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Annual State	COMPARISON OF MATERNAL AND FETAL OUTCOMES IN PREGNANT WOMEN WITH CONGENITAL AND ACQUIRED HEART DISEASE: A PROSPECTIVE STUDY	
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	und: The incidence of pregnancy in women with heart disease is a high-risk condition. Aim: The tudy aimed to compare the maternal and fetal outcomes in pregnant women with congenital	

present study aimed to compare the maternal and fetal outcomes in pregnant women with congenital heart disease (CHD) and acquired heart disease (AHD) presenting to a tertiary care center in India. **Methods:** A prospective, observational analysis of 71 women who presented with singleton pregnancies at any gestational age with CHD (n=26) or AHD (n=45). **Results:** The primary cause of cardiac lesion was rheumatic heart disease (82.23 %). New-onset arrhythmia during pregnancy was found significantly higher in the AHD group (P=0.024). There were four maternal deaths attributed to cardiac failure. The cardiac and obstetric complications and perinatal outcomes were similar in both groups. **Conclusion:** Overall results indicate that feto-maternal outcomes in pregnancy complicated by either CHD or AHD are comparable. However, the incidence of new-onset arrhythmia was associated with AHD.

KEYWORDS : Maternal complications, maternal death, rheumatoid heart disease, perinatal outcomes.

INTRODUCTION

Incidence of pregnancy in women with heart disease is a highrisk condition. In Western world, pregnancy complications associated with heart disease is found to vary between 1-3% [1,2]. A recent confidential review suggested that heart disease has been the major cause of maternal death in India [3]. Therefore, pregnancy in women with cardiovascular disease has been associated with marked increase in maternal morbidity and mortality.

Heart disease is mainly categorized into congenital and acquired. The acquired group consists of rheumatoid heart disease (RHD), cardiomyopathies and ischemic heart disease. Of these, in developing countries RHD is the most common cause of heart disease in pregnancy [4-7], whereas cardiomyopathies and congenital heart disease (CHD) are more common in developed countries [8]. Amongst RHD, predominant lesion is mitral stenosis while atrial septal defect remains the most common lesion found in CHD.

In the presence of maternal heart disease, hemodynamic changes during pregnancy may result in adverse consequences, including death of the mother and fetus. Maternal morbidity including heart failure, arrhythmia, pulmonary edema, shock (cardiogenic), and thromboembolism is reported in the range of 4.5% to 20% [9]. Further, pregnancy is associated with an increased risk of low birth weight baby, intrauterine growth retardation (IUGR), preterm birth and fetal CHD [10]. Hence, pregnancy with heart disease is a challenging problem to obstetricians as well as cardiologists as marked hemodynamic changes in pregnancy and cardiac output in particular, have profound effect on heart disease.3

The rationale of this study is to assess feto-maternal outcome in pregnant women with heart disease who presented to a tertiary care center. Previous Indian studies have reported prevalence and feto-maternal outcomes in pregnant women with heart disease [10-14]. However, none of them have compared maternal congenital and acquired heart disease (AHD) in terms of feto-maternal complications, with a view to identify the high-risk group for adverse outcomes. Therefore, present study was aimed to compare the maternal and fetal outcome in pregnant women with CHD and AHD presenting to a tertiary care center in India.

METHODS

Study design- This was a prospective, observational, analytical study conducted at the Department of Obstetrics & Gynecology, IPGMER and SSKM hospital between February 2014 and July 2015.

Study population- Women with singleton pregnancies at any gestational age with congenital or acquired heart disease were included in this study. Women with coexisting medical or surgical complications and women referred for termination of pregnancy for non-cardiological reasons were excluded.

The study was approved by Institutional Ethics Committee and study procedure was in accordance with the principles of the Declaration of Helsinki. Informed consent was taken from every woman for their voluntary participation. Women were counseled about the possible outcomes.

Baseline data including maternal age, parity status, gestational age, nature of the underlying cardiac lesion, New York Heart Association (NYHA) functional class, cardiac intervention prior to or during pregnancy, cardiac medication and anticoagulants were recorded.

Criteria for maternal outcome: Change in NYHA functional class, new onset of congestive heart failure (CHF), hospitalizations not related to labor and delivery, new onset or exacerbation of arrhythmias, need either to initiate or enhance dose of cardiac medications, indicated terminations of pregnancy, mode of delivery and mortality.

Criteria for fetal outcome: Miscarriage, preterm labor, stillbirth, birth weight, APGAR score, NICU admissions, and NICU stay. Pregnant women with heart disease were divided into two groups based on whether they have congenital or acquired heart disease. The feto maternal outcomes in the two groups were compared on the basis of above-mentioned parameters.

Statistical analysis-Statistical analysis was performed using SPSS software (Version 6). The qualitative data were expressed as number and proportions while the quantitative data were expressed as mean (SD) or median (IQR). Numerical variables were compared between groups by Student's independent sample t-test. Chi square test or Fischer's exact test were employed for intergroup comparison of categorical variables. Analysis was two tailed and P<0.05 was considered statistically significant.

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RESULTS

A total of 71 women with heart disease were included in this study. Of these, 26 (36.61%) suffered with CHD and 45 (63.39%) belonged to AHD.

Clinical presentation

Among CHD, the majority of women had atrialseptal defect (57.69%) followed by ventricular septal defect (19.23%), coarctation of aorta (11.54%), Tetralogy of Fallot (TOF) (7.69), and patent ductus arteriosus (3.85%). Rheumatic heart disease (82.23%) was the main contributor to the acquired heart disease (AHD) [Table 1]. Among the RHD group 26 cases (70.27%) were stenotic lesions of the mitral valve (isolated or associated with other lesions).

Table 1. Distribution of women according to cardiac lesions

Cardiac lesions	Number (N=71)
Congenital heart disease	26 (36.61)
Atrialseptal defect	15 (57.69)
Ventricular septal defect	5 (19.23)
Coarctation of aorta	3 (11.54)
Tetralogyof Fallot	2 (7.69)
Patent ductusarteriosus	1 (3.85)
Acquired heart disease	45 (63.39)
Rheumatic heart disease	37 (82.23)
Cardiomyopathy,	4 (8.89)
Supraventricular tachycardia	2 (4.44)
Sick sinus syndrome	2 (4.44)
Data represented as n (%).	

The mean (SD) age of women in the CHD and AHD group was 24.23 and 25.22 years, respectively. The majority of women from both groups belonged to the age group of 21-30 years. Twenty-one (80.77 %) women among the CHD group were primigravida, while in AHD group the number of primigravida was 32 (71.11%). Majority of the women from both the groups belonged to the average socioeconomic status. It was noted that most women in both groups were booked. However, unbooked women were mostly referrals from peripheral hospitals or nursing home [Table 2].

Table 2. Demographic characteristics

Characteristics	CHD	AHD	P value
	(N=26)	(N=45)	
Age (years), mean (SD)	24.23 (3.78)	25.22 (4.56)	0.353
Age group (years), n (%)			
<20	5 (19.23)	10 (22.22)	
21-30	19 (73.07)	27 (60.00)	
31-40	2 (7.69)	8 (17.78)	
Parity			0.412
Primigravida	21 (80.77)	32 (71.11)	
Multigravida	5 (19.23)	13 (28.89)	
Socioeconomic status			0.124
Good	0	4 (8.89)	
Average	22 (84.62)	29 (64.44)	
Poor	4 (15.38)	12 (26.67)	
Admissions			0.790
Booked	17 (65.39)	32 (71.11)	
Unbooked	9 (34.62)	13 (28.89)	
Gestational age at			0.650
admission (weeks)	32.96 (7.94)	31.96 (9.49)	

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≤20	2 (7.69)	5 (11.11)	
20-24	1 (3.85)	0	
25-29	2 (7.69)	4 (8.89)	
30-34	6 (23.78)	13 (28.89)	
≥35	15 (57.69)	23 (51.11)	
NYHA class at admission			0.751
Class I	11 (42.31)	16 (35.56)	
Class II	9 (34.62)	13 (28.89)	
Class III	4 (15.38)	11 (24.44)	
Class IV	2 (7.69)	5 (11.11)	
Prior medication			>0.05
Yes	15 (57.69)	25 (55.56)	
No	11 (42.31)	20 (44.44)	
LVEF on admission (%)			
<60	6 (23.08)	13 (28.89)	
>60	20 (76.92)	32 (71.11)	
Data above as n (%) unloss otherwise apositiod			

Data shown as n (%), unless otherwise specified. AHD, acquired heart disease; CHD, congenital heart disease; LVEF, left ventricular ejection fraction; NYHA, New York heart association.

The mean gestational age at admission in CHD and AHD group was 32.96 (7.94) weeks and 31.96 weeks (9.49), respectively. Half of the population of both the groups had gestational age \geq 35 weeks at admission. In the CHD group 15 women (57.69 %) were on some kind of medications. No prior surgical procedures were done in this group. While in the AHD group 25 women (55.56%) were on medication. Three of these underwent balloon mitral valvotomy (BMV), two had valve replacements and two gave a history of previous interventions and had scars of surgery too but since no documents were available the procedure they underwent is difficult to say. All the procedures had been done prior to present pregnancy. The medications consisted of either diuretic, digoxin, beta blockers or a combination of these. Five women were on anticoagulants.

Maternal outcome

During the course of pregnancy ten women (38.46 %) had a change in there NYHA class in CHD group, among these seven (26.92%) belonging to NYHA class >2. In AHD group, change in NYHA class during pregnancy was seen 21 (46.67%) women, of these 14 (31.11) changed to NYHA class >2 [Table 3].

Table 3. Comparison of maternal outcomes between CHD and AHD group

Characteristics	CHD (N=26)	AHD (N=45)	P value
Change in NYHA class			
during pregnancy	10 (38.46)	21 (46.67)	
Class II	3 (30.00)	7 (33.33)	0.621
Class III	3 (30.00)	5 (23.81)	
Class IV	4 (40.00)	9 (42.86)	
Heart failure	5 (19.23)	10 (22.22)	>0.05
New onset arrhythmia during	1 (3.85)	12 (26.67)	0.024
pregnancy			
Initiate or enhance dose of	7 (26.92)	16 (35.56)	0.599
medication during pregnancy	/ (20.92)	16 (33.36)	0.599
Hospitalization other than	6 (23.08)	13 (28.89)	0.782
labor or delivery	0 (23.00)	13 (20.03)	0.702
Termination of pregnancy	2 (7.69)	3 (6.67)	>0.05
Gestational age at delivery	N=24	N=39	
(weeks)	35.88	36.00	
<34	2 (8.33)	6 (15.38)	0.860
34-<37	5 (20.83)	11 (28.20)	0.000
37-<40	17 (70.84)	21 (53.84)	
>40	0	1 (2.56)	
Mode of delivery	N=24	N=39	
Vaginal	16 (66.67)	22 (56.41)	0.715
Forceps	4 (16.67)	8 (20.51)	0.715
LSCS	4 (16.67)	9 (23.08)	

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Data shown as n (%).

AHD, acquired heart disease; CHD, congenital heart disease; LSCS, lower segment caesarean section; NYHA, New York heart association.

In CHD group, a total of five women reported heart failure. Two of these had heart failure at the time of presentation, one was case of COA and the other was VSD. Three women developed heart failure during the course of pregnancy, one each from COA, ASD and VSD groups. On the other hand, 10 women from AHD group reported heart failure. Five had heart failure during presentation (all with RHD) while five developed heart failure during pregnancy, three with RHD and two with cardiomyopathy. New onset arrhythmia during pregnancy was found significantly higher in AHD group compared to CHD group (26.67% vs. 3.85%, P=0.024). Majority of women had normal vaginal delivery (CHD, 66.67% and AHD, 56.41%). Caesarean sections in both groups were for obstetric indication.

Fetal outcome

Out of 71 women, there were four maternal deaths. Two women from AHD group had miscarriage. Fetal outcomes are summarized in [Table 4]. The proportion of infants with Apgar scores lower than 7 at 5 min of birth were 20.83% and 12.82% in the CHD and AHD group, respectively. In CHD and AHD group, 37.50% and 28.21% NICU admissions and among them 33.33% and 45.45% had NICU stay >7 days, respectively.

Table 4. Fetal outcomes

Outcomes	CHD (N=26)	AHD (N=45)	P value
Miscarriage	0	2 (4.44)	0.529
IUFD	0	1 (2.22)	>0.05
Preterm delivery	8 (30.77)	16 (35.56)	0.797
LBW	N=24 13 (54.17)	N=39 23 (58.97)	>0.05
APGAR at 5 min <7	N=24 5 (20.83)	N=39 5 (12.82)	0.485
NICU admission NICU stay >7 days	N=24 9 (37.50) 3 (33.33)	N=39 11 (28.21) 5 (45.45)	0.596 0.396

Data shown as n (%).

AHD, acquired heart disease; APGAR, Appearance, Pulse, Grimace, Activity, and Respiration; CHD, congenital heart disease; IUFD, Intrauterine fetal death; LBW, low birth weight; NICU, neonatal intensive care unit.

DISCUSSION

In developing countries, quite a large number of women become pregnant without seeking therapeutic intervention for cardiac lesions and many of them are only diagnosed with heart disease during pregnancy. Acquired heart lesions are frequently undiagnosed before pregnancy, remaining undetected until pregnancy exposes underlying heart disease or precipitate symptoms for the first time. Diagnosis may be delayed because many of the symptoms and signs that occur in decompensated heart disease, such as shortness of breath and ankle swelling, are commonly experienced by the woman in a 'normal pregnancy'.

This study provides an assessment of maternal and neonatal complications associated in women with heart disease in pregnancy in a tertiary care center in Kolkata and a comparison between congenital and acquired heart disease with respect to these outcomes.

During this 18-month study period, there were a total of 7097 deliveries, which placed the incidence of heart disease in pregnancy at 1.00%. The prevalence reported by various Indian studies varies between 0.4% and 4.3% [10-12,15,16]. These variations are due to different geographical locations, seasons and incidence of rheumatic fever. The mean age of

women with heart disease including CHD and AHD was 24.23 years and 25.22 years, respectively which agreed with other studies [11,13,14,17,18]. In the present study, 80.77% and 71.11% of pregnant women suffering from CHD and AHD were primigravida which is similar to study conducted by Abhilashi et al. in which 80.4% were primigravida [14]. On the contrary, a study done by Khan et al. reported majority of women were multigravida (50.91%) followed by primigravida (38.18%) [10]. In the current study, majority of women (63.39%) had AHD and RHD (82.23 %) was the main contributor to the AHD and stenotic lesions of the mitral valve was most common cardiac lesion in patents with RHD. These findings were in accordance with the previous studies where RHD was the principal cardiac lesion and mitral stenosis was the most common cardiac lesion [11-14]. Literature suggest that the CHD is more frequently observed in developed world and RHD is more common in developing countries due to inadequate antibiotic treatment of streptococcal infection, poor socioeconomic condition, overcrowding, and lack of access to proper medical facilities [12].

Maternal complications depend mainly on ventricular function and include hemorrhage, thromboembolism (owing to polycythemia secondary to hypoxia), arrhythmia, and heart failure. In the present study, five women had heart failure during presentation (all with RHD) while another ten had heart failure during pregnancy. Arrhythmia during pregnancy was found significantly higher in AHD group compared to CHD group (26.67% vs. 3.85%, P=0.024). This may be due to the bulk of RHD formed by mitral stenosis in AHD group showing early arrhythmia formation where the septal defect cause by CHD develop arrhythmias in the 3rd- 4th decade. Other studies from India revealed similar findings. A study done by Sen et al. reported cardiac complications including congestive cardiac failure (n=14), pulmonary edema (n=6), cardiac arrhythmias like atrial fibrillation (n=10). Heart failure was more prevalent during pregnancy, labor and puerperium (35%) [13]. Another study from north reported cardiac failure in 17.2%, anemia in 12.1%, pulmonary artery hypertension in 10.3%, and arrhythmia in 3.4% women with heart disease during pregnancy [12].

In the present study, overall maternal mortality was 5.63% which was very low compared to studies carried out by Anubhuti et al., Sen et al., and Khan et al [13,14,17]. Mortality in pregnant women with heart disease is mainly due to cardiac failure and pulmonary edema. Four females in our study died mainly due to cardiac failure, antenatal, and fetal death in utero. Prepregnancy counseling and close monitoring is essential therapeutic approach for managing pregnancy outcomes in women with heart disease.

In this study, 66.67% women with CHD and 56.41% women with AHD had vaginal delivery and caesarean Section was done only for obstetrical indications. This result was comparable with previous studies where majority of women had spontaneous vaginal delivery and LUCS was indicated only for obstetric cause [12-14].

Preterm birth and low birth weight are known complications in women with heart disease during pregnancy. The incidence of preterm delivery was 30.77% and 35.56% in CHD and AHD group and low birth weight observed in 54.17% and 54.76% of babies, respectively. Prematurity was found to be higher in the present study compared to previous studies [10,12-14,18]. However, this was not iatrogenic as most women delivered vaginally and very few were induced. It can be explained as there was random inclusion of women with mean gestational age at admission being 32 weeks and that at delivery being 35 weeks.

The APGAR score of infants born to mothers with heart disease were higher in the present study compared study done in Western country [18]. Though significant progress made in the diagnostic evaluation and management of women with heart disease, complications resulting in unfavorable fetal outcomes remain of concern. These observations underscore the importance of optimal management of maternal health, which is important to the health of the mother and to the health of the newborn.

The present study has some limitations. This was a prospective comparative study from single institution, and results were based on relatively small sample size. The duration of study was shorter only of 18 months. Since the study was conducted in government setup participants were mostly of low to average socio-economic strata with low level of education so it's difficult to project results on the society as a whole. Majority of the subjects in the study were primigravidas in their early twenties, and among the underlying cardiac lesions ASD and RHD formed the bulk. Both these lesions may be relatively asymptomatic at this early age leading to an uneventful first pregnancy.

CONCLUSION

Overall observations showed that fetomaternal outcomes in pregnancy complicated by either congenital or acquired heart disease are comparable. The incidence of new onset arrhythmia was found to be significantly higher in the AHD group. It was noted that more sever NYHA class at presentation is mainly responsible for pregnancy complications including heart failure, new onset arrhythmias, higher maternal morbidity and mortality.

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