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Outcomes in Elderly Patients with Mechanical Aortic Valve Replacement: Systematic Review and Meta-Analysis

MOHAMED ABDELMOTTAAL TAWAB, M.Sc.; HOSSAM ASHOUR, M.D.;
MOHAMED NABIL, M.D. and MOHAMED T. ELSAYEGH, M.D.

The Department of Cardiothoracic Surgery, Faculty of Medicine, Ain Shams University

Abstract

Background: The current gold standard of care for the majority of patients with severe aortic stenosis is aortic valve replacement (AVR). According to the most recent recommendations from the European Society of Cardiology and the European Association of Cardio-Thoracic Surgery, bioprostheses should be taken into consideration as the preferred course of treatment for patients over 65. Nonetheless, both mechanical and biological valve types are regarded as suitable choices for patients between the ages of 60 and 65. (recommendation class Il-a).

Aim of Study: This study aimed to systematically compare outcomes in elderly patients with surgically implanted mechanical versus biological aortic prosthesis.

Patients and Methods: A comprehensive literature search was performed using the following search engines, Ovid, Medline, Embase, Pubmed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, and Database of Abstracts of Review of Effectiveness from their dates of inception to 2022.

Results: A total of 4120 patients were analyzed in six articles. Mean age was similar in both groups of patients (61.1±4.3 vs 61.2±4.8 years) in bioprosthetic group and mechanical valve group, respectively. The occurrence of major bleeding was in favour of bioprothetic valve (less major bleeding) With an odds ratio of 0.73 odd and $p<0.001$. The occurrence of thrombo-embolic manifestation was in favour of bioprosthetic valve (less stroke) with protective effect by 10%. The effect estimate of OR was 0.9. The need for re-operation was in favor of mechanical group with an odds ratio of 3.11. The occurrence of mortality is mildly higher in bioprosthetic group compared to mechanical group with an odds ratio of 1.16.

Conclusion: Our analysis therefore supports the current practice of using BVs for patients who are 60 years of age or older, including renal patients on dialysis, even though longer-term data are anticipated.

Key Words: *Elderly patients – Mechanical aortic valve replacement.*

Correspondence to: Dr. Mohamed Abdelmottaal Tawab, E-Mail:tawab2728@gmail.com

Introduction

IT is still controversial whether to replace the aortic valve using a biological or mechanical prosthesis in patients aged 50 to 70 years. While current guidelines recommend using a mechanical prosthesis in individuals beyond the age of 60, the use of biological prostheses is increasing **[1]**.

Each prosthetic type has its advantages and disadvantages that have been listed **[2,3]**. Long-term durability has been regarded as a significant benefit for mechanical prostheses over biological prostheses. However, physicians and patients are frequently compelled to choose a biological prosthesis due to concerns regarding the possibility for bleeding and cerebrovascular complications associated with long-term anti-coagulation. Biological prostheses, on the other hand, have a limited lifespan, particularly in young patients **[4-9]**. However, New biological prosthesis, appear to have a longer lifespan than traditional ones. As a result, earlier trial results are no longer valid **[2,10,11]**. Furthermore, re-operation does not appear to be associated with an increased morbidity and mortality risk **[12-15]** and trans-catheter valve-in-valve replacement could be a useful future re-operative choice **[16,17]**.

According to the most recent recommendations from the European Society of Cardiology and the European Association of Cardio-Thoracic Surgery (ESC/EACTS), bio-prostheses should be considered as the preferred treatment option for patients over 65. However, both mechanical and biological valve types are thought to be effective solutions for patients between the ages of 60 and 65 (recommendation class Il-a). As a result, the decision should be based on a full analysis of other critical variables; **[18]** difficult decision that the patient and surgeon

should make together. In this decision, prosthesis considerations include hemodynamics, thrombogenicity, durability, and re-operation risk, whereas patient concerns include life expectancy, lifestyle, chronic medical conditions as CKD and medication compliance **[19]**.

Aim of the study:

To provide the best available evidence, we present a meta-analysis of interventional studies published from 1990 till 2022 that compared outcomes in elderly patients with surgically implanted mechanical versus biological aortic prosthesis.this study started from Jan. 2021 – Jan. 2022.

Patients and Methods

The type of the study is systematic review and meta-analysis.

Selection criteria:

- Types of studies:

Interventional studies (Randomized controlled clinical trials) and observational studies including the comparison of outcomes between surgically implanted mechanical versus biological aortic prosthesis were included in this systematic review and meta-analysis.

- Types of participants:

Both genders were included in the review, the age of the patients is above 50 years with the maximum age is 70 years, publications limited to those involving human subjects only were included in this review, the study included patients with end-stage renal disease who are on regular renal dialysis.

- Types of outcome measures:

The primary endpoint was long term survival, the secondary endpoints were rate of re-operation, major bleeding and stroke.

- Types of interventions:

Eligible studies for this systematic review and meta-analysis were those that compared biological valves with Mechanical valves received by surgical AVR in patients aged less than 70 years. Studies that did not contain a comparative group, specify the age of patients, include actuarial survival rate, or include complications as endpoints were excluded. All publications are limited to those involving none human subjects, abstracts, case reports, conference presentations, editorials, reviews, and expert opinions were excluded.

Search strategy for identification of studies:

Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, electronic searches were performed using Ovid, Medline, Embase, Pubmed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, and Database of Abstracts of Review of Effectiveness from their dates of inception to 2022.

To achieve maximum sensitivity of the search strategy, we combined the terms “middle-age,” “elderly,” “younger,” “aortic valve replacement,” “biological,” “bioprosthetic,” “mechanical,” “valve,” or “prosthesis” as both text keywords and exploded MeSH headings where possible.

The reference lists of all retrieved articles were reviewed for further identification of potentially relevant studies assessed using the inclusion and exclusion criteria.

Data extraction:

Numbers of patients who died after 10 years of aortic valve replacement were extracted. Numbers of patients who had post-operative bleeding, stroke or needed re-operation were extracted. All data were extracted from article texts, tables, and figures. Each article included in our analysis according to a critical review checklist of the Dutch Cochrane center.

Statistical methods:

Data was revised for its completeness and consistency. Data entry was done on Microsoft Excel workbook. The program used for building the meta-analysis model is Review Manager (RevMan) [Computer program]. Version 5.4. The Cochrane Collaboration, 2020. The used models were tested by Random effect. The graphical presentation was extracted from Review manager 5.4.

Results

This meta-analysis included 6 published studies in cases without renal failure,total number of studies included in the analysis six studies that fitted the inclusion and exclusion criteria, the total number of included patients was 4120 patients, the mean age of patients in the total six studies 61.2±4.3 years, the mean age of bioprosthetic patients is 61.1±4.8 years while the mean age of mechanical valve patients 61.2±4.3 years with no significant difference statistically, the male gender were 2728 patients (66.2%).

Major bleeding:

Random effect mode:

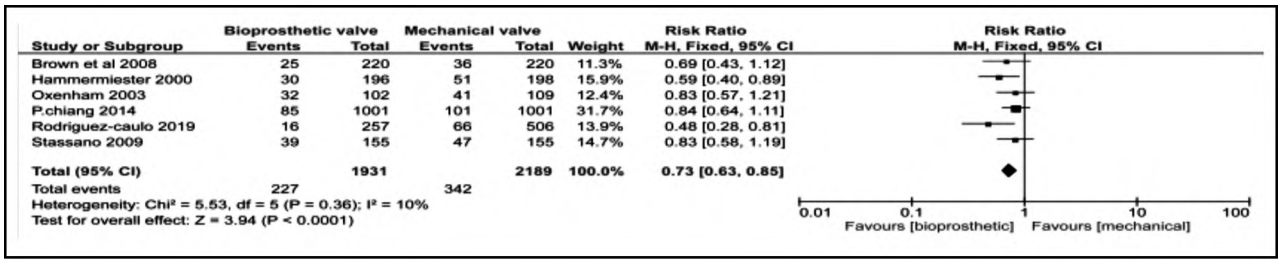

Table (1): The table showing major bleeding results.

	Studies	Participants	Statistical methods	Effect estimate
Major bleeding	6	4120	Odds Ratio (M-H, Fixed, 95% CI)	0.73 [0.63, 0.85]

This table shows the results of meta-analysis on the occurrence of major bleeding is in favour of Bioprothetic valve (less major bleeding). With an odds ratio of 0.73 odds. Protection from bleeding during operation by 27%. The overall occurrence of major bleeding in bioprosthetic arm is 11.7% while the overall occurrence of major bleeding in mechanical arm is 15.6%. (Less occurrence of major bleeding among bioprosthetic valve arm). The test of heterogeneity is very low as the I^2 is 10% (homogeneity) and the p-value of overall effect is highly significant. $p<0.001$.

Stroke and thrombo-embolic manifestations:

Random effect model:

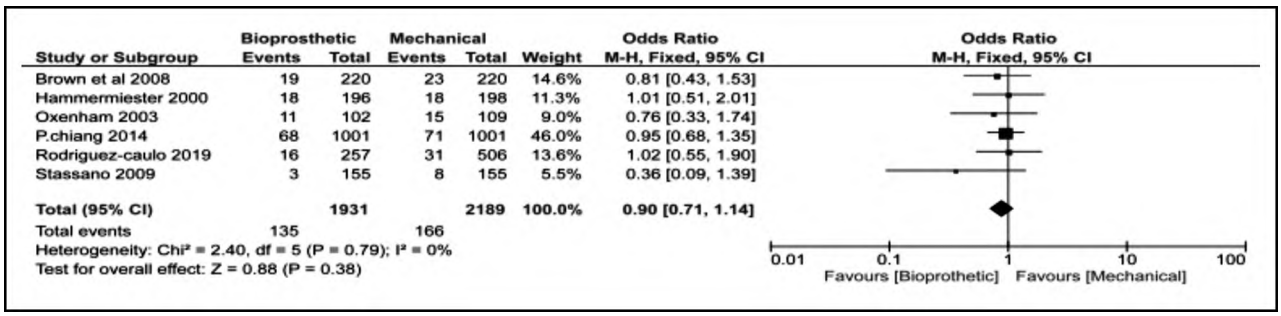

Table (2): The table showing stroke and thrombo-embolic manifestations results.

	Studies	Participants	Statistical methods	Effect estimate
Stroke or thrombo- embolic manifestations	6	4120	Odds Ratio (M-H, Fixed, 95% CI)	0.9 [0.71, 1.14]

The occurrence of thrombo-embolic manifestation is in favour of bioprosthetic valve (less stroke) with protective effect by 10% the effect estimate of OR is 0.9. The occurrence of overall stroke in bioprosthetic arm is 6.9% while the occurrence of stroke in mechanical valve arm is 7.6%. (Less stroke rate in bioprosthetic arm). The test of heterogeneity shows no heterogeneity as the I^2 is 0% and the p-value of overall effect is not significant. $p>0.05$ not significant.

Re-operation:

Random effect model:

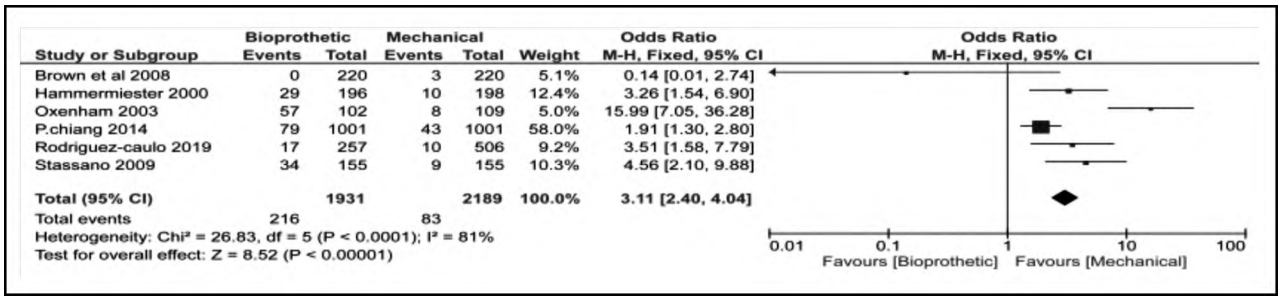

Table (3): The table showing re-operation results.

	Studies	Participants	Statistical methods	Effect estimate
Re-operation	6	4120	Odds Ratio (M-H, Fixed, 95% CI)	3.11 [2.40, 4.04]

This table shows that the need for re-operation is in favor of mechanical group. With an odds ratio of 3.11. Cases in bioprosthesis intervention group have three times more risk of having reoperation compared to mechanical group. The overall rate of reoperation in prosthetic valve arm is 11.1% while the rate of operation in mechanical arm is 3.8%. The difference is significant statistically (higher need for reoperation among bioprosthetic arm). The test of heterogeneity is high as I^2 value is 81% (heterogeneity) the overall effect is highly significant $p<0.01$.

Mortality after 10 years:

Random effect model:

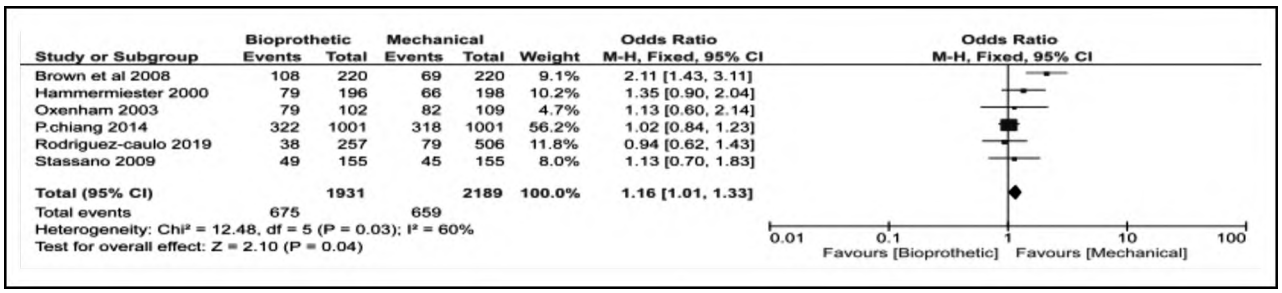

Table (4): The table showing mortality after 10 years results.

	Studies	Participants	Statistical methods	Effect estimate
Long term Mortality	6	4120	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [1.01, 1.33]

This table shows that the occurrence of mortality is mildly higher in bioprosthetic group compared to mechanical group. With an odds ratio of 1.16. Occurrence of mortality in bioprosthetic arm is 34.9% while mortality in mechanical arm is 30.1%. (Insignificantly higher long term survival in patients with mechanical arm). The test of heterogeneity shows moderate heterogeneity.

Cases with renal failure:

The total number of studies that fitted the inclusion criteria for patients with renal failure is two studies. The total number of patients in the studies 803 patients with 542 patients with bioprosthetic valve replacement and 262 patients with mechanical valve replacement. The mean age of the patients in the studies were 67.2±6.8 years. The male patients 410 patients (51% of the patients were males).

Major Bleeding in renal patients:
Random effect model:

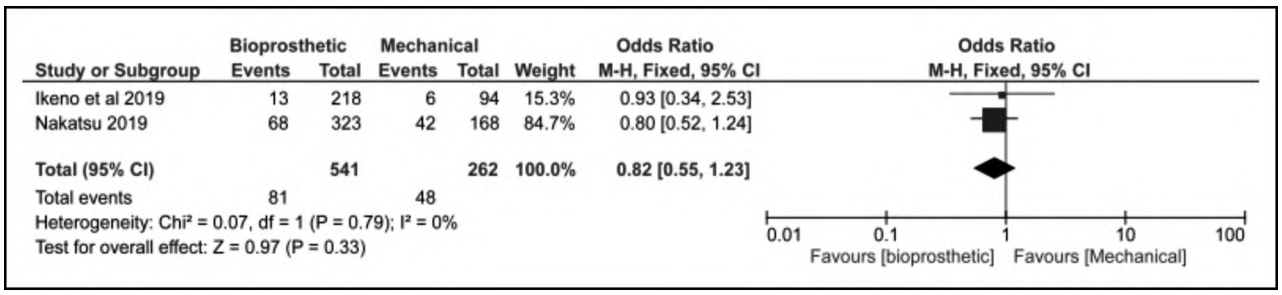

Table (5): The table showing major bleeding results in renal patients.

	Studies	Participants	Statistical methods	Effect estimate
Bleeding in RF patients	2	803	Odds Ratio (M-H, Fixed, 95% CI)	0.82 [0.55, 1.23]

This table shows that the occurrence of bleeding is in favor of bioprosthetic valves (less in bleeding). With an odds ratio of 0.82. Protection from bleeding by 18%. Overall major bleeding occurrence in bioprosthetic arm is 14.9% while the major bleeding in mechanical arm is 18.3% (less major bleeding in bioprosthetic arm in cases with renal failure). The test of heterogeneity shows no heterogeneity and the p-value of overall effect is not significant.

Stroke in renal failure patients:
Random effect model:

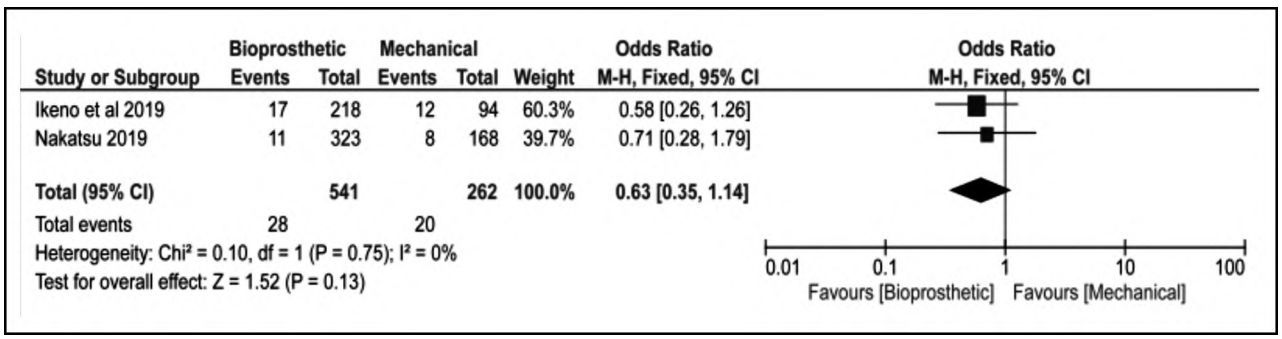

Table (6): The table showing stroke in renal patients results.

	Studies	Participants	Statistical methods	Effect estimate
Stroke	2	803	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.35, 1.14]

This table shows that the occurrence of post operative AR is in favor of biprosthetic valve compared to mechanical valve with odds ratio 0.63 (protective). Overall stroke occurrence in bioprosthetic arm is 5.2% while stroke in mechanical arm 7.6%. (Less occurrence of stroke among bioprosthetic arm in renal failure patients). The test of heterogeneity shows no heterogeneity and the p-value of overall effect is not significant $p>0.05$.

Reoperation in renal failure patients:
Random effect model:

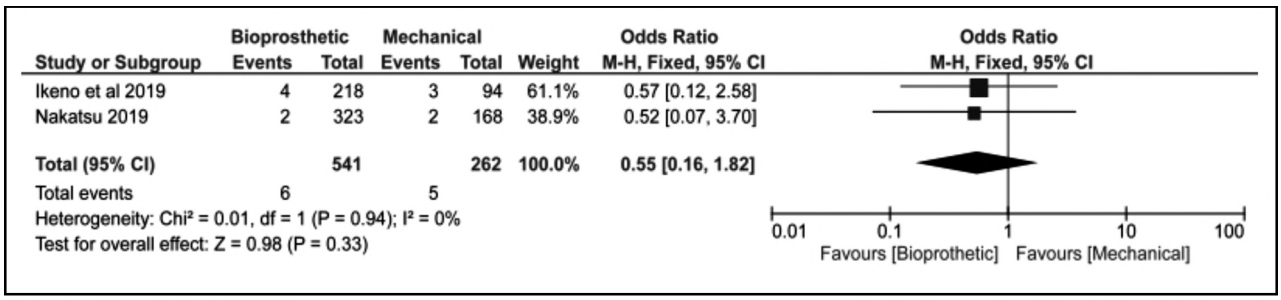

Table (7): The table showing re-operation results in renal patients.

	Studies	Participants	Statistical methods	Effect estimate
Re-operation	2	803	Odds Ratio (M-H, Fixed, 95% CI)	0.55 [0.16, 1.82]

This table shows that the occurrence of Reoperation in renal failure patients is in favor of bioprosthetic valve (less reoperation) with odds ratio of 0.55.Overall, the need for reoperation in bioprosthetic arm 1.1% while the need for reoperation in mechanical arm 2%. (Less need for reoperation among bioprosthetic arm). The test of heterogeneity shows no heterogeneity and the *p*-value of overall effect is not significant $p>0.05$.

Mortality in renal patients:
Random effect model

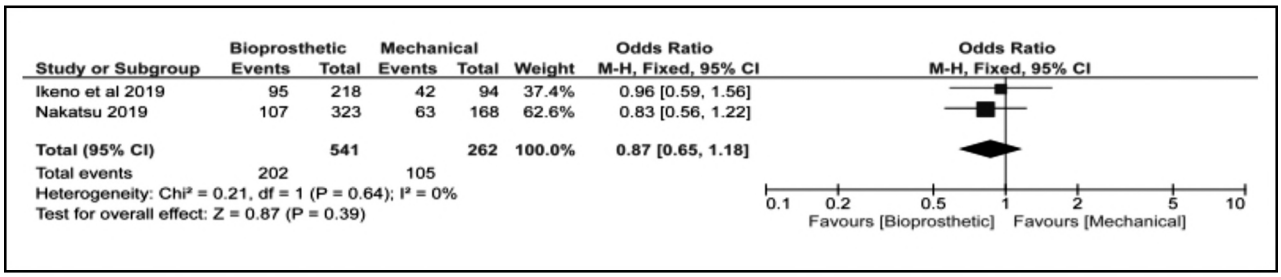

Table (8): The table showing mortality results in renal patients.

	Studies	Participants	Statistical methods	Effect estimate
Mortality in renal failure patients	2	803	Odds Ratio (M-H, Fixed, 95% CI)	0.87 [0.65, 1.18]

This table shows that the occurrence of mortality is in favor of bioprosthetic valve (less mortality) with odds ratio of 0.87. Higher survival in renal failure patients in bioprosthetic valve operation. Overall occurrence of mortality in bioprosthetic arm 37.3% while overall mortality in mechanical arm 40% (higher survival among bioprosthetic arm in cases with renal failure). The test of heterogeneity shows no heterogeneity 0% and the *p*-value of overall effect is not significant $p>0.05$.

Discussion

The prognosis for patients with aortic valve disease has largely changed as a result of prosthetic valve replacement. The benefits and drawbacks of the two major groups of prostheses-MV and BV-respectively are widely established. Anticoagulation therapy generally increases the risk of significant bleeding in patients with MVs, while structural valve deterioration generally increases the need for reoperation in patients with BVs. Due to many crucial factors, selecting the best aortic valve prosthesis for elderly individuals might be particularly difficult. This is a difficult choice that needs to be made with each patient individually due to the development of new prosthesis and surgical methods (such as VIV TAVI) as well as the ongoing reporting of long-term outcomes in comparison studies. The present systematic review and meta-analysis included 6 studies encompassing 4120 patients aged 50 to 70.

There was insignificant difference in mortality between BV and MV for patients aged 50 to 70 years favoring MV (OR 1.16). Because MVs are more durable, our meta-analysis discovered that they are much more resistant to structural valve deterioration. As a result, this analysis revealed that BVs had a significantly higher long-term risk of re-operation (OR 3.11).

BV failure is mostly caused by tissue deterioration, which manifests itself in the form of cusp calcification, cusp tears, perforation, stretching, thickening, stiffness, and prolapse. The predominant mode of SVD is calcification, which is brought on by the immunologic response, dystrophic calcification, and chemical interactions between phospholipids with aldehyde groups and circulating calcium ions.

Re-operative patients are typically seen as having a higher risk of perioperative mortality and morbidity because of their older age, a possibly more comorbidities, and more complexity because of sternal re-entry and adhesions.

Despite MVs being more durable than BVs, lifelong anticoagulation medication is necessary for them because of the increased risk of stroke and thromboembolic events. Our meta-analysis found significantly lower rates of major bleeding events with BVs (OR 0.73) and insignificant lower rates of stroke and thrombo-embolic manifestations (OR 0.9). However, other factors can affect the likelihood of severe bleeding and thrombosis. In anticoagulated MV patients, old age, CKD, liver cell failure, cancer and co-medication with anti-platelets agents and NSAIDS are linked to an increased incidence of major bleeding incidents. Although the Dabigatran Etexilate in Patients with Mechanical Heart Valves (RE-ALIGN) trial indicated that Dabigatran in MV patients was linked to higher rates of thromboembolic and bleeding problems than warfarin, the impact of new oral anticoagulant use in MV patients is still largely understudied.

According to Puvimanasinghe and colleagues' meta-analysis, a 65-year-old man's life expectancy following implantation with an MV or BV was 10.4 or 7.7 years, respectively. A MV had a lifetime risk of 48% and a BV had a risk of 44% of experiencing at least one valve-related incident **[20]**. These results suggested that the 65-year-old age recommendation for BV implantation might be decreased.

Results from The Society of Thoracic Surgeons National Database further confirm this, showing a trend towards BVs in AVR patients (mean age, 65.9 years), which rose from 43.6% to 78.4% of all prosthetic valve implantations between 1997 and 2006 **[21]**. Our meta-analysis supports this trend for using BVs in elderly patients.

The American Heart Association/American College of Cardiology recommendations stress the value of an informed patient decision when choosing a prosthetic valve **[22]**. The presence of a MV in another position is the only Class I signal for MV placement. However, patient desire is a major factor in the majority of the remaining suggestions. Additional causes for BV placement in a patient of any age include lifestyle factors and a patient's reluctance to take warfarin (Class IIa).

Rahimtoola and associates **[23]** suggested lowering the age threshold for routine BV implantation from 65 to 60 years old after analyzing recent data on the advantages and disadvantages of prosthetic valve options. It was proposed that in elderly AVR patients, a BV should be strongly preferred over an MV if external variables prohibited good adherence to anticoagulation guidelines. These include a history of drug addiction or noncompliance with drug therapy, as well as restricted patient access to monitoring or therapy due to financial, social, or geographic considerations.

As regards renal patients, recent studies have suggested that given dialysis patients' short life expectancies and the risk of structural valve deterioration with BV, BV should be given preference over MP in these patients **[24-26]**. In a meta-analysis, Phan and colleagues **[28]** found that patients on

dialysis who received either MV or BV experienced comparable mid- to long-term survival. The BV group also had fewer bleeding (MP: 6.4%, BP: 5.2%, *p* 0.04) and thromboembolism events (MP: 12.8%, BP: 2.7%, *p* 0.020). These findings led to the European Society of Cardiology issuing recommendations favouring the use of BV over MV **[28]**. Nonetheless, there is concern about the rapid calcification of BV in dialysis patients **[29]**.

Our findings support these studies by showing that the BV group had a decreased rate of embolic events with statistically insignificant lower rates of major bleeding and re-operation.

The method of anticoagulation therapy for dialysis patients is also a topic of debate. We showed that compared to the BV group, the MV group was more likely to experience bleeding and embolic events. The unique characteristics of dialysis patients, various platelet and coagulation abnormalities, frequent heparin use, and accelerated vascular calcification **[30]** may all contribute to the higher incidence of thromboembolic and major bleeding events in patients on dialysis with MV compared to the general population. Moreover, patients on dialysis who do not adhere to their anticoagulant medication may have subtherapeutic INR, which may be a factor in the high risk of embolic events. The use of BV may lessen the burden of anticoagulation and the significant risk of bleeding or thromboembolism in this patient population, which is important given that patients on dialysis with inadequate anticoagulation treatment have a higher risk for stroke or thromboembolic events **[31]**.

Conclusion:

While choosing a prosthesis type in the clinical practice for patients aged 50 to 70 years, a variety of considerations are taken into account, including the patient's choice. In this meta-analysis, there was no significant difference between the long-term mortality of the BV and MV groups. Major bleeding and anticoagulant-related events are more likely to occur in MVs than BVs, while reoperation is higher with BVs. Hence, although longer-term data are anticipated, this analysis supports the current practice of using BVs for patients who are 60 years of age or older including renal patients on dialysis.

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النتائج فى المرضى كبار السن الذين تم إجراء جراحة قلب لهم لاستبدال الصمام الأورطى بصمام أورطى صناعى ميكانيكى

المقدمة : المعيار الذهبى الحالى لرعاية غالبية المرضى الذين يعانون من تضيق الأبهر الشديد هو استبدال الصمام الأبهرى. وفقاً لأحدث التوصيات الصادرة عن الجمعية الأوروبية لأمراض القلب والرابطة الأوروبية لجراحة القلب والصدر، يجب أن تؤخذ التعويضات الحيوية فى الاعتبار باعتبارها المسار المفضل للعلاج للمرضى الذين تزيد أعمارهم عن ٦٥ عاماً. ومع ذلك، ينُظر إلى كلا النوعين من الصمامات الميكانيكية والبيولوجية على أنها اختيارات مناسبة للمرضى الذين تتراوح أعمارهم بين ٦٠ و٦٥). (فئة التوصية II-a) نتيجة لذلك، يجب أن يقوم الاختيار على الفحص الدقيق للمتغيرات الحاسمة الأخرى. تم تخفيض النطاق العمرى لكلا النوعين من الإجراءات من ٦٠ إلى ٧٠ عاماً إلى ٥٠ إلى ٧٠ عاماً فى أحدث منشور صادر عن جمعية القلب الأمريكية / الكلية الأمريكية لأمراض القلب، والذى يؤكد على قيمة عملية اتخاذ القرار المشتركة المستنيرة بين يختار الطبيب والمريض البديل الأكثر عملية.

الهدف من الدراسة : هدفت دراستنا إلى مقارنة النتائج بشكل منهجى فى المرضى المسنين الذين تم زرعهم جراحياً فى مقابل البدلة الأبهرى البيولوجية.

المرضى وطرق البحث : تم إجراء بحث شامل عن الأدبيات باستخدام محركات البحث التالية، Ovid و Medline و Embase و PubMed، وسجل كوكرين المركزى للتجارب ذات الشواهد، وقاعدة بيانات كوكرين للمراجعات المنهجية، ونادى مجلة الكلية الأمريكية للأطباء، وقاعدة بيانات ملخصات مراجعة الفعالية من تواريخ التأسيس حتى عام ٢٠٢٢.

النتائج : تم تحليل ما مجموعة ٤١٢٠ مريضاً فى ستة مقالات. كان متوسط العمر متشابهاً فى كلا المجموعتين من المرضى (٦١.١±٤.٣ مقابل ٦١.٢±٤.٨ سنة) فى المجموعة التعويضية ومجموعة الصمامات الميكانيكية، على التوالى. كان حدوث نزيف كبير لصالح الصمامات التعويضية الحيوية (أقل نزيفاً كبيرا) مع نسبة أرجحية قدرها ٠.٧٣ فردى و $p<0.001$، وكان حدوث مظاهر الانسداد الخثارى لصالح الصمامات التعويضية الحيوية (أقل سكتة دماغية) مع تأثير و قائى بمقدار ١٠٪. كان تقدير تأثير RO 0.9. كانت الحاجة إلى إعادة التشغيل لصالح المجموعة الميكانيكية بنسبة أرجحية قدرها ٣.١١. معدل حدوث الوفيات أعلى بشكل معتدل فى المجموعة التعويضية الحيوية مقارنة بالمجموعة الميكانيكية مع نسبة أرجحية قدرها ١.١٦.

الخلاصة : لذلك، يد عم تحليلنا الممارسة الحالية لاستخدام الصمامات البيولوجية للمرضى الذين تبلغ أعمارهم ٦٠ عاماً أو أكثر، بما فى ذلك مرضى الكلى الذين يخضعون لغسيل الكلى، على الرغم من توقع البيانات طويلة الأجل. النتائج فى المرضى كبار السن الذين تم إجراء جراحة قلب لهم لاستبدال الصمام الأورطى بصمام أورطى صناعى ميكانيكى.