



## Original Article

# Clinical Outcomes and In-hospital Mortality Rate following Heart Valve Replacements at a Tertiary-care Hospital



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## Abstract

**Background and objectives:** Mechanical valve replacement is a primary treatment for rheumatic heart disease, yet prosthesis-related adverse outcomes remain underreported in India. This study aimed to examine the in-hospital mortality rate among patients who underwent prosthetic heart valve replacement surgeries in the past five years.

**Methods:** A retrospective analysis of 221 rheumatic heart disease patients (2019–2023) who underwent aortic valve replacement (AVR), mitral valve replacement (MVR), or double valve replacement (DVR) was conducted. Comorbidities (hypertension, type-2 diabetes mellitus) and valve origin (Indian vs. foreign-made) were also evaluated. Data were analyzed using SPSS (v25.0), with  $p < 0.05$  considered statistically significant.

**Results:** Among 221 patients, 262 valves were implanted (54 AVR, 126 MVR, 41 DVR). Overall in-hospital mortality was 7.24% (16/221), with rates of 5.55% (AVR), 7.14% (MVR), and 9.75% (DVR). No sex-based differences were observed ( $p > 0.05$ ). The five-year actuarial survival rate was  $92.8 \pm 4.8\%$ , with no intergroup disparities ( $p > 0.05$ ). Mortality was higher in patients  $>50$  years (13/16 deaths) and in females (10/16 deaths), though these differences were not statistically significant. Hypertension was more prevalent in females and type-2 diabetes mellitus in males, but neither condition showed a significant association with outcomes ( $p > 0.05$ ). Most fatalities were associated with thromboembolism, acute kidney injury, and congestive heart failure, and valve origin did not significantly impact mortality.

**Conclusions:** Over the past five years, we observed a 7.24% mortality rate at our tertiary care facility following prosthetic heart valve implantation across all age groups. The data suggest that mortality may be more common among females and older individuals; however, these differences did not reach statistical significance.

**Keywords:** In-hospital mortality rate; Rheumatic heart disease; Mechanical heart valve replacements; Transcatheter valve replacement; Cardiac implants; Medical devices; Medical device adverse events.

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## Introduction

Rheumatic heart disease (RHD) has become one of the specific contributors to deaths associated with heart failure and other cardiovascular complications. Additionally, drug treatment to reduce the prevalence of RHD is still unsuccessful and has undesirable side effects upon long-term application. Patients with RHD frequently have both aortic and mitral valve diseases.<sup>1,2</sup> The choice of surgery in managing RHD has been a matter of concern regarding whether to use mechanical or bioprosthetic heart valve replacements; conversely, their use is mostly decided based on the severity of complications and the age of the patients. Moreover, the use of mechanical heart valve replacements (hereafter referred to as mechanical valves) in RHD patients is supported due to the repeated reoperations required for bioprosthetic heart valve replacements

(hereafter referred to as bioprosthetic valves), which are brought on by the short lifespan of these prostheses within a short period after implantation.<sup>3</sup>

The recent improvements in mechanical valves' qualities, new design features, and the limited affordability of repeated surgeries in low- and middle-income nations like India have further boosted their usage.<sup>4-6</sup> These devices present a suitable valve replacement option for most RHD patients. However, while bioprosthetic valves have the potential disadvantage of requiring reoperation, mechanical valves also have limitations due to prolonged anticoagulation therapy-induced complications and mechanical property-induced thrombosis events.<sup>7-9</sup> Therefore, there has been ongoing discussion for decades over the best valve surgery, particularly among people in underdeveloped nations such as India. Indeed, since the beginning of valve replacement, non-thrombogenic alternatives have been recommended for patients to prevent complications such as bleeding, which can occur due to the permanent anticoagulation therapy needed following mechanical valve surgery.<sup>10</sup> Consequently, these long-term, life-threatening outcomes in individuals who received valve repair with mechanical prostheses might be suboptimal. As far as we are aware, there has been no research conducted in India on hospital deaths induced by mechanical prostheses following aortic valve replacement (AVR), mitral valve replacement (MVR), and double valve replacement (DVR). Moreover, we have not found any study that compares the utilization of mechanical valves manufactured in India with those produced abroad.

In a nutshell, this study aimed to explore the "all-cause in-hospital mortality rate" in the AVR, MVR, and DVR groups over the past five years, from 2019 to 2023, at a tertiary care facility.

## Materials and methods

By reviewing various relevant investigations, we recorded the patients' characteristics and followed the methodologies lying within the scope of our study.<sup>10-13</sup> These optimized characteristics and methods are discussed below.

### Study setting

From 2019 to 2023, demographic and relevant data were collected for 221 patients who underwent prosthetic heart valve replacement surgeries at our tertiary care hospital. Data were initially sourced from the Cardiothoracic and Vascular Surgery (CTVS) laboratory of the JN Medical College & Hospital (JNMCH), Aligarh Muslim University (India). Any missing information in the CTVS laboratory records was subsequently retrieved from individual patient files, obtained upon request from the hospital's Central Record Section. This work was granted consent to study the collected data from the CTVS department of the JNMCH and ethical approval with the approval number *IEC/JNMC/1662* from the Institutional Ethics Committee of the JNMCH (Aligarh Muslim University, Aligarh, India).

### Selection criteria

This study focused exclusively on patients who underwent AVR, MVR, or DVR, including those with pathophysiology of aortic root enlargement, pericardiectomy, or valve-related repairs (AVR with mitral valve repair, MVR with aortic valve repair, or AVR/MVR with tricuspid valve repair). Patients with concurrent procedures such as coronary artery bypass grafting, congenital heart diseases, closure of atrial septal defects, or emergency procedures were excluded. Additionally, patients with a history of stroke, cor-

onary heart disease, or thoracic aorta surgery were excluded, while hypertension and type-2 diabetes mellitus (T2DM) were the only comorbidities included in the analysis (Fig. 1).

### Interventions and procedures

All patients had intraoperative transesophageal echocardiography to determine the valves' functional and morphological features. As per the surgery to be performed, cardiopulmonary bypass was achieved by cannulating both caval veins (*i.e.*, the right atrium and ascending aorta) or individually. In all instances, a complete median sternotomy was always performed. The route of delivery and type of cardioplegic solutions, for example, warm blood or Custodiol HTK in its crystalloid form, were selected based on the interventional cardiologist's prudence. The mitral valve was mostly accessed by a standard left atriotomy, whereas the majority of aortic surgeries used a supra-coronary "hockey stick" aortotomy. The choice to replace the cardiac valves with mechanical ones was usually made by a senior surgeon in the department based on prosthesis availability at the time of surgery. Whenever possible, in patients undergoing MVR, the subvalvular apparatus was preserved, and the mitral valve's posterior leaflets were maintained in instances with minimal fibrotic involvement, particularly in the context of decreased preoperative-type left ventricular function. Alternatively, artificial polytetrafluoroethylene ropes were implanted following full excision of calcified fibrosed subvalvular apparatus. However, in all patients, AVRs were done in the supra-annular position only.

### Anticoagulation protocol

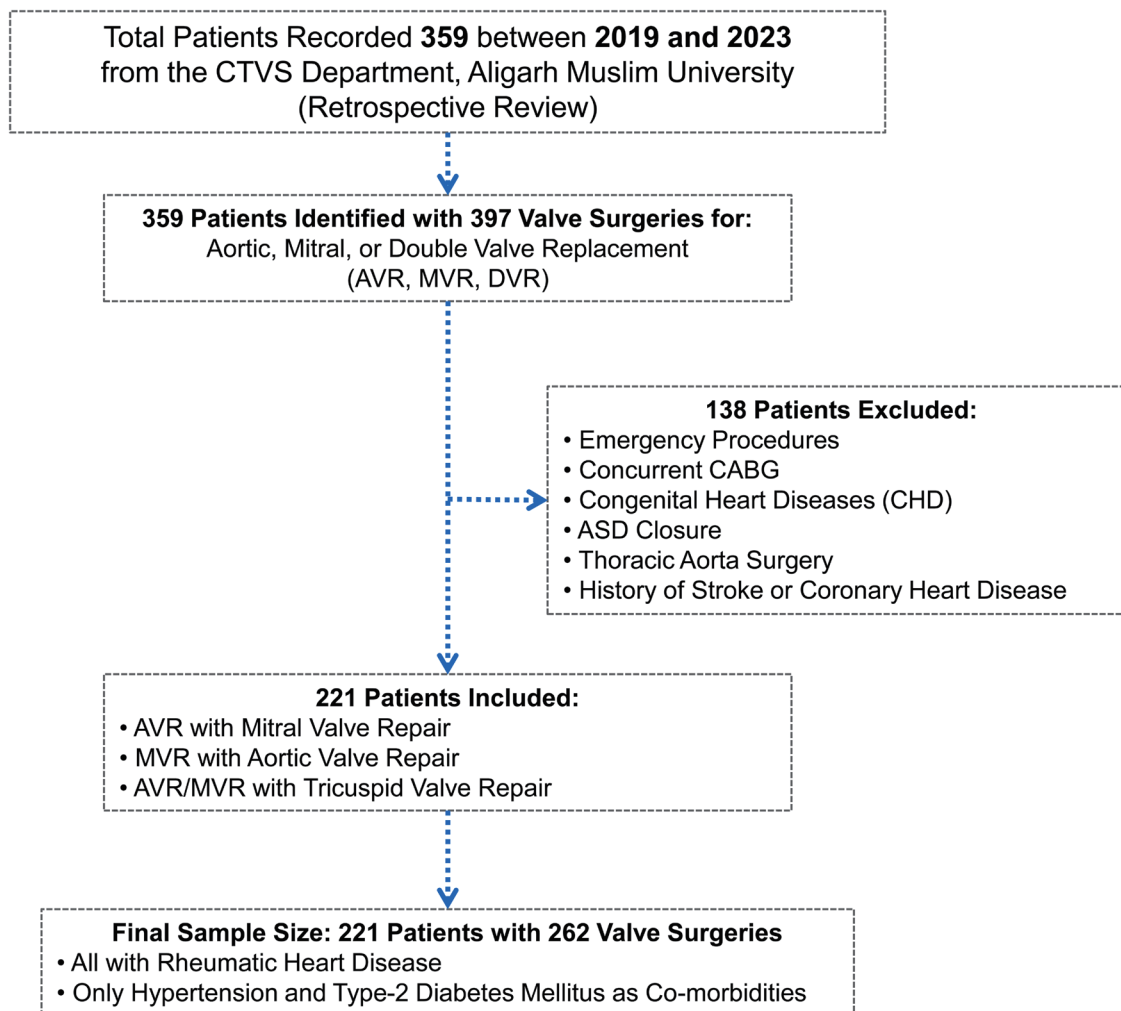
Starting on the first postoperative day, all patients were given acenocoumarol and aspirin for the rest of their lives. In adherence to established protocols governing antithrombotic therapy for patients with prosthetic heart valves,<sup>14,15</sup> the dosage of acenocoumarol was tailored to maintain a specific international normalized ratio (INR) range. Patients undergoing DVR were targeted to achieve an INR of 2.5 to 3.5, while those undergoing AVR or MVR were targeted to attain an INR of 2.0 to 3.0. Post-hospital discharge, monitoring of INR levels occurred at regular intervals of one, three, and six months within our healthcare facility, contingent upon the stability and adherence of the INR within the desired therapeutic range. Given the geographical diversity of patient origins spanning across India, individuals were advised to undergo routine INR assessments near their residential locations at a minimum frequency of once per month.

### Data collection

Data were extracted for the following parameters: patient hospital ID, name, age, gender, diagnosis, surgery type, device type, device size, device manufacturer, valve replacement date, and other important data. We included both males and females of varied ages. We only collected data on AVR, MVR, and DVR surgeries for patients with RHD. This included individuals with: (1) Mild, moderate, or severe aortic and/or mitral stenosis; (2) Mild, moderate, or severe aortic and/or mitral regurgitation; (3) Tricuspid stenosis or regurgitation along with aortic or mitral valve obstruction. The device types were either mono-leaflet or bi-leaflet.

### Study endpoint and definition of outcomes

The primary endpoint of this study was to explore the all-cause in-hospital mortality rate and complications following mechanical valve implantation in RHD patients. "*RHD patient*" is defined as a patient suffering from 'rheumatic-type heart disease,' whether



**Fig. 1. A flowchart of patient selection methodology.** This flowchart illustrates the methodology followed to screen the study's population as per the STROBE guidelines. It includes both the cohort's inclusion and exclusion criteria and the final sample size, depicted in the form of a flowchart. ASD, atrial septal defect; AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CTVS, cardiothoracic and vascular surgery; DVR, double valve replacement; MVR, mitral valve replacement; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

(1) aortic stenosis, aortic regurgitation, or both; (2) mitral stenosis, mitral regurgitation, or both; or (3) mixed valvular disorder. “All-cause in-hospital mortality” is defined as death occurring within 30 days of a patient's stay in hospital from the date of valve replacement.<sup>10,16</sup> “In-hospital complications” are defined as the causes taken into account to identify in-hospital deaths. The in-hospital complications may therefore include various illnesses, such as arrhythmias, acute renal damage, a stuck valve, etc.<sup>17</sup>

### Statistical analysis

We performed an analysis of several predictors of in-hospital mortality, including age, gender, type of RHD, and mortality causes. Continuous variables were expressed as means and analyzed by an independent Student's t-test, while categorical variables were expressed as numbers (percentages) and examined by Chi-square or Fisher's exact tests, as appropriate. Actuarial survival and the survival rates in the groups were expressed as mean  $\pm$  standard deviation. The SPSS version 29.0.2.0 (from SPSS Inc.) was used, and Kaplan–Meier analysis was applied to determine the survival

curve, whereas the log-rank test was used to estimate the differences between the obtained Kaplan–Meier analysis curves. Furthermore, a logistic regression model was also used to analyze the variables: treatment, age, gender, and company. The  $p$ -value of less than 0.05 (*i.e.*,  $p < 0.05$ ) for all statistical analyses was set as the significant value.

### Results

#### Study population

A total of 221 patients were identified and included in this work after reviewing medical records of patients who underwent mechanical valve procedures in the CTVS department over the last five years, from 1<sup>st</sup> January 2019 to 31<sup>st</sup> December 2023. All mechanical heart valve surgeries performed were divided into three groups: AVR, MVR, and DVR. The comorbidities, namely hypertension, T2DM, or both, were included. RHD can be classified as stenosis, regurgitation, or mixed obstruction of the heart valves, and there-

**Table 1.** Characteristics of the patients who underwent mechanical heart valve surgeries in the past five years

| Patients characteristics | Total (n, %)      | Male              | Female            | p-value |
|--------------------------|-------------------|-------------------|-------------------|---------|
| Number of patients       | n = 221           | n = 114 (52%)     | n = 107 (48%)     |         |
| Age (years)              |                   |                   |                   |         |
| Mean $\pm$ SDEV          | 37.50 $\pm$ 14.34 | 37.54 $\pm$ 14.41 | 37.45 $\pm$ 14.27 | 0.96    |
| Range                    | 12–72             | 12–72             | 12–65             |         |
| Operation performed      |                   |                   |                   |         |
| Aortic valve replacement | 54 (24%)          | 34 (63%)          | 20 (37%)          | 0.08    |
| Mitral valve replacement | 126 (57%)         | 58 (46%)          | 68 (54%)          | 0.23    |
| Double valve replacement | 41 (19%)          | 22 (54%)          | 19 (46%)          | 0.56    |
| Comorbidities            |                   |                   |                   |         |
| HTN                      | 9 (4%)            | 3 (33%)           | 6 (67%)           | 0.29    |
| T2DM                     | 17 (8%)           | 12 (71%)          | 5 (29%)           | 0.06    |
| HTN + T2DM               | 5 (2%)            | 3 (60%)           | 2 (40%)           | 0.65    |

HTN, hypertension; SDEV, standard deviation; T2DM, type-2 diabetes mellitus.

fore, we have specifically distributed these incidences into aortic, mitral, and mixed RHD. In this work, we only cited the data of males and females.

#### Patient characteristics

The baseline characteristics of patients include the number of patients implanted with mechanical valves, age, gender, operations performed, RHD type, and comorbidity. All included patients had RHD and ranged in age from 12 to 65 years, with an average age of  $36.11 \pm 14.84$ . In 221 patients, 262 mechanical heart valve surgeries were performed, including 54 in the AVR group (24.44%), 126 in the MVR group (57.01%), and 41 in the DVR group (18.55%). In the total of 221 patients, comorbidity complications—hypertension, T2DM, and both—were recorded at 4.07% (nine cases), 7.69% (17 cases), and 2.26% (five cases), respectively. However, there were no statistical differences between males and females for several variables ( $p > 0.05$ ), except for the higher incidence of AVR and T2DM in males. In general, the distribution of device implantation in males versus females [114 (52%): 107 (48%)] was found to be approximately equal (Table 1). Furthermore, out of 221 extracted cases, we recorded 106 cases of valve stenosis (47.96%), 77 of valve regurgitation (34.84%), and 38 cases of mixed valvular disorder (17.20%), which were further specifically distributed into aortic, mitral, or mixed RHD (Table 2).

#### Indian vs. foreign-made prostheses utilization

The extracted data of mechanical valve prostheses implanted at the CTVS department in the last five years were observed to be mostly from Indian manufacturers. Therefore, we hypothesized that analyzing the utilization of Indian-made mechanical valve prostheses would reveal their in-hospital mortality and morbidity incidences. In 221 patients, mechanical valve prosthesis utilization was distributed as follows: 95% (210/221) from Indian manufacturers—Meril Life Sciences Pvt. Ltd. and TTK Healthcare (Indian group), whereas 5% (11/221) prostheses were from foreign manufacturers—St. Jude Medical, ATS Medical, and On-X Life Technologies (Foreign group). The recorded deaths were as follows: 7.14% (15/210) mortality rate in the Indian group and 9.09% (1/11) mortality rate in the foreign group (*i.e.*, one death); nevertheless, the

logistic regression analysis showed no significant difference between the groups (Table 3).

#### In-hospital mortality rate

All-cause hospital deaths were recorded in 16 out of 221 individuals, *i.e.*, a 7.24% mortality rate following mechanical valves in a retrospective follow-up of five years. The mortality rate by individual groups was as follows: 5.55% (3/54) in AVR, 7.14% (9/126) in MVR, and 9.75% (4/41) in the DVR group. However, logistic regression showed no significant differences among all treatment groups. The  $p$ -value corresponding to AVR and MVR is greater than 0.05, which shows that there is no significant difference between AVR and DVR and between MVR and DVR, but the negative sign in the estimate of AVR and MVR covariates indicates that those who received DVR treatment are at higher risk of death (Table 3). Most of the recorded deaths (82%) were in those over 50 years of age. Moreover, the logistic regression results also indicate that patients aged above 50 are at higher risk of death following MHVR surgeries (Table 3). Ten of the 16 patients who died were female, *i.e.*, 63% of in-hospital mortality was in women from the whole cohort. In terms of regression analysis, the results (Table 3) show that there is no significant difference between males and females, but female patients are at higher risk of death.

#### Complications of in-hospital deaths

The majority of the fatalities were linked to thromboembolism ( $n = 3$ ), acute renal damage ( $n = 2$ ), congestive heart failure ( $n = 2$ ), arrhythmias ( $n = 2$ ), hemorrhage ( $n = 2$ ), mediastinal infection ( $n = 2$ ), and others ( $n = 3$ ) (see Fig. 2 and Table 2).

The hospital deaths caused by a thromboembolic event were identified in three patients. In this analysis, one patient died in the AVR group and two in the MVR group; however, no patient died in the DVR group. The in-hospital mortality rate of thromboembolism was recorded at 1.35% (3/221) in the whole population and 18.75% (3/16) among the total deaths observed in the study. Thromboembolic in-hospital mortality was found to be associated with atrial fibrillation in both groups. Acute kidney damage itself might not cause any serious fatality; however, mechanical valve-related complications can result in reduced blood flow and

**Table 2. Number of lesions and in-hospital mortality in each valve replacement group**

| Parameters                                  | AVR         | MVR         | DVR      |
|---------------------------------------------|-------------|-------------|----------|
| Number of lesions (n = 221)                 |             |             |          |
| Valve stenosis (n = 106)                    | 21          | 85          | –        |
| Valve regurgitation (n = 77)                | 31          | 46          | –        |
| Mixed valve disease (n = 38)                | –           | –           | 38       |
| Aortic stenosis + mitral stenosis           |             |             | 14       |
| Aortic regurgitation + mitral regurgitation |             |             | 6        |
| Aortic regurgitation + mitral stenosis      |             |             | 10       |
| Aortic stenosis + mitral regurgitation      |             |             | 8        |
| Total deaths (n = 16)                       | 03 (18.75%) | 09 (56.25%) | 04 (25%) |
| Gender (male:female)                        | 2:1         | 2:7         | 2:2      |
| Causes of death                             |             |             |          |
| Thromboembolism                             | 1           | 2           |          |
| Acute kidney injury                         |             | 2           |          |
| Hemorrhage                                  | 1           | 1           |          |
| Congestive heart failure                    | 1           | 1           |          |
| Ventricular tachycardia                     |             | 1           | 1        |
| Mediastinal infection                       |             | 1           | 1        |
| Stroke                                      |             |             | 1        |
| Patient-prosthesis mismatch                 |             |             | 1        |
| Unknown status                              |             | 1           |          |

AVR, aortic valve replacement; DVR, double valve replacement; MVR, mitral valve replacement.

other associated factors, which may indirectly trigger severe acute kidney damage and further lead to a patient's death. Here, we observed two deaths in the MVR group and none in the AVR and

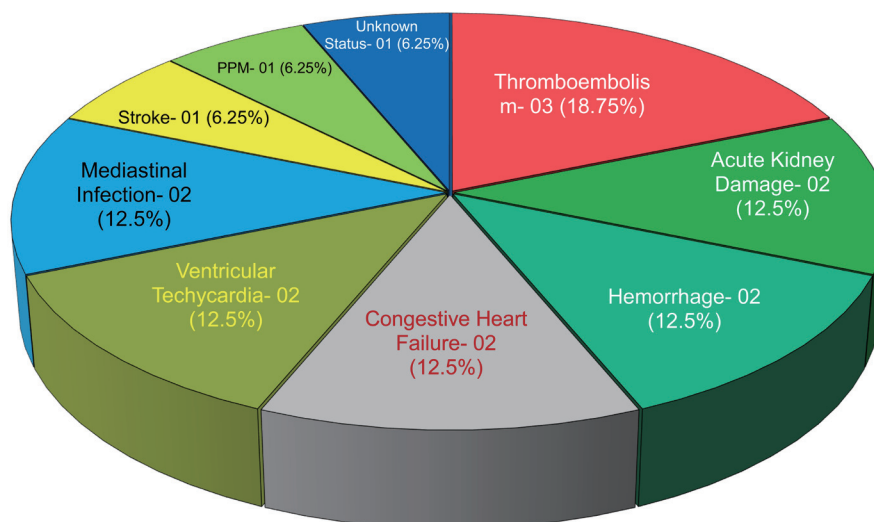
DVR groups. Hemorrhage or internal bleeding can take several forms. Two hospital deaths were recorded in our data analysis: one in the AVR group and one in the MVR group, with the known

**Table 3. Manufacturer, treatment, age, & gender variables analysis by the logistic regression model**

| Parameter    | Estimate | Std. Error | z-value | p-value |
|--------------|----------|------------|---------|---------|
| Manufacturer |          |            |         |         |
| (Intercept)  | –2.3026  | 1.0488     | –2.195  | 0.02    |
| India        | –0.2624  | 1.0825     | –0.242  | 0.80    |
| Treatment    |          |            |         |         |
| (Intercept)  | –2.2246  | 0.5263     | –4.227  | 2.37    |
| AVR          | –0.6086  | 0.7937     | –0.767  | 0.44    |
| MVR          | –0.3403  | 0.6298     | –0.540  | 0.58    |
| Age          |          |            |         |         |
| (Intercept)  | –2.3979  | 0.6030     | –3.976  | 6.99    |
| Age          | –0.1846  | 0.6681     | –0.276  | 0.78    |
| Gender       |          |            |         |         |
| (Intercept)  | –2.2721  | 0.3321     | –6.841  | 7.86    |
| Gender       | –0.6182  | 0.5350     | –1.156  | 0.24    |

Manufacture: A comparison of in-hospital mortality between the Indian-manufacturer group and the foreign-manufacturer group; Treatment: A comparison of in-hospital mortality among all three treatment groups, viz. aortic valve replacement (AVR), mitral valve replacement (MVR), and double valve replacement (DVR); Age: A comparison of in-hospital mortality between two age groups: below 50 years and 50 years or over; Gender: A comparison of in-hospital mortality between males and females. AVR, aortic valve replacement; MVR, mitral valve replacement.

Percentage Distribution of Causes of Deaths



**Fig. 2. A representation of the distribution of different causes of death in percentage.** Nine causes of in-hospital mortality were observed in the study. These events are presented as percentages, with the highest incidence being thromboembolism. Events such as acute kidney damage, hemorrhage, congestive heart failure, ventricular tachycardia, and mediastinal infections have similar mortality rates. Moreover, 6.25% of the total mortality was observed for each of patient-prosthesis mismatch (PPM) and unknown causes of death.

causes being major gastrointestinal bleeding and hemoptysis, respectively. Congestive heart failure-induced deaths were observed in two patients. These patients were chronically suffering from myocardial infarction. One death was found in the AVR group and one in the MVR group. Arrhythmia is a well-known contributor to heart disease. Among the patients with either AVR or MVR, ventricular tachycardia has been reported as a cause of sudden death in several investigations. Here, we found two deaths with ventricular tachycardia: one in the MVR group and another in the DVR group. Mediastinal infection-related deaths were also observed in two individuals: one in the MVR group and another in the DVR group.

Three deaths were due to complications other than those mentioned above. Two deaths were recorded in the DVR group: one associated with stroke and another with patient-prosthesis mismatch. Moreover, one death of unknown status was observed in the MVR group. The in-hospital mortality rate associated with other complications was the same as for thromboembolism.

#### Actuarial survival

Actuarial survival at five years was observed at  $92.8 \pm 4.8\%$  for the whole cohort and divided into groups as follows:  $94.4 \pm 4.8\%$  in AVR,  $90.2 \pm 4.9\%$  in MVR, and  $92.9 \pm 4.8\%$  in the DVR group. No significant differences ( $p > 0.05$ ) were noticed between the groups in the log-rank (Mantel–Cox) test of Kaplan–Meier analysis (Fig. 3). The mortality causes are listed in Table 2.

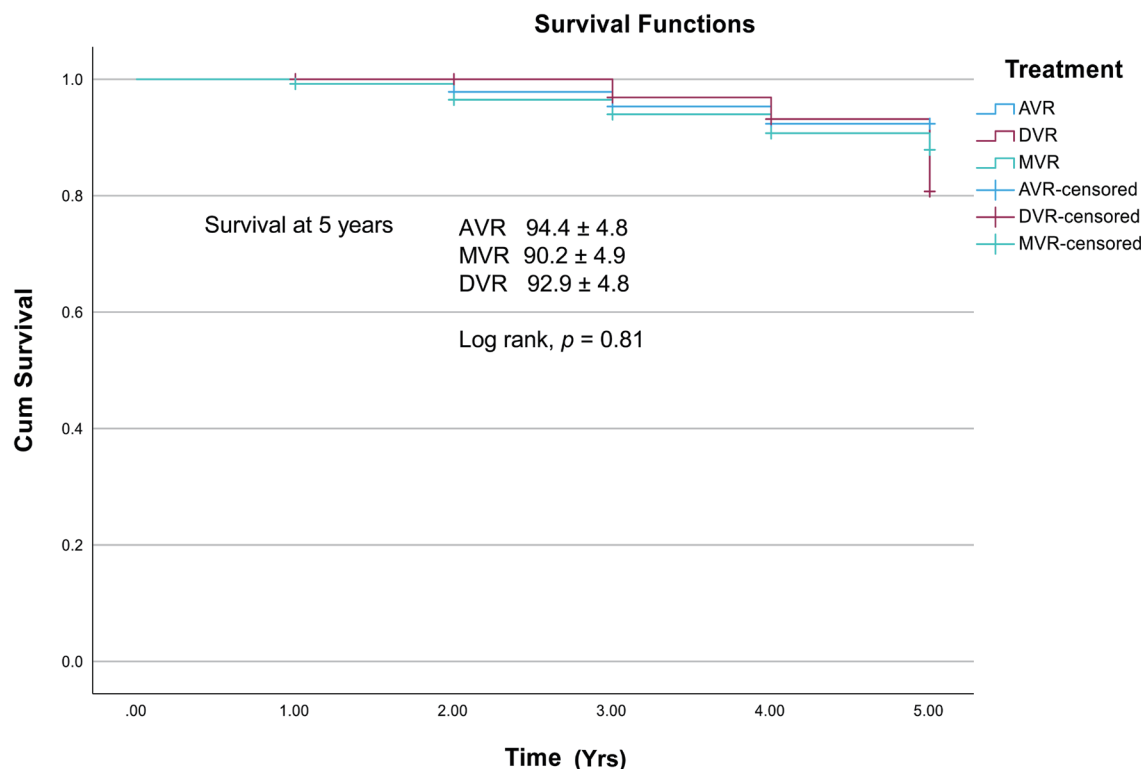
#### Discussion

The utilization of mechanical prosthetic heart valves in populations with poor compliance, particularly in low-income countries, is subject to controversy due to inadequate facilities for anticoagulation management and the presence of socio-economic disadvantages, which are associated with a heightened risk of complications related to prosthetic valve implantation.<sup>18,19</sup> To date, several inves-

tigations have been carried out to determine the survival and mortality rates of mechanical valves. Long-term outcomes following mechanical valve replacement exhibit variability across different patient cohorts and can be influenced by varying risk profiles, such as patients with a heightened predisposition to thromboembolism or those requiring anticoagulation, who are at increased risk of valve-related complications. In this study, we have also observed a higher incidence of death due to thromboembolism, which supports the above statement.

Besides, a study by Sotade *et al.*<sup>9</sup> revealed that the rates of survival and mortality vary at different age points; for example, among patients aged 55 to 64 years, mortality was similar between both valve types (*i.e.*, mechanical and bioprosthetic valves) up to 10 years but higher for bioprosthetic valves after 10–15 years. Similarly, Khan *et al.*<sup>20</sup> observed that patients undergoing mechanical valve replacement achieved freedom from all valve-related complications, with rates of  $76 \pm 2.4\%$  for MVR and  $80 \pm 1.8\%$  for the AVR group at a five-year follow-up; Svennevig *et al.*<sup>21</sup> documented survival rates of 78.6% in 816 AVR patients with mono-leaflet mechanical valves at five years; Toole *et al.*<sup>22</sup> detailed survival rates of  $84 \pm 2\%$  at five years for MVR and rates of  $81 \pm 2\%$  at five years for AVR in 945 patients with bi-leaflet mechanical valves; Mve Mvondo *et al.*<sup>10</sup> also reported an overall survival rate of  $78.7 \pm 3.3\%$  at six years, whereas survival rates for AVR, MVR, and DVR were  $89.3 \pm 4.8\%$ ,  $73.2 \pm 5.4\%$ , and  $79.3 \pm 5.8\%$ , respectively. In our study, we found overall survival rates of  $92.8 \pm 4.8\%$  for the whole cohort, divided into groups as follows:  $94.4 \pm 4.8\%$  in AVR,  $90.2 \pm 4.8\%$  in MVR, and  $92.9 \pm 4.9\%$  in the DVR group. Among the groups, no statistically significant differences in survival rates were detected. However, the survival rates were found to be significantly superior compared to the above-discussed reports. Our data on survival strength and in-hospital mortality of mechanical valve implantation may serve as a foundation for conducting future retrospective studies.

Our study indicates that patients aged above 50 may be at a



**Fig. 3. Survival functions analysis for the whole cohort and the surgical procedures associated.** Kaplan–Meier analysis revealed a survival rate of  $92.8 \pm 4.8\%$ . Furthermore, the log-rank test showed no significant differences between the individual groups, with a  $p$ -value of 0.81 (*i.e.*,  $p > 0.05$ ) at five years (Yrs). This indicates that mortality among the groups is not significantly higher or lower relative to each other. However, the logistic regression model showed that the double valve replacement (DVR) group is at a higher risk of in-hospital mortality compared to the aortic valve replacement (AVR) and mitral valve replacement (MVR) groups.

higher risk of death and that females could be more prone than males to death, as we observed 10 deaths in females only, out of sixteen. Furthermore, the statistical analysis indicates that those who underwent DVR treatment are at higher risk of death than AVR and MVR. These inferences support the fact that patient-specific factors such as age, gender, surgery type, and underlying medical conditions play crucial roles in developing risks for events such as thrombosis, bleeding, and heart failure. Additionally, we propose that the stability of our healthcare delivery factors, such as timely diagnosis, appropriate management of minor mechanical valve-associated complications, and recommendation of a referenced anticoagulant therapy, could also have contributed significantly to the overall enhanced survival from mechanical valve implantation.

Analyzing a dataset exclusively composed of Indian-manufactured valves, our findings strongly suggest that these valves are of comparable quality to those produced internationally,<sup>23–25</sup> a conclusion further reinforced by the statistical logistic regression results. Moreover, the results revealed that the prostheses implanted from Indian manufacturers have a superior survival rate compared to previously reported data in India, as well as being close to data or reports from abroad.<sup>26–31</sup> This observation led us to conclude that mechanical heart valve replacements from Indian manufacturers are as safe as those from foreign manufacturers; however, the optimization of long-term patient outcomes with mechanical heart valve replacements still presents a complex challenge. In our investigation, the valve-specific rates of death and survival were found to be aligned with findings from comparable studies such

as Mve Mvondo *et al.*,<sup>10</sup> Svennevig *et al.*,<sup>21</sup> and Toole *et al.*<sup>22</sup> The principal drawbacks associated with mechanical valves observed during the study include, in particular, the perpetual risk of thromboembolism and heart failure. Despite numerous studies reporting acceptable durability of mechanical valves, we suggest that these enduring risks remain significant.<sup>26,27</sup> Our data also suggest that individuals implanted with mechanical heart valves at our hospital may experience an increased life expectancy, as around 82% of deaths were recorded in patients aged 50 or over. India undergoes numerous valve replacement surgeries each year; yet, we think the quest for an optimal prosthetic heart valve persists.

### Future directions

The study highlights the need for further research to optimize post-implantation outcomes of prosthetic heart valves, particularly mechanical valves, in low- and middle-income countries like India. Future investigations should focus on expanding the sample size and extending follow-up periods to better assess long-term survival and valve-related complications. A multi-center, prospective/retrospective study design would enhance the generalizability of findings and provide more accurate data on mortality trends, particularly among high-risk groups such as elderly patients and females. Researchers should also explore the impact of socioeconomic factors on postoperative outcomes, including access to anticoagulation therapy and adherence to INR monitoring, which are critical for preventing thromboembolic events. Moreover, com-

parative studies between Indian and foreign-manufactured valves with larger cohorts are warranted to validate the current findings and ensure the reliability of locally produced prostheses. Lastly, integrating patient-reported outcomes and quality-of-life metrics into future research will provide a holistic view of the safety and long-term impact of prosthetic heart valves. Addressing these gaps will not only refine clinical practices but also inform policy decisions to enhance cardiac care in resource-limited settings.

### Limitations

A retrospective observational study may have limitations such as reliance on incomplete or inaccurate records, lack of control over confounding variables, and selection bias can also occur if cohorts are not representative. Therefore, the retrospective nature of this study may hinder the final inferences, and such factors may compromise the validity and generalizability of our findings. Specifically, the relatively small sample size and short duration of patient monitoring in this study might hinder the ability to draw definitive conclusions regarding mortality rate, actuarial survival, and long-term outcomes. We had a small proportion of valves from foreign-made prostheses, which can also affect the study results and comparisons between Indian- and foreign-made prosthetic heart valves.

### Conclusions

At our tertiary care center, we observed a 7.24% mortality rate over the past five years following prosthetic heart valve implantation across all age groups. While trends indicated potentially higher mortality rates among female and elderly patients, these differences were not statistically significant. The in-hospital mortality rate of 7.24% is consistent with studies conducted in India but exceeds those reported in Western data. This elevated mortality in Indian patients could be attributed to delayed surgeries, which often result in established right heart failure and organ dysfunction. Furthermore, improving long-term outcomes, such as reducing thromboembolism, in patients with mechanical valves presents a continuing challenge. To improve long-term patient outcomes, it is crucial to gather comprehensive data on delayed valve-related complications and mortality. Although this study is limited by its small sample size and single-arm design, its findings can provide valuable insights for designing similar single-center, single-arm, long-term retrospective studies.

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### Conflict of interest

The authors declare no conflict of interest.

### Author contributions

Study concept and design (JA, MAH), acquisition of data, analysis

and interpretation of data, drafting of the manuscript (JA), critical revision of the manuscript for important intellectual content (MAH), final review and editing (AH, MS), study supervision (SZR, MAH). All authors have made significant contributions to this study and have approved the final manuscript.

### Ethical statement

This work was granted consent to study the collected data from the Cardiothoracic and Vascular Surgery department of the JN Medical College & Hospital and ethical approval with the approval number *IECJNMC/1662* from the Institutional Ethics Committee of the JN Medical College & Hospital (Aligarh Muslim University, Aligarh, India). This study was conducted in accordance with the guidelines of the Declaration of Helsinki (as revised in 2024). The individual informed consent for this retrospective analysis was waived.

### Data sharing statement

No additional data are available.

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