Med. J. Cairo Univ., Vol. 87, No. 5, September: 2877-2883, 2019
www.medicaljournalofcairouniversity.net

Meta-Analysis of Clinical Outcomes of Tricuspid Valve Replacement

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Abstract

Background: The long-term results of Tricuspid Valve Replacement (TVR) depend on factors related to the original valve disease more than on the prosthesis type. Tricuspid valve prosthesis; either mechanical or bioprosthetic, should be chosen according to the individual patient's characteristics.

Aim of Study: The aim of the study was to analyze the clinical results of tricuspid valve replacement, comparing the different types of tricuspid valve prostheses.

Patients and Methods: A meta-analysis study was done to evaluate TVR results in adults in the literature published in the period of 20 years "1995: 2015", focusing on literature published in English comparing mechanical valves to bioprosthetic valves. We performed a search over published literature of different databases "Embase, PubMed, Ovid, Justor, Science Direct, and Wiley Blackwell."

Results: The total of 17 studies evaluating 1020 mechanical valve and 1199 bioprosthetic valve patients were included in the meta-analysis. Valve thromboses, and emboli are less reported with bioprosthetic valve (RR=6.52; 95% CI: 3.00, 14. 15; p<0.00001) and (RR=2.25; 95% CI: 1.14, 4.46; p= 0.02) respectively. There was no statistically significant difference between valve types as regards to bleeding, heart block, low cardiac output, valve failure, infective endocarditis, stroke, and renal failure.

Conclusion: The type of the tricuspid valve prosthesis should be chosen based on patient's characteristics but occasionally it's equivocal, that's when the bioprosthetic valve should be preferred because of its less morbidity.

Key Words: *Tricuspid valve replacement – Mechanical valves – Bioprosthetic valves.*

Introduction

HISTORICALLY, Tricuspid Valve (TV) surgery has been associated with high operative mortality and morbidity and considered a marker for end-stage valvular heart disease [1]. When the anatomical abnormality of the TV leaflets is severe, Tricuspid Valve Replacement (TVR) is necessary [3], especially in re-operations on highly deformed valves and in the case of a second or third intervention performed for residual or recurrent Tricuspid Regurgitation (TR) [2]. Currently, right sided valve replacement might be considered for patients with only mild symptoms [2], avoiding the high mortality risk associated with right ventricular dilatation in late intervention [3]. The outcome of TV surgery is less predictable than that of other valves; with higher risk and a worse outcome than the mitral valve replacements, because of the complex anatomy and late repeated interventions [2]. The durability of mechanical heart valves leads to low rates of re-operation, compared with that of bio-prosthetic valves. But, mechanical valve dysfunction (nonstructural), such as prosthetic leaflet restriction due to thrombus or pannus formation and para-valvular leak, has been problematic [4]. There is insufficient data to determine which valve prosthesis is better for tricuspid valve replacement [5]. The objective of this meta-analysis is to compare the outcomes of TVR using mechanical versus bioprosthetic valves in the studies published in 20 years.

Material and Methods

We identified relevant studies published in the past 20 years (1995 to 2015), through Embase, PubMed, Ovid, Science Direct, Wiley Blackwell and Justin and we included related articles found through manual search. The data were reviewed by the 1st and 2nd authors followed by the third one to confirm that the studies meet the inclusion criteria. The text strings used were formatted for PubMed as 1- (Tricuspid valve disease) 2- AND 3- (Tricuspid valve replacement) 4- AND 5- (Mechanical-OR-Bioprosthetic) or ((Mechanical) then (Bioprosthetic)). To further reduce the probability

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of losing any major related study, all references of included studies were evaluated. Data extraction was conducted independently by two authors and a third one if there is a discrepancy in the collected data.

According to the pre-set strict criteria "intra-institutional comparison between the outcomes of bioprosthetic and mechanical tricuspid valve in adult patients" relevant papers in English were selected from the search result. The exclusion criteria were: Studies that have no direct comparison between the bioprosthetic and the mechanical valve studies that do not report the outcomes and studies that were produced at the same institution and there was a sample overlap, in this case, the most updated study was included.

After excluding non-relevant studies, we found 17 studies comparing the two valves. We found 1724 from search and related articles, after removal of duplicates, 1505 studies remained. From them, 1319 were excluded: 1189 irrelevant studies, 10 of percutaneous TVR, 23 of tricuspid valve repair, 58 before 1995 or after 2015, 26 including children, infants, and neonates, ten not in English, 2 of cadavers, and 1 in cardiac transplantation patients. Then we fully assessed 186 studies to include 17 and exclude 169: 25 of population less than 10 patients,1 study was repeated with the same institution data, 104 abstract, editorial, conference papers, and not enough supplied data, 9 did not discuss morbidity, 5 studies on mechanical valves only, 9 on bioprosthetic tricuspid valve only, 16 studies on TVR with no data comparison Fig. (1).

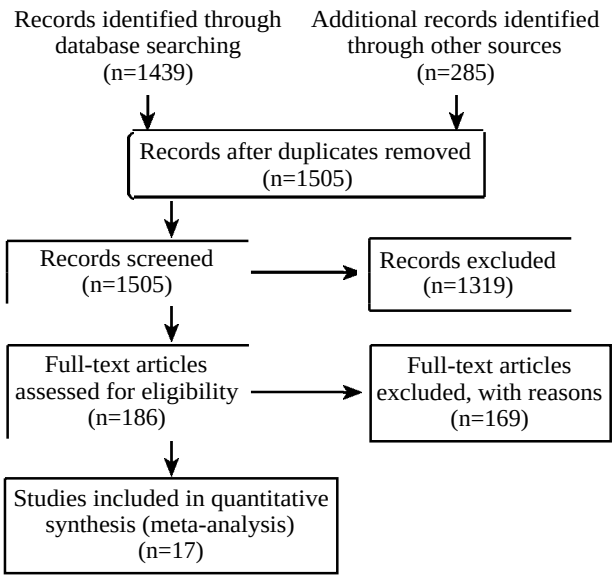

Fig. (1): PRISMA flowchart (preferred reporting items for systematic reviews and meta-analyses).

Statistical analysis:

Forest plots were used to summarize the results of each outcome. The effect size is shown as a square, and its size is related and proportionate to the weight of each study. Black diamond presents the pooled effect size which indicates the overall results. If it lies completely at one side of the solid central vertical line without crossing it, this indicates significant results **[6-20]**. Statistical significance was set at a p-value of 0.05 or less.

Funnel plots were used to asses publication bias, and the dots around the central vertical line have to be distributed in an equal way on both sides to exclude publication bias **[6-20]**.

The endpoints were postoperative morbidity including; valve thromboses, emboli, heart block, bleeding, low cardiac output, infective endocarditis, valve failure, stroke, and renal failure.

All analyses were performed using RevMan (Version 5.3. Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration, 2014).

Results

Study summary:

Database research yielded 17 studies meeting the inclusion criteria and reporting an institutional comparison between the tricuspid bioprosthetic valve and the mechanical valve. These studies are presenting the outcome of 1020 mechanical and 1199 bioprosthetic valve. Studies are summarized in (Table 1) which shows the date of publication, number of patients, the time range of the operation and geographical distribution of the studies.

Post-operative thrombosis:

Fourteen studies compared thrombosis with mechanical Vs. bioprosthetic valve, all of them favored the bioprosthetic valve, and our meta-analysis revealed the significantly lower risk of thrombosis with bioprosthetic valve, and there is no publication bias (Pooled RR=6.52; 95% CI: 3.00-14.15 and p-value >0.001) Figs. (2A, 3).

Post-operative valve failure:

Twelve studies compared valve failure in patients receiving bioprosthetic Vs. mechanical valve, 9 of them favored the mechanical valve and three favored bioprosthetic valve. Our meta-analysis revealed insignificant difference between the both valves with no publication bias (Pooled RR=0.51; 95% CI: 0.25-1.04 and p-value=0.07) Figs. (2B, 4).

Post-operative embolic events:

Post-operative embolic events were presented by five studies comparing mechanical and bioprosthetic valve from which 4 favored the bioprosthetic valve and one favored the mechanical valve. Our results showed that bioprosthetic valve has significant better outcome (Pooled RR=2.25; 95% CI: 1.14-4.46 and p-value=0.02) Fig. (5).

Post-operative stroke and cerebrovascular events:

Six studies reported post-operative stroke, and cerebrovascular events, 4 of them favored the mechanical valve and 2 favored the bioprosthetic valve, our meta-analysis revealed insignificant difference for both valves (Pooled RR=0.63; 95% CI: 0.22-1.80 and p-value=0.39) Fig. (6).

Post-operative infective endocarditis:

Five studies compared infective endocarditis between both valves (mechanical and bioprosthetic), 2 of them favored the mechanical valve while 3 favored the bioprosthetic valve. Our meta-analysis revealed no significant difference was between the both valves (Pooled RR=1.09; 95% CI: 0.35-3.39 and p-value=0.89).

Post-operative low cardiac output:

Five studies compared post-operative low cardiac output in mechanical Vs. bioprosthetic tricuspid valves, 2 supported the mechanical valve, and 3 supported the bioprosthetic valve. Our meta-analysis revealed insignificant difference between both valves (Pooled RR=0.95; 95% CI: 0.62-1.45 and p-value=0.82).

Post-operative atrioventricular block:

Four studies compared post-operative atrioventricular block in mechanical and bioprosthetic tricuspid valves, all of them supported the mechanical valve, but no significant difference was found Pooled RR=0.61 (95% CI: 0.25-1.50 and p-value= 0.279).

Post-operative renal failure:

Post-operative renal dysfunction was reported in 4 studies 2 of them favored the mechanical valve and 2 favored the bioprosthetic valve, and there was the non-significant difference between both valves (Pooled RR=0.73 (95% CI: 0.38-1.39 and p-value=0.42).

Post-operative bleeding:

Post-operative bleeding was reported by nine studies from which 5 showed better results with the mechanical valve and 4 showed better results with the bioprosthetic valve, and our meta-analysis showed a statistically non-significant difference for the two valves (Pooled RR=0.96; 95% CI: 0.51-1.81 and p=0.91).

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

First author	Publication date	Patients number	Patients receiving a mechanical valve	Patients receiving a bioprosthetic valve	Time range of the operation	Location of the study
Scully HE et al., **[7]**	1995	60	32	28	1978:1993	Canada
Van Nooten GJ et al., **[8]**	1995	146	77	69	1967:1987	Belgium
Hayashi J et al., **[9]**	1996	29	15	14	1978:1995	Japan
Ratnatunga CP et al., **[10]**	1998	425	200	225	1986:1997	UK
Mehmet Kaplan et al., **[11]**	2002	129	97	32	1980:2000	Turkey
Carrier M et al., **[12]**	2003	97	15	82	1977:2002	Canada
Farzan Filsoufi et al., **[13]**	2005	81	47	34	1985:1999	USA
Tokunaga S et al., **[14]**	2008	23	4	19	1975:2004	Japan
Moraca RJ et al., **[15]**	2009	93	21	72	1986:2006	USA
Toplisky Y et al., **[1 6]**	2011	189	35	154		
Ho Young Hwang et al., **[17]**	2012	119	70	49	1996:2010	South Korea
Cho WC et al., **[18]**	2013	104	59	45	1991:2009	South Korea
Chang BC et al., **[19]**	2013	138	103	35	1978:2003	South Korea
Capitán JR **[20]**	2013	35	24	11	1996:2010	Spain
Ho Young Hwanget et al., **[21]**	2014	224	121	103	1994:2012	South Korea
Songur CM et al., **[22]**	2014	132	64	68	1993 :20 11	Turkey
Connolly HM et al., **[23]**	2015	195	36	159	1985:2012	USA

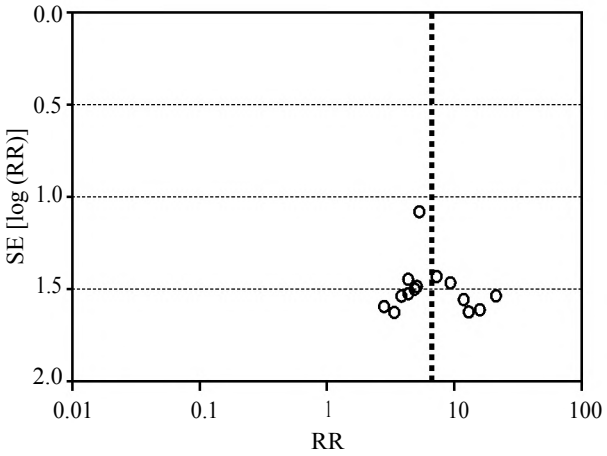

Fig. (2A): Publication bias funnel plots for thrombosis-equal distribution around vertical central line=no publication bias.

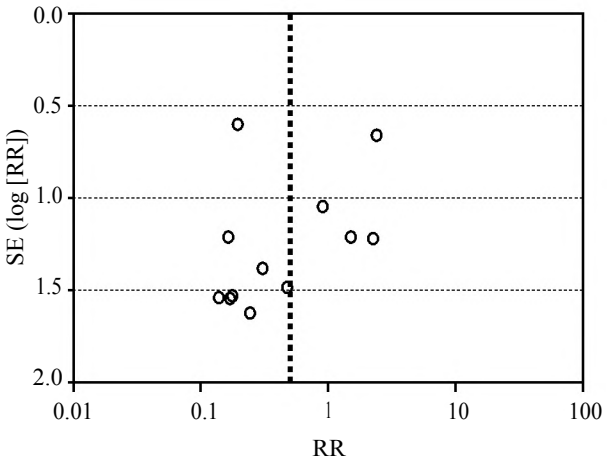

Fig. (2B): Publication bias funnel plots for valve failure-equal distribution around vertical central line=no publication bias.

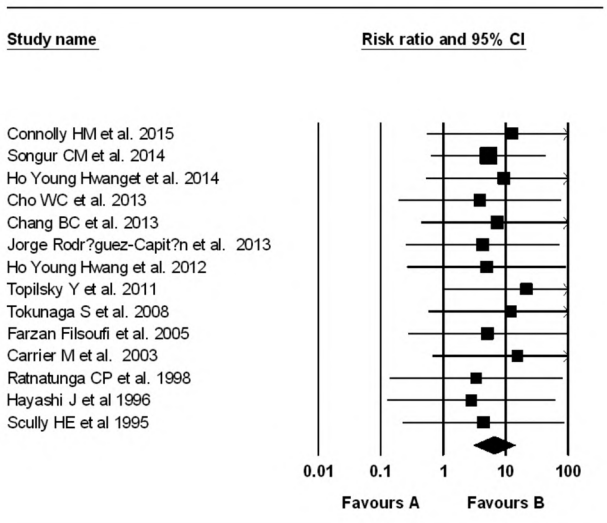

Fig. (3): Forest plot of post-operative thrombosis, in favor of bioprosthetic valve-CI: Confidence Interval, (A) Mechanical valve, (B) Bioprosthetic valve-(Pooled RR=6.52; 95% CI: 3.00-14.15 and p-value >0.001).

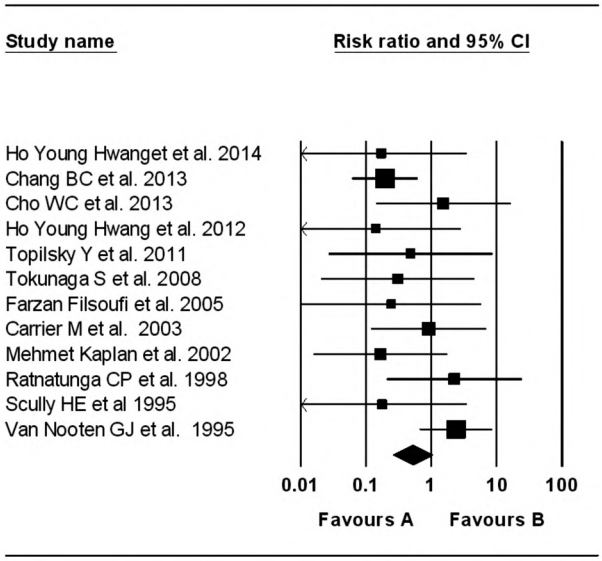

Fig. (4): Forest plot of post-operative valve failure-CI; Confidence Interval, (A) Mechanical valve, (B) Bioprosthetic valve-(Pooled RR=0.51; 95% CI: 0.25-1.04 and p-value=0.07).

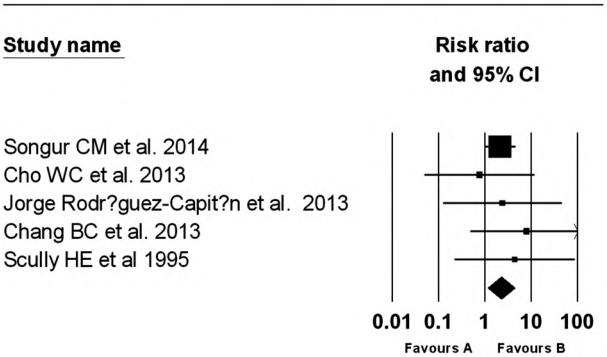

Fig. (5): Forest plot of post-operative embolic events- in favor of the bioprosthetic valve, CI; Confidence Interval, (A) Mechanical valve, (B) Bioprosthetic valve-(Pooled RR=2.25; 95% CI: 1.14-4.46 and p-value=0.02).

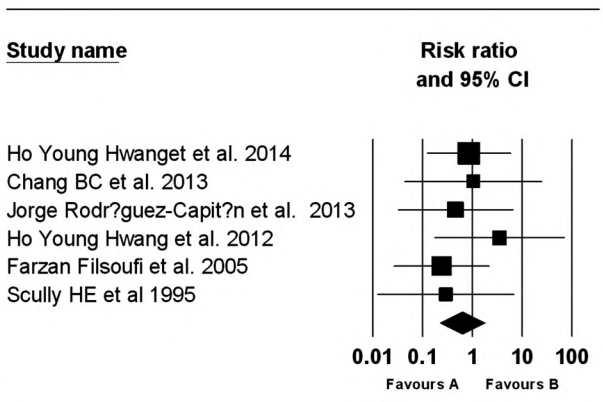

Fig. (6): Forest plot of post-operative stroke and cerebrovascular events-CI; Confidence Interval, (A) Mechanical valve, (B) Bioprosthetic valve-(Pooled RR=0.63; 95% CI: 0.22-1.80 and p-value=0.39).

Discussion

Tricuspid valve repair is the first option in tricuspid valve surgery **[24]**. When repair is not feasible, and tricuspid valve replacement becomes mandatory, the question which prosthesis is better in this tricuspid position is still debatable. No optimum valve substitute is available and comparing tricuspid bioprosthesis and mechanical valves; each one has its advantages and disadvantages. Recent guidelines in the management of the valvular heart disease stated that not enough evidence of the superiority of one valve over the other **[25]**.

Bioprosthetic valves were considered the best choice for tricuspid valve replacement as anticoagulation is not needed, and degeneration is expected on a more extended period than the mitral valves due to the low right side pressure. However, some studies reported short durability of the bioprosthetic valves and determination occurred in less than nine years **[12-26]**, and some were associated with pannus formation **[27,28]**. While studies proved the new bi-leaflets mechanical valves function in low gradient with optimum durability **[11]**.

We did a meta-analysis study to compare the outcome and post-operative morbidity following mechanical and bioprosthetic tricuspid valves. These data were presented by studies comparing the two group of patients under the same post-operative care and in the same institution.

For post-operative valve thrombosis, in general, the tricuspid valve is bigger than a mitral, and aortic valve with low velocity across it increases the risk of thrombosis. All the 14 studies showed better outcome with the bioprosthetic valve, which justifies the rationale of most of the surgeons preferring bioprosthetic valve, and that is explained by the high risk of thrombosis with mechanical valve when the INR is below therapeutic level **[22,23]** and reported with multiple redo cases **[22]** and some of them required re-replacement **[21]**. The same for post-operative embolic events, the majority of the studies (4 of 5) favored the bioprosthetic valve, which could be explained by the high risk of thrombosis with the mechanical valve **[22,23]** even with anticoagulation treatment **[18]**. Several factors could affect the incidence of embolic events, such as ventricular function, valve position, rhythm, prosthetic valve type, coagulation status, and patient compliance **[19]**. But infective endocarditis either early or late was nearly the same in both groups, even though thrombosis is significantly more with the mechanical valve **[8,22,23]**. Infective endocarditis increased the incidence of reoperation **[8-14]** and increased mortality **[7-11]**.

On the other side, the majority of the studies (9 of 12) showed better postoperative valve failures results with the mechanical valve, and that's related to its longer durability as compared to the bioprosthetic valve **[13-19]**. Mechanical valve failure was due to pannus formation, and the paravalvular leak which was reported more frequently with the mechanical valves **[19,29]**. These complications make the bioprosthetic valve the valve of choice if no other indications necessitate the insertion of mechanical valve like concomitant anticoagulation therapy.

Post-operative stroke and cerebrovascular presented as cerebral infarction **[13-19]**, stroke **[2,7,13,19,21]** and mostly related to short periods of perioperative hypoperfusion or patients' related risk factor which could occur with both valve types **[19]**. Other complications including atrioventricular block, renal failure, low cardiac output, and bleeding occurred equally in both valve types with no significant difference. Causes of death following TVR were a progressive myocardial failure and acute pulmonary edema **[7,13,21]**, bleeding and reoperation **[2,7,13,21]** and renal failure requiring dialysis **[13,21]**.

Study strength and limitations:

The study contributes to the clinician knowledge to which TV prosthesis to choose for their patients based on literature evidence during 20 years. All the included studies are retrospective which presents a study limitation; however, no available randomized trial comparing valve types in the literature due to the infrequency of the procedure.

Conclusion:

The choice of the prosthesis in tricuspid valve replacement depends on the risk factors of the patient as each type of prosthesis has its own risk and complications. Re-operation, bleeding, valve failure, infective endocarditis, cerebrovascular events, low cardiac output, AV block, and renal failure didn't differ significantly between the two types. Bioprosthetic valve is a significantly lower risk of thrombosis and embolism. So, when the choice of the prosthesis is equivocal, the bioprosthetic valve should be preferred because of its less morbidity.

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التحليل الإحصائى للنتائج الطبية المختلفة لجراحة إستبدال الصمام ثلاثى الشرفات

تعتمد النتائج طويلة المدى لجراحة إستبدال الصمام ثلاثى الشرفات على العوامل المتعلقة بالمرض المصاحب لإصابة الصمام. حيث يتم إختيار نوع الصمام سواء كان نسيجى آو عدنى على حسب الخصائص المختلفة للمريض. تم إجراء هذه الدراسة لمقارنة النتائج المختلفة لجراحة إستبدال الصمام ثلاثى الشرفات مع كل نوع من الصمامات.

تم إجراء البحث خلال قواعد البيانات العلمية المختلفة للوصول إلى الآبحاث العلمية المقارنة للنتائج بين النوعين من الصمام التى تم نشرها خلال فترة ٢٠ عاماً من ١٩٩٥ حتى ٢٠١٥ باللغة الإنجليزية التى تناقش النتائج للمرضى البالغين وخضعت النتائج المختلفة للتحليل العلمى للوصول إلى آفضل تفسير.

تضمن التحليل العلمى والإحصائى ١٧ بحث علمى وتم تقييم إجمالى عدد ١٠٢٠ صمام معدنى وعدد ١١٩٩ صمام نسيجى وتم مقارنة النتائج الطبية المختلفة التى تم ذكرها فى مختلف الآبحاث. وذلك فى إطار المضاعفات حيث كانت جلطات على الصمام وإنتشارها آقل حدوثاً مع الصمام النسيجى ولم يكن هناك إختلاف فى النتائج بين نوعى الصمام مع النزيف بعد الجراحة – عدم إنتظام ضربات القلب – ضعف عضلة القلب – فشل عضلة القلب – الإلتهابات بالقلب – إصابة المخ والفشل الكلوى.

بعد الإنتهاء من الدراسة تم التوصل لآن نوع الصمام ثلاثى الشرفات يجب آن يتم إختياره بناءاً على الخصائص المختلفة للمريض وعند ما يكون الإختيار متشابه فالآفضل هو الصمام النسيجى نظراً لقلة مضاعفاته مقارنتاً بالصمام المعدنى.