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Mechanical Versus Bioprosthetic Valve Replacement in the Tricuspid Valve Position: A Systematic Review and Meta-analysis

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The ideal prosthesis for tricuspid valve replacement (TVR) continues to be debated. There are few series comparing mechanical and bioprosthetic valves, and all are retrospective studies with a relatively small sample size. This meta-analysis was conducted to compare mechanical vs bioprosthetic valves for tricuspid valve replacement.

A literature search of six databases was performed: PubMed, Embase, Ovid, Science Direct, Justor, and Wiley Blackwell. The keywords that were used were: “tricuspid valve disease, tricuspid valve replacement and (bioprosthetic or mechanical)”. The primary outcomes were hospital mortality, long-term survival, tricuspid valve reoperation, valve failure, thrombosis, and thromboembolism. Risk ratio (RR) was used to compare dichotomous parameters, and time-to-event outcomes “survival and reinterventions” were pooled using meta-analysis of hazard ratios (HR). Publication bias was assessed using a funnel plot.

Nineteen retrospective studies, published between 2002 and 2017 and including 840 mechanical and 1,065 biological tricuspid prostheses, were included in this meta-analysis. Hospital mortality did not differ between groups (RR, 0.79; 95% CI, 0.56–1.12; $p=1.19$). Long-term survival was evaluated in 13 studies, and it was not significantly different between patients with mechanical vs bioprosthetic valves, with a pooled HR 0.90 (95% CI, 0.72–1.12; $p=0.35$). Freedom from tricuspid valve reoperation was assessed in seven studies, and no between-group difference was found, with a pooled HR 1.01 (95% CI, 0.59–1.73; $p=0.97$). The 5-year incidence of valve failure was evaluated in seven studies, and there was no significant between-group difference, with a pooled RR 1.33 (95% CI, 0.42–4.27; $p=0.63$).

The results of this meta-analysis suggest an equal risk of 30-day and late mortality, reoperation, and 5-year valve failure in patients with mechanical vs biological tricuspid valve replacement. The choice of the prosthesis in the tricuspid position should mainly depend on the patient’s risk factors as no superiority of one prosthesis over the other was found in this position.

Keywords

Tricuspid valve replacement • Mechanical valves • Bioprosthetic valves • Meta-analysis • Long-term survival • Reoperation

Introduction

Tricuspid valve replacement (TVR) is rarely used for the management of tricuspid valve diseases requiring surgical

interventions [1,2], and tricuspid annuloplasty is considered the procedure of choice in most cases [3]. Patients undergoing TVR mostly have a high-risk profile with a high mortality rate and inconclusive long-term outcome irrespective of the

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type of prosthesis that is used [4]. Mechanical heart valves are durable and have low rates of reoperation; however, non-structural mechanical valve dysfunction [5], bleeding and thrombosis with long-term anticoagulation [6] have been problematic; in addition, they preclude the use of transvenous pacing. On the other hand, bioprosthetic valves do have the advantages of avoiding anticoagulation therapy but are more prone to structural valve dysfunction [4]. However, in a recent meta-analysis, patients aged <55 years who had mechanical valve replacement were found to have sub-optimal survival and an increased lifetime risk of anticoagulation-related complications and reoperations [7]. The choice of the prosthesis at the tricuspid position is still controversial [1], and there are few published series comparing mechanical and bioprosthetic valves; all are retrospective, and the small sample size is a limitation in most of these studies. This meta-analysis was performed with the aim of having a better view of the controversy by evaluating 30-day mortality, time-related reoperation, long-term survival, and 5-year valve failure in patients who received mechanical vs bioprosthetic tricuspid valves.

Materials and Methods

The meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA) [8].

Literature Search

The literature search was performed over multiple comprehensive databases to identify studies comparing mechanical vs bioprosthetic tricuspid valves. The literature search was limited to English language studies published between 2002 and 2017, and available online through PubMed, Embase, Ovid, Science Direct, Justor, and Wiley Blackwell. The following keywords were searched through Medline: (((tricuspid valve disease) AND tricuspid valve replacement) AND mechanical) OR bioprosthetic OR (((Tricuspid valve disease[Title/Abstract]) AND tricuspid valve replacement [Title/Abstract]) AND mechanical valve[Title/Abstract]) OR bioprosthetic valve[Title/Abstract]. Search strategies were adapted based on the database strategy.

Study Selection

The research question comprised four components: population, intervention, comparison, and outcome. The population was adult patients requiring tricuspid valve replacement, and comparisons were made between bioprosthetic vs mechanical valves regarding 30-day mortality, long-term survival, time-related reoperation, and valve failure in 5 years. Studies reporting data for adult patients who had TVR were included. The causes of TVR were organic lesions such as rheumatic tricuspid valve stenosis, rheumatic tricuspid valve regurgitation, tricuspid valve endocarditis, traumatic injury of the tricuspid valve, and carcinoid tricuspid valve disease. All the studies were observational retrospective studies. Two

reviewers decided if the studies met the inclusion criteria, and a third reviewer revised the study if there was any disagreement. All studies were screened at two levels: the title and abstract, then the text was reviewed.

Included Studies

Search results returned 1,871 studies and 1,699 were excluded, including studies: with irrelevant subject (n=1,351); with insufficient data; published outside specified dates (n=264); discussing tricuspid valve repair (n=23); with <10 patients (n=20); with paediatric populations (n=24); published in languages other than English (n=12); including patients with percutaneous TVR (n=20); on non-human subjects (n=2); and of TVRs in cardiac transplantation (n=1). Figure 1 shows the study flow diagram.

After full-text assessment of the studies, an additional 153 studies were excluded because of: nonspecific data (n=106); a population <10 participants (n=18); an overlapping population (n=3); lack of a target endpoint (n=2); lack of the valve type (n=13); studying mechanical tricuspid valve replacement only (n=6); and studying bioprosthetic tricuspid valve replacement only (n=5). Studies comparing bioprosthesis and mechanical valves (n=19) were included, and a meta-analysis of weighted proportions was performed. Post-operative outcomes were extracted from the original articles and categorised according to the type of prosthesis—mechanical or bioprosthetic—into 30-day mortality, long-term survival, time-related reoperation, and valve failure in 5 years. Publication biases for each outcome were assessed using a funnel plot (Figure 2).

Female predominance was clear among both the mechanical and bioprosthetic groups, with the male percentage ranging between 16% [9] and 33% [3] in the mechanical groups and between 19% [10] and 46% [11] in the bioprosthetic groups. Mean age was variable between the study groups, from 37±13 years [12] to 62±9.8 years [13] for the mechanical groups and from 33±10 years [12] to 63±12 years [11] for bioprosthetic groups. Mean left ventricular ejection fraction varied between 47±23% [14] and 60±10% [15] in the mechanical groups and from 56±9.7% [11] to 60±6.8%⁹ in the bioprosthetic groups. Mean pulmonary artery pressure (PAP) was approximately 47 mmHg [9,15] in the mechanical groups and between 39±9.5 mmHg [9] and 48±15 mmHg [14] in the bioprosthetic groups. Mean cross-clamp time ranged between 93±47 minutes [11] and 126±58 minutes [10] in the mechanical groups and 85±47 minutes [11] and 121±52 minutes [10] in the bioprosthetic groups. Mean bypass time varied between 135±44 minutes [14] and 211±82 minutes [10] in the mechanical groups and between 116±53 minutes [9] and 204±74 minutes [10] in the bioprosthetic groups. Isolated TVR was reported in selected groups [2,9,11]; however, the majority of TVR was a concomitant procedure. Between 44% [12] and 74% [10] of patients in the mechanical groups had reoperation, and 42% [11] and 90% [9] in the bioprosthetic groups. Most tricuspid valve diseases are associated with multiple co-morbidities,

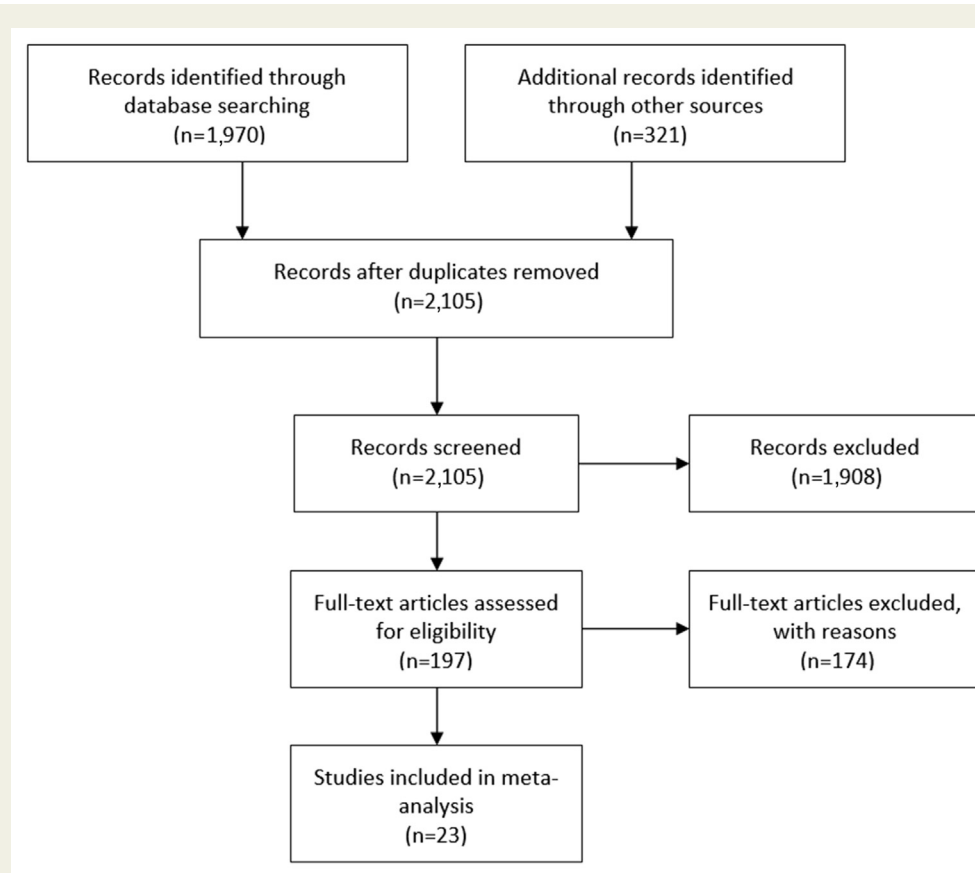


Figure 1 PRISMA flow chart.

and that was reported in multiple studies: heart failure with congestive symptoms [2,11,14,15] and most of the patients showed NYHA class III and IV [2,3,10,11,14–16]; renal insufficiency [9,10,14]; atrial fibrillation [3,10,11]; preoperative infective endocarditis [3,11,12,15]; and prosthetic valve failure [11] were variably reported.

Statistical Analysis

Forest plots provide a summary of the statistics. They involve a weighted compilation of all the effect sizes reported by each study and provide an indication of heterogeneity between studies. For each study, the effect size is represented by a square and horizontal line, representing the point estimate and 95% confidence interval, respectively. The size of the square is proportional to the weight assigned to that particular study for the meta-analysis. The pooled effect size following meta-analysis is represented by the black diamond, the width of which indicates the overall 95% CI. If this diamond lies totally to one side of the solid vertical line in the centre, the pooled point estimate indicates a significant difference in effect size between mechanical and bioprosthetic valves.

Summary statistics used for point estimates were risk ratio (RR) and 95% CI for dichotomous parameters (30-day

mortality and 5-year valve failure). Time-to-event outcomes such as survival and reoperation were pooled using meta-analysis of hazard ratios (HR) and 95% CI. The HR was not reported and individual patient data were unavailable in some studies. Therefore, Tierney et al.'s [17] associated Excel sheet was used to calculate the HR using Kaplan-Meier curves data, which were extracted by DIGITIZE IT (Version 2.3.3 I. Bormann 2011-2016) [8]. An HR of <1 indicated better results of mechanical valves, and >1 indicated a higher risk of mechanical prostheses and better outcome with the bioprosthetic valve. Heterogeneity of the studies was tested using I-squared and tau-squared, and a p-value <0.05 indicated heterogeneity of the included studies. There was no significant heterogeneity between the included studies, and the fixed-effect assumption was used to pool the RR and HR of all study endpoints.

Publication biases were presented using funnel plots. In minimal publication bias, the points of the funnel plot were symmetrically distributed around the mean effect size. The asymmetrical distribution indicated potential publication bias. Descriptive summary statistics were used for post-operative thrombosis and thromboembolism because of the considerable variability in reporting these outcomes in different studies.

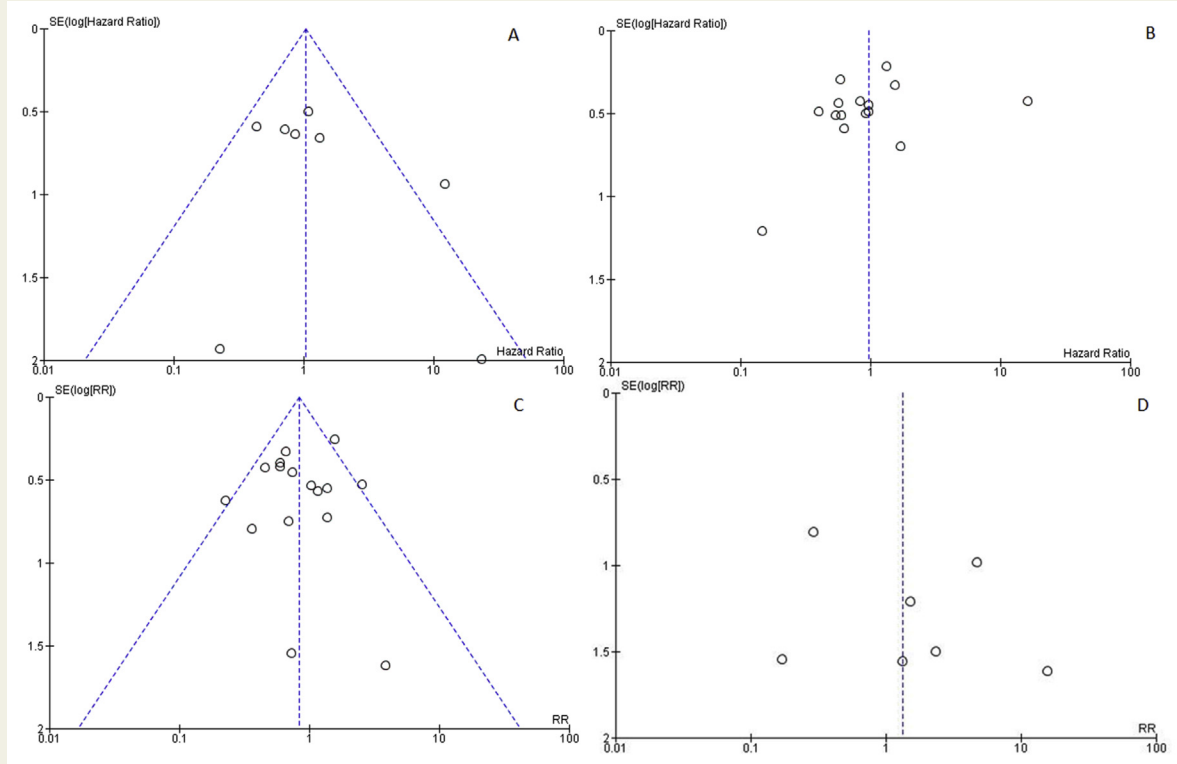


Figure 2 Publication bias funnel plots for: A. 30-day mortality; B. long-term survival; C. reoperation; D. 5-year valve failure. Abbreviations: RR, Risk Ratio; SE, Standard Error.

Results

Study Summary

The search results yielded 19 studies that reported an intra-institutional comparison of the bioprosthetic valve vs the mechanical valve in the tricuspid position. Nineteen studies with 840 mechanical and 1,065 biological tricuspid prostheses were further analysed. The studies are summarised in Table 1.

30-day mortality

30-day mortality was reported in 12 studies, seven studies were in favour of the mechanical valve, and five studies were in favour of the bioprosthetic valve. There was no significant difference between both types of valves, with pooled RR 0.79 (95% CI, 0.56–1.12; $p=0.19$) (Figure 3).

Survival

Long-term survival was reported in 13 studies showing follow-up to 20 years postoperatively: 10 of them were in favour of the mechanical valve and three were in favour of the bioprosthetic valve. Pooled HR did not show a significant difference between both types in terms of long-term survival: HR, 0.90 (95% CI, 0.72–1.12; $p=0.35$) (Figure 4).

Reoperation

Time-related freedom from reoperation was assessed in seven studies, three of them were in favour of the mechanical valve, three were in favour of the bioprosthetic valve, one

revealed similar outcomes, and the current analysis revealed a non-significant difference between both types of valves with pooled HR 1.01 (95% CI, 0.59–2.12; $p=1.73$) (Figure 5).

Valve failure

Seven studies discussed valve failure in 5 years, two of them were in favour of the mechanical valve, and five were in favour of the bioprosthetic valve. There was no significant between-group difference in pooled RR 1.33 (95% CI, 0.42–4.27; $p=0.63$) (Figure 6). Nine studies discussed the total incidence of valve failure: 14 events occurred in 512 implanted mechanical valves (2.73%) and 48 events in 524 implanted bioprosthetic valves (9.16%) (Table 3).

Thrombosis and thromboembolism

Ten studies discussed postoperative valve thrombosis. Songur et al. [13] reported one event of thrombosis with a bioprosthetic valve among 68 participants vs five of 60 events with a mechanical valve. Nine studies reported thrombosis with mechanical valves only during the follow-up. Thirty-six events occurred in 570 implanted mechanical valves (6.31%) and one event in 588 bioprosthetic valves (0.17%) (Table 3). Thromboembolic events were reported in nine studies, with 42 events in 464 mechanical valves (9.05%) and eight events in 470 bioprosthetic valves (1.7%) (Table 3).

Pacemaker insertion

Pacemaker insertion and incidence of atrioventricular block were reported in three studies. Cho et al. [11] reported

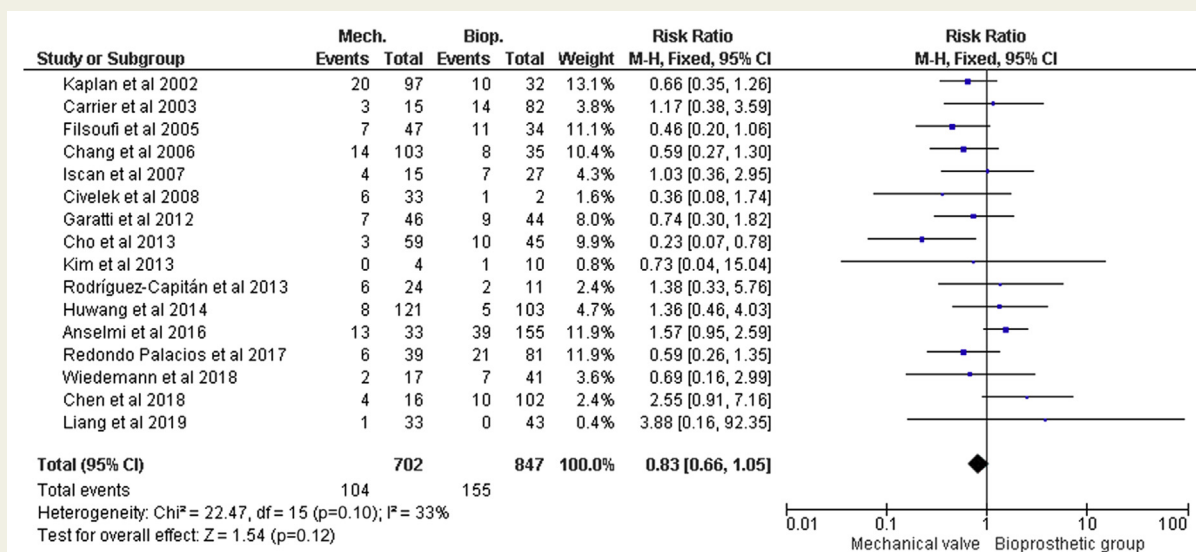
Table 1 Summary of the studies included in the meta-analysis.

First Author	Date of Publication	Total Number of Patients	Number of Mechanical Valves	Number of Bioprosthetic Valves	Operative Time Range	The Geographical Location of the Study
Kaplan et al. [12]	2002	129	97	32	1980–2000	Turkey
Carrier et al. [2]	2003	97	15	82	1977–2002	Canada
Rizzoli et al. [26]	2004	101	23	78	1970–2002	Italy
Soloman et al. [16]	2004	104	33	71	1966–2002	New Zealand
Farzan et al. [32]	2005	81	47	34	1985–1999	USA
Chang et al. [3]	2006	138	103	35	1978–2003	South Korea
Iscan et al. [33]	2007	42	15	27	1987–2004	Turkey
Civelek et al. [4]	2008	35	33	2	1996–2006	Turkey
Tokunaga et al. [27]	2008	23	4	19	1975–2004	Japan
Moraca RJ et al. [34]	2009	93	21	72	1986–2006	USA
Sung K et al. [23]	2009	80	62	18	1994–2007	South Korea
Garatti et al. [15]	2012	90	46	44	1980–2005	Italy
Cho et al. [11]	2013	104	59	45	1991–2009	South Korea
Kim et al. [35]	2013	14	4	10	1996–2010	Korea
Capitán et al. [9]	2013	35	24	11	1996–2010	Spain
Ho Young et al. [10]	2014	224	121	103	1994–2012	South Korea
Songur et al. [13]	2014	132	64	68	1993–2011	Turkey
Connolly et al. [25]	2015	195	36	159	1985–2012	USA
Anselmi et al. [14]	2016	188	33	155	1971–2012	France

pacemaker insertion in two of 57 and two of 43 in mechanical and bioprosthetic groups, respectively. Songur et al. [13] reported pacemaker insertion in one of 63 and two of 66, and Anselmi et al. [14] reported an incidence of six of 27 and 21 of 134 in mechanical and bioprosthetic groups, respectively.

Discussion

Tricuspid valve repair remains the preferred technique for the management of tricuspid valve disease requiring surgery [18]. However, tricuspid valve replacement may be necessary for a specific situation in which repair is unfeasible or

**Figure 3** Forest plot of 30-day mortality.

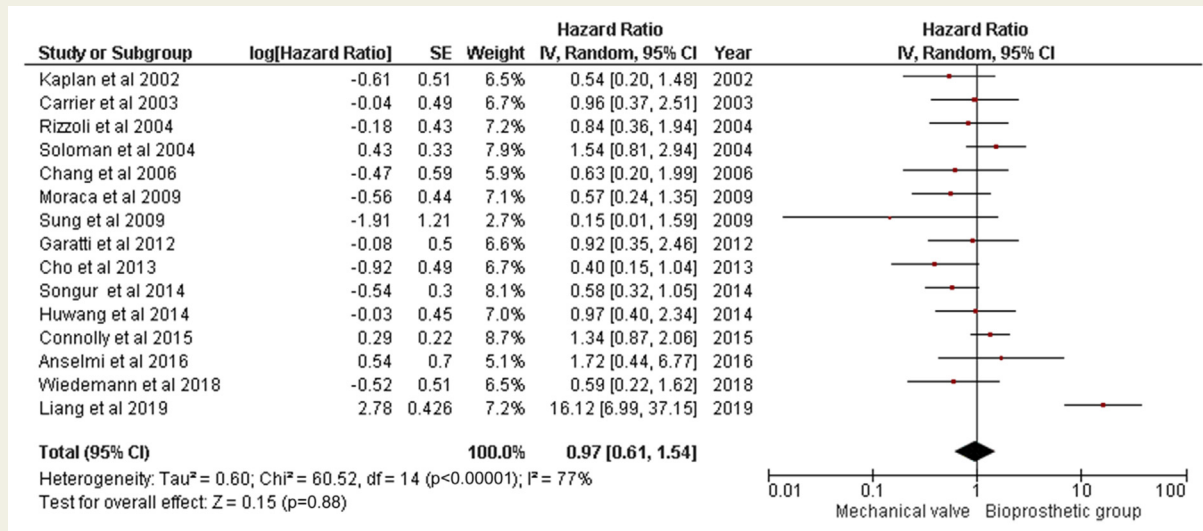


Figure 4 Forest plot of long-term survival.

with a failed repair. The choice of the prosthesis for TVR continues to be debated. The literature lacks a randomised trial comparing mechanical vs bioprosthetic valve in the tricuspid position, and all the available studies have few numbers and are retrospective. This could be attributed to the few numbers of patients who require TVR compared with repair. Current guidelines for the management of valvular heart disease state that there is not enough evidence that one type of prosthesis is better than the other [19]. Biological prostheses were considered to be ideal in the tricuspid position, as they do not require anticoagulation and were expected to have a slower degeneration than a left-sided valve; however, this belief was contradicted by the finding of pannus formation on the mural cusp [20,21] and other studies reporting durability between 7 and 9 years [2,22]. The new generations of bileaflet mechanical valves function with low gradient, low turbulence, and optimal durability [12].

This meta-analysis was performed to combine studies comparing mechanical vs bioprosthetic tricuspid valves, and

it only selected studies presenting comparison data of patients in the same institution under the same perioperative care (to reduce referral and selection biases of retrospective studies). The endpoints were 30-day mortality, long-term survival, reoperations, and valve failure. For long-term survival, most of the studies reported a non-significant difference between mechanical and bioprosthetic valves in the tricuspid position; however, Cho et al. [11] and Sung et al. [23] reported significant superiority of the mechanical valve in the tricuspid position with p-values 0.031 and 0.004, respectively. The combined results show no difference in survival between both types of prosthesis ($p = 0.5$). These results can be explained by the limited life expectancy of patients requiring TVR, which could be unrelated to the type of prosthesis used [24], in addition to the excellent performance of both prostheses. Regarding freedom from reoperation, all six studies reported an insignificant difference between both types of valves. Structural valve failure was the main cause of reoperation with a bioprosthetic valve; mechanical valve

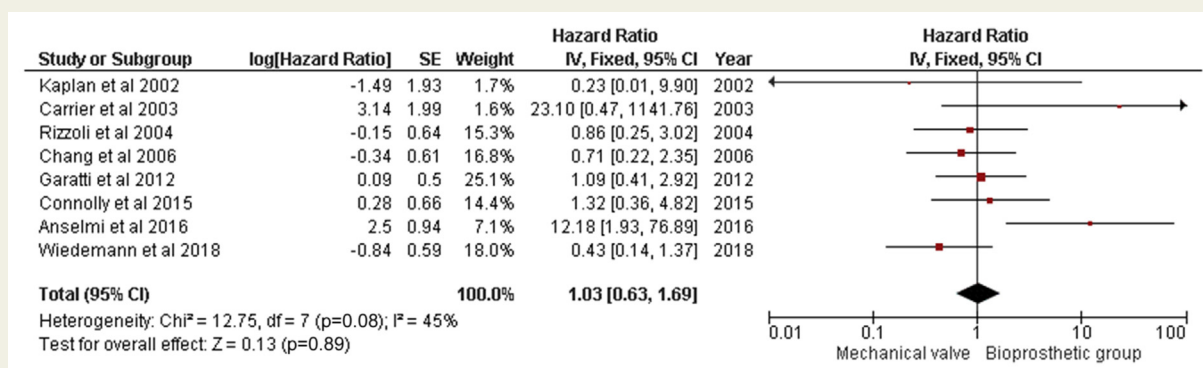


Figure 5 Forest plot of reoperation.

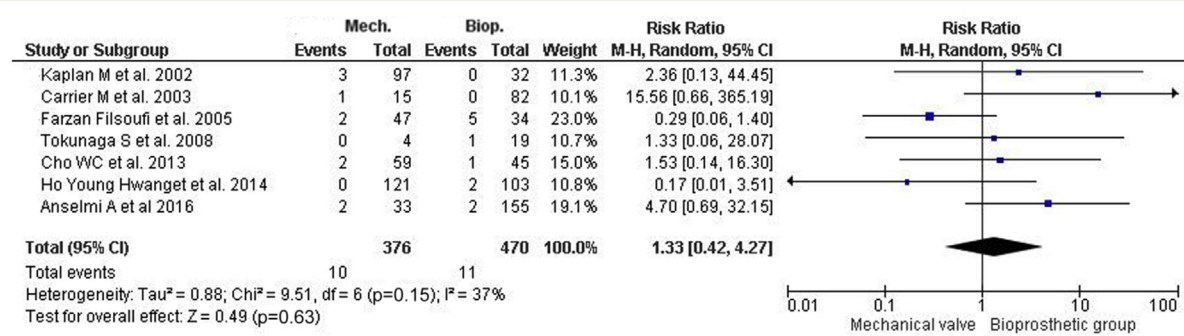


Figure 6 Forest plot of the 5-year valve failure.

failure was reported by Chang et al. [3] along with anticoagulation-related haemorrhage and thrombosis, which were reported by Connolly et al. [25]. A meta-analysis by Rizzoli et al. [26] demonstrated that the mean reoperation rate due to structural valve degeneration of bioprosthesis was similar to that of reoperations due to thrombosis of the mechanical valve.

The current results suggest an identical risk for both prostheses, with 1,065 biological and 840 mechanical valves followed for up to 20 years. The choice of prosthesis in the tricuspid position should mainly depend on the patient's risk factors and surgical team experience. There was no statistically significant difference between mechanical and bioprosthetic valves in terms of valve failure in 5 years, but this has been reported more with mechanical valves [2,11,12,14,27], which was explained by valve thrombosis [2,11,12,27], infective endocarditis [12] and structural deterioration [14]. However, during long-term follow-up, the high failure rate of the bioprosthetic valve was evident, with 9.16% of all patients affected vs 2.73% of all patients receiving mechanical valves. It can be seen in the study by

Carrier et al. [2] that one valve failure was reported in the first 5 years, and it was a mechanical valve, then six bioprosthetic valves were affected between 9 and 13 years during 21 years of follow-up, and no mechanical valve failure was reported (Table 3). Although tricuspid bioprosthetic valves have a longer half-life than mitral valves, they are still limited by fibro-calcifications and fatigue-related disruption [28]. Thrombosis is almost always reported with mechanical valves, and that explains the higher rate of thromboembolic events. Pulmonary embolism was reported at 18 years by Tokunaga et al.: some of the affected cases were treated with thrombolytics and others required reoperation [9]. Due to the fact that anticoagulation therapy has been associated with bleeding and harm during pregnancy [29], many patients choose bioprosthetic valves. Bioprosthetic valves are either stented or stentless and manufactured from porcine or bovine pericardium. They have fewer thrombosis events due to improved haemodynamics with less obstruction to blood flow, especially in stentless valves [30]. The risk of thromboembolism is higher in the first 3 months due to defected endothelialisation of the prosthetic material [31].

Table 2 Preoperative data.

	Number of Males		Mean AGE		Number of Redo Cases		NYHA Class III, IV	
	Mechanical	Bioprosthetic	Mechanical	Bioprosthetic	Mechanical	Bioprosthetic	Mechanical	Bioprosthetic
Kaplan et al. [12]	19 (19%)	7 (21%)	37.38±12.67	33.16±10.45	43	16	-	-
Carrier M et al. [2]	5 (33%)	21 (25%)	48±11	53±13	12	64	14	71
Rizzoli G et al. [26]	-	-	48	46	-	-	-	-
Soloman et al. [16]	9 (26%)	20 (25%)	-	-	21 (65%)	52 (64%)	17 (52%)	36 (45%)
Chang et al. [3]	35 (33%)	15 (42%)	43.4±13.9	44.5±22.9	65	14	82	33
Sung et al. [23]	-	-	45.2±11.8	60.7±10.8	-	-	-	-
Garatti et al. [15]	9 (19%)	16 (36%)	53.9±14.0	53.7±14.0	29	31	32	38
Cho et al. [11]	12 (20%)	21 (46%)	51.5±9.8	62.7±11.8	39	19	16	22
Kim et al. [35]	-	-	-	-	-	-	-	-
Capitán et al. [9]	4 (16%)	3 (27%)	55.9±10.7	57.1±14.8	14	10	-	-
Ho Young et al. [10]	35 (28%)	20 (19%)	49.1±11.3	60.1±12.0	90	75	60	46
Songur et al. [13]	-	-	62.3±9.8	61.6±10.4	-	-	-	-
Anselmi A et al. [14]	10 (30%)	70 (45%)	51.2±12.8	57.4±15.6	-	-	30	122

Table 3 Valve failure, thrombosis and thromboembolic events after tricuspid valve replacement.

Study	Mechanical Valve Failure (n/Total)	Bioprosthetic Valve Failure (n/Total)	Mechanical Valve Thrombosis (n/Total)	Bioprosthetic Valve Thrombosis (n/Total)	Mechanical Valve Thromboembolism (n/Total)	Bioprosthetic Valve Thromboembolism (n/Total)
Kaplan et al. [12]	3 of 97 (3.09%)	2 of 32 (6.25%)	3 of 97 (3.09%)	0 of 32	6 of 97 (6.18%)	0 of 32
Carrier et al. [2]	1 of 15 (6.66%)	6 of 82 (7.31%)	2 of 15 (13.33%)	0 of 82	-	-
Solomon et al. [16]	0 of 33	16 of 71 (22.53%)	-	-	9 of 33 (27.27)	2 of 71 (2.81%)
Farzan et al. [32]	2 of 47 (4.25%)	5 of 34 (14.7%)	3 of 47 (6.38%)	0 of 34	3 of 47 (6.38%)	0 of 34
Chang et al. [3]	4 of 103 (3.88%)	7 of 35 (20%)	10 of 103 (9.7%)	0 of 35	11 of 103 (10.67%)	0 of 35
Tokunaga et al. [27]	0 of 4	6 of 19 (3.15%)	1 of 4 (25%)	0 of 19	1 of 4 (25%)	0 of 19
Cho et al. [11]	2 of 59 (3.38%)	1 of 45 (2.22%)	2 of 59 (3.38%)	0 of 45	1 of 59 (1.69%)	1 of 45 (2.22%)
Capitán et al. [9]	-	-	4 of 24 (16.66%)	0 of 11	2 of 24 (8.33%)	0 of 11
Ho Young et al. [10]	0 of 121	3 of 103 (2.91%)	5 of 121 (4.13%)	0 of 103	-	-
Songur et al. [13]	-	-	5 of 64 (7.81%)	1 of 68 (1.47%)	4 of 64 (6.25%)	1 of 68 (1.47%)
Connolly et al. [25]	-	-	1 of 36 (2.77%)	0 of 159	-	-
Anselmi et al. [14]	2 of 33 (6.06%)	2 of 155 (1.29%)	-	-	5 of 33 (15.15%)	4 of 155 (2.58%)
Total	14 of 512 (2.73%)	48 of 524 (9.16%)	36 of 570 (6.31%)	1 of 588 (0.17%)	42 of 464 (9.05%)	8 of 470 (1.7%)

Study Limitations and Recommendations

The major limitation of this study was the retrospective nature of all included studies. Several risk factors could have affected the outcome other than the type of prosthesis. However, there are no available randomised trials comparing the two prostheses in the tricuspid position. Therefore, this is an acceptable method with which to study the outcomes of infrequently performed procedures. The study showed comparable outcomes in patients who received mechanical vs bioprosthetic valves in the tricuspid position. Since there is no superiority of one valve over the other in the short-term and long-term outcomes, patients' specific risk factors should govern the choice of the prosthesis. Bioprosthetic valves offer the advantages of avoiding anticoagulation and the possibility of a future transcatheter tricuspid valve in valve replacement. Despite the belief that prosthetic valves last longer, the reoperation rate was similar in both groups. Patients who do not have indications for anticoagulants could have bioprosthetic valves with comparable survival and reoperation rates to those with mechanical valves.

Conclusion

Tricuspid valve replacement is not a common procedure. The choice of the prosthesis has no effect on the short-term and long-term outcomes, and there is no superiority of one type over the other in this position. The selection of the tricuspid valve prosthesis should be based on each patient's specific character.

Funding

Nil.

Conflicts of Interest

Nil.

Uncited Table

Table 2.

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