Comparison of a novel mechanical valve versus stented bioprosthetic valves for isolated mitral valve replacement in patients older than 65 years

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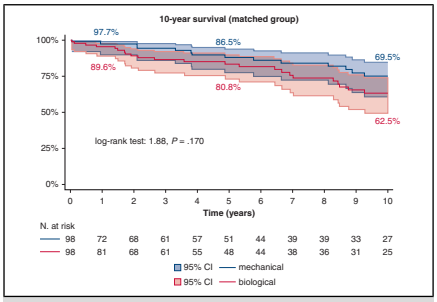
ABSTRACT

Objective: To compare early and long-term clinical outcomes of bioprosthetic versus mechanical (On-X) mitral valve replacement (MVR) in patients aged 65 years and older.

Methods: This single-center retrospective study included consecutive patients equal to or older than 65 years underwent isolated MVR from 2005 to 2023. A propensity score-matched analysis was performed to compare early- and long-term clinical outcomes between patients with bioprostheses and mechanical On-X valve.

Results: A total of 330 patients were included, of whom 232 (70.3%) experienced bioprosthetic mitral valve replacement (BMVR group) and 98 (29.7%) mechanical mitral valve replacement (MMVR group) with On-X prosthesis. Propensity score analysis allowed to match 98 patients from each group. In the matched cohorts, the overall survival at 1, 5, and 10 years was 97.7%, 86.5%, and 69.5% for the MMVR group and 89.6%, 80.8%, and 62.5% for the BMVR (log-rank test: 1.88, $P = .170$). The 1-, 5-, and 10-year freedom from reoperation, endocarditis, pacemaker implantation, and hemorrhagic events were comparable between the 2 groups.

Conclusions: In patients older than 65 years requiring isolated MVR, the use of On-X mechanical prosthesis showed comparable long-term outcomes over bioprostheses. (JTCVS Open 2025;26:85-93)



Kaplan-Meier survival estimates in matched groups.

CENTRAL MESSAGE

In patients older than 65 years requiring isolated mitral valve replacement, the use of On-X mechanical prosthesis showed comparable long-term outcomes over bioprostheses.

PERSPECTIVE

The use of the On-X mechanical prosthesis can be considered in patients older than 65 years of age undergoing isolated mitral valve replacement, ensuring efficacy and 10-year outcomes comparable with bioprostheses.

Mitral valve disease represents a significant aspect of the global burden of cardiovascular morbidity and mortality, with an increasing prevalence in the aging populations, particularly in those older than 65 years of age.[1-3] Isolated mitral valve replacement is typically reserved for patients in whom mitral valve repair is either infeasible or unsuccessful.[4] Current international guidelines recommend mechanical prostheses for patients younger than 65 years

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Abbreviations and Acronyms

BMVR = biological mitral valve replacement
EuroSCORE II = European System for cardiac operative risk evaluation
LVEF = left ventricular ejection fraction
MMVR = mechanical mitral valve replacement
VKA = vitamin K antagonist

because of their durability and favorable long-term outcomes.[5] Conversely, biological prostheses are often preferred in older patients to reduce the risks associated with lifelong anticoagulation therapy. Although numerous studies have documented superior outcomes with mechanical prostheses in patients younger than 65 to 70 years, evidence supporting their use in older populations remains limited. Notably, studies focusing on patients older than the age of 65 years frequently include cohorts undergoing concomitant procedures or previous models of mechanical prostheses, which may not reflect current standards. The newest mitral mechanical prosthesis, the On-X Conform-X Valve (Artivion), has shown promising results, with good hemodynamic performance and acceptable rates of thromboembolic and hemorrhagic events.[6,7]

Despite these advances, the application of On-X prostheses in patients older than 65 years has not been adequately explored in the literature. The objective of this study is to compare the outcomes of patients older than 65 years undergoing isolated mitral valve replacement with either a stented biological prosthesis or the On-X mechanical prosthesis. By focusing on isolated procedures and the last generation of prosthesis, this study aims to provide a clearer understanding of the optimal prosthesis choice for this growing patient population.

METHODS

Ethical Statement

The study was approved by the institutional review board of the University Hospital of Bologna (CE AVEC 593/2022/Disp/AOUBo; date: December 22, 2022). Written informed consent from patients was waived. We ensured compliance with ethical standards, including respect for anonymity, adherence to professional confidentiality, and the use of collected data exclusively for scientific purposes, in accordance with the applicable legal framework (General Data Protection Regulation).

Study Population, Surgical Indication, and Data Collection

Between 2005 and 2023, a total of 551 consecutive patients underwent isolated mitral valve replacement at our institution. Among these, 261 received stented biological prostheses (47.4%) and 290 (52.6%) received On-X mechanical prostheses.

This study is focused on patients older than 65 years of age, including 232 who underwent biological mitral valve replacement (BMVR) and 98 who received mechanical mitral valve replacement (MMVR). Preoperative and postoperative echocardiographic evaluations were performed by board-certified cardiologists following the international guidelines in effect during the study period.[8]

The primary indications for surgery were mitral valve regurgitation of degenerative or functional origin, endocarditis, and mitral valve stenosis. In all patients, valve repair was the first-line treatment whenever feasible. Valve replacement with a prosthesis was performed only in cases of nonrepairable mitral valve pathology or repair failure. When replacement was necessary, the discussion with patients was guided by current clinical guidelines. In patients aged $\geq$65 years, a biological prosthesis was initially recommended as per standard practice. However, in 98 patients, a mechanical valve was ultimately chosen as the result of the patient's preference, the desire to avoid future reoperations, or the presence of preexisting oral anticoagulation therapy. In the BMVR group, all types of stented biological prostheses were included, whereas the MMVR group exclusively comprised On-X mechanical prostheses, model 25/33 Conform-X. Concomitant procedures such as atrial fibrillation ablation and left atrium appendage closure were performed on the basis of the patient's specific condition and the surgeon's discretion. However, in patients undergoing mechanical valve implantation with lifelong anticoagulation, these procedures were rarely performed.

Data were collected retrospectively from institutional electronic health records. For patients lost to follow-up, additional data were obtained through telephone surveys. The follow-up period ended in October 2024.

Study Outcomes

The primary outcomes of the study were long-term survival, whereas the secondary end points were freedom from reintervention, endocarditis, new pacemaker implantation, and major thrombohemorrhagic events. Morbidity events were defined following the Guidelines for Reporting Mortality and Morbidity After Cardiac Valve Interventions issued by the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, and the European Association of Cardio-Thoracic Surgery.[9,10]

Thromboembolic events were classified as any occurrence of neurologic or peripheral thromboembolic complications, whereas hemorrhagic events were defined as episodes of major bleeding requiring transfusion, hospitalization, or resulting in permanent injury or death. Postoperative management for patients in the BMVR group included anticoagulation with vitamin K antagonists (VKAs) for the initial 3 months (target international normalized ratio, 2.5-3.0), followed by long-term aspirin therapy (100 mg daily). For patients with atrial fibrillation or other specific indications, long-term anticoagulation with VKAs was continued. For patients in the MMVR group, long-term anticoagulation with VKAs was adopted with international normalized ratio target at 3.0.

Statistical Analysis

To adjust for pretreatment observable differences between patients with BMVR and MMVR, a propensity score matching method based on Mahalanobis distance was used.[11] Patients were matched by age, gender, European System for Cardiac Operative Risk Evaluation (EuroSCORE II), and body surface area. The covariate balance between the 2 groups was assessed using boxplots and density plots of the propensity score and standardized mean differences between groups. The Love plot was also used to depict the covariate balance before and after adjusting. Preoperative, intraoperative. and postoperative characteristics were compared between groups using the χ^2 test for categorical variables and

TABLE 1. Baseline demographics and procedural details

Variables	Before matching			After matching		
	Mechanical (n = 98)	Biological (n = 232)	*P* value	Mechanical (n = 98)	Biological (n = 98)	*P* value
Male, n (%)	48 (49.0)	98 (42.2)	.260	48 (49.0)	51 (52.0)	.669
Age, y, median (IQR)	69 (67-73)	75 (71-79)	<.001*	69 (67-73)	71 (69-74)	.012
Hypertension, n (%)	66 (67.4)	165 (71.1)	.467	66 (67.4)	69 (70.4)	.643
Diabetes, n (%)	15 (15.3)	33 (14.2)	.799	15 (15.3)	16 (16.3)	.845
Dyslipidemia, n (%)	48 (49.0)	115 (49.6)	.922	48 (49.0)	49 (50.0)	.886
Smoking, n (%)	49 (50)	73 (31.5)	.001*	49 (50)	37 (37.8)	.084
EuroSCORE II, median (IQR)	2.55 (1.3-4.8)	2.97 (1.64-6.0)	.026	2.55 (1.3-4.8)	2.55 (1.58-5.48)	.344
BSA, median (IQR)	1.76 (1.61-1.89)	2 (1.64-2.13)	<.001	1.76 (1.61-1.89)	1.78 (1.59-2.05)	.171
eGFR, median (IQR)	61.7 (46.1-80.1)	51.3 (40.3-63.4)	<.001*	61.7 (46.1-80.1)	53.8 (46.6-66.2)	.064
Dialysis, n (%)	2 (2.04)	1 (0.43)	.159	2 (2.04)	1 (1.02)	.561
Peripheral vasculopathy, n (%)	9 (9.18)	42 (18.1)	.041*	9 (9.18)	14 (14.3)	.267
Cerebrovascular arteriopathy, n (%)	4 (4.08)	8 (3.45)	.779	4 (4.08)	4 (4.08)	1.000
Previous stroke, n (%)	9 (9.18)	14 (6.03)	.305	9 (9.18)	4 (4.08)	.151
Previous TIA, n (%)	6 (6.12)	9 (3.88)	.371	6 (6.12)	1 (1.02)	.054
Coronary artery disease, n (%)	27 (27.6)	78 (33.6)	.279	27 (27.6)	32 (32.7)	.436
Recent MI, n (%)	5 (5.1)	7 (3.02)	.355*	5 (5.1)	2 (2.04)	.248
Preoperative AF, n (%)						
Paroxysmal	13 (13.3)	41 (17.7)	.323	13 (13.3)	20 (20.4)	.181
Persistent	8 (8.16)	11 (4.74)	.223	8 (8.16)	7 (7.14)	.788
Longstanding	3 (3.06)	1 (0.43)	.046*	3 (3.06)	1 (1.02)	.312
Permanent	28 (28.6)	74 (31.9)	.550	28 (28.6)	22 (22.5)	.326
Previous cardiac surgery, n (%)	40 (40.8)	8 (3.45)	<.001*	40 (40.8)	4 (4.08)	<.001*
Active endocarditis, n (%)	10 (10.2)	15 (6.47)	.241	10 (10.2)	8 (8.16)	.621

The χ^2 was used for categorical variables and Mann-Whiney *U* test for continuous variables. *IQR*, Interquartile range; *EuroSCORE II*, European System for Cardiac Operative Risk Evaluation; *BSA*, body surface area; *eGFR*, estimated glomerular filtration rate; *TIA*, transient ischemic attack; *MI*, myocardial infarction; AF, atrial fibrillation. *Statistically significant for *P* value <.05.

Mann-Whiney *U* test for continuous variables. Kaplan-Meier estimates were obtained for time to events analyses and log-rank test was used to compare MMVR and BMVR survival curves. All statistical analyses were carried out using R and Stata, version 18.0.

RESULTS

Study Population and Baseline Characteristics

The study population and baseline characteristics are summarized in Table 1. Before propensity score matching, patients in the BMVR group were generally older than those in the MMVR group (75 vs 69 years; $P < .001$) and exhibited greater surgical risk scores, as indicated by a greater EuroSCORE II (2.97% vs 2.55%; $P = .026$). In addition, the BMVR group had poorer renal function (estimated glomerular filtration rate, 51 vs 61 mL/min/1.73 m^2; $P < .001$) and a greater prevalence of peripheral vascular disease (18% vs 9%; $P = .041$).

However, patients in the MMVR group had a significantly greater incidence of previous cardiac surgery (reintervention) compared with the BMVR group (40% vs 3.5%; $P < .001$). The propensity score matching resulted in the selection of 98 pairs of patients with BMVR and MMVR, with balance in the baseline characteristics. The covariate balance before and after matching is shown in Figure 1.

Intraoperative Details

Table 2 summarizes the intraoperative details. In the MMVR group, 8 patients underwent surgery classified as urgent, whereas no urgent cases were observed in the BMVR group. The surgical approach involved a right mini-thoracotomy in 3 patients (MMVR), whereas all remaining cases in both groups were performed through a standard median longitudinal sternotomy. No significant differences were found between the 2 groups regarding atrial/transseptal access sites or arterial cannulation.

The median cardiopulmonary bypass time was 118 minutes (range, 103-146 minutes) in the MMVR group and 116 minutes (range, 101-141 minutes) in the BMVR group. Similarly, the mean aortic crossclamp time was comparable between the 2 groups, at 83 (71-111) minutes for the MMVR group and 84 (71-107) minutes for the BMVR group ($P = .829$).

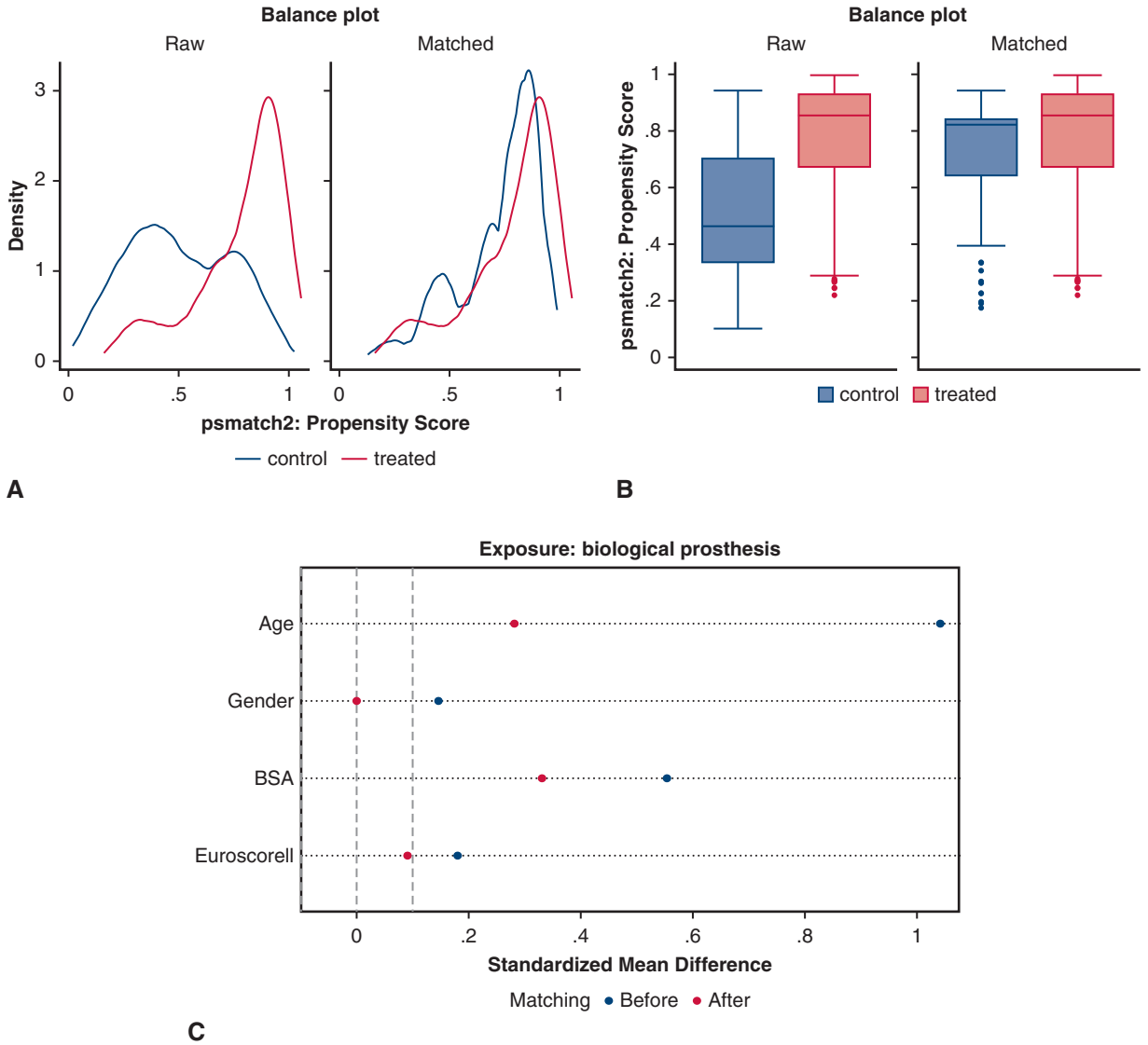

FIGURE 1. Covariate balance plots in 2 groups before and after matching: (A) density distribution of the propensity score, and (B) box-and-whisker plot showing the distribution of patients. The *box* represents the interquartile range (IQR), with the *lower and upper edges* indicating the 25th and 75th percentiles, respectively. The *horizontal line* within the box denotes the median. *Whiskers* extend to the smallest and largest values within 1.5 times the IQR from the lower and upper quartiles. Values outside this range are shown as *individual dots* and represent outliers. C, Boxplots of the propensity score for the unmatched and matched groups.

In-Hospital Outcomes

Early postoperative outcomes are summarized in Table 3. Postoperative reintubation or tracheostomy occurred significantly more frequently in the BMVR group compared with the MMVR group (5.1% vs 0%; $P = .024$). Conversely, the median length of stay in the intensive care unit was longer in the MMVR group than in the BMVR group (3 days [1-5] vs 2 days [1-4]; $P = .008$).No significant differences were observed between the groups in terms of median hospital length of stay (10 days [8-13] for BMVR vs 11 days [7-15] for MMVR; $P = .926$).

The overall 30-day mortality was 4.8%, with 6 deaths in the MMVR group and 10 in the BMVR group ($P = .506$). The mean preoperative EuroSCORE II for these patients was 5.64%, with 3.5% for patients in the MMVR group and 7.9% for patients in the BMVR group.

Specifically, in the MMVR group, the 6 deaths were attributed to the following causes: 1 multiorgan failure, 2 cardiac arrests, 2 cases of cardiogenic shock, and 1 case of hemorrhagic shock. In the BMVR group, the 10 deaths were attributable to the following: 2 cases of septic shock, 1 suicide, 1 left ventricular rupture, and 6 cases of multiorgan failure.

TABLE 2. Intraoperative characteristics

Variables	Before matching			After matching		
	Mechanical (n = 98)	Biological (n = 232)	*P* value	Mechanical (n = 98)	Biological (n = 98)	*P* value
Urgency, n (%)	8 (8.16)	19 (8.19)	.994	8 (8.16)	8 (8.16)	1.0
Surgical approach (thoracotomy), n (%)	3 (3.06)	0 (0.00)	.007	3 (3.06)	0 (0.00)	.081
Atrial access, n (%)						
Paraseptal	85 (86.7)	217 (93.5)	.043	85 (86.7)	92 (93.9)	.091
Guiraudon	12 (12.2)	15 (6.47)	.080	12 (12.2)	6 (6.12)	.138
Right atrium	1 (1.02)	0 (0.00)	.123	1 (1.02)	0 (0.00)	.316
Arterial cannulation site, n (%)						
Ascending aorta	85 (86.7)	213 (93.5)	.043	85 (86.7)	92 (93.9)	.091
Femoral artery	12 (12.2)	15 (6.47)	.080	12 (12.2)	6 (6.12)	.138
Axillary artery	1 (1.02)	0 (0.00)	.123	1 (1.02)	0 (0.00)	.316
Venous cannulation site, bicaval, n (%)	89 (90.8)	232 (100)	<.001*	89 (90.8)	98 (100.0)	.002*
Cardioplegia, Crystalloid, n (%)	97 (99.0)	232 (100.0)	.123	97 (99.0)	98 (100.0)	.316
Surgery type: replacement due to unsuccessful valve repair, n (%)	7 (7.14)	17 (7.33)	.953	7 (7.14)	10 (10.2)	.446
Maze, n (%)	3 (3.06)	46 (19.8)	<.001*	3 (3.06)	15 (15.3)	.003*
AF energy source, n (%)	1 (1.02)	47 (20.3)	<.001*	1 (1.02)	14 (14.3)	<.001*
LAA closure, n (%)	3 (3.06)	71 (30.7)	<.001*	3 (3.06)	25 (25.5)	<.001*
CPB time, median (IQR)	118 (103-146)	114 (98-134)	.064	118 (103-146)	116 (101-141)	.341
Crossclamp time, median (IQR)	83 (71-111)	81 (69-104)	.275	83 (71-111)	84 (71-107)	.829

AF, Atrial fibrillation; *LAA*, left atrial appendage; *CPB*, cardiopulmonary bypass; *IQR*, interquartile range. *Statistically significant for *P* values <.05.

No significant differences were found between the 2 groups regarding the incidence of reoperation for bleeding ($P = .774$), stroke ($P = .316$), permanent pacemaker implantation ($P = 1$), or myocardial infarction. Similarly, there were no differences in the rates of low cardiac output syndrome ($P = .147$), postoperative extracorporeal membrane oxygenation or intra-aortic balloon pump implantation ($P = .551$), acute kidney injury ($P = .756$), dialysis ($P = .306$), vascular complications ($P = .316$), or thoracic wound complications ($P = .312$).

Sepsis was reported in 1 patient in each group. However, pneumonia occurred significantly more frequently in the BMVR group compared with the MMVR group (4.1% vs 0%; $P = .043$).

Hemodynamic Considerations

Before surgery, the median left ventricular ejection fraction (LVEF) was comparable between the 2 groups: 70% (range, 69%-72%) in the BMVR group and 69% (range, 67%-73%) in the MMVR group ($P = .347$). Severe mitral stenosis was 3 times more prevalent in patients in the MMVR group than patients in the BMVR group (27.6% vs 9.2%), whereas severe mitral regurgitation was more frequent in the BMVR group (88.8%) compared with the MMVR group (64.3%).

No significant differences were observed between the 2 groups regarding left ventricular end-diastolic volume ($P = .415$), end-diastolic diameter ($P = .962$), or left ventricular end-systolic volume ($P = .338$).

Postoperatively, the BMVR group showed a slight reduction in LVEF compared with the MMVR group (58% vs 61%; $P = .020$). However, there were no significant differences between the groups in terms of mean transvalvular gradient (5.7 mm Hg for BMVR vs 5.0 mm Hg for MMVR; $P = 1.05$) or valvular area ($P = .352$).

At the last echocardiographic follow-up, no significant differences were found between the groups in terms of LVEF ($P = .550$), incidence of paravalvular leak ($P = .873$), valve area ($P = .115$), or mean transvalvular gradients ($P = .934$). However, systolic pulmonary artery pressure was significantly greater in patients in the MMVR group compared with patients in the BMVR group (40 mm Hg [range, 33-50] vs 30 mm Hg [range, 25-36]; $P = .025$).

Long-Term Outcomes

In the matched cohorts, 98 patients were alive and followed for at least 5 years, and 52 patients for at least 10 years. Kaplan-Meier survival estimates are depicted in Figure 2.

Survival rates in the matched groups at 1, 5, and 10 years were 97.7%, 86.5%, and 69.5%, respectively, for patients in the MMVR group and 89.6%, 80.8%, and 62.5%, respectively, for patients in the BMVR group (log-rank = 1.88, $P = .170$). In addition, the Fisher exact test showed no significant difference between porcine and bovine prostheses in terms of mortality during follow-up (29% vs 37.9%, $P = .262$, respectively). Freedom from reintervention was similar between the groups (log-rank = 0.9, $P = .342$), being

TABLE 3. Postoperative characteristics

Variables	Before matching			After matching		
	Mechanical (n = 98)	Biological (n = 232)	*P* value	Mechanical (n = 98)	Biological (n = 98)	*P* value
Intubation time, h, median (IQR)	8 (6-16)	8 (6-15)	.797	8 (6-16)	8 (6-15)	.899
Reintubation and/or tracheostomy, n (%)	0 (0.00)	12 (5.17)	.022	0 (0.00)	5 (5.10)	.024*
Reoperation for bleeding, n (%)	7 (7.14)	10 (4.31)	.287	7 (7.14)	6 (6.12)	.774
Stroke, n (%)	1 (1.02)	3 (1.29)	.836	1 (1.02)	0 (0.00)	.316
Transient ischemic attack, n (%)	0 (0.00)	2 (0.86)	.357	0 (0.00)	0 (0.00)	–
Delirium, n (%)	3 (3.06)	7 (3.02)	.983	3 (3.06)	2 (2.04)	.651
New-onset atrial fibrillation, n (%)	18 (18.4)	52 (22.4)	.411	18 (18.4)	28 (28.6)	.092
Advanced AV block, n (%)	6 (6.12)	29 (12.5)	.086	6 (6.12)	12 (12.2)	.138
Ventricular fibrillation, n (%)	0 (0.00)	3 (1.29)	.258	0 (0.00)	0 (0.00)	–
Ventricular tachycardia, n (%)	0 (0.00)	3 (1.29)	.258	0 (0.00)	3 (3.06)	.081
Definitive pacemaker implantation, n (%)	5 (5.10)	14 (6.03)	.740	5 (5.10)	5 (5.10)	1.0
Myocardial infrarction, n (%)	0 (0.00)	2 (0.86)	.359	0 (0.00)	0 (0.00)	–
Low cardiac output syndrome, n (%)	10 (10.2)	37 (15.95)	.172	10 (10.2)	17 (17.4)	.147
ECMO, n (%)	0 (0.00)	0 (0.00)	–	0 (0.00)	0 (0.00)	–
IABP, n (%)	5 (5.10)	12 (5.17)	.979	5 (5.10)	7 (7.14)	.551
Peak serum creatinine	1.26 (0.99-1.70)	1.2 (0.95-1.6)	.331	1.26 (0.99-1.70)	1.16 (0.97-1.46)	.184
AKI, n (%)	5 (5.10)	22 (9.52)	.181	5 (5.10)	6 (6.12)	.756
Postoperative dialysis, n (%)	6 (6.12)	10 (4.31)	.484	6 (6.12)	3 (3.06)	.306
Redo early failure, n (%)	1 (1.02)	3 (1.29)	.836	1 (1.02)	0 (0.00)	.316
Multiorgan failure, n (%)	0 (0.00)	3 (1.29)	.258	0 (0.00)	0 (0.00)	–
Infectious complications, n (%)						
Local infection, n (%)	0 (0.00)	2 (0.86)	.357	0 (0.00)	2 (0.86)	.155
Pneumonia, n (%)	0 (0.00)	12 (5.17)	.022	0 (0.00)	4 (4.08)	.043*
Sepsis, n (%)	1 (1.02)	5 (2.16)	.481	1 (1.02)	1 (1.02)	1.0

The χ^2 test was used for categorical variables and Mann-Whiney *U* test for continuous variables. *IQR*, Interquartile range; *AV*, atrioventricular; *ECMO*, extracorporeal membrane oxygenation; *IABP*, intra-aortic balloon pump; *AKI*, acute kidney injury. *Statistically significant for *P* values <.05.

at 1, 5, and 10 years 100%, 95.4%, and 88.5% for mechanical prostheses, and 97.9%, 92.9%, and 85.3% for biological prostheses. Even in this case, results of the Fisher exact test showed no significant difference between porcine and bovine prostheses in terms of reintervention during follow-up (7.5% vs 12.5%, $P = .354$, respectively). Freedom from endocarditis was also comparable (log-rank = 1.24, $P = .265$). In particular, at 1, 5, and 10 years, it was 98.3%, 96.2%, and 96.2% for mechanical prostheses and 97.6%, 92.2%, and 91.1% for biological prostheses. The rates of freedom from pacemaker implantation were similar (log-rank = 0.2, $P = .656$). For mechanical prostheses, this remained consistently at 94.8% over time, whereas for biological prostheses, it was 95.9% at 1 year, 94.1% at 5 years, and 90.1% at 10 years. Freedom from thrombohemorrhagic events was comparable between the groups (log-rank = 0.36, $P = .55$) being at 10 years 91.6% for mechanical prostheses and 93.5% for biological prostheses.

DISCUSSION

This study provides valuable insights into the outcomes of isolated mitral valve replacement in patients aged ≥65 years, for whom mitral repair was not an option. Considerable effort was made to minimize the risk of confounding factors commonly seen in studies that include concomitant procedures and different types of prostheses. The inclusion criteria and the focused rationale of the study increase the reliability of the results and helps draw more specific conclusions about the long-term outcomes of mechanical and biological prostheses in this patient population. The first strength of the study is represented by the lack of concomitant procedures. In fact, previous studies included patients with concomitant procedures such as myocardial revascularization and tricuspid surgery ranging from 15% to 85% of the entire cohorts.[12-18] This might affect early- and long-term outcomes of these patients. Our focus on patients without concomitant procedures

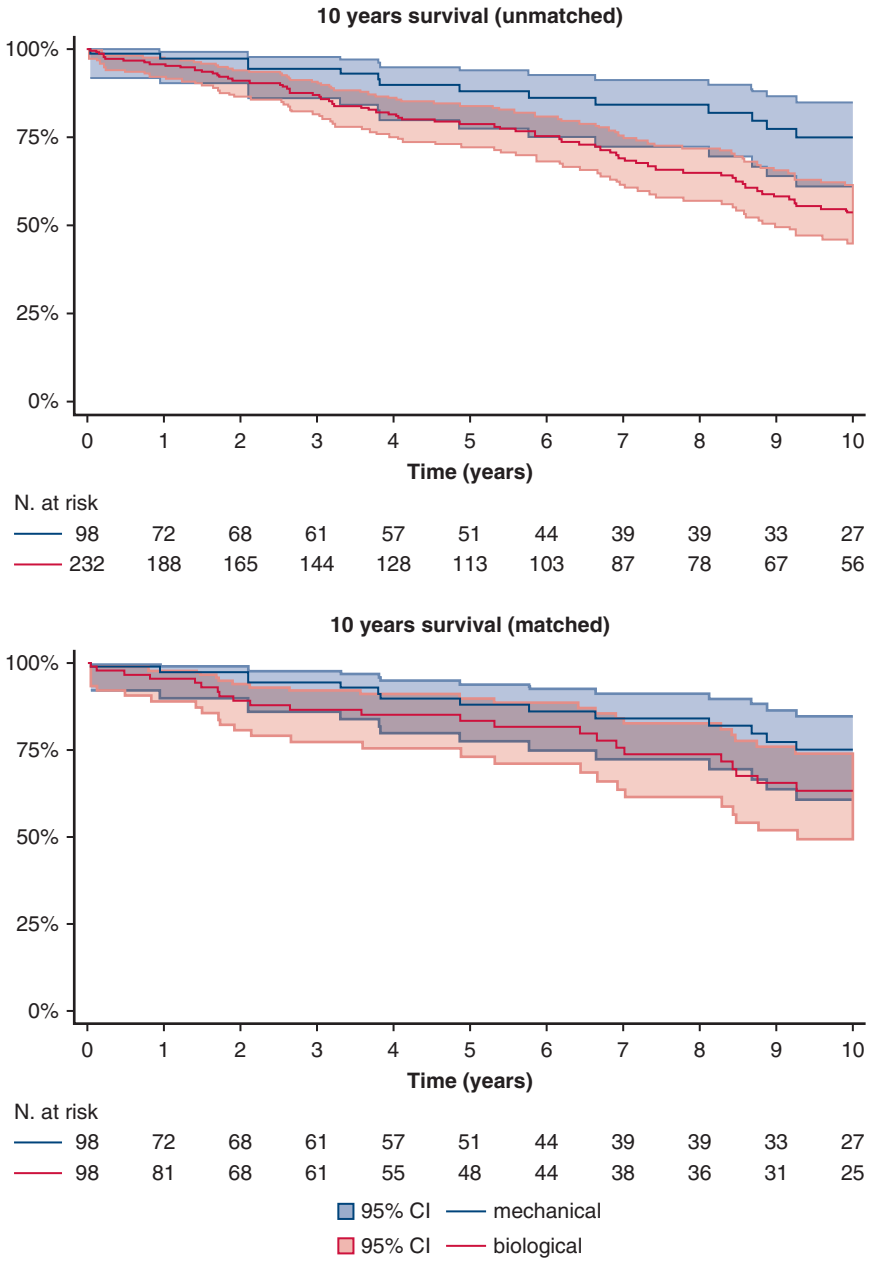

FIGURE 2. Kaplan-Meier survival estimates in unmatched (A) and matched (B) groups. CI 95%, 95% Confidence interval.

and the study design with propensity score matching allowed us to compare "clean" groups of patients with similar characteristics, thereby reducing the common imbalance that is found in observational studies.

Rokui and colleagues[19] report a 10-year survival for isolated mitral valve replacement in patients 65 to 75 years of 64.6% with mechanical prostheses and 60.8% with biological prostheses, and a freedom from reoperation of 94% and 97.2% respectively. Consistent with these results, our study reports a 10-year survival of 69.5% for mechanical prostheses, 62.5% for biological prostheses, with a 10-year freedom from reoperation of 88.5% and 85.3% respectively. However, it should be noted that the study from Rokui and colleagues[19] includes 10.3% of On-X, 10.3% of Carbomedics, and 29.1% of St Jude medical valves. The second strength of our study is the focus on a single mechanical prosthesis model, the On-X Mitral Conform-X. In fact, currently available data, including those on St Jude, ATS (Abbott), and Sorin (Sorin Group) prostheses, describe survival rates ranging from approximately 61% to 83% at 10 years and from 44% to 70% at 15 years for mechanical prostheses in the mitral position.[20-24] In contrast, the estimated 10-year

mortality associated with the use of bioprostheses for MVR ranged from 22% to 58%.[25] On the basis of our experiences with both mechanical and biological prostheses, On-X valves have demonstrated excellent and highly encouraging results. In support of this, Reyes and collegues[26] published the results of the largest study in the literature evaluating the performance of On-X in the mitral position, reporting a 10-year survival rate of 71% and a 10-year freedom from reoperation rate of 95% (mean age 63 at time of implant). Our study aligns with these findings, providing clear and consistent results in a cohort focused exclusively on isolated MVR and the use of On-X mechanical prostheses.

In addition, this work provides several notable observations. First, the use of both mechanical and biological prostheses for patients undergoing isolated mitral valve replacement provides excellent and effective results. Second, On-X valves, which represent the latest generation of mechanical prostheses, designed for improved hemodynamic performance and reduced thrombogenicity, do not appear to carry an increased risk of thromboembolic or hemorrhagic events during follow-up compared with biological prostheses. Consequently, freedom from hemorrhagic events was comparable between the 2 groups (log-rank = 0.36, $P = .55$), with rates at 10 years of 91.6% for mechanical prostheses and 93.5% for biological prostheses. It is important to note that during the follow-up period, patients may have experienced anticoagulation therapy mismanagement or temporary anticoagulant use for other indications that the study could not fully detect. In this context, the only reasonable conclusion to draw is that within the observed cohort, despite a greater incidence of postoperative atrial fibrillation in the BMVR group, no significant differences in thromboembolic or hemorrhagic events were observed during follow-up.

Third, we found no significant difference in freedom from reoperation between the 2 cohorts, with 10-year rates of 88.5% for MMVR and 85.3% for BMVR. These findings highlight the strong outcomes achievable with modern mechanical prostheses, particularly On-X valves, in the context of isolated mitral valve replacement. However, a 10-year follow-up period may be insufficient to fully evaluate the long-term impact of structural valve degeneration in biological prostheses. Previous studies have demonstrated that structural valve degeneration in biological valves becomes more pronounced after 10 years, resulting in a greater incidence of reinterventions due to calcification and valve dysfunction.[27-30] This aspect deserves a closer evaluation and additional studies with longer follow-up periods to better define its long-term impact.

However, we believe that the main goal of this study is not merely to further investigate bioprosthesis durability but rather to compare clinical outcomes between patients receiving a biological valve and those, in the same age group, who for various reasons receive a mechanical prosthesis.

A recent meta-analysis involving more than 20,000 patients revealed a significantly lower but relatively narrow difference in the risk of mitral valve reoperation, with an estimated 10-year risk of 0% to 8% for mechanical MVR compared with 8% to 22% for biological MVR.[25] This aspect should be taken into account, considering that mitral valve reoperation carries a significant operative mortality (11%-12%), especially when concomitant with cardiogenic shock, tricuspid valve regurgitation, or other associated comorbidities.[31,32] For this reason, although mechanical prostheses are known for their longevity and lower risk of valve degeneration, biological valves may still offer better outcomes in terms of reducing the need for long-term anticoagulation therapy.

The decision regarding valve choice in older patients remains complex and should be individualized, taking into account factors such as patient preferences, comorbidities, and the potential risks associated with anticoagulation. For this reason, cardiologists and cardiac surgeons should be aware regarding the indications and the choice of which type of prosthesis to propose, considering not only the risks related to the lifelong anticoagulation therapy but also the risk of reoperation and the future transcatheter options.

In this regard, the long-term balance between mechanical and bioprosthetic mitral valve replacement will likely be influenced by the evolving impact of anticoagulation-related risks versus the durability of bioprostheses and the outcomes of transcatheter reinterventions. Ongoing technological advancements may significantly reshape these dynamics over the next decades.

Limitations

Although this study provides important insights, there are several limitations that must be considered. The most important limitation is the observational study design that does not allow to draw definite conclusions concerning differences in long-term outcomes between patients with biological and mechanical MVR due to the possible presence of unknown latent confounders. Still, the similarity between the 2 groups after matching in the large number of characteristics investigated partially mitigates this limitation. In addition, there is still a significant age difference between the 2 groups after matching, which could influence the results. The 10-year follow-up period, although useful for assessing early postoperative outcomes, is insufficient for fully evaluating the long-term durability of both mechanical and biological prostheses. Longer follow-up studies are needed to capture the impact of structural valve degeneration in biological prostheses, which typically occurs after the 10-year mark and may influence the need for reintervention. In addition, this study was conducted in a single institution, which may limit the generalizability of the findings. Multicenter studies involving larger cohorts would enhance the external validity of the results and provide a more comprehensive understanding of the long-term outcomes of mechanical versus biological prostheses in elderly patients. In addition, further studies exploring the impact of anticoagulation therapy on quality of life and survival in patients with mechanical valves would provide

valuable insights into the overall benefits and risks associated with these prostheses in elderly populations.

Conflict of Interest Statement

Pr Davide Pacini discloses that he has received grants from Artivion, Corcym, and Terumo. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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