in TR severity, we observed a modest decline in TAPSE, indicating a potential reduction in right ventricular longitudinal function. This finding has been previously described and may reflect afterload mismatch, where acute reduction in TR increases effective forward flow and ventricular loading conditions, transiently impacting RV mechanics.[5] Notably, the clinical significance of this finding remains uncertain, particularly in the context of improved symptoms and functional capacity.

Functional outcomes in our analysis were particularly encouraging. We observed a significant improvement in 6-minute walk distance, with subgroup differences favoring the PASCAL system. While the reasons for this variation are not entirely clear, they may relate to differences in device design, leaflet grasping mechanics, or patient selection. Similarly, the proportion of patients achieving NYHA class I/II was highest in the TriClip subgroup, suggesting potential differences in clinical response that warrant further investigation. These findings are consistent with recent randomized and single-arm studies such as TRILUMINATE and CLASP TR, which demonstrated improvements in quality of life and functional capacity following TTVr.

Comparison between leaflet repair and annuloplasty (Cardioband)

A central finding of this analysis is the comparable efficacy across device classes, despite their fundamentally different mechanisms of action. Annuloplasty using the Cardioband system demonstrated a significant reduction in TR severity, with

a pooled risk ratio (RR) of 0.43 (95% CI: 0.35-0.54). While leaflet-directed therapies such as TriClip (RR 0.19) and MitraClip (RR 0.30) showed numerically lower RRs, this likely reflects differences in endpoint definitions and patient selection rather than true inferiority or superiority. Importantly, Cardioband directly targets annular dilation – a predominant driver of functional TR – thereby addressing the underlying pathophysiology rather than solely improving leaflet coaptation.

Functional outcomes further reinforce this observation. The proportion of patients with advanced symptoms (NYHA Class III/IV) decreased markedly from 81% pre-procedure to 24% post-procedure in the Cardioband cohort. This degree of improvement is comparable to that observed with leaflet repair systems such as TriClip (17%) and PASCAL (16%), suggesting that both approaches yield clinically meaningful symptomatic relief, regardless of the anatomical target. Similarly, Cardioband achieved a pooled reduction in vena contracta width of −5.54 mm (95% CI: −6.65 to −4.44), which closely parallels reductions observed with MitraClip (−4.94 mm) and PASCAL (−6.54 mm).

Clinical significance and mechanistic correlation

The clinical relevance of these findings lies in the multidimensional improvement observed across anatomical, functional, and patient-centered outcomes. First, the significant increase in Kansas City Cardiomyopathy Questionnaire scores (mean change: +15.78 points) reflects a meaningful improvement in quality of life, exceeding established thresholds for clinical significance. Second, the improvement in 6-minute walk distance (mean increase: +36.14 meters) demonstrates enhanced exercise capacity, a critical outcome in a population characterized by limited functional reserve.

From a mechanistic perspective, the observed reductions in EROA (−0.35 cm^2) and regurgitant volume (−21.53 mL) suggest favorable reverse remodeling of the tricuspid valve apparatus. Notably, annuloplasty (Cardioband) achieves this by reducing annular dimensions, whereas leaflet repair devices improve coaptation. Despite these differing mechanisms, both approaches ultimately lead to reduced volume overload on the right ventricle, which likely underpins the observed clinical improvements.

The high degree of heterogeneity observed across several outcomes likely reflects clinical and methodological variability, including differences in baseline TR severity, RV function, procedural techniques, and follow-up duration. Nonetheless, the direction of effect remained consistent across studies and subgroups, supporting the robustness of our findings.

Strengths and limitations

Strengths

This study has several important strengths. First, it represents a comprehensive synthesis of multiple clinically relevant outcomes, including both echocardiographic and functional endpoints. Second, we performed device-specific subgroup analyses, allowing for comparison across major TTVr platforms. Third, the inclusion of a large cumulative sample size enhances the statistical power and generalizability of our findings.

Limitations

Several limitations should be acknowledged. Most included studies were observational in nature, which introduces the potential for selection bias and confounding. The absence of patient-level data limited our ability to adjust for baseline differences or perform more granular analyses. Additionally, heterogeneity was high across several endpoints, reflecting variability in study design and reporting. The lack of long-term follow-up data also limits conclusions regarding durability and survival benefit. Finally, direct head-to-head comparisons between devices remain scarce, and subgroup analyses should be interpreted cautiously.

Future directions

Future research should focus on large-scale randomized controlled trials directly comparing different TTVr systems to establish relative efficacy and safety. Long-term studies are needed to evaluate durability of TR reduction, right ventricular remodeling, and survival outcomes. Standardization of outcome definitions and imaging parameters would further improve comparability across studies. Additionally, identifying optimal patient selection criteria and timing of intervention will be critical to maximizing clinical benefit.

In particular, well-designed head-to-head randomized controlled trials directly comparing annuloplasty systems such as Cardioband with leaflet-directed therapies (*e.g.*, TriClip and PASCAL) – particularly across different phenotypes of tricuspid regurgitation (predominant annular dilation versus leaflet tethering) – are needed. There is also a growing need for a phenotype-guided therapeutic approach integrating multimodal imaging and clinical characteristics to better match patients with the most appropriate intervention. Extended longitudinal studies are essential to evaluate sustained efficacy and structural integrity beyond five to ten years. Finally, future studies should elucidate whether the observed decline in TAPSE reflects true impairment in RV function or a consequence of altered loading conditions.

Conclusions

TTVr is associated with significant improvements in TR severity, echocardiographic parameters, and functional outcomes, including NYHA class and exercise capacity. These benefits were consistently observed across edge-to-edge repair systems (MitraClip, PASCAL, and TriClip), with no major differences in most endpoints, suggesting a potential class effect.

Annuloplasty with the Cardioband system demonstrated comparable efficacy, achieving meaningful TR reduction and symptomatic improvement by directly targeting annular dilation. Despite a modest decline in TAPSE, the overall clinical profile favored intervention, with substantial improvements in functional status. The comparable outcomes between leaflet repair and annuloplasty highlight their complementary roles in addressing different mechanisms of TR. Future randomized studies with long-term follow-up are needed to clarify comparative efficacy, durability, and impact on survival. Overall, transcatheter tricuspid interventions represent effective therapeutic options for patients with moderate-to-severe TR at high surgical risk.

Authors' contributions

All the authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest

The authors declare that they have no known financial or personal relationships that could have influenced the work reported in this paper.

Funding

The authors report no financial interests in any of the procedures, devices, or products mentioned in this manuscript. No funding or grants were received for this study.

Ethics approval and consent to participate

This study is a meta-analysis of previously published randomized controlled trials and did not involve direct data collection from human participants. Therefore, ethical approval and informed consent were not required. All included studies had obtained appropriate ethical approval from their respective institutional review boards. No IRB approval was required for this manuscript as no new human subjects were involved.

Availability of data and materials

All studies included in this research are publicly available through PubMed Central. Data supporting the findings of this study are provided within the article and Supplementary Material files. Additional information can be obtained from the corresponding author upon request.

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Online supplementary material:

upplementary Figure S1. Prisma flow diagram.

Supplementary Figure S2. Tricusp regurgitation volume.

Supplementary Figure S3. TAPSE.

Supplementary Figure S4. 6 MWT.

Supplementary Figure S5. TR severity.

Supplementary Figure S6. Post treatment NYHA Class greater than 3.

Supplementary Figure S7. Pre treatment NYHA Class greater than 3.

Supplementary Figure S8. Vena contracta width.

Supplementary Figure S9. EROA.

Supplementary Figure S10. NYHA lesser than 3.

Supplementary Figure S11. KCCQ.

Supplementary Table S1. Search strategy.

Supplementary Table S2. Study Characteristics table.

Supplementary Table S3. Quality assessment of included observational studies using the Newcastle–Ottawa Scale (NOS). Studies were evaluated across three domains: selection of study groups, comparability of cohorts, and ascertainment of outcomes/exposures. Higher scores indicate better methodological quality.

Supplementary Table S4. Risk of bias assessment of included randomized controlled trials using the Cochrane Risk of Bias (RoB 2) tool. Studies were evaluated across five domains: bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of the reported results.

Supplementary Table S5. Methodological quality assessment of included non-randomized single arm studies using the Methodological Index for Non-Randomized Studies (MINORS) criteria.

Supplementary Table S6. Summary of the outcomes.