

REVIEW

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Tricuspid valve replacement with mechanical versus biological prostheses: a systematic review and meta-analysis

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Abstract

Background and objective Tricuspid valve replacement (TVR) is required when repair is not feasible, and it continues to be a relatively high-risk procedure owing to the complex medical and/or surgical profile of patients. The choice between mechanical and biological prostheses for TVR remains a subject of debate owing to their distinct advantages and disadvantages. This study aimed to analyse and compare the clinical outcomes of these two types of prostheses in the tricuspid position.

Methods PubMed, EMBASE, Web of Science, and the COCHRANE library were searched from 1995 to April 2023 for studies comparing clinical outcomes of mechanical versus biological valves in the tricuspid position. Data on 30-day mortality, reoperations, 5-year valve failure rates, thrombotic/thromboembolic events, and long-term survival were extracted, pooled, and analysed. Forest plots were generated using a random-effects model.

Results From an initial pool of 4716 citations, 37 studies meeting our inclusion criteria were assessed, collectively encompassing 8316 prostheses (3796 mechanical, 4520 bioprostheses). Our analysis revealed that mechanical valves exhibited a non-significant trend towards diminished 30-day mortality (RR = 0.85, 95% CI = 0.69–1.06). A distinct disparity emerged in valve durability, with mechanical valves demonstrating a significantly increased risk of 5-year valve failure (RR = 2.21, 95% CI = 1.38–3.56). Strikingly, mechanical valves displayed a substantial six-fold elevated risk of thrombotic events (RR = 6.29, 95% CI = 3.98–9.92). In contrast, the long-term survival and reoperation rates demonstrated no statistically significant differences between the two valve types.

Conclusions This systematic review and meta-analysis provides insights into the selection of mechanical and bioprosthetic valves for TVR. These findings highlight the potential advantages and disadvantages of mechanical and bioprosthetic valves in terms of early mortality, valve durability, and thrombotic risk. Our analysis provides clinicians with evidence-based guidance for optimizing outcomes in TVR, offering a foundation for informed decision-making in this intricate surgical landscape. Despite these insights, clinicians must overcome the limitations of retrospective studies, evolving healthcare, and anticoagulant disparities to ensure careful consideration in tricuspid valve replacement decisions.

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Keywords Tricuspid valve replacement, Mechanical valve, Bioprosthetic valve, Clinical outcomes, Meta-analysis, Long term survival, Mortality

Introduction

Tricuspid valve replacement (TVR) is considered a relatively infrequent surgical procedure, primarily reserved for patients presenting with significant structural or advanced functional issues within their tricuspid valve. Consequently, individuals undergoing TVR often exhibit a high-risk profile, with many having previously undergone tricuspid valve (TV) repair and experiencing complications such as right ventricular dysfunction [1]. Tricuspid valve replacement (TVR) is associated with elevated mortality and morbidity rates, with operative mortality ranging from 5 to 50% [2–5].

TV surgery has consistently posed formidable challenges [6–14]. When confronted with the decision to replace TV, the choice between mechanical and biological prostheses remains controversial. The implantation of mechanical valves theoretically carries an escalated risk of thromboembolic complications, particularly when the right ventricular function is less than normal. Conversely, bioprosthetic valves are susceptible to tissue degeneration and dysfunction, especially in the younger population and in pathological conditions characterized by progressive tissue infiltration and degeneration, such as carcinoid syndrome and end-stage renal disease. Additional complications related to anticoagulation within the mechanical valve group compared to the bioprosthetic group represent an additional challenge [15].

The principal objective of this meta-analysis was to compare the early and late outcomes among patients who have undergone TVR with either mechanical or biological prostheses. The resulting findings are anticipated to provide guidance to physicians and patients when making informed decisions regarding optimal valve selection for those undergoing TVR.

Materials and methods

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [16] (Supplementary Fig. 1).

Data sources and search strategy

A comprehensive literature search was performed in electronic databases including PubMed, Embase, Web of Science, and the Cochrane Library, from 1995 to April 2023. All relevant articles comparing the outcomes of mechanical and bioprosthetic tricuspid valves

were retrieved. Only articles published in English were selected. Additional articles were manually identified by screening the reference lists of the obtained studies and similar clinical trials. Duplicate studies were eliminated using Endnote X7 (Clarivate Analytics, PA, USA). In cases where multiple studies by the same author or institution were conducted within a similar timeframe and reported comparable outcomes with the potential for overlap, only the most recent study was incorporated into this meta-analysis. A broad search strategy was employed to encompass the full breadth of articles using the following search string: “tricuspid valve replacement AND mechanical OR bioprosthetic”.

Study selection

The studies were deemed qualified for our systemic review and meta-analysis if they met the following requirements: (a) they were randomized controlled trials or observational studies (prospective or retrospective cohort or case–control studies); (b) they compared mechanical and biological valves; (c) their participants were adults only (including a paediatric population can introduce significant heterogeneity because of differences in their cardiovascular morphology physiology compared with adults); and (d) they evaluated at least one of the following predefined outcomes: 30-day mortality, reoperations/reinterventions, 5-year valve failure rates, thrombotic/thromboembolic events, and long-term survival. Studies with insufficient data, those with data not related to our prespecified objectives, letters and editorials, case reports, case series, or reviews were excluded.

Data extraction and quality assessment

Two independent researchers shortlisted the studies based on their titles and abstracts. The full texts of the remaining articles were thoroughly assessed. The results were compared side-by-side, and any discrepancies were resolved by a third researcher. The data extracted from the studies included study characteristics such as the first author’s surname, date of publication, total number of patients, number of patients in both groups, operative time range, and country of origin. The risk of bias was assessed using the Cochrane Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool [17].

Statistical analysis

Statistical analysis was performed using Review Manager, version 5.4 (Nordic Cochrane Center, Copenhagen,

Denmark) and Comprehensive Meta-analysis Software (CMA). We pooled our results as risk ratios (RRs) with 95% confidence intervals (CIs) for 30-day mortality, 5-year valve failure, reoperation rate, and thrombotic and thromboembolic events, and hazard ratios (HRs) with 95% CIs for long-term survival using a random effects model. Forest plots were created to visually assess the results; a subgroup analysis was performed to differentiate the outcomes between studies using isolated TVR and TVR with concomitant procedures. Funnel plots, trim and fill sensitivity analysis, and Egger's test were used to assess publication bias.

Results

Among the 4716 papers retrieved, 78 full-text articles were reviewed, and 37 were included in the final study cohort [1, 2, 5, 18–51] (Fig. 1). The analysis included 8380 prostheses, with 3860 (46.1%) being mechanical and 4520 (53.9%) being biological. The baseline characteristics, study design, and outcomes of the included studies are shown in Table 1. The analyses were performed to analyse the long-term outcomes of tricuspid valve replacement separately and with concomitant procedures such as atrial septal defect closures, arrhythmia surgery, pulmonary valvectomy, pulmonary valvotomy, repair of ruptured sinus of Valsalva, pericardiectomy, and coronary artery bypass graft.

Long-term survival

A total of 26 studies reported long-term survival rates with follow-up to 20 years postoperatively; 11 studies reported long-term survival rates in the isolated TVR subgroup, of which two favoured bioprosthetic valves, while the remaining found no significant difference between the two valve types. Fifteen studies reported long-term survival rates in the TVR with concomitant procedures subgroup, of which only one study [33] favoured bioprosthetic valves, while others found no significant difference between the two types of valves. The pooled result did not reveal a significant difference between the two types of valves (HR=1.09, 95% CI=0.88–1.34, $p=0.43$, $I^2=70\%$). To account for the substantial heterogeneity, we conducted a sensitivity analysis using the leave-one-out method, but the results remained non-significant (HR=1.02, 95% CI=0.87–1.20, $I^2=43\%$). (Fig. 2 and Supplementary Fig. 1a).

30-day mortality

16 studies reported 30-day mortality for isolated TVR, of which 3 favored mechanical valves, and 13 studies found no significant difference between the two valve types. 16 studies reported 30-day mortality of TVR with concomitant procedures, of which all showed no significant

difference between the two. The meta-analysis found a pooled relative risk (RR) of 0.91 (95% CI=0.62–1.34, $p=0.64$, $I^2=60\%$) and 0.80 (95% CI=0.64–1.00, $p=0.05$, $I^2=12\%$) for isolated TVR and TVR with concomitant procedures, respectively, suggesting a 20% lower risk of mortality with mechanical valves when TVR is performed with concomitant procedure. (Fig. 3, Supplementary Fig. 1b).

5-year valve failure

6 studies reported 5-year valve failure of isolated TVR, of which 1 [38] favored bioprosthetic valves, while the remaining found no significant difference between the two valve types. 5 studies reported TVR with concomitant procedures, of which 1 study [1] favored bioprosthetic valves whereas the remaining found no significant difference between the outcome of the two valves. The results of the pooled studies were statistically significant, with a relative risk (RR) of 2.2 (95% CI=1.38–3.56, $p=0.001$, $I^2=0\%$) (Fig. 4). The results suggest that mechanical valves may be associated with an increased risk of valve failure at 5 years compared to bioprosthetic valves.

Reoperation

12 studies reported reoperation rate of isolated TVR, of which none showed a significant difference between the two types of valve. 10 studies reported reoperation rate of TVR with concomitant procedures, of which [29] favored mechanical valves, and [1] favored bioprosthetic valves, while the remaining showed no significant difference. The pooled risk ratio (RR) was 0.95 (95% CI=0.69–1.32, $p=0.01$, $I^2=45\%$) (Fig. 5).

Thrombosis and thromboembolism

13 studies reported thrombosis and thromboembolism events in isolated TVR subgroup of which 5 favored bioprosthetic valve, and 11 studies reported thrombosis and thromboembolism events in TVR with concomitant procedures subgroup of which 4 favored bioprosthetic valve type, whereas the remaining studies in both subgroups showed no significant difference between the two types. The results of the pooled studies showed a relative risk (RR) of 6.67 (95% CI=4.24–10.49), $p=0.00001$, $I^2=0\%$) (Fig. 6). Data from the studies pooled in the meta-analysis indicate statistically significant results, suggesting a six-fold increased risk of thrombotic events with mechanical valves compared to biological prosthesis.

Pacemaker insertion

Pacemaker insertion was reported in six studies, of which five were in the isolated TVR subgroup and one was in the TVR with concomitant procedures subgroup.

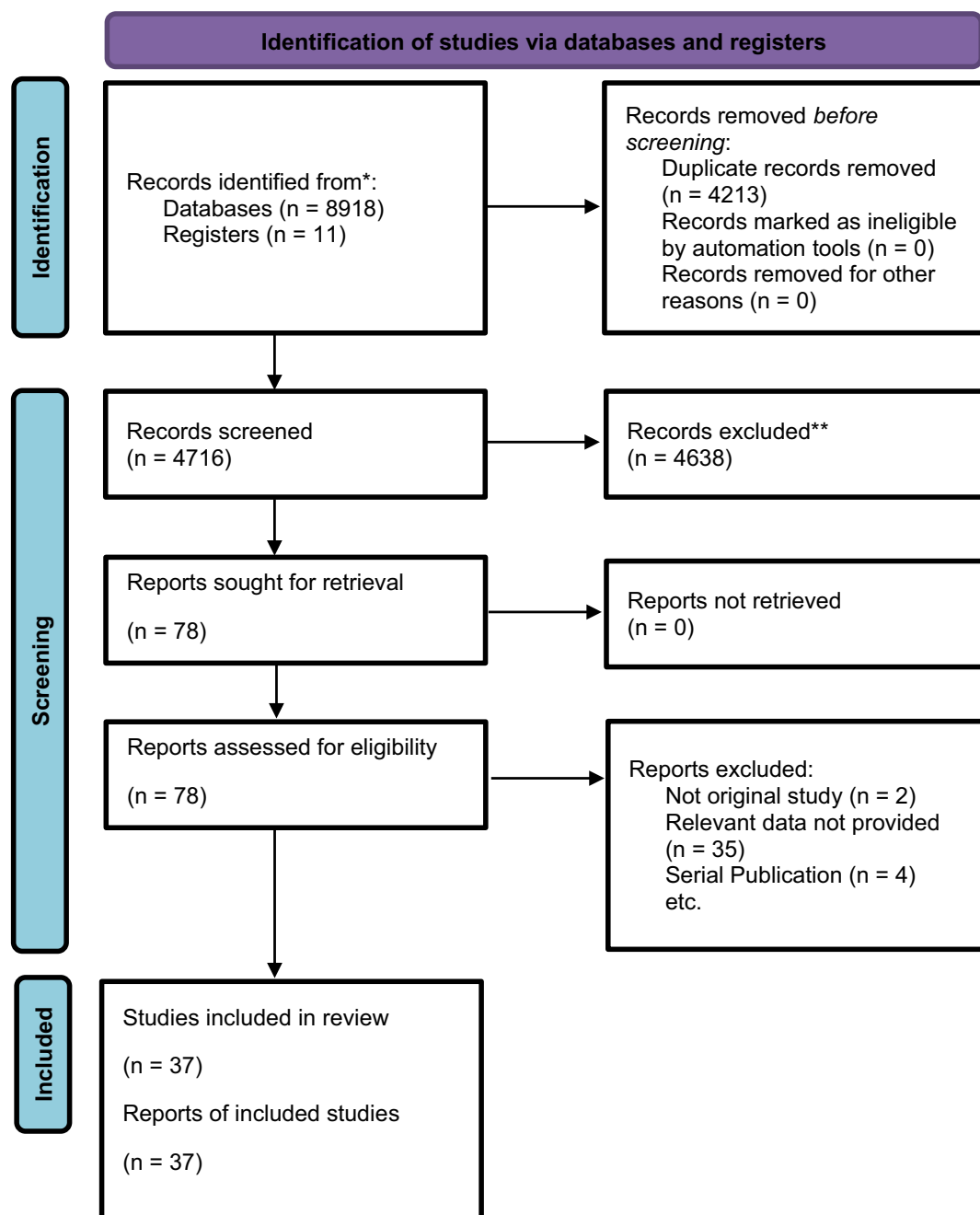


Fig. 1 PRISMA flow chart summarizing results of literature search. *Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers). **If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools. From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. <https://doi.org/10.1136/bmj.n71>. For more information, visit: <http://www.prisma-statement.org/>

In isolated TVR subgroup, 2 studies favored mechanical while other studies showed no significant difference between the two. The one study that reported TVR with concomitant procedures showed no significant difference. The result of the pooled studies showed a relative

risk (RR) of 0.66 (95% CI=0.48–0.90, $p=0.009$, $I^2=0\%$) (Fig. 7). Data from the pooled results indicated a statistically significant difference in the risk of pacemaker insertion between the two types of valves, that is, patients receiving mechanical valves had a 34% lower risk of

Table 1 Baseline characteristics of the included studies

Study Name	Date of Publication	Total Number of Patients	Number of Mechanical (%)	Number of Bioprosthetic (%)	Operative Time Range	Country	Male patients	Female patients	Average age(Years)
1. Munro [18]	1995	97	14 (14.4)	83 (85.6)	1975–1992	Canada	16	78	55.4
2. Scully [19]	1995	60	32 (83.3)	28 (46.7)	1978–1993	Canada	19	41	50
3. Van Nooten [3, 20]	1995	146	77 (52.7)	69 (47.3)	1967–1987	Belgium	32	114	51.4
4. Hayashi [21]	1996	29	15 (51.7)	14 (48.3)	1978–1995	Japan	12	17	40
5. Ratnatunga [23]	1998	425	200 (47.1)	225 (52.9)	1986–1997	UK	91	334	57.1
6. Rizzoli [22]	1998	100	30 (30)	70 (70)	1996–1996	Spain	54	46	45
7. Dalrymple [24]	1999	87	35 (40.2)	52 (59.8)	1973–1996	UK	13	74	59.4
8. Kaplan [25]	2002	129	97 (75.2)	32 (24.8)	1980–2000	Turkey	28	101	35
9. Carrier [28]	2003	97	15 (15.5)	82 (84.5)	1977–2002	Canada	26	71	52
10. Rizzoli [27]	2004	101	23 (22.8)	78 (77.2)	1970–2002	Italy	38	63	49.3
11. Solomon [26]	2004	104	33 (31.7)	71 (68.3)	1966–2002	New Zealand	24	77	40.9
12. Filsoufi [5]	2005	81	47 (58.0)	34 (42.0)	1985–1999	USA	24	57	61
13. Chang [29]	2006	138	103 (74.6)	35 (25.3)	1978–2003	South Korea	50	75	43.7
14. Iscan [2]	2007	42	15 (35.7)	27 (64.3)	1987–2004	Turkey	16	26	33
15. Civelek [30]	2008	35	33 (94.3)	2 (5.7)	1996–2006	Turkey	23	12	49.6
16. Tokunaga [31]	2008	23	4 (17.4)	19 (82.6)	1975–2004	Japan	N/A	N/A	N/A
17. Brown [33]	2009	378	45 (11.9)	333 (88.1)	1972–2006	USA	N/A	N/A	41.7
18. Moraca [32]	2009	93	21 (22.6)	72 (77.4)	1986–2006	USA	58	138	52.2
19. Sung [34]	2009	80	62 (77.5)	18 (22.5)	1994–2007	South Korea	24	56	48.7
20. Garatti [35]	2012	90	46 (51.1)	44 (48.9)	1980–2005	Italy	25	65	53.8
21. Hwang [36]	2012	119	70 (58.8)	49 (41.2)	1996–2010	Korea	28	91	53
22. Altani (2013)	2013	21	5 (23.8)	16 (76.2)	2002–2010	Tunisia	7	14	52.3
23. Cho [37]	2013	104	59 (56.7)	45 (43.3)	1991–2009	South Korea	33	71	57
24. Kim [39]	2013	14	4 (28.6)	10 (71.4)	1996–2010	Korea	6	9	55.8
25. Rodríguez Capitán [40]	2013	35	24 (68.6)	11 (31.4)	1996–2010	Spain	7	28	57.1
26. Hang (2014)	2014	224	121 (54.0)	103 (46.0)	1994–2012	South Korea	55	169	54.1
27. Songur [42]	2014	132	64 (48.5)	68 (51.5)	1993–2011	Turkey	34	98	61.6
28. Connolly [43]	2015	195	36 (18.5)	159 (81.5)	1985–2012	USA	98	97	61
29. Anselmi [44]	2016	188	33 (17.6)	155 (82.4)	1971–2012	France	80	108	51.2
30. Redondo Palcios A [45]	2017	110	29 (26.4)	81 (73.6)	2005–2015	Spain	34	86	62.6
31. Chen [46]	2018	1984	1378 (69.5)	606 (30.5)	1995–2015	Taiwan	1,120	864	63.7
32. Wiedeman [47]	2018	110	29 (26.4)	81 (73.6)	1996–2014	Vienna	75	35	53.3
33. Liang [48]	2019	76	43 (56.6)	33 (43.4)	2010–2017	China	25	51	47.7
34. Kang [49]	2020	226	106 (46.9)	120 (53.1)	1994–2017	Korea	46	180	60.8
35. Albacker [1]	2022	159	20 (12.6)	139 (87.4)	2009–2019	Saudi Arabia	42	117	52.4
36. Patlolla [50]	2022	1043	149 (14.3)	894 (85.7)	1993–2018	USA	449	594	68.8
37. Sohn [37]	2023	1241	679 (54.7)	562 (45.3)	2003–2018	Korea	179	375	61.5

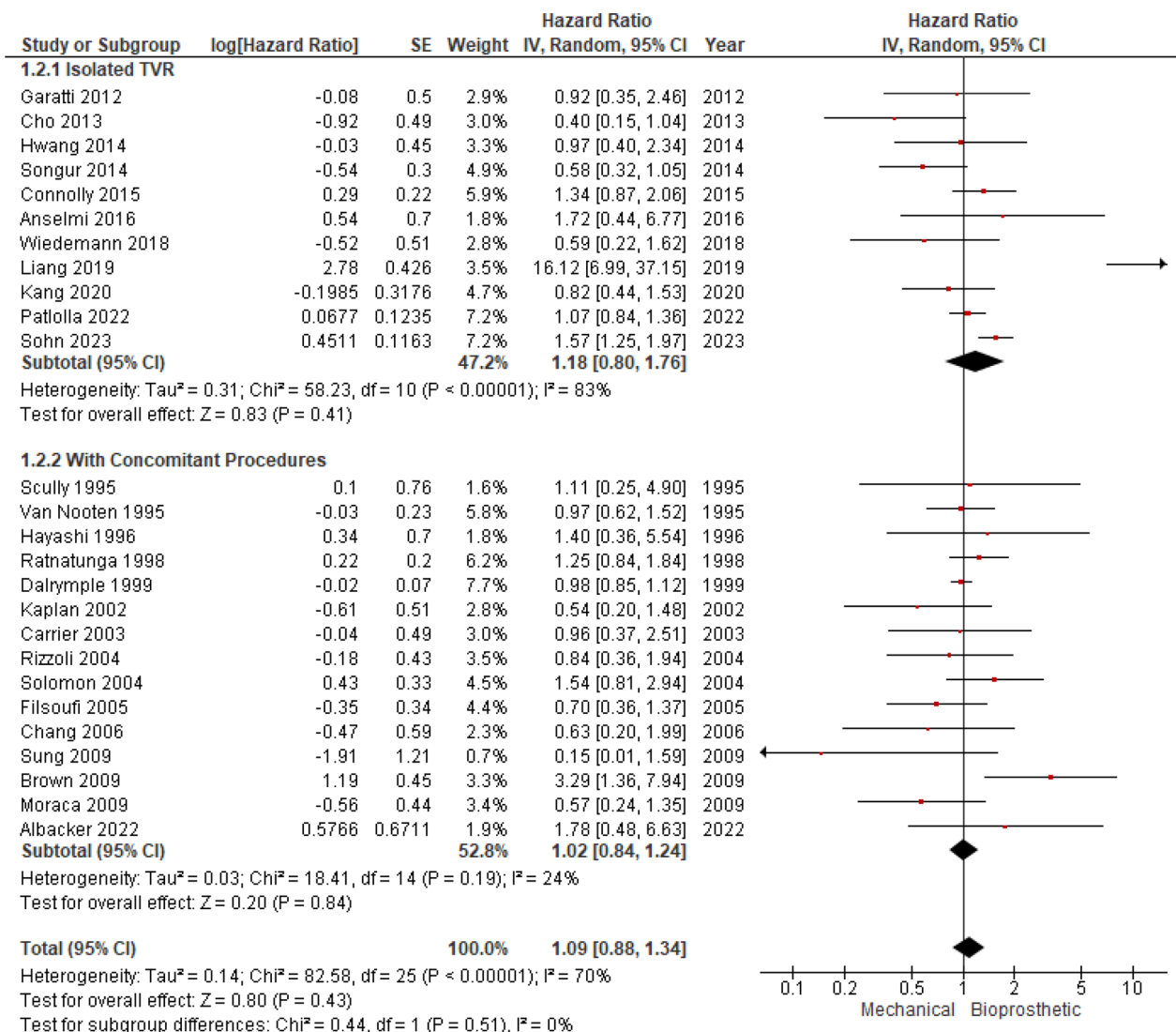


Fig. 2 Long-term survival hazard ratio of each study with related 95% confidence limit

needing pacemaker insertion than those receiving bioprosthetic valves.

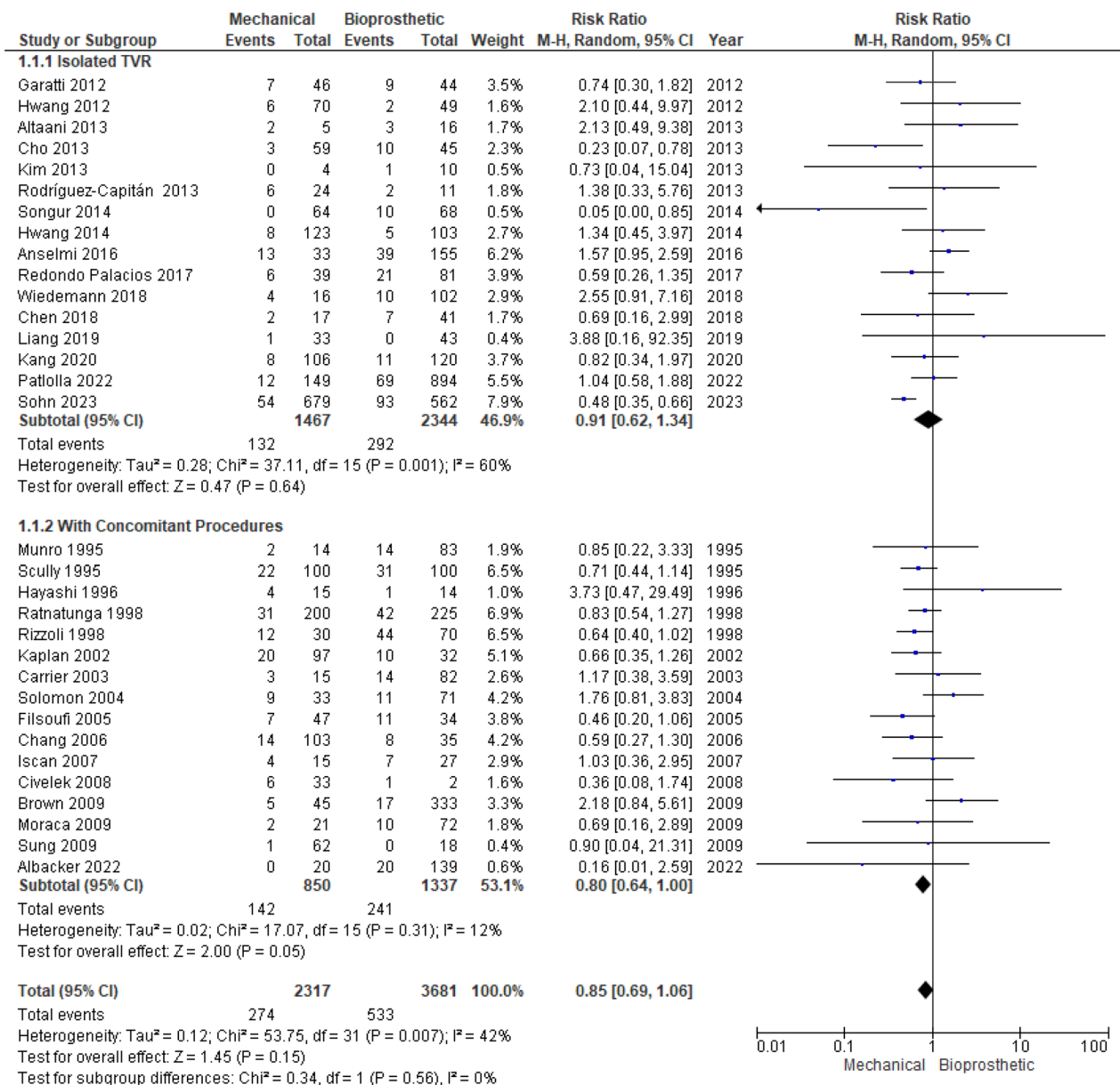
Publication bias

Examination of the funnel plot indicated some evidence of publication bias (Supplementary Fig. 2a–f). In addition to this potential bias, an Egger test was conducted to further assess the reliability of the results. Remarkably, the outcomes of the trim-and-fill sensitivity analysis demonstrated a minimal influence on the findings. A slight attenuation in the pooled risk ratio was observed, implying that the potential omission of studies would not significantly alter the overall conclusion. Furthermore, the trim-and-fill analysis estimated that a small number of studies might be missing from our meta-analysis

due to publication bias; however, even considering these hypothetical studies, the overall effect remained relatively stable. These combined findings, along with the results of the Egger test, collectively suggest that the overall integrity of the analysis remains robust (Supplementary Fig. 3a–f, 4a–f). However, it is important to acknowledge that while our analysis accounts for potential publication bias to some extent, the presence of such bias can introduce uncertainty in the interpretation of our results.

Risk of bias assessment

Using the ROBINS-I tool, 14 of the included studies were at high risk of bias—12 with risk of bias due to confounding, one with risk of bias due to missing data, and one with risk of bias both due to confounding and due

**Fig. 3** Forest plot for 30-day mortality

to missing data. The remaining studies were judged to have a low risk of bias, but the full text of the study by Dalrymple-Hay et al. could not be assessed as the journal had been discontinued and the authors did not respond to our request for the manuscript.

Discussion

Current guidelines recommend TV surgery in cases of severe and progressive tricuspid regurgitation [52]. Repair is considered the intervention of choice and is

superior to valve replacement [53]. TVR is indicated only in cases where TV repair is not feasible or has failed [54]. In such instances, the choice of bioprosthetic or mechanical valve is crucial and the subject of much controversy. The most recent meta-analysis on this subject was conducted by Cheng et al. [55]. However, the body of literature on this topic has grown significantly since that time. We conducted this systematic review and meta-analysis of thirty-seven studies to compare the short- and long-term surgical outcomes and complications associated with both valve types.

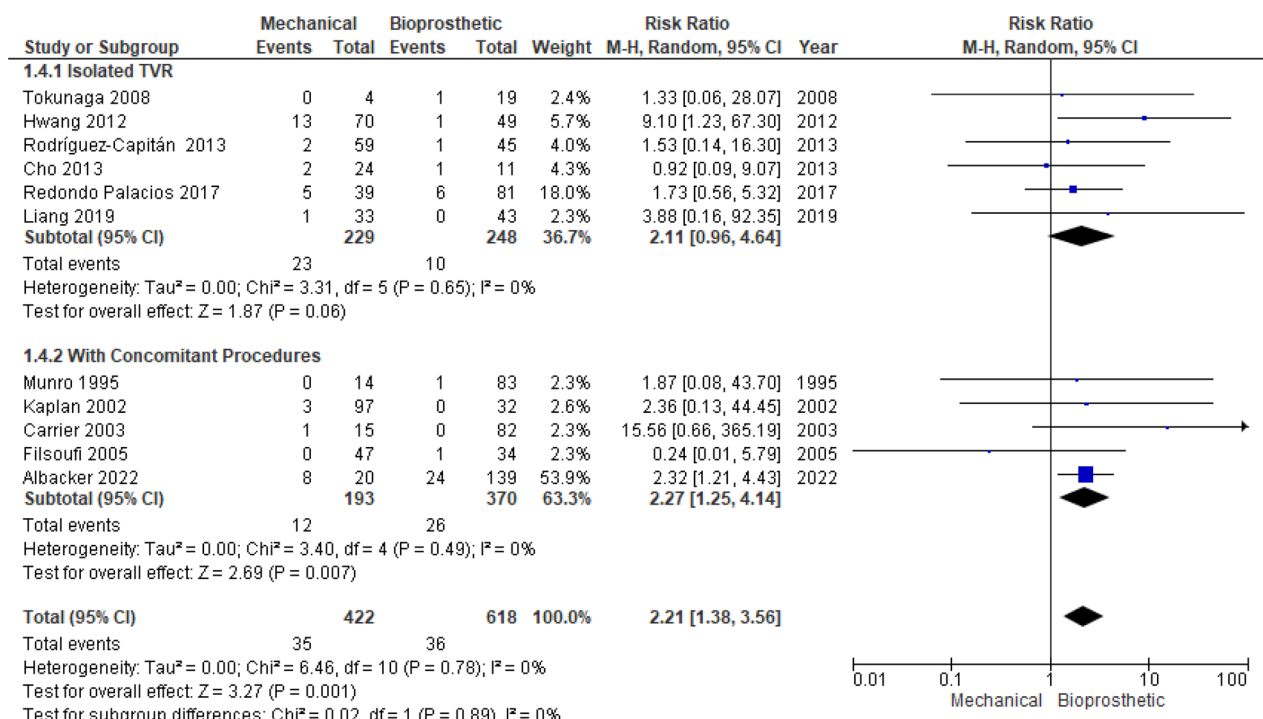


Fig. 4 Forest plot of the 5-year valve failure

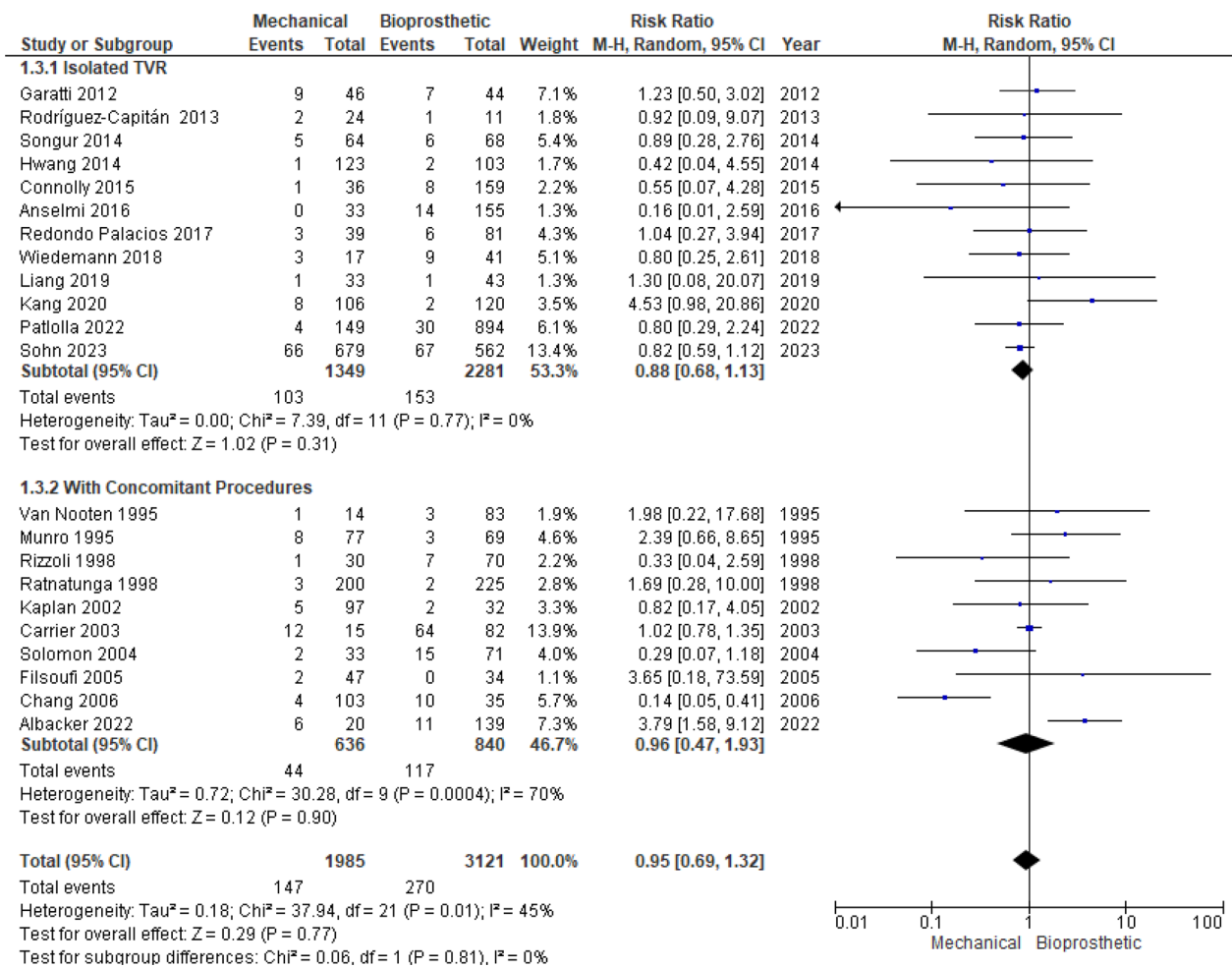
Our findings suggest no significant difference in long-term survival or reoperation rates associated with either type of valve. As TVR is used only in advanced cases, these findings can be explained by the poor survival rate of such patients regardless of the type of valve used [19]. Short-term mortality was also similar in both groups. These results suggest that both types of prostheses perform equally well. The comparable reoperation rates in both groups reinforce this argument. Our findings are similar to those of Cheng et al. [55].

We found a statistically significant difference in valve failure after five years. Our findings suggest that mechanical valves are more likely to fail than bioprosthetic valves, which is consistent with the findings of Cheng et al. [55]. The greater sample size of our analysis further reinforces this finding. We observed no heterogeneity between the studies, which increased the confidence in these findings. Subgroup analysis revealed no significant difference in case of isolated TVR, indicating that concomitant procedures might be responsible for the higher mechanical valve failure. Previously, mechanical aortic valves have been reported to cause more complications such as atrial fibrillation [56]. However, bioprosthetic valves are also

prone to structural and non-structural problems, with the most critical causes of failure being calcification [57] and leaflet thickening [58]. There is variation in the failure rates of porcine and bovine valves. Calcification is more evident in bovine valves, whereas porcine valves are prone to tears and stenosis [59]. No studies have assessed bovine and porcine valves for tricuspid replacement.

Our most important finding is the exceptionally high rate of thrombotic and thromboembolic complications seen in mechanical valves compared to bioprosthetic valves. On the other hand, studies on aortic valves have shown twice the risk of cerebral and gastrointestinal bleeding with mechanical valves compared to bioprosthetic valves, highlighting the need for balanced anticoagulation therapy [60]. There was no heterogeneity among the studies, demonstrating the generalizability of these results. As our included studies did not mention the type of anticoagulation therapy administered after the procedure, future studies should explore the optimal anticoagulation therapy that minimizes the risk of thrombosis and bleeding.

Our results suggest an increased requirement for pacemaker insertion into biological valves. Previous

**Fig. 5** Forest plot of reoperation

studies did not have enough data for a meta-analysis of this outcome [61]. Previous studies involving the mitral and aortic valves have shown an increased incidence of atrioventricular block and pacemaker insertion [62, 63]. The conduction tissue is closely related to the TV, and TVR carries a high risk of trauma to the His bundle [64]. The reasons necessitating pacemaker insertion after TVR have not been studied previously and warrant further investigation.

Our findings should be interpreted in light of certain limitations. The included studies were mainly retrospective and observational, which may introduce confounding bias. The studies span a considerable time period, and the results of recent studies differ from those of older studies owing to advances in healthcare. The geographical distribution of our study is also quite broad, and these results may only apply to specific populations. Owing to their

high cost, newer anticoagulant therapies are unavailable in many low-income countries. We could not analyse the difference in outcomes between primary TVR and reoperation because of a lack of data. Only a few studies included children, so we could not evaluate the benefits or risks of TVR in the paediatric population. Lastly, we observed unexplained heterogeneity in survival outcomes and reoperation rates. Additionally, it is important to consider the impact of publication bias, which may influence the representation of studies in our analysis. Although we have made efforts to assess and address this bias, its potential presence can introduce uncertainty in the interpretation of our findings.

Surgeons should consider patient demographics and medical history to lower the risk of thromboembolic complications. Studies have shown a lower mortality risk with TV surgery using the beating heart technique

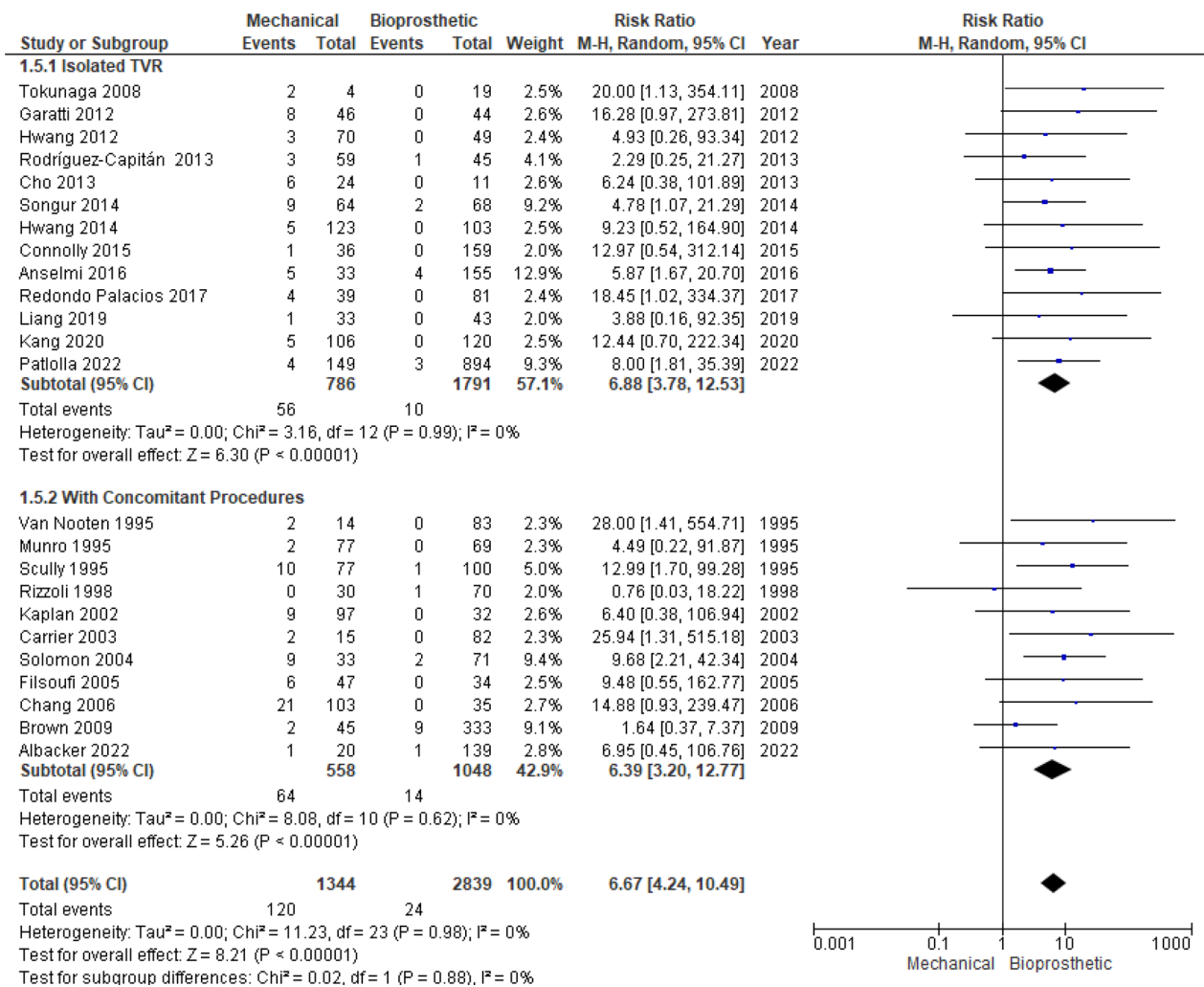


Fig. 6 Forest plot for thrombosis and thromboembolism

instead of cardioplegia [65]. Newly developed transcatheter approaches have shown promising results, but these techniques are still under investigation [66]. The optimal anticoagulation regimen, especially after mechanical valve insertion, should be comprehensively studied as mechanical valves are usually used in young patients. Future research should focus on randomized controlled trials to reduce confounding and to evaluate the safety profile of both prostheses and optimal adjunctive anticoagulant therapy, both in adults and in children. Bovine and porcine bioprosthetic valves should be compared and high-risk populations should be specifically monitored for adverse events. The effects of prior treatment, previous TV repair, reoperation with TVR, and concomitant procedures on long-term outcomes should be addressed.

Conclusion

Our systematic review and meta-analysis compared bioprosthetic and mechanical valves for tricuspid valve replacement. A key finding of our meta-analysis was that mechanical valves had a six-fold higher risk of thrombotic and thromboembolic complications. Furthermore, the incidence of five-year-valve failure and pacemaker insertion were found to be reduced with the bioprosthetic valves. No significant difference was found in long-term survival and 30-day mortality between the two types of valves. Bioprosthetic valves are associated with an increased requirement for pacemaker insertion. Surgeons should consider patient demographics and medical history when selecting the appropriate valve type.

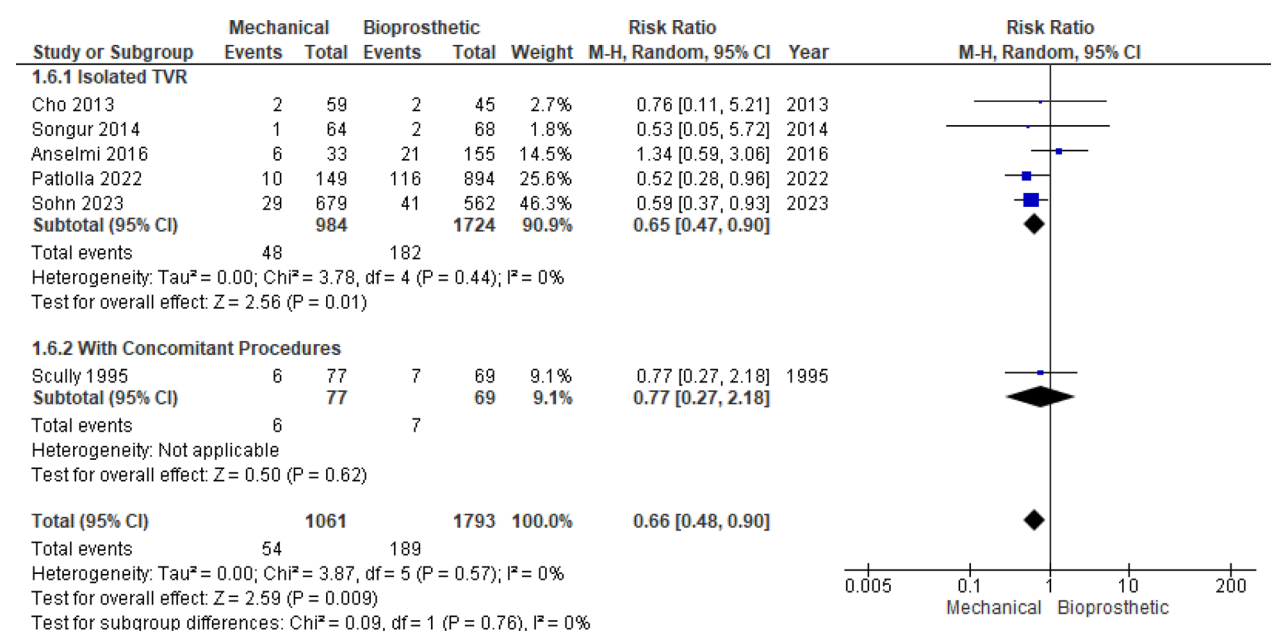


Fig. 7 Forest plot for Pacemaker insertion

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13019-024-03014-0>.

Additional file 1.

Author contributions

Muhammad Abdul Qadeer Conceptualization, Formal analysis, Methodology, Project administration, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing Ali Abdullah Formal analysis, Methodology, Software, Validation, Visualization Amber Noorani Conceptualization, Methodology, Project administration, Supervision, Validation, Writing – original draft Abdul Hadi Khan Writing – original draft Muhammad Saqlain Mustafa Validation, Writing – original draft, Writing – review & editing Zain Ali Nadeem Project administration, Validation, Writing – original draft, Writing – review & editing Shahzaib Samad Formal analysis, Software, Visualization, Writing – original draft Muhammad Usama Siddiq Writing – original draft Rabeeya Qutub Uddin Data curation, Writing – original draft Sameh M. Said Project administration, Supervision, Validation, Writing – review & editing.

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Availability of data and materials

Data and materials can be obtained by contacting the corresponding author.

Declarations

Ethics approval and consent to participate

Not Applicable.

Competing interests

The author Sameh M. Said is a consultant for Artivion, Abbott, and JOMDD.

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