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# Survival outcomes in isolated severe tricuspid regurgitation according to therapeutic modalities: a systematic review and meta-analysis

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## ABSTRACT

**Importance** Managing isolated severe tricuspid regurgitation (TR) poses significant challenges, with questions recently arising about the efficacy of surgery and percutaneous therapies compared with conservative approaches in improving survival.

**Objective** We aimed to assess the available evidence on mortality associated with different treatment modalities for isolated severe TR.

**Evidence review** A comprehensive search of medical databases was conducted. Studies reporting mortality of isolated TR at 1-year follow-up, with TR severity classified as moderate-to-severe or worse, were included. Exclusion criteria were TR associated with left-heart disease and combined procedures (treating other valves). The primary endpoint was all-cause mortality at 1 year, with secondary outcomes including in-hospital, 2-year and 5-year mortality. Mortality was compared by meta-analysis and meta-regression using age, sex and left ventricular ejection fraction as confounders.

**Findings** 25 studies met the inclusion criteria. Mean age was 72.0 years among the 5702 patients managed medically, 71.3 years among the 1416 patients treated percutaneously and 59.3 years among the 1990 patients managed surgically. In medically managed patients, 1-year, 2-year and 5-year mortality rates were 14%, 20% and 46%, respectively. Among percutaneously managed patients, there was an in-hospital mortality of 1% and a 1-year mortality rate of 18%, which increased to 22% at 2 years. Surgically managed patients experienced an in-hospital mortality of 8% with 1-year, 2-year and 5-year mortality rates of 15%, 20% and 30%, respectively. No statistical differences in mortality were observed at 1, 2 or 5 years. Those results were confirmed after adjusted meta-regression.

**Conclusions** These findings underscore the significant long-term mortality associated with isolated severe TR, regardless of treatment group. Despite potential selection bias, both percutaneous and surgical interventions did not offer lower mortality rates compared with medical management after 2 years. Further research is warranted to improve outcomes in the management of isolated TR.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Optimal management remains challenging in isolated tricuspid regurgitation (TR). While tricuspid surgery carries high mortality rates, emerging transcatheter therapies provide promising alternatives, particularly for high-risk patients. However, studies have questioned the survival benefits of both surgical and transcatheter interventions compared with conservative management, leaving the best approach to severe isolated TR still under debate.

### WHAT THIS STUDY ADDS

⇒ In this systematic review, tricuspid valve intervention (either percutaneous or surgical) was not associated with lower mortality rates compared with medical management in isolated TR.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Randomised controlled trials are warranted to refine patient selection in isolated TR.

## INTRODUCTION

Isolated significant tricuspid regurgitation (TR)[1] has garnered increased attention in recent years[2] due to its impact on functional status and its association with mortality. Determining the optimal management of patients with severe isolated TR is complex, considering the high risk and comorbidity burden of affected patients. Tricuspid surgery is associated with high mortality rates and may not be suitable for a significant number of patients.[3] The emergence of new transcatheter therapies offers promising alternatives, particularly for patients at high or prohibitive surgical risk.[4 5] Several studies have raised concerns regarding the lack of survival benefits associated with surgical[6] or transcatheter intervention[7] compared with conservative approaches. To date, the

optimal management of severe isolated TR remains a topic of ongoing debate.

The objective of this meta-analysis is to describe and compare mortality rates in severe isolated TR patients across different treatment modalities: medical management, cardiac surgery and percutaneous procedures.

## METHODS

We conducted a systematic review of published studies reporting mortality rates associated with isolated TR, regardless of its aetiology. Patients were categorised according to management, including medical, percutaneous or surgical approaches. Studies reporting mortality of isolated TR at 1-year follow-up, with TR severity classified as moderate-to-severe or worse, were included. Exclusion criteria were: (1) TR associated with left-heart disease, notably aortic or mitral valvular disease or congenital heart disease; (2) combined valvular procedures for the percutaneous and surgical groups, defined as associated concomitant management of the mitral and/or aortic valve and (3) studies without mortality data.

Following Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines,[8] searches were conducted in the PubMed and Medline databases using the terms "severe tricuspid regurgitation." Publications were initially screened based on their titles, followed by abstract screening if the title was deemed relevant. Full manuscripts of relevant abstracts were retrieved for inclusion. Studies published between 1 January 2000 and 31 December 2023 were considered eligible. This timeline was chosen to ensure that only relatively recent research was included, thereby minimising the potential for heterogeneity in medical therapies and clinical practices that might arise from older studies. Two trained physicians (GS and JM) independently conducted the screening, with results subsequently consolidated. Any discrepancies were resolved through collegial discussion. To avoid duplicates, when multiple studies originated from the same database, either trial or registry, only the most relevant manuscript with the largest number of patients or reporting the primary endpoint was included.

Patients were categorised based on the management of severe isolated TR into three groups. The surgical group comprised patients who underwent open-heart surgery for isolated TR intervention, irrespective of the specific type of intervention or prosthesis implanted. The interventional group consisted of patients who underwent isolated tricuspid valve repair or replacement using any devices, including caval valve implantation (CAVI) devices. The medical therapy group included patients with isolated TR managed medically without any intervention. We analysed outcomes by pooling mortality rates with 95% CIs at 1, 2 and 5 years, categorised by treatment group (medical therapy, interventional and surgical).[9] Mortality data were extracted from the abstract or manuscript text. If not available in the text, they were extracted from tables. In cases where mortality data were not available in either text or tables, they were estimated using Kaplan-Meier curves and the number of patients at risk. If propensity score matching was employed, the results from the largest cohort with available outcomes were reported. Data collection was conducted using a predesigned Excel sheet, which included trial or registry details, basic population and procedural characteristics, and mortality rates at the prespecified time points. Three trained physicians (GS, JM and AC) independently collected the data. Any discrepancies in data collection were resolved through consensus. Periprocedural outcomes for the percutaneous and surgical groups were reported using the definition stated in each study.[10] In patients undergoing interventions (either surgical or percutaneous), we reported the residual leak, length of hospital stay and complications, including in-hospital mortality, pacemaker implantation rates, unplanned surgical interventions, bleeding and vascular complications.[10] Inclusion and exclusion criteria for each study were reported.

The primary outcome was all-cause mortality at a 1-year follow-up. Secondary endpoints included all-cause mortality at hospital discharge for both the percutaneous and surgical groups, as well as at 2-year, 5-year and 10-year follow-ups.

Two prespecified sensitivity analyses were conducted: one excluding CAVI patients, as it is considered a palliative procedure, and the other separating percutaneous repair or percutaneous replacement cases after excluding the CAVI cases. Bias in the studies was assessed using RoB 2 for randomised trials and the Newcastle-Ottawa scale for observational studies.

### Statistical analysis

The number of patients at risk and the number of events were collected for all studies based on their treatment group (medical, percutaneous and surgical).

Pooled Kaplan-Meier curves, categorised by treatment groups, were collected using the IPDfromKM package.[11] Comparisons among the three treatment groups were conducted using pooled mortality rates with corresponding 95% CIs, derived from the number of patient deaths divided by the total number of patients at risk during the study period. A random-effects meta-regression model, using the restricted maximum likelihood method, was applied to assess the relationship between treatment group and mortality, while accounting for between-study heterogeneity. To explore the impact of potential confounders, we implemented two statistical models. Model 1 assessed the association between treatment group, age and sex with mortality, while model 2 examined the relationships among age, sex and left ventricular ejection fraction (LVEF). All analyses were conducted using the R statistical software (RStudio, Boston, Massachusetts, USA), leveraging the metafor package for meta-analysis and the survival package for mortality-related outcomes. A $p<0.05$ was considered statistically significant.

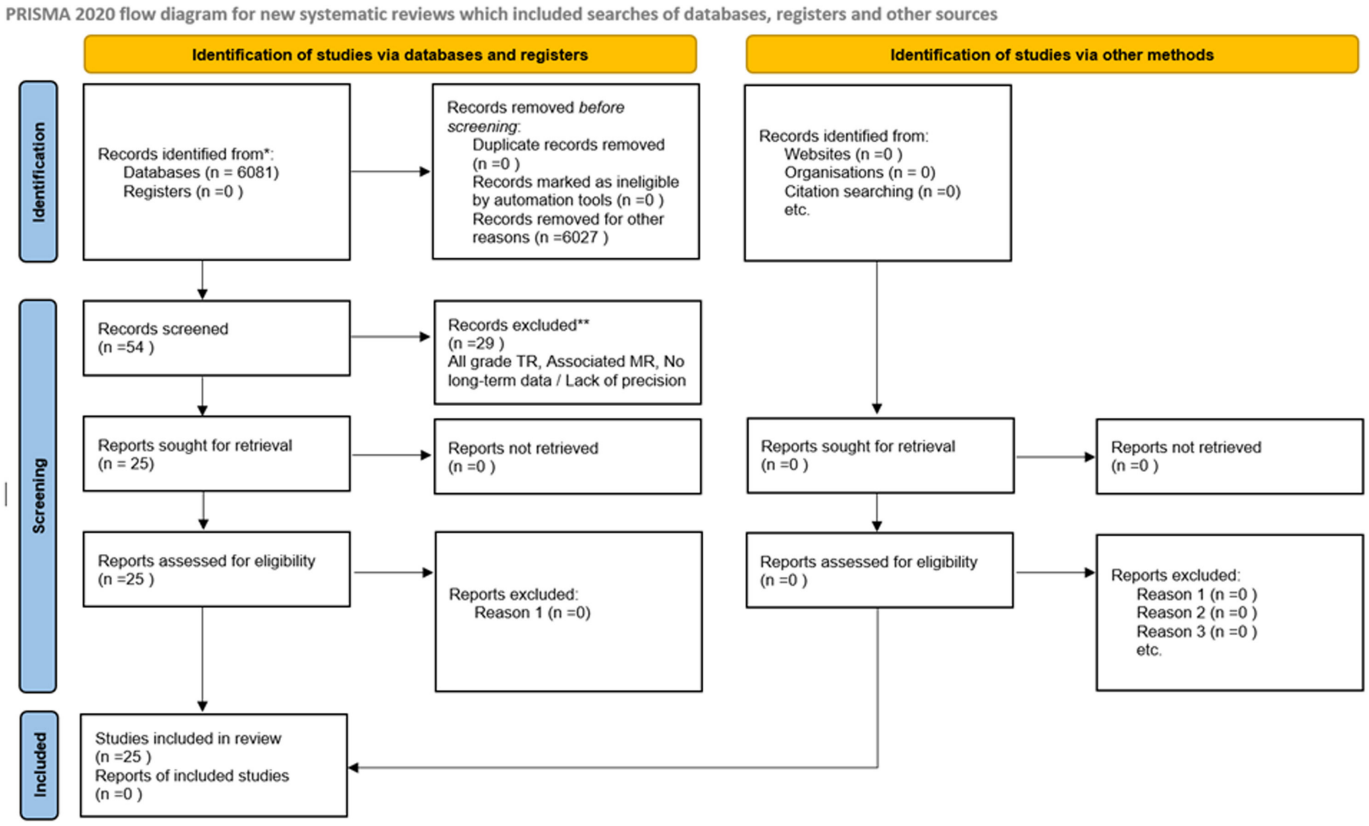



**Figure 1** Flow chart. *Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers). **If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools. Source: Page *et al*.[8] PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; TR, tricuspid regurgitation.

## RESULTS

In total, 7 studies were included in the medical management group, 13 studies in the transcatheter group and 12 studies in the surgery group (figure 1).

Table 1 presents a summarised overview of pooled baseline characteristics, while detailed characteristics of each study are provided in online supplemental table 1, and patient characteristics for each included study are reported in online supplemental table 2. Kaplan-Meier curves of mortality according to treatment group are reported in figure 2. Mortality rates at 1, 2 and 5 years, according to treatment group are reported in figures 3–5, respectively. The risk of bias in studies is reported in online supplemental figure 1. In-hospital mortality according to treatment group is reported in online supplemental figure 2.

**Table 1** Pooled characteristics of the populations

| | Medical management N=5702 | Percutaneous treatment N=1416 | Surgery N=1990 |
|---|---|---|---|
| Female (%) | 53.6 | 60.0 | 55.8 |
| Mean age (years) | 72.0 | 71.3 | 59.3 |
| Mean LVEF (%) | 53.6 | 55.6 | 56.3 |

Pooled baseline characteristics in included studies, when available.
LVEF, left ventricular ejection fraction.

### Pooled Kaplan-Meier curves

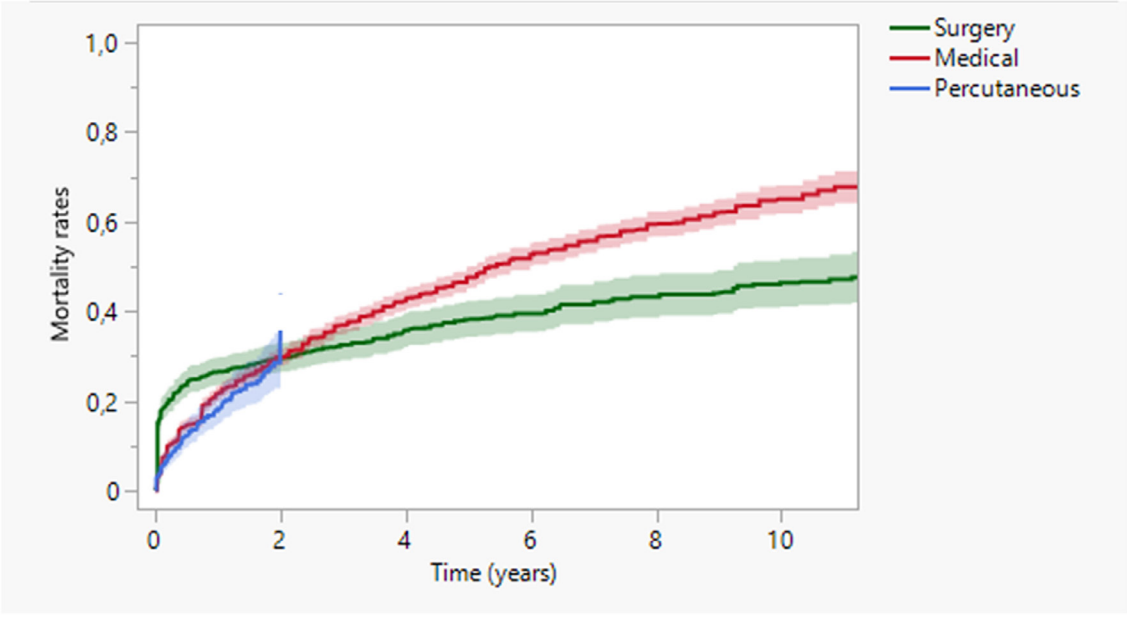
Pooled Kaplan-Meier curves according to treatment group are presented in figure 2. Despite the surgical group initially experiencing higher early mortality, the Kaplan-Meier curves intersect at the 2-year mark.

### Medical management group

Seven studies, encompassing 5702 patients, reported outcomes of medical therapy in severe isolated TR.[6 7 12–16] Studies were published between 2010 and 2023.[14] Five studies were observational, while two were the control group of randomised controlled trials.[12 15] In this group, the mean age was 72.0 years old, the mean LVEF was 53.6% and 53.6% of patients were female. At the 1-year follow-up, 14.3% (95% CI 6.8% to 21.8%, $I^2$ 98%) patients had died. Mortality increased to 20.1% (95% CI 9.9% to 30.4%, $I^2$ 99%), at the 2-year follow-up and 46.2% (95% CI 30.6% to 61.7%, $I^2$ 98%) at the 5-year follow-up.

### Percutaneous group

13 studies including 1416 patients reported outcomes of transcatheter therapy in isolated TR.[7 12 15 17–27] Studies were published between 2018 and 2023 and were mostly




| Number at risk | | | | | | |
|---|---|---|---|---|---|---|
| Surgical | 1962 | 1092 | 611 | 373 | 244 | 166 |
| Medical | 5970 | 3014 | 1973 | 1157 | 650 | 255 |
| Percutaneous | 1205 | | | | | |

**Figure 2** Kaplan-Meier curves of mortality according to treatment group.

prospective registries.[21 28] Two randomised clinical trials were included.[12 15] In this group, the mean age was 71.3 years, with 60.0% of female patients.

Transcatheter tricuspid valve repair was the most common percutaneous therapy included (81.1%), with mostly percutaneous edge-to-edge repair devices (either the TriClip transcatheter tricuspid valve repair system (Abbott) or the PASCAL (Edwards) device). Notably, the interventional arm of the TRILUMINATE randomised control trial was included.[15] Other repair devices included were the FORMA Transcatheter Tricuspid Valve Repair System (Edwards) and the Cardioband tricuspid valve reconstruction system (Edwards). Two studies reported the results of CAVI for a total of 53 patients (4.4%).[12 21]

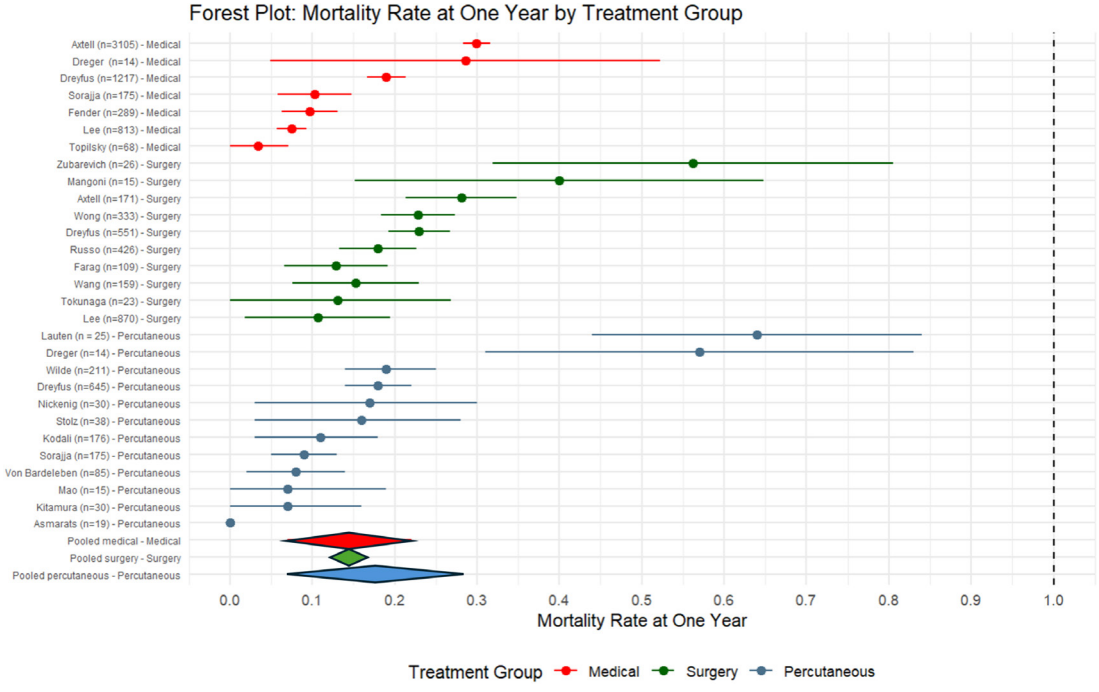



**Figure 3** Mortality rates at 1 year in the medical therapy, surgery and percutaneous therapy group.

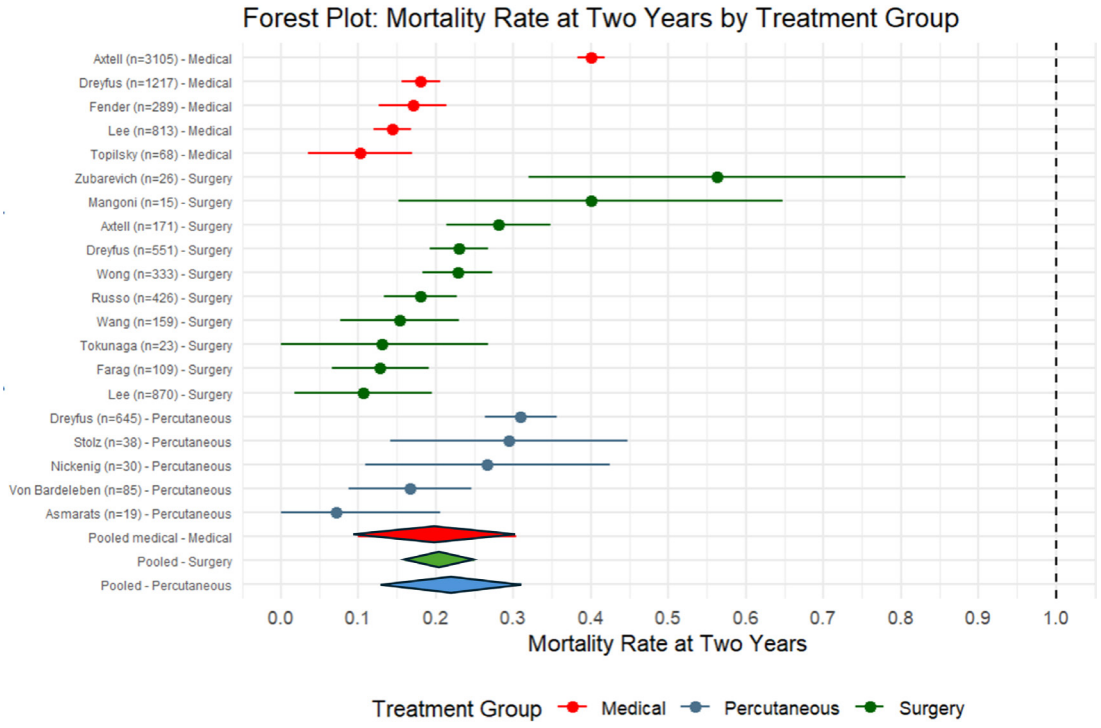



**Figure 4** Mortality rates at 2 years in the medical therapy, surgery and percutaneous therapy group.

Percutaneous transcatheter tricuspid valve replacement was performed in three studies, for a total of 80 patients (6.6%). The implanted valves were the LuX-Valve[22] (Ningbo Jenscare Biotechnology) and the EVOQUE valve (Edwards).[19 25]

Periprocedural outcomes for each study are reported in online supplemental table 3. Residual TR after percutaneous management (excluding CAVI procedures) was graded moderate or less in 77.0% of cases. Transcatheter tricuspid valve repair[15 18 20 26] showed excellent procedural safety but with 68.8% of residual TR graded moderate or less. Conversely, transcatheter valve replacement[19 22 25] was associated with more procedural complications but a lower rate of residual TR (97.6% of residual regurgitation graded below moderate).

The pooled in-hospital mortality was 1.2% (95% CI 0 to 2.4%, $I^2$ 99%). At 1-year follow-up, 18% (95% CI 8.0% to 28.1%, $I^2$ 97%) had died. Five studies reported outcomes at 2-year follow-up, with a pooled event rate of 22.5% (95% CI 13.6% to 31.4%, $I^2$ 74%), Due to the recent


**Figure 5** Mortality rates at 5 years in the medical therapy and surgery group.

nature of percutaneous studies, follow-up after 2 years was not available.

### Surgical group

12 studies, which included 1990 patients, reported outcomes of isolated TR surgery.[6 7 14 27 29–36] All studies were observational, and most were single-centre registries. Publication dates ranged from 2000 to 2023.[31] Mean age was 59.3 years old, with 55.8% female patients. 673 (33.8%) of reported interventions were tricuspid valve repair.

The pooled in-hospital mortality rate was 7.7% (95% CI 6.0% to 9.4%, $I^2$ 30.6%) following isolated tricuspid surgery. The most common complication was pacemaker implantation (ranging from 3.8% to 21.7%). At 1-year follow-up, mortality was 14.6% (95% CI 12.4% to 16.8%, $I^2$ 27.6%). At 2-year and 5-year follow-ups, mortality rates were 20.4% (95% CI 15.6% to 25.1%, $I^2$ 77%) and 30.4% (95% CI 21.1% to 39.7%, $I^2$ 88%), respectively.

### Comparison between groups

Mortality rates by therapeutic approaches at 1 year are reported in figure 2. Mortality rates by therapeutic approaches at 2 years are reported in figure 3. Mortality rates by therapeutic approaches at 5 years are reported in figure 4. At 1 year and 2 years, no difference in mortality was observed between the groups (p medical vs surgery=0.79, p percutaneous vs surgery=0.26, $I^2$ 91% and p medical vs surgery=0.87, p percutaneous vs surgery=0.82, $I^2$ 94%). At 5 years, a trend towards lower mortality was observed between the surgical group and the medical group, p=0.08, $I^2$ 95%.

The mortality according to groups was tested using a meta-regression to consider potential confounders. Two models were tested. In model 1, with age and sex as confounders, treatment group was not associated with mortality at 1 year (p=0.26 for surgery vs medical, p=0.14 for surgery vs percutaneous, $I^2$ 87%), at 2 years (p=0.27 for surgery vs medical, p=0.48 for surgery vs percutaneous, $I^2$ 92%) or 5 years (p 0.59 for surgery vs medical, $I^2$ 90%). At 5 years, the only parameter associated with mortality was age, p=0.03.

In model 2, after adjustment on age, sex and LVEF, the treatment group was not associated with mortality at 1 year (p=0.24 for surgery vs medical, p=0.23 for surgery vs percutaneous, $I^2$ 83%), at 2 years (p=0.45 for surgery vs medical, p=0.13 for surgery vs percutaneous, $I^2$ 94%) or 5 years (p=0.32 for surgery vs medical, $I^2$ 78%). At 5 years, the only parameter associated with mortality was age, p 0.04.

### Sensitivity analysis

The same meta-analysis was performed after exclusion of CAVI. The pooled 1-year mortality rate was 15.0% (95% CI 10.6% to 19.4%) in the surgery group, 14.1% (95% CI 7.1% to 21.0%) in the medical group and 11.0% (95% CI 4.5% to 17.4%) in the percutaneous group. No difference in mortality between groups was observed (p=0.78 for surgery vs medical, p=0.21 for surgery vs percutaneous, $I^2$ 90%). The same meta-analysis was performed after stratification of percutaneous therapy between repair and replacement. The pooled mortality rate in the surgical group was 15.05% (95% CI 10.46% to 19.65%). The pooled mortality rate was 14.1% (95% CI 6.9% to 21.2%) in the medical group, 11.1% (95% CI 3.8% to 18.3%) in the repair group and 11.2% (95% CI 2.6% to 24.9%) in the replacement group. No difference in mortality was observed (p=0.78 for surgery vs medical, p=0.28 for surgery vs percutaneous repair, p=0.58 for surgery vs percutaneous replacement, $I^2$ 91.6%).

## DISCUSSION

The findings of this review, whose strengths lie in its contemporary nature and substantial sample size notably in the percutaneous group, underscore several key points: (1) In patients with severe isolated TR, long-term mortality is high regardless of therapeutic option; (2) While selection bias (such as right ventricular dysfunction or heart failure) could not be accounted for, invasive management, through either percutaneous or surgical interventions, does not seem to be associated with lower mortality rates compared with medical management after meta-regression and (3) Surgery could be associated with the lowest long-term mortality, although in younger, fitter and selected patients.

### Indications for intervention in severe TR

Invasive management of isolated TR is an unsolved challenge. Online supplemental table 4 provides a summary of changes in European and North American guidelines for TR management over time. In the 2006 AHA/ACC (American Heart Association/American College of Cardiology) guidelines,[37] surgery was not recommended for asymptomatic patients, while surgical intervention was considered reasonable for symptomatic patients. The 2007 ESC (European Society of Cardiology) guidelines[38] marked the first acknowledgement that surgical therapy may be considered for asymptomatic patients with right ventricle dilatation or dysfunction (IIbC), although specific thresholds were not provided. The 2014 ACC/AHA guidelines[39] proposed therapy for asymptomatic patients with progressively worsening degrees of right ventricular dilation and/or systolic dysfunction. In 2021, transcatheter therapy was mentioned in the ESC guidelines[40] for patients deemed inoperable (IIbC). Interestingly, the 2020 AHA/ACC guidelines did not include a recommendation for transcatheter therapy in severe TR.[41]

### Medical treatment group

The medical management group reports major mortality rates of 14% at 1 year and 46% at 5 years. The substantial proportion of patients receiving medical treatment for severe TR in most cohorts[42–44] likely stems from several factors. Chief among these is the limited level of evidence supporting intervention and the considerable risk

associated with surgery, which remains the gold-standard treatment to date.

### Percutaneous therapy group

The aggregated findings of the percutaneous therapy studies confirm the excellent safety of transcatheter valve repair, and to a lesser extent, valve replacement. First, in-hospital mortality was low (1.2%), especially in a very high-risk population. In contrast, surgical therapy for TR[3] carries a higher periprocedural risk, with an in-hospital mortality rate of 8%. Second, the main complications of percutaneous management were severe bleeding and the need for permanent pacemaker implantation, with a higher incidence in percutaneous valve replacement compared with repair.[15 18 20 26] Nonetheless, percutaneous therapy allowed for shorter hospital stays compared with surgical interventions.

At 1-year follow-up, 18% of percutaneously treated patients had died, increasing to 22% at 2 years. It is important to note that significant discrepancies exist among studies in the selection of patients, as evidenced by the EuroSCORE II. In most percutaneous studies, patients were considered inoperable or at high surgical risk,[26] with some studies reporting compassionate use.[25] Conversely, in another study, patients were included if they had moderate or severe TR deemed suitable for TEER therapy,[45] resulting in very low mortality rates at 1 year, which were concordant in the control group. Moreover, in the randomised controlled trial by Sorajja *et al*,[15] the very low mortality rate in the control group underscores the 'control arm benefit' in this population (ie, patients in the control groups of trials fare better than those not included because of the intensive and thorough medical follow-up). Therefore, prospective studies have mainly demonstrated an improvement in quality of life in patients treated by transcatheter tricuspid valve repair.[46]

With a 2-year mortality of 22% in our analysis in the percutaneously managed patient, mortality rates align to those observed in the percutaneous group with intermediate TRISCORE (4 or 5) in the TRIGISTRY study (29%).[47] In this study, within this risk group category, successful percutaneous TR correction reduced mortality to 19% while unsuccessful correction was associated with a 66% 2-year mortality. Additionally, in the high TRISCORE group (≥6), patients exhibited similar survival rates across all treatment modalities, suggesting futility in the most at-risk patients.

### Surgery group

In the USA, tricuspid surgery is uncommon, accounting for only 5% of cardiac surgeries in 2021, with approximately 80% of cases being associated with left-heart valve surgery.[48] Consequently, patients undergoing isolated TR surgery are meticulously selected, typically exhibiting both symptoms and operability criteria.[30 33] Despite this stringent selection process, the surgery group reported a pooled in-hospital mortality of 7.7%. Interestingly, this mortality rate would be deemed high risk in patients undergoing aortic valve replacement,[49] highlighting the need for a percutaneous alternative. The 2-year shift observed in the Kaplan-Meier curves suggests that surgical therapy in selected patients could alter the long-term evolution of severe TR. However, after adjustment for confounding factors, only age, not surgery, was independently associated with mortality. Long-term benefit of tricuspid valve surgery has recently been linked with the severity of clinical presentation, described by the TRI-SCORE.[50]

There are no controlled studies comparing medical therapy to surgery, leading to low levels of evidence in current guidelines. The only studies comparing surgery to medical therapy are matched controlled studies, inherently biased.[6] Moreover, these studies do not include asymptomatic or pre-symptomatic patients, as seen in other valvular heart diseases.[51]

Finally, surgical management of isolated TR, when deemed at reasonable risk, seems to be an underused curative solution. Recent adapted scores should be employed to better estimate the operative risk of patients with isolated symptomatic TR.[52]

### Limits

Substantial heterogeneity across the studies, reflected in high $I^2$ values, represents a limitation of this analysis and restricts the generalisability of the findings. The percutaneous treatment group encompasses a wide array of devices with varying goals, operator experience and levels of immediate correction of TR. Indeed, CAVI procedures have been described as a palliative procedure compared with TEER or TTVR. Furthermore, many of these studies reported initial experiences with these devices, and the mortality could not be stratified according to the extent of TR reduction.[47] Similarly, surgical studies reported the results of tricuspid valve repair or replacement alike, with likely various surgeon experience, including minimally invasive surgery.[34] This study represents a pooled analysis primarily composed of observational studies, lacking control over potential confounders. Therefore, the risk of residual confounding persists despite adjustments for age, sex and LVEF. Nonetheless, the raw long-term mortality data offer crucial insights for future clinical trials and serve as a summation of existing knowledge. Second, the percutaneous studies are relatively recent, thus lacking long-term results. Extended follow-up will provide invaluable insights.[21] Third, the aetiology of isolated TR (functional vs primary) was often not reported, yet it could significantly impact outcomes.[3]

Ongoing randomised trials such as the CLASP II TR (NCT04097145) randomised, open-label, (Pascal device vs OMT), the TRISCEND II (NCT04482062) randomised, open-label, (Evoque vs OMT) and the TriFR trial (NCT04646811) randomised, open label (Triclip vs OMT) will provide invaluable data on survival and quality of life improvement associated with intervention in severe TR.

## CONCLUSIONS

The findings of this study highlight the substantial long-term mortality risk associated with isolated severe TR. While selection bias (such as right ventricular dysfunction or heart failure) could not be accounted for, invasive management, through either percutaneous or surgical interventions, does not seem to be associated with lower mortality rates compared with medical management in this meta-analysis. Further research is warranted to refine patient selection criteria and optimise therapeutic strategies to improve outcomes in the management of isolated TR.

**Contributors** GS: screened the articles, collected the data, performed the analysis, drafted the manuscript. GS: guarantor. JM: screened the articles, collected the data, performed the analysis, drafted the manuscript. JM: guarantor. AC: collected the data, reviewed the manuscript. MH: collected the data, reviewed the manuscript. CD: reviewed the manuscript. DA: reviewed the manuscript. DH: reviewed the manuscript. GD: reviewed the manuscript. EB: reviewed the manuscript. AV: reviewed the manuscript. BL: reviewed the manuscript. MU-A: reviewed the manuscript. GS and JM are guarantors.

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