

Maternal Health Outcomes in Nepalese Women After Mitral Valve Replacement

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ABSTRACT

Background: The effects of anticoagulation on maternal health in patients with prosthetic valves remain understudied. Our study aims to assess maternal health post-mitral valve replacement (MVR), pregnancy-related complications, maternal mortality, coagulation issues, and fetal and neonatal outcomes post-MVR.

Methods: This exploratory retrospective study, conducted from 2017-2020, included female patients of reproductive age who underwent MVR. Eligible participants were identified from hospital records, and pregnancy-related maternal outcomes were ascertained through review of medical records and a single cross-sectional telephone follow-up conducted between June and August 2023. Data on childbirth, abortion, anticoagulation management, and related complications were collected. Descriptive statistics were used for analysis.

Results: Of 474 female patients of childbearing age who underwent MVR, 380 responded to our survey. Of these, 18 cases (4.73%) involved pregnancy post-MVR. All pregnant patients were on anticoagulant therapy during pregnancy, with no maternal deaths reported. However, one patient experienced heart failure post-delivery. Bleeding was the most common complication, occurring in 5/18 pregnancies (27.7%). Seven pregnancies resulted in live births (38.8%), with one low birth weight infant. There were no congenital anomalies, but there was one intrauterine fetal death at 7 months and 2 spontaneous abortions. Seven pregnancies were electively terminated, though the reasons were not studied. One pregnancy was ongoing at the time of the study. All but one delivery occurred under medical supervision, with most patients following a warfarin-to-heparin regimen.

Conclusions: In this cohort, 4.73% of women experienced pregnancies post-MVR, with anticoagulation posing significant challenges. The low rate of maternal and fetal complications suggests a need for further research, particularly regarding the high rate of elective terminations.

Keywords: Maternal health; Nepalese women; outcomes.

INTRODUCTION

Nepal bears a significant burden of rheumatic heart disease (RHD), representing one of the highest documented rates globally, with an estimated prevalence of 1.1 per 1,000 children according to recent studies.¹ This condition predominantly affects children and young adults, necessitating interventions such as MVR to mitigate its life-threatening complications. Despite advancements in MVR and postoperative care, the effects of lifelong anticoagulation on maternal health

are not well understood. Women face unique challenges related to fertility, pregnancy, and heightened risks of bleeding and thrombosis due to physiological changes. Understanding these specific outcomes is vital for improving clinical management and support for this high-risk group.

Our study investigates maternal health outcomes in Nepalese women who underwent MVR, focusing on pregnancy-related complications, maternal mortality, and anticoagulation management during pregnancy.

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The findings aim to improve clinical guidelines and care for women with prosthetic heart valves during their reproductive years.

METHODS

Although patients were identified retrospectively as a cohort based on prior exposure to MVR, pregnancy outcomes were assessed at a single follow-up time point rather than through continuous longitudinal follow-up. Therefore, the study represents a retrospective cohort with cross-sectional outcome to exploratory retrospective study ascertainment outcome ascertainment.

Data were analyzed using descriptive statistics. Categorical variables were summarized as frequencies and percentages, and continuous variables as means with standard deviations or medians with ranges, as appropriate. Given the exploratory nature of the study and the limited sample size, no formal sample size calculation or inferential statistical testing was performed. This was an exploratory retrospective study conducted at a tertiary cardiac referral center in Nepal. The study retrospectively identified women who had undergone MVR during the period from follow-up: June-August 2023 and assessed maternal outcomes related to subsequent pregnancies.

Each eligible patient was contacted via telephone to participate in a structured interview by trained healthcare professionals. The interview protocol was standardized to ensure consistency in data collection. Medical records provided baseline clinical data, while telephone interviews gathered follow-up information on pregnancy and maternal health outcomes. The structured interview included questions on pregnancy occurrences, complications, and anticoagulation therapy adherence.

Women of reproductive age who underwent MVR during the specified period were identified from hospital surgical records. Participants who reported at least one pregnancy following MVR were included in the analysis. Patients who could not be contacted after two telephone attempts were excluded from the analysis.

Baseline clinical and surgical data were obtained retrospectively from hospital records. Maternal and pregnancy outcomes were assessed through a single-time, cross-sectional telephone interview conducted between June-August 2023. Information collected included pregnancy occurrence, pregnancy outcomes

(live birth, elective termination, or miscarriage), and maternal complications during pregnancy. The study protocol was approved by the Institutional Review Committee (IRC Number: 14-2021) and informed consent was obtained from each participant before conducting the interviews. Participants were assured of the confidentiality of their data and their right to withdraw from the study at any time. Whenever a cardiac surgical team is consulted for pregnancy and anticoagulation management, we suggest the anticoagulation regimen mentioned in the **Table 1** for all our patients.

Table 1. Anticoagulation Regimen for Pregnant Patients.

Pre-pregnancy Planning	1 st Trimester	2 nd and 3 rd Trimester	Peripartum
➤ Define Risk Profile ➤ Discuss the benefit of bioprosthetic valves if desiring pregnancy ➤ Eliminate modifiable risk factors, Stop Smoking	Warfarin if dose < 5 mg or, Dose adjusted LMWH	Warfarin	Dose adjusted LMWH or IV UFH

RESULTS

Out of the initial cohort of 474 female patients of reproductive age who underwent MVR, all patients were contacted for the telephonic survey on the telephone number/telephone numbers registered in the hospital records. If the patient did not wish to participate, it was documented as not participating. A maximum of two telephone attempts was made for each patient. Ninety-four patients could not be contacted, including those with incorrect or inactive telephone numbers. Consequently, responses from 380 patients were obtained and included in the final analysis (Figure 1).

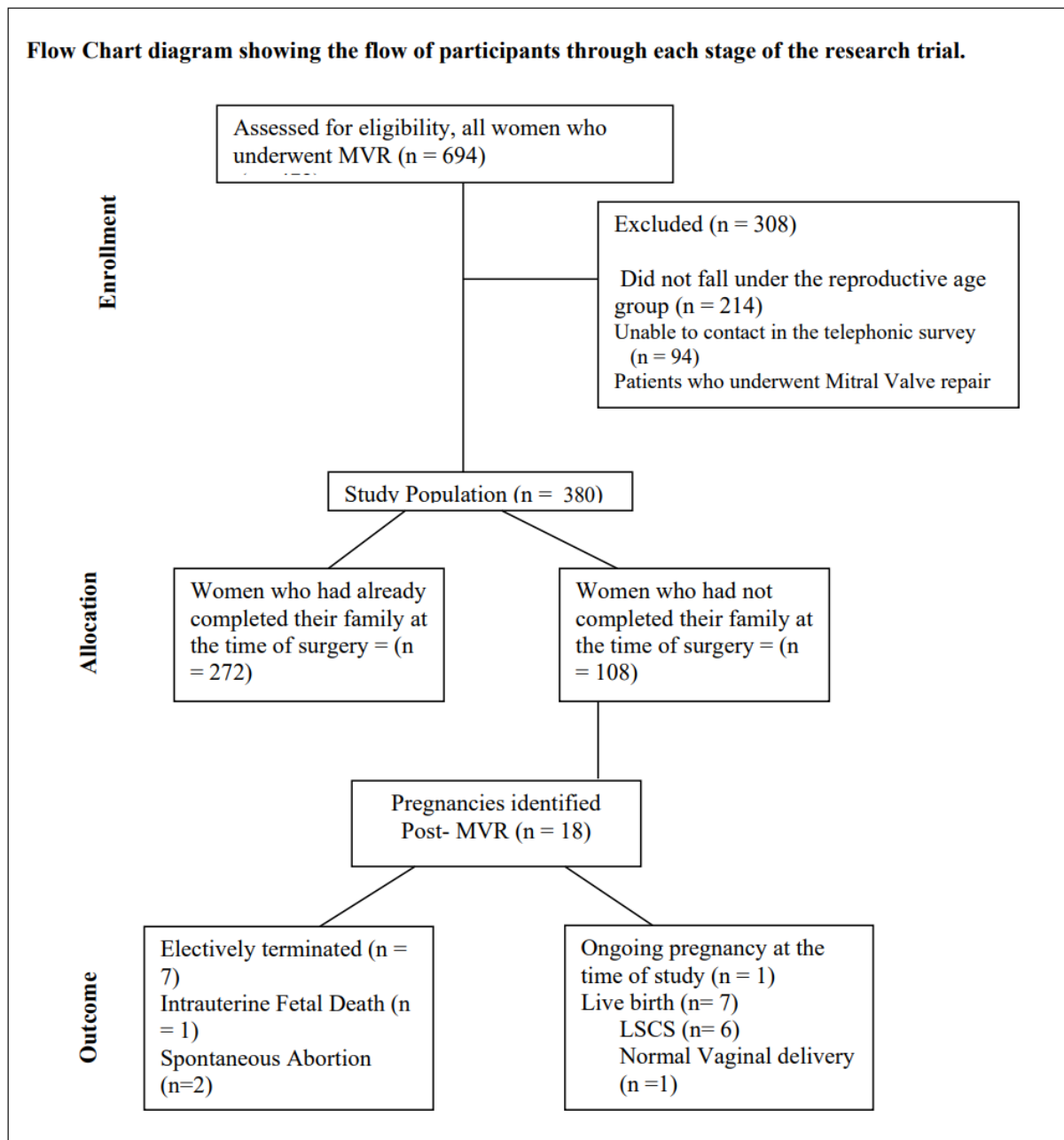


Figure 1. Flow Chart diagram showing the flow of participants through each stage of the research trial.

The baseline demographic and clinical characteristics of the participants are summarized in Table 2. The mean age of participants was 31.72 ± 14.28 years, with the majority being married (371, 97.6%). The duration of follow-up ranged from 4 to 6 years, depending on the year of MVR. At the time of follow-up, 151 patients had approximately 6 years of follow-up, 121 had 5 years, and 108 had 4 years. The distribution of patients undergoing MVR through different years, according to the type of operation performed and the participants' preoperative NYHA grade classification are shown in figure 2, figure 3 and figure 4. Educational backgrounds varied, with 1 participant being illiterate, 66 having completed grade 10 or less, and 313 having education above the sSchool Leaving Certificate (SLC). Among the respondents, 18 pregnancies were identified post-MVR. Seven of these pregnancies were electively terminated, although the reasons behind the high termination rate were not studied in this analysis. At the time

of the survey, one pregnancy was ongoing. Pregnancy outcomes included one case of intrauterine fetal death at 7 months of gestation and two cases of spontaneous abortion. Elective lower segment cesarean section (LSCS) was performed in six cases, while one participant delivered vaginally. The most frequent pregnancy complication reported was bleeding, observed in 5 out of 18 pregnancies.

Table 2. Patients' Demographics. (n=380)

Demographic Data

Mean Age	31.72±14.28 years
Married at the time of surgery	371 (97.6%)
Educational Background	
Illiterate	1
Completed Grade 10 or less	66
Education Above School leaving Certificate	313

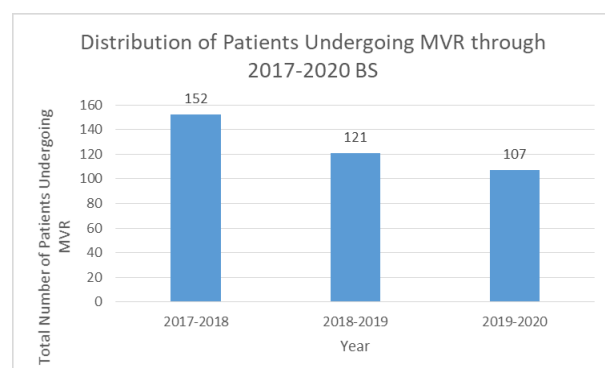


Figure 2. Distribution of patients undergoing MVR through different years.

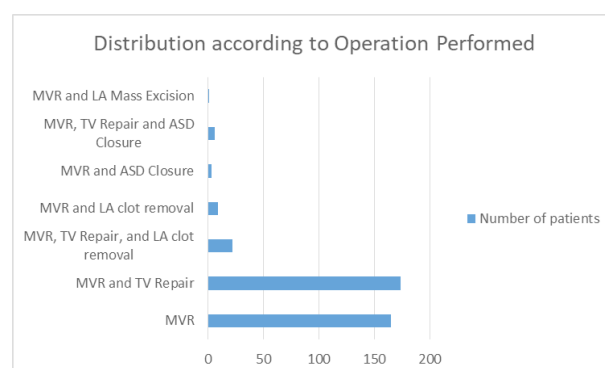


Figure 3. Distribution according to Operation Performed.

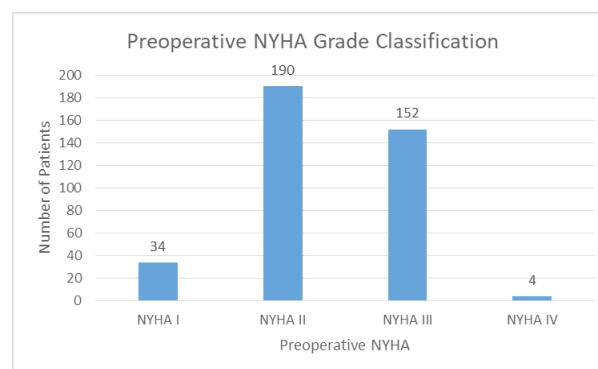


Figure 4. Preoperative NYHA Grade Classification.

Regarding maternal health, one participant developed heart failure during pregnancy, characterized by a left ventricular ejection fraction (LVEF) of 35% and mild tricuspid regurgitation (TR). She underwent emergency cesarean delivery and delivered a low-birth-weight baby. A significant number of women experienced complications during pregnancy, including 27.8% experiencing significant bleeding, however, interestingly there was no thromboembolic event in any of these 18 patients. Anticoagulation therapy consisted predominantly of a warfarin-to-heparin regimen during pregnancy. There was 94.4% (17/18) patient adherence to this anticoagulation regimen, except for one participant who successfully delivered a healthy term baby vaginally without cardio-obstetric team supervision. Detailed summary of the patients' pregnancy outcomes are presented in Table 3.

Table 3. Detailed Summary of the Patients' Pregnancy Outcomes.

Total Number of Pregnancies	18
Live Birth	7
Elective lower segment cesarean section (LSCS)	6
Normal Vaginal Delivery	1
Ongoing pregnancies at the time of study	1
Elective Terminations	7 (39%)
Intrauterine Fetal Death	1 (5.5%)
Spontaneous Abortion	2 (11%)
Maternal Complications	
Thromboembolic events	0
Bleeding Complications	5 (27.8%)
Heart Failure	1 (5.5%)

DISCUSSION

Our small cohort highlights the maternal health challenges encountered by women who become pregnant after MVR, a critical intervention for managing RHD, which remains highly prevalent in Nepal. These preliminary findings suggest that pregnancy following MVR is associated with substantial maternal risks, particularly related to anticoagulation management. However, given the limited number of observed pregnancies, the findings should be interpreted cautiously.

Among 380 respondents, we identified 18 pregnancies post-MVR, highlighting the reproductive potential and desires of women despite their cardiac condition. However, the high rate of elective pregnancy terminations (39%) observed in this small cohort raises important considerations regarding family planning and perceived maternal risk.^{2,3} Although the exact medical indications for these terminations were beyond the scope of this study, patients predominantly cited presumed high risks associated with continuing pregnancies post-MVR as their rationale. These preliminary observations suggest that reproductive decisions may be influenced more by perceived or anticipated risks than by individualized medical assessment. This finding points toward a potential gap in patient education and counseling regarding pregnancy feasibility after valve surgery. Given that, with proper management, successful pregnancies are attainable for women with mechanical heart valves, it is imperative to enhance preconception counseling. A multidisciplinary approach involving cardiologists and obstetricians can provide comprehensive guidance, ensuring patients make informed decisions based on accurate risk assessments.

Complications such as bleeding (observed in 5 cases) and spontaneous abortions (2 cases) underscore the delicate balance required in managing anticoagulation therapy during pregnancy. These findings are consistent with previous studies that highlight the complexities of managing pregnancy in women with mechanical heart valves. Warfarin, while effective in preventing thromboembolic events in these patients, poses significant risks to the fetus, including amplified microhemorrhages due to low fetal vitamin K-dependent clotting factors. A meta-analysis of 2113 pregnancies reported a 33% fetal demise rate among women who used warfarin throughout pregnancy, with the rate rising to 63% for those on high-dose warfarin (>5 mg/day).⁴ In our study, two patients experienced a spontaneous abortion. However, our study provides preliminary data from a low-resource setting such as Nepal, where

healthcare access and adherence to medical protocols may present additional challenges.

One participant developed heart failure during pregnancy, highlighting the ongoing cardiovascular risks post-MVR. Although this occurred infrequently in our cohort, it underscores the importance of close monitoring and multidisciplinary care involving cardiologists and obstetricians to optimize maternal outcomes.⁵ Such cases emphasize the critical need for tailored anticoagulation strategies and vigilant surveillance throughout pregnancy to mitigate adverse maternal and fetal outcomes.

The majority of participants (17/18) in our study were managed on a warfarin-to-heparin regimen during pregnancy (Table 1), consistent with current guidelines aimed at minimizing fetal exposure to teratogenic effects. The successful term vaginal delivery in one participant suggests the feasibility of non-surgical delivery methods under careful supervision, although elective cesarean sections were predominant. These findings should be interpreted cautiously given the small number of cases. This underscores the complexity of managing anticoagulation therapy and delivery methods in this high-risk population.

Managing anticoagulation therapy during pregnancy, especially for women with mechanical heart valves, presents significant challenges.⁶ Warfarin, though effective, poses teratogenic risks, necessitating a switch to heparin around the 6th week of gestation. However, heparin requires careful monitoring due to potential suboptimal anticoagulation, and the timing of transitions between anticoagulants is critical to balance maternal and fetal risks. Besides management during the antepartum period, timing and mode of delivery should be decided upon jointly by the obstetrician, cardiologist, and obstetric anesthesiologist. The single successful vaginal delivery observed in this study suggests feasibility in carefully selected circumstances.⁷⁻¹⁰

No thromboembolic events were observed among the 18 pregnancies in this cohort. While this may reflect the high reported adherence to anticoagulation therapy (94.4%), the limited sample size restricts the study's power to detect less common complications. Bleeding complications occurred in 27.8% of cases, a rate slightly higher than that reported in some previous studies, where bleeding is a recognized trade-off of anticoagulation therapy.¹¹ These findings underscore the importance of patient education, close monitoring, and the need for further research to optimize anticoagulation strategies

during pregnancy. Larger studies are required to better balance thromboembolic and bleeding risks in this population.

Educational attainment and marital status were significant demographic factors among participants, potentially influencing healthcare decision-making and adherence to medical recommendations. These factors highlight the need for tailored patient education and support programs to enhance compliance with anticoagulation therapy and prenatal care guidelines.^{11,12}

In Nepal, as of the most recent census data from the National Population and Housing Census (2021), the literacy rate for women in Nepal stands at approximately 69.4%. In contrast, our study shows an even higher level of educational attainment among participants, with only 1 participant identified as illiterate. In the general population, many women complete only up to grade 10 or less. Our study finds that 66 participants fall into this category, which may be reflective of national trends. One of the most striking differences is seen in the proportion of women with education above the SLC level. Nationally, a smaller percentage of women pursue higher education due to socioeconomic barriers, early marriage, and cultural expectations. In our study, however, 313 participants have education above the SLC level, which is significantly higher than the national average. This finding may reflect that women with higher educational attainment are more likely to access and participate in specialized healthcare services, such as mitral valve replacement, or it could indicate a regional or demographic bias in our sample. The comparison reveals that the participants in our study generally have higher educational attainment compared to the broader population of women in Nepal. This difference could indicate that education is a factor associated with access to or interest in healthcare services like mitral valve replacement.

This study has several important limitations. First, the small number of observed pregnancies limits the statistical power to detect less common maternal complications and restricts the generalizability of the findings. Second, pregnancy outcomes were assessed through a single cross-sectional telephone follow-up, which introduces the possibility of recall bias and selection bias, as outcomes were self-reported and dependent on participant availability and willingness to respond. Third, a high proportion of pregnancies resulted in elective termination; however, the underlying reasons for these decisions were not systematically explored. This represents a significant limitation, as it affects

interpretation of pregnancy outcomes and highlights an important gap in patient counseling and shared decision-making that warrants further investigation. Finally, the retrospective design and reliance on existing records limited the availability of detailed clinical variables, including anticoagulation adherence, and socioeconomic factors, which may influence maternal outcomes.

CONCLUSIONS

In conclusion, our study highlights maternal outcomes post-MVR for rheumatic heart disease, emphasizing the importance of anticoagulation management during pregnancy. Despite the small sample size, the observed pregnancy outcomes demonstrate that women with MVR may achieve successful pregnancies with careful medical supervision. While our study provides important preliminary data, further research is needed to fully understand the well-being and future motherhood prospects of these women.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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