Clinical impact of patient-prosthesis mismatch after aortic valve replacement with a mechanical or biological prosthesis

Milos Matkovic[1], Nemanja Aleksic[1], Ilija Bilbija[1], Ana Antic[1], Jelena Milin[2], Marko Cubrilo[1], Aleksandar Milojevic[1], and Svetozar Putnik[1]

[1]Univerzitetski klinicki centar Srbije
[2]Univerzitet u Beogradu Medicinski fakultet

February 22, 2024

Abstract

Objectives: Patient-prosthesis mismatch (PPM) may impair functional capacity and survival after aortic valve replacement (AVR). A mechanical prosthesis tends to have less PPM than a biological prosthesis, but these differences in clinical outcomes remain unclear. This study aimed to investigate the impact of PPM on long-term survival and quality of life (QoL) after mechanical and biological AVRs. **Methods:** The presence of PPM was defined in 595 consecutive patients who had undergone isolated AVR. Patients were divided into two groups according to whether they had received a biological or mechanical prosthesis. The groups with and without PPM present were compared with regard to baseline characteristics, operative characteristics, survival, severe complications, freedom from angina and QoL up to 6 years of follow-up. PPM calculation was performed using the EOA value provided by the manufacturer for every prosthesis divided by the patient's body surface area. **Results:** The moderate-to-severe PPM rates were 69.8% and 3.7% after biological and mechanical prostheses implantation, respectively. Patients with a biological prosthesis implanted had mean survival significantly shorter in the PPM group (50.2 months, 95% confidence interval [CI] 45.2-55.3) when compared to the no-PPM group (60.1 months, 95% CI 55.7-64.4) ($p = 0.035$). In the mechanical prosthesis group, there was no difference in mean survival between the PPM group (66.6 months, 95% CI 58.3-74.9) when compared to the no-PPM group (64.9 months, 95% CI 62.6-67.2) ($p = 0.50$). The physical score of the QoL questionnaire was significantly lower in the PPM group when compared to the no-PPM group with a biological prosthesis (39.4 ± 8.4 vs. 45.7 ± 10.1, $p < 0.001$) compared to patients with a mechanical prosthesis (43.9 ± 9.4 vs. 46.9 ± 8.3, $p = 0.18$). **Conclusions:** PPM is common after biological valve implantation and significantly impacts long-term survival and QoL. If the risk of PPM after implantation of a biological prosthesis is suspected, prospective strategies to avoid PPM at the time of operation are warranted.

Clinical impact of patient-prosthesis mismatch after aortic valve replacement with a mechanical or biological prosthesis

Milos Matkovic [1,2*], Nemanja Aleksic[1,2], Ilija Bilbija[1,2], Ana Antic[1], Jelena Milin Lazovic[3], Marko Cubrilo[1], Aleksandar Milojevic[1] and Svetozar Putnik[1,2]

[1]Department for Cardiac Surgery, Clinical Center of Serbia, Belgrade, Serbia

[2]Faculty of Medicine, University of Belgrade, Belgrade, Serbia

[3]Department for Biostatistics, Faculty of Medicine, University of Belgrade, Belgrade, Serbia

Total number of words: 4714

*** Correspondence to:**

Milos Matkovic, MD PhD

Department for Cardiac Surgery

Clinical Center of Serbia

8 Koste Todorovica St.

11000 Belgrade, Serbia

Tel: +381113663201

E-Mail: dr.matko@hotmail.com

Presented at the 35th Annual Meeting of the European Association for Cardio-Thoracic Surgery, Barcelona, Spain, October 13-15, 2021.

ABSTRACT

Objectives: Patient-prosthesis mismatch (PPM) may impair functional capacity and survival after aortic valve replacement (AVR). A mechanical prosthesis tends to have less PPM than a biological prosthesis, but these differences in clinical outcomes remain unclear. This study aimed to investigate the impact of PPM on long-term survival and quality of life (QoL) after mechanical and biological AVRs.

Methods: The presence of PPM was defined in 595 consecutive patients who had undergone isolated AVR. Patients were divided into two groups according to whether they had received a biological or mechanical prosthesis. The groups with and without PPM present were compared with regard to baseline characteristics, operative characteristics, survival, severe complications, freedom from angina and QoL up to 6 years of follow-up. PPM calculation was performed using the EOA value provided by the manufacturer for every prosthesis divided by the patient's body surface area.

Results: The moderate-to-severe PPM rates were 69.8% and 3.7% after biological and mechanical prostheses implantation, respectively. Patients with a biological prosthesis implanted had mean survival significantly shorter in the PPM group (50.2 months, 95% confidence interval [CI] 45.2-55.3) when compared to the no-PPM group (60.1 months, 95% CI 55.7-64.4) ($p = 0.035$). In the mechanical prosthesis group, there was no difference in mean survival between the PPM group (66.6 months, 95% CI 58.3-74.9) when compared to the no-PPM group (64.9 months, 95% CI 62.6-67.2) ($p = 0.50$). The physical score of the QoL questionnaire was significantly lower in the PPM group when compared to the no-PPM group with a biological prosthesis (39.4 ± 8.4 vs. 45.7 ± 10.1, $p < 0.001$) compared to patients with a mechanical prosthesis (43.9 ± 9.4 vs. 46.9 ± 8.3, $p = 0.18$).

Conclusions: PPM is common after biological valve implantation and significantly impacts long-term survival and QoL. If the risk of PPM after implantation of a biological prosthesis is suspected, prospective strategies to avoid PPM at the time of operation are warranted.

Keywords: Patient-prosthesis mismatch, survival, quality of life, surgical aortic valve replacement, mechanical prosthesis, biological prosthesis

ABBREVIATIONS AND ACRONYMS

AVR = Aortic Valve Replacement

PPM = Patient-Prosthesis Mismatch

QoL = Quality of life

EOA = Effective orrifice area

iEOA = Indexed effective orrifice area

SVD = Structural valve degeneration

TAVR - Transcatheter aortic valve replacement

INTRODUCTION

Patient-prosthesis mismatch (PPM) represents the mismatch between the prosthetic valve's effective orifice area (EOA) and the patient's haemodynamic requirements.(1) Given the large heterogeneity of the patient population, PPM is most commonly presented as EOA divided by the patient's body surface area (BSA), resulting in indexed EOA (iEOA) values. An iEOA between 0,85 $cm^2/m^2$and 0,65 cm^2/m^2 is considered moderate PPM, while an iEOA $< 0{,}65$ cm^2/m^2 is considered severe PPM.(2) Furthermore, it can be calculated as measured or predicted. If it is measured, it is usually done via a transthoracic echocardiography exam before hospital discharge. However, this echocardiographer-dependent method is subject to diversity in findings. Also, it is flow dependent and may lead to overestimating PPM in a heart with a diminished ejection fraction. To avoid these limitations, predicted PPM, which is calculated by using EOA values provided by the manufacturer divided by the patient's BSA, has been introduced to calculate PPM.(2, 3)

PPM leads to higher transprosthetic gradients that may impair mass myocardial reduction and impair functional capacity and survival after aortic valve replacement (AVR).(4, 5) Several published studies advocate the negative impact of PPM on survival.(6-9) Mild or moderate PPM is commonly found after AVR, ranging from 20% to 70% (10), depending on the definition and method of calculation. The severity of PPM is the primary determinant of its influence on clinical outcomes. Although severe PPM is most responsible for worse long-term survival, it is found in less than 2% of all AVRs.(7)

Although a similar rate of valve-related complications has been reported after mechanical and biological prostheses implantation, PPM is more frequently observed in a biological prosthesis. The impact of structural valve deterioration in a biological prosthesis and the stable haemodynamic performance of a mechanical prosthesis on PPM, and subsequently on survival, is yet to be determined.(11) Besides the impact of PPM on survival, the question of the quality of life (QoL) of patients arises. Some authors claim that PPM after AVR diminishes patients' physical and mental capacities, especially in an elderly patient population.(9, 12) Overall, a mechanical prosthesis tends to have less PPM than a biological prosthesis, but the clinical outcomes remain unclear.

This study aimed to investigate the impact of an implanted mechanical or biological prosthesis with PPM on long-term survival and QoL after an isolated AVR procedure.

METHODS

Ethical approval

The ethical committee approved the study, and all patients signed the informed consent form (KH151/2020).

Study design

Between January 2015 and December 2020, 652 consecutive patients underwent an isolated AVR procedure at the Clinical Centre of Serbia in Belgrade. This observational analysis included elective, urgent, and emergent cases performed due to any pathology. Combined surgery was the exclusion criterion. Forty-six patients refused to participate in research, while 11 patients were lost to follow-up (Fig. 1).

Patients were divided into two groups according to whether they had received a biological or mechanical prosthesis. Furthermore, they were evaluated for the presence or absence of PPM. The groups with and without PPM present were compared with regard to baseline characteristics, operative characteristics, survival, complications, freedom from angina and QoL up to 6 years of follow-up. The data were obtained from medical records and via telephone surveys during the follow-up period.

Surgical procedure

The surgical procedures were done using cardiopulmonary bypass (CPB), and cardioplegic arrest was achieved using a cold crystalloid cardioplegic solution. Standard median sternotomy, upper mini-sternotomy through the fourth intercostal space or anterior mini-thoracotomy were used for the surgical approach. The following mechanical prostheses were used: St. Jude Regent, St. Jude Masters (Abbott, Chicago, IL),

ATS Open Pivot (Medtronic, Minneapolis, MN), ONX (CryoLife Inc., Kennesaw, GA) and Carbomedics (LivaNova, London, UK). The biological prostheses used in the study were as follows: Hancock (Medtronic, Minneapolis, MN), Epic, Trifecta (Abbott, Chicago, IL), Crown (LivaNova, London, UK), Solo Smart (LivaNova, London, UK) and sutureless Perceval S valve (LivaNova, London, UK). The choice of the implant procedure was made according to the current guidelines and the surgeon's discretion alongside the fully informed patient.

Definitions and study endpoints

The data were extracted from our institutional Aortic Valve Registry, a prospectively maintained clinical registry of all patients undergoing AVR or repair at our institution and double-checked for accuracy (M.M. and A.M.). All operative survivors were followed up regularly and completed in 641 out of 652 patients (98.3%). All clinically gathered data, including adverse events during follow-up and cause of death, were registered and reported according to the standardized institutional protocol.

Patient prosthesis mismatch

PPM was defined as an iEOA $< 0{,}85$ cm^2/m^2. An iEOA between $0{,}85$ cm^2/m^2 and $0{,}65$ cm^2/m^2 was considered moderate PPM, while an iEOA $< 0{,}65$ cm^2/m^2 was considered severe PPM. PPM calculation was performed using the EOA value provided by the manufacturer for every prosthesis divided by the patient's body surface area (BSA). Patients with mechanical and biological prostheses were compared according to the presence (iEOA $< 0{,}85$ cm^2/m^2) or absence (iEOA $> 0{,}85$ cm^2/m^2) of PPM.

Quality of life survey

QoL was estimated using the QoL Short Form Survey (SF-12). The SF-12 is derived from the SF-36 Short Form survey by scoring the responses of the mental and physical components of the study. The physical SF-12 component (PCS) investigates physical functioning, pain, and physical role, while the cognitive component (MCS) summarizes mental health and social and emotional functioning. The results of these two components were scored 0-100 by scoring the standard answers to standard questions, where higher scores represented better mental and physical health.

Statistical analyses

Descriptive statistics were calculated for the baseline demographic and clinical features and treatment outcomes. Graphical and mathematical methods tested the normality of distribution. As appropriate, continuous variables were presented as means with standard deviations or medians with 25^{th}-75^{th} percentiles. Categorical variables were presented as numbers and percentages. Differences between groups were analysed using Student's t-test for continuous variables (or the Mann-Whitney test) and the Pearson chi-squared test for categorical variables. Survival analysis was performed using the Kaplan-Meier method, and the groups were compared using the log-rank test. In addition, Kaplan-Meier survival curves were truncated at a timepoint in follow-up, when at least 10% of patients were still at risk, to avoid visual misinterpretation.(13) The significance level was set at 0.05, and all testing was two-sided. Statistical analysis was performed using the IBM SPSS Statistics for Windows, version 21.0. (Armonk, NY, USA) package.

RESULTS

Of the 595 patients enrolled, 159 (26.7%) of them received a biological prosthesis, while 436 (73.3%) received a mechanical prosthesis. The baseline characteristics of patients with biological and mechanical valves are presented in Table 1. Patients with biological valves were significantly older than patients with mechanical valves (69.9 +7.7 years vs. 62.6 + 12.1 years, $p < 0.001$). A mechanical prosthesis was more frequently implanted in men than a biological prosthesis (60.4% vs. 49.1%, $p = 0.014$). Also, in the mechanical prosthesis group, 5.5% of patients had native valve endocarditis compared to 0.6% of patients in the biological prosthesis group ($p = 0.009$). There was no statistically significant difference in the other preoperative characteristics and demographics.

The operative characteristics are presented in Table 2. There was no significant difference between the groups in EuroSCORE II, CPB or aortic cross-clamp times. Ejection fraction and mean ICU stay were similar between groups. PPM (moderate and severe, iEOA $< 0{,}85$ cm^2/m^2) was present in 69.8% of patients in the biological prosthesis group in comparison to 3.7% in the mechanical prosthesis group ($p < 0.001$) (Table 3). Severe PPM (iEOA $< 0{,}65$ cm^2/m^2) was present in 5.1% of patients in the biological group and 1.3% of patients in the mechanical prosthesis group, with a statistically significant difference ($p < 0.001$). There was no difference in the number of redo surgeries or the frequency of postoperative endocarditis in the follow-up period between the mechanical and biological prostheses groups. Freedom from angina at the time of the latest follow-up was also similar between the groups (85.1 % vs. 88.8%, $p = 0.28$). The distribution of prosthesis manufacturers and models in compared groups is shown in Table 4.

The median follow-up was 31.8 (1-74) months. When analysed overall for mechanical and biological prostheses combined, mean survival was significantly shorter in the PPM group (57.0 months, 95% confidence interval [CI] 51.9-62.2) when compared to the no-PPM group (65.2 months, 95% CI 63.1-67.4) (log-rank test $p = 0.008$) (Fig. 2). When data were analysed separately for biological prosthesis, mean survival was significantly shorter in the PPM group (50.2 months, 95% CI 45.2-55.3) when compared to the no-PPM group (60.1 months, 95% CI 55.7-64.4) (log-rank test $p = 0.035$) (Fig. 3). Analysis of survival in patients who had a mechanical prosthesis implanted did not show a difference in mean survival in the PPM group (66.6 months, 95% CI 58.3-74.9) when compared to the no-PPM group (64.9 months, 95% CI 62.6-67.2) (log-rank test $p = 0.50$) (Fig. 4). Also, there was no statistically significant difference in baseline characteristics between the PPM and NO PPM groups in both patients with mechanical or biological valves, especially in age, BSA and body mass index.

The response rate for the QoL survey was 87.6 % for all patients enrolled in the study. The SF-12 questionnaire was analysed separately in patients with mechanical and biological prostheses (Table 5). There was no significant difference between the physical and mental scores in patients with PPM and patients with no-PPM who had a mechanical prosthesis. (43.9 ± 9.4 vs. 46.9 ± 8.3, $p = 0.18$). The physical score was significantly lower in patients with PPM vs. patients without PPM in those with an implanted biological prosthesis (39.4 ± 8.4 vs. 45.7 ± 10.1, $p < 0.001$) compared to those with an implanted mechanical prosthesis (43.9 ± 9.4 vs 46.9 ± 8.3, $p = 0.18$), respectively. There was no significant difference between the mental score in patients with PPM and without PPM, irrespective of the type of prosthesis (Table 5).

DISCUSSION

The present study analysed the impact of a mechanical or biological prosthesis with PPM on survival and QoL after AVR. The significant findings include: (1) AVR with a mechanical prosthesis had markedly less risk of PPM than AVR with a biological prosthesis; (ii) patients with moderate to severe PPM and an implanted biological prosthesis are at the highest risk of long-term mortality; and (iii) patients with biological prosthesis and PPM had impaired QoL up to 6 years of follow-up.

PPM is associated with a higher risk of poor outcomes after AVR, and its prevention is of paramount importance when selecting a surgical heart valve for implantation.(14) Valve manufacturers provide iEOA values as the most appropriate for predicting PPM after implantation.(15) A cut-off level of iEOA $< 0{,}85$ cm^2/m^2 has been introduced to define moderate-to-severe PPM. In our study population, PPM was found in 21.5% of all patients who underwent AVR. However, when analysed separately, 69.8% of patients with biological valves implanted had PPM, while just 3.7% of patients with mechanical valves implanted had PPM ($p < 0{,}001$).

The Quebec group brought PPM into the spotlight, publishing several studies that showed significantly reduced long-term survival in those patients with PPM.(15, 16) The Toronto group confirmed their findings.(17) In a large study that enrolled 1856 patients with mechanical prostheses and 2275 patients with biological prostheses implanted after AVR, the presence of PPM significantly reduced both short-term and long-term survival. Our study supports these findings, showing lower survival in prostheses with PPM than those without PPM. However, none of these studies distinguished outcomes by the presence of a biological or

mechanical prosthesis. Our study revealed lower survival with PPM remains for biological prostheses, while PPM for mechanical prostheses did not affect survival or the physical component of QoL.

Hoffmann et al. analysed 632 patients with consecutive AVR procedures with only Hancock II biological prostheses. PPM was present in 93.8% of patients, whereas 71% of patients had moderate and 22.8% of patients had severe PPM.(12) The authors found no difference in 5-year survival within the groups with and without PPM. Our study found a similar distribution of moderate PPM in the biological prosthesis group, while severe PPM was found in only 5.1% of patients. Besides, patients with a biological prosthesis and PPM had significantly lower survival after 6 years of follow-up than those without PPM. One potential explanation for the observed differences is that our study included several biological prosthesis types and complete follow-up. Sportelli et al. conducted an observational study that included 152 patients with both mechanical and biological prostheses used for AVR.(4) The overall PPM rate was 53.%, while 11.7% of patients had severe PPM. They reported no influence of the presence of PPM on survival after long-term follow-up. However, no separate analyses for the biological and mechanical prostheses were reported. Finally, Weber et al. revealed more frequent PPM in the biological prosthesis group than in the mechanical prosthesis group. Still, they did not perform a survival analysis for this group.(11) Severe PPM was a rare occurrence in our study, so it was not suitable for the subanalysis of this population. It should also be mentioned that none of the listed studies included patients with the sutureless biological prosthesis as in our study.

Also, it should be mentioned that nearly 37% of the biological valves implanted in our study population were Trifecta valves that had an issue of frequent SVD raised in a few previously published studies. However, the prosthesis used in these studies was a previous Trifecta model, while in our study the new Trifecta GT model was used. The clinical importance of this fact is yet to be determined.(18, 19)

Some studies that enrolled a small cohort have warned about the negative impact of PPM on QoL, especially on the physical component.(9, 20) As it is shown that PPM is associated with higher transprosthetic gradients, it can be expected that, with physical exercise, a rise in the gradient can come close to the values in mild and moderate native valve aortic stenosis.(21) The median values of the QoL measurements in the present study were close to the normal values. The values of the QoL mental component did not show a significant difference in both groups in patients with and without PPM. However, the physical component of the questionnaire revealed significantly lower scores in patients with a biological prosthesis and PPM than in those without PPM. In the mechanical prosthesis group, this difference was not observed. The freedom from angina on follow-up also did not differ in the groups. These results are similar to those published by Hoffman et al., who also found the difference only in the physical component of QoL, and Urso et al. (163 patients enrolled), who found lower physical scores in elderly patients.(12, 22) Sportelli et al. (152 patients enrolled) and Reskovic Luksic et al. (46 patients included) failed to demonstrate the difference in the QoL in patients that have PPM. Once again, neither of these studies performed subanalyses for biological and mechanical prostheses.

As it is well known that perioperative results are affected mainly by the type of valve implanted, the haemodynamic properties of each valve type can also influence the outcome. It is well known that, in every biological prosthesis, structural valve degeneration (SVD) will happen to some extent over time. SVD in prostheses with PPM with higher transprosthetic gradients could lead to further augmentation of gradients, especially during exercise. On the other hand, the transprosthetic gradients remain the same over time in a mechanical prosthesis.(23) Although the surgeon must strive to implant the largest valve possible if PPM is suspected in a biological prosthesis, if it is not possible, then a mechanical valve, sutureless valve implantation or the root enlargement procedure should be considered. The root enlargement procedure is also a debated and contemporary issue. It can be safely performed but requires advanced experience of both the surgeon and the centre. However, according to available publications, the volume of the procedures does not add to the operative risk. (24) Also, as the valve in valve TAVR clinical use expands its indications rapidly, the size of the implanted biological prosthesis should be carefully planned.

Study limitations

The present study has several significant limitations. First, the study was observational. More extensive prospective randomized trials are needed to explore these results and their clinical application. Second, it was performed in a single centre. Third, the response rate for the QoL survey was 87.6%, and data was not available for all patients enrolled in the study. Finally, the present study results should be interpreted as observational and hypothesis-generating only due to their exploratory data analysis nature.

CONCLUSIONS

PPM is common after biological valve implantation and significantly impacts long-term survival and QoL. If the risk of PPM after the implantation of a biological prosthesis is suspected, prospective strategies to avoid PPM at the time of the operation are warranted.

Funding statement

The authors report no funding.

Conflict of interest statement

None declared.

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

Author contributions statement

Milos Matkovic - Conceptualization; Investigation; Methodology; Writing-original draft

Nemanja Aleksic - Methodology; Writing—review & editing

Ilija Bilbija - Conceptualization; Methodology; Writing—review & editing

Ana Antic - Data curation; Validation; Writing—review & editing

Marko Cubrilo - Methodology; Writing—review & editing

Jelena Milin Lazovic - Data curation; Statistical analysis; Software

Aleksandar Milojevic - Data curation; Validation; Writing—review & editing

Svetozar Putnik - Investigation; Methodology; Supervision; Writing—review & editing.

Acknowledgements

The authors would like to thank Sonja Lukendic, Sofija Negrojevic and Katarina Lausevic for their invaluable assistance in data procurement and telephone interviews during this study.

REFERENCES

1. Rahimtoola SH. The problem of valve prosthesis-patient mismatch. Circulation. 1978;58(1):20-4.

2. Ternacle J, Pibarot P, Herrmann HC, Kodali S, Leipsic J, Blanke P, et al. Prosthesis-Patient Mismatch After Aortic Valve Replacement in the PARTNER 2 Trial and Registry. JACC Cardiovasc Interv. 2021;14(13):1466-77.

3. Lancellotti P, Pibarot P, Chambers J, Edvardsen T, Delgado V, Dulgheru R, et al. Recommendations for the imaging assessment of prosthetic heart valves: a report from the European Association of Cardiovascular Imaging endorsed by the Chinese Society of Echocardiography, the Inter-American Society of Echocardiography, and the Brazilian Department of Cardiovascular Imaging. Eur Heart J Cardiovasc Imaging. 2016;17(6):589-90.

4. Sportelli E, Regesta T, Salsano A, Ghione P, Brega C, Bezante GP, et al. Does patient-prosthesis mismatch after aortic valve replacement affect survival and quality of life in elderly patients? J Cardiovasc Med (Hagerstown). 2016;17(2):137-43.

5. Jamieson WR, Ye J, Higgins J, Cheung A, Fradet GJ, Skarsgard P, et al. Effect of prosthesis-patient mismatch on long-term survival with aortic valve replacement: assessment to 15 years. Ann Thorac Surg. 2010;89(1):51-8; discussion 9.

6. Hernandez-Vaquero D, Garcia JM, Diaz R, Calvo D, Khalpey Z, Hernandez E, et al. Moderate patient-prosthesis mismatch predicts cardiac events and advanced functional class in young and middle-aged patients undergoing surgery due to severe aortic stenosis. J Card Surg. 2014;29(2):127-33.

7. Hong S, Yi G, Youn YN, Lee S, Yoo KJ, Chang BC. Effect of the prosthesis-patient mismatch on long-term clinical outcomes after isolated aortic valve replacement for aortic stenosis: a prospective observational study. J Thorac Cardiovasc Surg. 2013;146(5):1098-104.

8. Chen J, Lin Y, Kang B, Wang Z. Indexed effective orifice area is a significant predictor of higher mid- and long-term mortality rates following aortic valve replacement in patients with prosthesis-patient mismatch. Eur J Cardiothorac Surg. 2014;45(2):234-40.

9. Concistre G, Dell'aquila A, Pansini S, Corsini B, Costigliolo T, Piccardo A, et al. Aortic valve replacement with smaller prostheses in elderly patients: does patient prosthetic mismatch affect outcomes? J Card Surg. 2013;28(4):341-7.

10. Dumesnil JG, Pibarot P. Prosthesis-patient mismatch: an update. Curr Cardiol Rep. 2011;13(3):250-7.

11. Weber A, Noureddine H, Englberger L, Dick F, Gahl B, Aymard T, et al. Ten-year comparison of pericardial tissue valves versus mechanical prostheses for aortic valve replacement in patients younger than 60 years of age. J Thorac Cardiovasc Surg. 2012;144(5):1075-83.

12. Hoffmann G, Abraham-Westphal S, Attmann T, Frank D, Lutter G, Cremer J, et al. Impact of Patient-Prosthesis Mismatch following Aortic Valve Replacement on Long-Term Survival and Quality of Life. Thorac Cardiovasc Surg. 2020;68(2):124-30.

13. Pocock SJ, Clayton TC, Altman DG. Survival plots of time-to-event outcomes in clinical trials: good practice and pitfalls. Lancet. 2002;359(9318):1686-9.

14. Durko AP, Pibarot P, Atluri P, Bapat V, Cameron DE, Casselman FPA, et al. Essential information on surgical heart valve characteristics for optimal valve prosthesis selection: expert consensus document from the European Association for Cardio-Thoracic Surgery (EACTS)-The Society of Thoracic Surgeons (STS)-American Association for Thoracic Surgery (AATS) Valve Labelling Task Force. Eur J Cardiothorac Surg. 2021;59(1):54-64.

15. Blais C, Dumesnil JG, Baillot R, Simard S, Doyle D, Pibarot P. Impact of valve prosthesis-patient mismatch on short-term mortality after aortic valve replacement. Circulation. 2003;108(8):983-8.

16. Pibarot P, Dumesnil JG, Lemieux M, Cartier P, Metras J, Durand LG. Impact of prosthesis-patient mismatch on hemodynamic and symptomatic status, morbidity and mortality after aortic valve replacement with a bioprosthetic heart valve. J Heart Valve Dis. 1998;7(2):211-8.

17. Rao V, Jamieson WR, Ivanov J, Armstrong S, David TE. Prosthesis-patient mismatch affects survival after aortic valve replacement. Circulation. 2000;102(19 Suppl 3):III5-9.

18. Fukuhara S, Shiomi S, Yang B, Kim K, Bolling SF, Haft J, et al. Early Structural Valve Degeneration of Trifecta Bioprosthesis. Ann Thorac Surg. 2020;109(3):720-7.

19. Kattach H, Shah BN, Harden S, Barlow CW, Miskolczi S, Velissaris T, et al. Premature Structural Failure of Trifecta Bioprosthesis in Midterm Follow-up: A Single-Center Study. Ann Thorac Surg. 2021;112(5):1424-31.

20. Koch CG, Khandwala F, Estafanous FG, Loop FD, Blackstone EH. Impact of prosthesis-patient size on functional recovery after aortic valve replacement. Circulation. 2005;111(24):3221-9.

21. Pibarot P, Dumesnil JG. Hemodynamic and clinical impact of prosthesis-patient mismatch in the aortic valve position and its prevention. J Am Coll Cardiol. 2000;36(4):1131-41.

22. Urso S, Sadaba R, Vives M, Trujillo J, Beltrame S, Soriano B, et al. Patient-prosthesis mismatch in elderly patients undergoing aortic valve replacement: impact on quality of life and survival. J Heart Valve Dis. 2009;18(3):248-55.

23. Kim DJ, Lee S, Joo HC, Youn YN, Yoo KJ, Lee SH. A Retrospective Comparison of Hemodynamic and Clinical Outcomes between Two Differently Designed Aortic Bioprostheses for Small Aortic Annuli. J Clin Med. 2021;10(5).

24. Yu W, Tam DY, Rocha RV, Makhdoum A, Ouzounian M, Fremes SE. Aortic Root Enlargement Is Safe and Reduces the Incidence of Patient-Prosthesis Mismatch: A Meta-analysis of Early and Late Outcomes. Can J Cardiol. 2019;35(6):782-90.

TABLES

Table 1. Baseline characteristics of patients with a biological or mechanical prosthesis.

		Biological n = 159	Mechanical n = 436	p-value
Age		69.9 + 7.7	62.6 + 12.1	0.001
Gender	Male	78 (49.1)	262 (60.4)	0.014
	Female	81 (50.9)	172 (39.6)	
Body surface area (m^2 + SD)		1.9 + 0.3	2.3 + 7.4	0.45
Body mass index		27.7 + 11.7 137	27.9 + 12.8 78	0.81 0.71 0.63
Aortic stenosis		(86.1) 22 (13.9)	(83.5) 72 (16.5)	
Aortic insufficiency				
HTA		131 (82.4)	364 (83.5)	0.75
HLP		76 (47.8)	222 (50.9)	0.50
COPD		22 (13.8)	56 (12.8)	0.75
CKD		16 (10.1)	58 (13.3)	0.29
DM		39 (24.5)	94 (21.6)	0.44
Previous stroke		5 (3.1)	18 (4.1)	0.58
Endocarditis		1 (0.6)	24 (5.5)	0.009

Values are presented as n (%) or mean + SD when indicated. * HTA - arterial hypertension, HLP - hyperlipidaemia, COPD - chronic obstructive pulmonary disease, CKD - chronic kidney disease, DM - diabetes mellitus, SD - standard deviation.

Table 2. Operative characteristics of patients with a biological or mechanical prosthesis.

	Biological n = 159	Mechanical n = 436	p-value
EuroSCORE II	1.9 + 1.4	1.6 + 1.3	0.54
CPB time (min + SD)	85.9 + 23.3	89.6 + 32.2	0.18
Aortic cross-clamp time (min + SD)	61.6 + 18.4	62.4 + 24.2	0.16
Ejection fraction (% + SD)	58.9 + 13.4	58.5 + 12.2	0.42

	Biological n = 159	Mechanical n = 436	p-value
ICU time (days + SD)	3.5 + 2.9	3.1 + 2.5	0.12

Values are presented as mean + SD. CPB - cardiopulmonary bypass, EuroSCORE II - European System for Cardiac Operative Risk Evaluation II, ICU - intensive care unit, SD - standard deviation.

Table 3. Patient-prosthesis mismatch and follow-up.

		Biological n = 159	Biological n = 159	Mechanical n = 436	p-value	p-value	
PPM, moderate-to-severe	111 (69.8)	111 (69.8)	16 (3.7)	16 (3.7)	16 (3.7)	< 0.001	< 0.001
Survival	133 (83.7)	133 (83.7)	381 (87.3)	381 (87.3)	381 (87.3)	0.24	0.24
Endocarditis	4 (2.5)	4 (2.5)	2 (0.5)	2 (0.5)	2 (0.5)	0.071	0.071
Redo surgery	3 (1.8)	3 (1.8)	5 (1.2)	5 (1.2)	5 (1.2)	0.53	0.53
Freedom from angina	114 (85.1)	114 (85.1)	340 (88.8)	340 (88.8)	340 (88.8)	0.28	0.28

Values are presented as mean + SD. PPM - patient-prosthesis mismatch, SD - standard deviation.

Table 4. Distribution of prosthesis manufacturers and models in groups.

Mechanical prosthesis St. Jude Masters (Abbott, Chicago, IL)	54 (12.4%)
St. Jude Regent (Abbott, Chicago, IL)	263 (60.3%)
ATS OPENPIVOT (Medtronic, Minneapolis, MN)	102 (23.4 %)
ONX (CryoLife Inc., Kennesaw, GA)	8 (1.8%)
Carbomedics (LivaNova, London, UK) **Biological prosthesis**	9 (2.1%)
Hancock II (Medtronic, Minneapolis, MN)	11 (6.9%)
Epic (Abbott, Chicago, IL)	30 (18.9%)
Trifecta (Abbott, Chicago, IL)	59 (37.1%)
Crown (LivaNova, London, UK)	19 (11.9%)
Solosmart (LivaNova, London, UK) Perceval S (LivaNova, London, UK)	1 (0.6%) 34 (21.3%)

Values are presented as n/N (%).

Table 5. SF-12 questionnaire among patients with a biological or mechanical prosthesis.

		PPM	NO PPM	p-value
Mechanical prosthesis	Physical score	43.9 ± 9.4	46.9 ± 8.3	0.18
	Mental score	54.8 ± 4.4	53.5 ± 5.9	0.43
Biological prosthesis	Physical score	39.4 ± 8.4	45.7 ± 10.1	0.005
	Mental score	53.9 ± 6.1	53.1 ± 8.1	0.51

PPM - Patient-prosthesis mismatch.

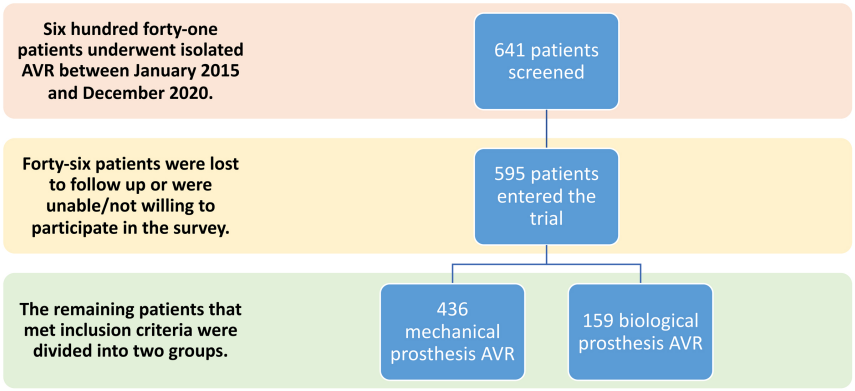
FIGURES LEGEND

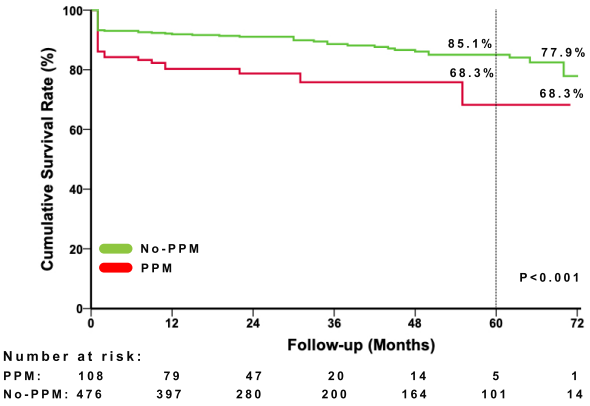
Figure 1. Flowchart of patient enrolment in the present study. AVR - aortic valve replacement.

Figure 2. Cumulative survival in patients with PPM compared with those without PPM, irrespective of the type of prosthesis. Values are Kaplan-Meier event rates with p-values from the log-rank test. PPM - patient-prosthesis mismatch.

Figure 3. Cumulative survival in patients with PPM compared with those without PPM in patients who had received a biological prosthesis. Values are Kaplan-Meier event rates with p-values from the log-rank test. PPM - patient-prosthesis mismatch.

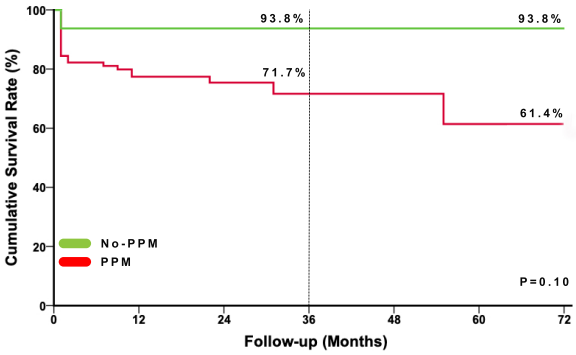
Figure 4. Cumulative survival in patients with PPM compared with those without PPM in patients who had received a mechanical prosthesis. Values are Kaplan-Meier event rates with p-values from the log-rank test. PPM - patient-prosthesis mismatch.





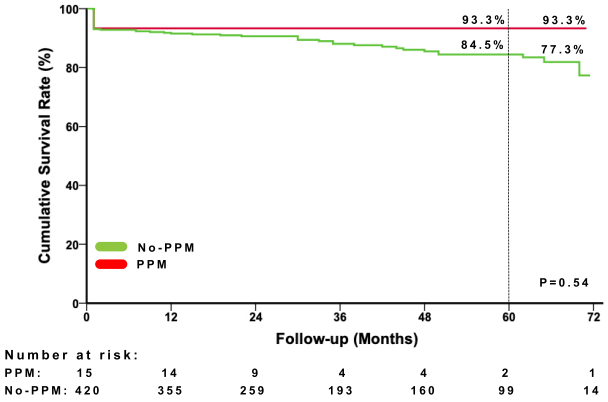
Number at risk:

PPM:	108	79	47	20	14	5	1
No-PPM:	476	397	280	200	164	101	14



Number at risk

PPM:	90	62	34	14	2	1	1
NO-PPM:	48	37	17	5	4	2	1



Number at risk:

PPM:	15	14	9	4	4	2	1
No-PPM:	420	355	259	193	160	99	14