

## Research Article

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## Pregnancy Outcomes in Patients with Prosthetic Heart Valves in Saudi Arabia

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### ABSTRACT

**Background:** Pregnancies in women with heart prostheses are high-risk pregnancies with increased maternal and fetal adverse outcomes. Advances in prosthetic heart valve design and anticoagulation have improved these outcomes over the past decades.

**Objectives:** To study the pregnancy outcomes in pregnancies with heart prostheses and to compare these outcomes between mechanical and biosynthetic heart prostheses in Saudi patients.

**Methods:** In this single centered retrospective study conducted at King Saud Medical City (KSUMC) between January 2011 and February 2020, we have reviewed all pregnant women's heart prostheses. Fetal and maternal data were obtained, and outcomes were compared between pregnancies with mechanical heart prostheses and bioprostheses.

**Results:** A total of 111 pregnancies were reviewed. A total of 51.4% of pregnancies had bioprostheses, 48.6% had mechanical prostheses, and 64.0% of participants were obese. The majority of the participants had a parity in the range of 2-9 (N=107, 96.4%). The most frequent type of rheumatic heart disease was mitral regurgitation (N=49, 44.1%), followed by mitral stenosis (N=32, 28.8%). There was no maternal mortality and no structural valve failure. There was a high rate of hospital admission in both groups, up to 55% of pregnancies. The rates of abortion, postpartum hemorrhage and transfusions were higher than those in general pregnancies; however, there was no difference in maternal and fetal complications between the two types of prostheses, i.e., bioprostheses and mechanical.

**Conclusion:** Although women with prosthetic heart valves have higher rates of adverse outcomes, they generally tolerate pregnancy well. There was no difference in adverse outcomes between bioprosthetic and mechanical prostheses.

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### Introduction

Valvular heart disease is the most common form of cardiovascular disease seen during pregnancy in developed countries, and it is one of the major causes of non-obstetric causes of maternal death (2.4%) worldwide [1-4].

Congenital heart disease is the leading cause of valvular heart disease in developed countries, while rheumatic heart disease is the main cause in developing countries [5,6]. Valvular damage starts following untreated or undertreated streptococcal throat or skin (scarlet fever) infection. It is the most commonly acquired heart disease in people under age 25. The global prevalence of Rheumatic Heart Disease (RHD) is 1%, and the disease is twice as common in women than men, particularly in women of childbearing age [5,7].

In Saudi Arabia, previous data showed that valvular heart disease was present, either as a single valve involvement or in combination, in 76% of pregnant patients with heart disease, and rheumatic heart disease was the main cause of valvular heart disease in 75.9% [8,9].

There are various types of prosthetic heart valves that can replace the diseased native valve. The two main types are bioprosthetic (tissue) and mechanical. Both bioprosthetic and mechanical valves are associated with many complications. Several small studies have identified that pregnancies in women with prosthetic heart valves are associated with heart failure, thrombosis, bleeding and an increased frequency of complicated pregnancy, low birth weight, and maternal and neonatal mortality. Women with mechanical valves have a higher complication rate, including an increase in both maternal and fetal events, and studies indicate that asymptomatic women with prosthetic heart valves usually tolerate the physiological burden of pregnancy. Managing such patients is challenging and continues to change with new surgical advances, and the use of anticoagulants in pregnancy and postpartum improves outcomes in such patients [10-15].

The objective of our study was to assess the outcomes of pregnancy in women with prosthetic heart valve(s) in our setting and to compare these outcomes between pregnant women with mechanical and bioprosthetic heart prostheses.

### Materials and Methods

This study is a retrospective study conducted at King Saud Medical City (KSUMC) between January 2011 and February 2020. All pregnant women with rheumatic heart disease who underwent heart valve replacement were reviewed. Information retrieved from medical records included demographic data, indication for and date of valve replacement, type of valve replacement, valve number, site, pregnancy outcome including maternal/fetal mortality and morbidity during pregnancy including the need for hospitalization or CCU admission. Data regarding any thromboembolic events was included.

All of our participants received anticoagulant prophylaxis during pregnancy and postpartum, and all patients were managed by a multidisciplinary team of obstetricians, cardiologists, and hematologists.

Descriptive statistics of the patient's characteristics were performed using frequencies and percentages for categorical variables and means with standard deviations for numerical variables. Chi-square or Fischer's exact test was used to compare the type of valve across types of heart valve disease, delivery outcome, and delivery complications. SPSS software version 28 was used for the statistical analysis, and a P value < 0.05 was considered significant.

Ethical approval for the conduct of the study was obtained from the Research Ethics Committee of Kind Saud University.

### Results

In the study period, there were approximately 18,000 pregnancies; 744 (4.13%) pregnancies had heart diseases, of which 149 pregnancies had rheumatic heart disease, and 111 pregnancies in 66 women had prosthetic valves. Regarding types of heart valve disease, 19.8% of the patients had aortic regurgitation, 32.4% of them had mitral stenosis, 59.5% of the patients had mitral regurgitation, only 0.9% of them had tricuspid regurgitation, and 4.5% of them had aortic stenosis. A total of 51.4% of patients had bioprosthetic valves, and 54 (48.6%) of patients had mechanical prosthetic valves. The mean age of the study participants was  $40.11 \pm 5.41$  years. A total of 64.0% of women were obese. The majority of the women were multipara, with parity in the range of 2-9 (N=107, 96.4%), and the mean age of valve replacement surgery was 16.8 years of age (Table 1).

Table 1: Patient Characteristics (N=111)

		N	%
BMI	Underweight	3	2.7
	Normal	22	19.8
	Overweight	15	13.5
	Obese	71	64.0
Age, Mean (SD)		40.1 (5.4)	
Types of Heart Valve Disease (multiple lesions may be present)	Aortic Regurgitation	22	19.8
	Mitral stenosis	36	32.4
	Mitral Regurgitation	66	59.5
	Tricuspid Regurgitation	1	0.9
	Aortic Stenosis	5	4.5
Type of Valve	Bioprosthetic	57	51.4
	Mechanical	54	48.6
Age at Valve Operation (for 50 Patients), Mean (SD)		16.8 (6.7)	

The mean gestational age at delivery was 38 weeks as shown in Table 2. Comparison of maternal outcomes between the two types of prosthetic valves. There was no maternal mortality in either group or structural valve failure. The rate of operative delivery (cesarean section and instrumental delivery) was approximately 20%, which was similar in both groups and comparable to our hospital rate. Almost 55% of patients needed hospital admission during their pregnancy, and there was only one CCU admission. Hospital admission, blood transfusion, and thrombosis were similar among both groups.

**Table 2: Delivery Outcomes and Maternal Complications of Pregnancies in Patients with Prosthetic Valves**

	Type of Valve			
	Bioprosthetic N=57	Mechanical N=54	Total	P value
	N (%)	N (%)	N (%)	
Hospital Admission During Pregnancy	29 (50.9%)	33 (61.1%)	62 (55.9%)	0.278
Operative Delivery	14 (25%)	8 (14.8)	22 (19.8%)	0.228
CCU Admission	1 (1.8%)	0 (0.0%)	1 (0.9%)	>0.999
Transfusion	7 (12.3%)	6 (11.3%)	13 (11.8%)	0.876
Thrombosis	0 (0%)	1 (1.9%)	1 (0.9%)	0.482
Delivery Complications	12 (21.1%)	7 (12.9%)	19 (17.3%)	0.227
Postpartum Hemorrhage	4 (7.0%)	4 (7.4%)	8 (7.2%)	>0.999

The fetal outcome is shown in table 3. both groups have similar rates of spontaneous abortion and intrauterine fetal death (fetal demise after 20 weeks) were high in both groups compared to the reported rates in general pregnant women, 28% and 4.5%, respectively. Although it was not significant, the trends of spontaneous abortion and IUFD were higher in patients with mechanical heart prostheses.

**Table 3: Fetal Outcomes in Patients with Prosthetic Valves**

	Type of Valve			
	Bioprosthetic N=57	Mechanical N=54	Total	P value
	N (%)	N (%)	N (%)	
Abortion	13 (22.8%)	19 (35%)	32 (28.8%)	0.230
Preterm	4 (8.2%)	6 (13.6%)	10 (10.8%)	0.395
NICU Admission	0 (0.0%)	3 (5.7%)	3 (2.7%)	0.109
IUFD	1 (1.7%)	4 (7.4%)	5 (4.5%)	0.086
Neonatal death	1 (1.7%)	0	1 (1.7)	>0.999
IUGR	1 (1.7%)	1 (1.8%)	2 (1.8%)	>0.999

There was no significant difference in pregnancy outcomes between different heart valve diseases as shown in Table 4.

**Table 4: Results of the Chi-Square Test to Test the Association between the Study Variables and the Type of Heart Valve Disease**

Type RHD		Aortic Regurgitation	Mitral Stenosis	Mitral Regurgitation	Combined Mitral and Tricuspid regurgitation	Combined Mitral and Aortic stenosis	Combined AR with MS	Combined AR with MR	Combined MS and MR	Chi-square P Value
Mode of delivery	VD	6	25	42	0	1	1	13	1	0.042
	IVD	1	1	3	0	0	0	0	0	
	C/S	0	6	4	1	4	0	1	1	
Transfusion		1	3	4	1	2	0	1	1	0.146
CCU admission		0	1	0	0	0	0	0	0	0.159
Thrombosis		1	0	0	0	0	0	0	0	0.58
Abortion		3	11	10	1	2	1	3	1	0.821
NICU admission		0	3	2	0	0	0	1	0	0.349
IUFD		0	1	3	0	0	0	1	0	0.717
Neonatal death		0	1	1	0	0	0	0	0	0.8
IUGR		0	1	2	0	0	0	1	0	0.716

## Discussion

The first successful replacement of the heart valve in humans was reported in 1960. Since then, Prosthetic Heart Valves (PHVs) have been developed into remarkably useful devices [16,17]. The improvement in the management of women with heart prostheses has contributed to an increase in the number of pregnant women with valvular heart disease. Maternal and fetal care of such women is challenging and evolving. Previous published data on the outcome of pregnancies in women with prosthetic heart valves showed that there are increases in mortality and morbidity among these patients. The maternal mortality was 4% in earlier reports [18]. Later data reported a lower mortality rate of 2-3% [12,19]. The WHO reported a maternal mortality rate in the general population from developed countries of lower than 0.1%. The mortality risk was higher in women with mechanical valves, and the most commonly reported cause in these cases was thrombosis of valve prostheses followed by bleeding and endocarditis [20]. In our series, there was no mortality, and the NYHA class was not documented for our patients. All patients received anticoagulants during pregnancy, and the indication for anticoagulation in the bioprostheses was mostly related to high BMI. The other indication was multiple pregnancy, and the patients were followed closely by cardiologists and high-risk pregnancy obstetricians.

There have been several studies looking at the outcome of pregnancies in women with prosthetic heart. These complications included increased fetal demise and spontaneous abortion, and women with mechanical valves have a higher complication rate, which was attributed to the use of anticoagulation. Our data showed a high rate of spontaneous abortion and intrauterine death compared to the general population of 28% and 6%, respectively; however, we did not find a significant difference between women with mechanical and women with bioprosthetic heart valves [21,22]. Patients in both groups received anticoagulants during pregnancy, and the indication for anticoagulant in bioprosthetic heart valve prostheses patients was obesity in 50% of cases. Other indications were multiple pregnancies and low maternal activity. Thromboembolic complications were low in both groups, being experienced by only one patient in the mechanical prosthesis group.

Other fetal outcomes were comparable to those of the general population, and previous data showed a higher rate of IUGR preterm labor and fetal anomalies [10,18]. Bleeding or postpartum hemorrhage is a major concern in these patients due to the use of anticoagulation. Results from another study indicated that the 8% rate for mechanical prostheses in our patients was higher than that in the general population (6%); however, we found that the rate of postpartum hemorrhage was similar in both types of heart prostheses since both groups received anticoagulation during pregnancy [19,23].

Hospital admission was high in both groups; almost 50% of our patients were admitted at some time during their pregnancy either for fetal close monitoring or due to complaints of palpitation. Only one patient needed cardiac ICU admission. The operative delivery (instrumental and cesarean section) rate was similar to that of noncardiac patients in our institute. Our data demonstrate the improvement in maternal and fetal outcomes of pregnancies in women with heart valve prostheses with almost no cardiac events during pregnancy, even with increased parity. Previous data showed an excellent outcome in cardiac women with NYHA class I and II disease, which is most likely due to the developments in heart valve prosthesis technology and close monitoring of these patients by specialized obstetricians and trained cardiologists. Moreover, there was no difference in pregnancy outcomes between pregnancies in women with mechanical prostheses and women with biological prostheses [24]. A systematic review comparing the two types of prostheses, including 256 mechanical and 59 bioprosthetics, showed that women with biological prostheses had significantly lower complications during pregnancy and in our series, anticoagulant was used in both groups, which could be a factor in the similar outcome [25].

Women who have prosthetic heart valves and are of childbearing age should be counseled about the potential issues that might arise during pregnancy. Having a prosthetic heart valve puts both the mother and fetus at risk; therefore, management of these women by a multidisciplinary team is required throughout pregnancy in a specialized program for high-risk patients.

## Conclusion

There was no variance in pregnancy outcomes observed between women with bioprostheses and those with mechanical prostheses. Although women with heart prostheses encountered elevated pregnancy complications compared to healthy women, these outcomes have nevertheless shown improvement compared to older publications.

## Disclosure

Ethics Approval and Consent to Participate: IRB Approval # E14-1318

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## Author's Contribution

LD conceived and designed the analysis, performed the analysis and review and edit the finalization of the manuscript. HB contributed data and analysis tools, FQ performed the analysis and a major contributor in writing the manuscript. FA, MA, HA data collection, FG writing and reviewing. All authors read and approved the final manuscript.

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