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Original Research Paper

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MATERNAL AND FETAL OUTCOMES IN PREGNANT WOMEN AFTER MECHANICAL VALVE REPLACEMENT.

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ABSTRACT

BACKGROUND- Significant hemodynamic changes occur during pregnancy, which can lead to decompensation in the setting of severe valvular disease. Prosthetic heart valves have been implanted in patients with both congenital and acquired valvular disease .The management of pregnant women with such prosthesis is complicated and challenging because of difficulty in balancing maternal and fetal outcomes.

OBJECTIVES- The aim of this study is to assess the pregnancy outcome after mechanical valve replacement.

Methods - It is a prospective observational case control study conducted at tertiary health institute over a period of 24 months from Oct 2017 to Sep 2019, 27 cases with 30 pregnancies with mechanical valve replacement admitted to emergency department and ward were enrolled. For control group 50 pregnant cases of heart disease without Mechanical Valve Replacement matched with respect to age and parity were enrolled in the study by simple random sampling. Information regarding the site of prosthetic valve along with the duration and type of valve used and the type of anticoagulation regime used in first, second and third trimester was reviewed from antenatal treatment records.matenal and fetal outcome was noted.

RESULTS - 83.3% (25/30) had Mitral valve replacement and 13.3% (4/30) had Aortic valve replacement and 3.3% (1/30) had double valve replacement (MVR+AVR). The subjects with valve replacement, 2 (6.66%) patients in cases group had heart failure and one patient suffered from valve dysfunction, 1 (3.33%) patient suffered from atrial fibrillation and one from ventricular fibrillation, 3 (9 %) patients died and no complication in 22%. the subjects in which mitral valve was replaced, there were noted, 12 term deliveries, 5 pre term deliveries and 8 abortions and 1 IUD. The subjects in which aortic valve was replaced, there were 3 term deliveries and one NICU admission. Subjects in which both mitral and aortic valve were replaced, one abortion was noted and no term and pre term deliveries were noted. There was no case of warfarin embryopathy although study population received warfarin at a dose of ≤ 5mg/day.

CONCLUSION- Warfarin was more effective than heparin in preventing thrombo-embolic complications and valvular dysfunction in the mother. Warfarin may be continued throughout pregnancy in doses of ≤ 5mg/day. Maternal deaths and adverse haemodynamic events could be reduced if patients are better educated, counselled and compliant with preconception and antenatal care.

KEYWORDS : pregnancy, anticoagulation,mechanical heart valves.

INTRODUCTION

The first successful replacement of heart valve in human was reported in1960. Since then prosthetic heart valves have been implanted in patients with both congenital and acquired valvular disease[1]. Many of the recipients of such valves are women of child bearing age who desire to have children. The management of pregnant women with such prosthesis is complicated and challenging because of difficulty in balancing maternal and fetal outcomes.[1]

These replacements may be mechanical or bio prosthetic (heterografts or homografts). Mechanical heart valves are thrombogenic, necessitating long- term anticoagulation to prevent adverse outcomes such as valve thrombosis, stroke or death. During pregnancy, There is an increase in the production of pro- coagulant factors, decreased levels of protein S,an acquired protein C resistance and impaired fibrinolysin leading to an increased risk of thrombo embolic events, which makes pregnant women especially vulnerable to thrombosis and mechanical heart failure.[2]

The vast improvement in the treatment of children and young adults with heart disease seen over the last decades has made issues related to pregnancy more relevant, perhaps most importantly for growing number of women with mechanical valve prosthesis, who previously were often encouraged to avoid pregnancy.[3]

Since the advent of prosthetic cardiac valves, there has been great concern about the outcome of pregnancy in patients who receive them, because mechanical valves require anticoagulation[4]. In general, the risk of thromboembolism is greater for older-generation prosthetic valves in the mitral position, such as the Bjork-Shiley tilting-disc prosthesis as compared with the St. Jude valve.[7]

Therefore, effective anticoagulation is critical in these patients during pregnancy. Despite numerous research, the optimal anticoagulation therapy during pregnancy remains a controversial issue in the field of obstetrics. Warfarin and heparin can be used during pregnancy as anticoagulants in pregnant women with mechanical heart valves, however the potential maternal and fetal side effects associated with these medications pose challenges[5,6,7]. The treatment of women in child bearing age with a mechanical heart valve is a real challenge for the medical staff[7].

Warfarin provides effective protection against thrombo-embolism, but its use in pregnancy is associated with an augmented rate of abortion and the risk of warfarin-induced embryopathy[7,8,9] Warfarin is teratogenic because of its ability to cross the placental barrier, particularly during early gestational age[5,7]. First trimester complications of warfarin include spontaneous abortion, prematurity, fetal deformity, stillbirth, retro-placental hemorrhage and intracranial hemorrhage. Warfarin embryopathy consists of bone and cartilage abnormalities, nasal hyperplasia, optic atrophy, blindness, mental retardation and seizures[7,9]. More recent reports on the dose dependent effects of warfarin indicate safe administration during pregnancy if adequate anticoagulation can be achieved at doses of 5 mg or less [10,11].

Treatment with Heparin during the first trimester decreases the rate of embryopathy, but increases maternal morbidity and mortality.[7]

Unfractionated heparin (UFH) provides an alternative therapy that avoids fetal side effects; however, the use of UFH is associated with increased maternal thrombo-embolic and bleeding complications [5,7,12,13]. Low molecular weight heparin (LMWH) may be more advantageous than UFH and appears a good alternative [14].

The management of a pregnant women with a prosthetic heart valve requires important considerations, especially when it comes to maintaining anticoagulation. Because there is a paucity of prospective data, one cannot make definitive recommendations for each patient [6,7].

Hence in the present study we studied the outcome of pregnancy after Mechanical Valve replacement.

AIM

The aim of this study is to assess the pregnancy outcome after mechanical valve replacement.

MATERIAL AND METHODS-

It is a prospective observational case control study conducted at tertiary health institute over a period of 24 months from Oct 2017 to Sep 2019, 27 cases with 30 pregnancies with mechanical valve replacement admitted to emergency department and ward were enrolled. For control group 50 pregnant cases of heart disease without Mechanical Valve Replacement matched with respect to age and parity were enrolled in the study by simple random sampling.

The study population was subjected to a detailed history taking including age of the patient, parity, LMP, gestational age, obstetric history, type of valvular lesion, type of valve replaced, period since valve replacement, type of the anticoagulation regime used with complications if any, personal history , present complaints were recorded from the patient followed by complete physical examination including general examination, cardiovascular and respiratory examination, obstetric and pelvic examination.

Information regarding the site of prosthetic valve along with the duration and type of valve used and the type of anticoagulation regime used in first, second and third trimester was reviewed from antenatal treatment records.

Patients were categorised according to the NYHA classification and whether in sinus rythem. They were subjected to ECG and echocardiography when needed during the follow up period. Baseline investigations like urine albumin, sugar, complete hemogram, sickling, blood grouping and typing (if Rh–ve then indirect coomb's test, HIV, HBsAg, VDRL, Serum TSH, 75gm OGCT done and venous blood sugar obtained after 2 hours. According to DIPSI guidelines, normal OGCT <140 mg/dl. Patients with abnormal OGCT was subjected to OGTT. Obstetric ultrasound with Doppler scan was done and level 2 scan was done with the help of radiologist. Multiple gestation, placental abnormalities and haemorrhage and fetal anomalies if any were noted. Fetal echo was done to rule out congenital heart disease. These women were closely monitored throughout their antenatal period along with the anticoagulation regime with INR for any complications. The patients were divided into groups, group 1 received warfarin throughout pregnancy and group 2 was treated with LMWH or unfractionated heparin during the first trimester of pregnancy, switching to warfarin in the second trimester. During heparin treatment a target activated prothrombin time (aPTT) was maintained two to three times higher than the control. During treatment with warfarin, treatment was adjusted to attain a target international normalised ratio(INR) of 2.5 to 3.5, as needed. Patients on warfarin treatment were shifted to heparin at around 36 weeks of gestation.

Complete labour record was analysed with mode of delivery. Fetal anomalies detected during ultrasound were confirmed after birth with paediatrician. All deliveries and caesarean section were attended by paediatricians who recorded, the APGAR score (at 1 min and 5 min) at delivery. Complete physical examination of the baby was also done by attending paediatrician. Baby was shifted to mother if there were no indications for admission to NICU.

Maternal outcome was noted in the form of mode of delivery, obstetric complications (abortion, stillbirth, preterm delivery, intrauterine growth restriction (IUGR) and hemorrhagic complications, congenital malformation, thrombo-embolic complications (valve thrombosis)). Thrombotic events included valve thrombosis, pulmonary embolism, deep vein thrombosis or any ischaemic cardiovascular and cerebrovascular event.

Spontaneous abortion was defined as any spontaneous fetal loss before 20 weeks of gestation. Therapeutic abortions included all medically indicated terminations before 20 weeks of gestation. Stillbirth was referred to as fetal loss after 20 weeks of gestation. Preterm delivery was defined as birth before 37 weeks of gestation. IUGR was defined as birth weight less than the 10th percentile for gestational age. Maternal mortality was defined as death during pregnancy and upto 42 days after delivery.

Fetal outcome were studied in the form of abortions, warfarin embryopathy, LBW, congenital anomalies, stillbirths, birth asphyxia, poor APGAR at 1 min and 5 min, live births and NICU admissions and neonatal mortality. At the end of the study, data was compiled and analysed.

STATISTICAL METHODS

Data analysis was carried out by SPSS software version 24. The results were studied using appropriate statistical methods. Variables were compared by Pearson CHI- square test and tests of significance used and p value calculated. All p values were two- tailed and values <0.05 were considered statistically significant.

RESULTS

Age- 8 (26.66%) subjects from 20 to 25 years of age followed by 20 (66.67%) subjects were in the age group of 26 to 30 years and remaining 2 (6.67%) subjects were from age group of more than 30 years of age in the cases group. Whereas, in controls, 13 (26%) subjects were from 20 to 25, 34 (68%) from 26 to 30 and 3 (6.0%) were in the above 30 age group, respectively. The association between cases and control with regards to age group is statistically not significant with the p value of 0.47, which means cases and control are matched for the study.

Gravida status- Out of 30 subjects 20 (66.67%) were multi gravidae and 10 (33.33%) were primi gravida in cases and in controls, 36 (72%) subjects were multi gravida and 14 (28%) subjects were primi gravida. The cases and control were matched with regard to gravidae status thus the association p value was 0.61 which is not significant.

NYHA classification : From the cases, dyspnoea was present in 14 (46.6%) subjects of which 9 (30%) subjects had Grade 4 and 5 (16.6%) had Grade 3 dyspnoea according to NYHA classification. Among controls, grade 1 dyspnoea was seen in 4 (8%) subjects, grade 2 in another three (6%) subjects and grade 3 dyspnoea was seen in 2 (4%) subject and the association between cases and control for Dyspnoea grading as per NYHA classification was found to be significant with the p value of 0.002, this is because more subjects 82 % from control group had grade 0 dyspnoea as compared to 53.4 % from cases.

Site of valve replacement: Mitral valve was replaced in 25 (83.33%) subjects and 4 (13.33%) subjects had their aortic valve replaced while only 1 (3.33%) subject had their both mitral and aortic valve replaced.

Model of valve replaced: 16 (53.33%) were St Judes, 9 (30%) were TTK chitra, 3 (10%) were Sorin, two cases had ATS and one case had Perimount Bi prosthetic valve.

Anticoagulants used: In 1st trimester 26 (86.66%) subjects were on warfarin only, followed by 2 (6.67%) subjects were on heparin and 1 (3.33%) subject on warfarin plus heparin combination.

In second trimester 25 (83.33%) subjects were on warfarin only followed by 1 (3.33 %) subject each on warfarin plus heparin and aspirin.

In third trimester 17 (56.67%) subjects were on warfarin only followed by 1 (3.33 %) subject each on warfarin plus heparin and aspirin.

Obstetric outcome: abortion was noted in 9 (30 %) cases, and 5 (16.66%) were born pre term and normal delivery and 1 (3.33 %) delivered pre term by LSCS and 8 (26.66 %) babies delivered at term normally, while 7 (23.33 %) delivered at term by LSCS. In controls, no abortion was noted, 7 (16%) babies were born pre term by normal delivery and 1 born pre term by LSCS and 25 (50%) babies were delivered at full tern normally, 17 (34%) were delivered through LSCS at term. The association between cases and control with regard to obstetric outcome was found to be significant with p value of 0.039, with controls had better outcome than cases.

Maternal outcome: Out of 8(26%) subjects in the age group of 20-25 years,1 had heart failure, 1 had valve dysfunction, 1 with atrial fibrillation and 1 with ventricular fibrillation and one death was reported in this age group. Likewise of 20 (66.6%) subjects in the age group of 26-30 years, one death was reported in this age group and out of 2(6.66%) subjects in the age group of >30 years, one death was reported in this age group.

Out of 10(33.3%) primi, 1 subject had heart failure, 1 had valve dysfunction and one death was reported in this age group. Out of 20(66.6%) multi parous subjects, 1 subject had heart failure, 1 with atrial fibrillation and 1 with ventricular fibrillation and two death was reported in this age group.

For interval between surgery and pregnancy, out of 5(16.6%) subjects in < 1 year, no heart failure, valve dysfunction, atrial fibrillation and ventricular fibrillation seen.Out of 10(33.3%) subjects in 1-5 years, 2 subjects had heart failure, 1 had valve dysfunction and 2 subjects died in this age group.Out of 13(43.3%) subjects in 6-10 years, 1 subject had atrial fibrillation and 1 had ventricular fibrillation and 1 subject died in this age group. No adverse outcome was seen in age group of > 10 years which had only 2(6.67%) subjects.

25(83.3%) subjects who had Mitral valve replaced, 1 had heart failure, 1 had atrial fibrillation, 1 had ventricular fibrillation and 2 subjects died in this group. 4(13.3%) subjects who had aortic valve replaced no adverse outcome were seen. Only 1(3.33%) subject had both mitral and aortic valve replaced, who suffered from heart failure and valve dysfunction and died.

When we compared maternal outcome with anticoagulant used throughout pregnancy, in 5(16.6%) subjects warfarin was used of them one subject suffered from heart failure and 1 death occurred. Of 24(80%) subjects in which heparin + warfarin used as an anticoagulant, 1 had atrial fibrillation and 1 subject had ventricular fibrillation and 2 subjects died in this group. Only 1(3.33%) subjects in which only heparin was used suffered from heart failure and valve dysfunction.

Fetal outcome: In the age group of 20-25 years, 3 babies born at term, 5 pre-term and intra uterine death occured and one baby was admitted in NICU. In the age group of 26-30 years, 7 babies born at term, 3 pre-term and 6 abortions were noted and one baby was admitted in NICU. In the age group of >30 years, 4 babies born at term, 1 pre-term and 1 abortion was noted.

In primi, 8 babies born at term, 3 at pre term and 5 abortions were noted and one baby was admitted in NICU. In multi para, 7 babies born at term, 2 at pre term and 4 abortions were noted and one intra uterine death noted and one baby was admitted in NICU

Relation of interval between surgery and pregnancy with foetal outcome, for duration < 1 year, 1 baby born at term, 1 at pre term and one abortion was noted. For duration 1-5 years, 1 baby born at term, 2 at pre term and two abortions were noted and one baby was admitted in NICU. For duration 6-10 years, 5 baby born at term, 2 at pre term and two abortions were noted and one baby died intra uterine and one baby was admitted in NICU. For duration >10 years, no baby born at term, 1 at pre term and 3 abortions were noted.

The subjects in which mitral valve was replaced, following foetal outcome were noted, 12 term deliveries, 5 pre term deliveries and 8 abortions and 1 IUD.

The subjects in which aortic valve was replaced, following foetal outcome were noted, 3 term deliveries and one NICU admission. Subjects in which both mitral and aortic valve were replaced, one abortion was noted and no term and pre term deliveries were noted.

In subjects in which warfarin was used as an anticoagulant, 5 abortions were noted and no term and pre term deliveries were present. In subjects in which warfarin+ heparin was used as an anticoagulant, 15 term deliveries, 6 pre term deliveries, 3 abortions, 2 intra uterine deaths and 2 NICU admissions were noted. In subjects in which only heparin was used as an anticoagulant, 1 abortion was noted and no term and pre term deliveries were present.

For gestational age with foetal outcome, 9 abortions were noted in <12 weeks of gestational age. One intra uterine death was noted in 28-32 weeks of gestational age. In 33-36 weeks of gestational age, 5 pre term delivered were noted and congenital anomalies were seen in 2 babies.15 term deliveries were noted in > 37 weeks of gestational age.

Table 1: Distribution of the study subjects according to their age

	Cases (n=30)	Control (n=50)	
Age group	**No of subjects (%)**	**No of subjects (%)**	**Chi square- 0.004, p value- 0.47**
20 to 25	8 (26.66 %)	13 (26.0 %)	
26 to 30	20 (66.66 %)	34 (68 %)	
>30	2 (6.67%)	3(6.0%)	
Total	30(100)	50(100)	

Table 2: Distribution of the study subjects based on gravida status

	Cases (n=30)	Control (n=50)	
Gravida status	**No of subjects (%)**	**No of subjects (%)**	**Chi square- 0.25 P value- 0.61**
Multi Gravida	20 (66.67%)	36 (72%)	
Primi Gravida	10 (33.33%)	14 (28%)	
Total	30 (100%)	50 (100%)	

Table 3: Distribution of the study subjects based NYHA classification of

		Cases (n=30)	Control (n=50)	
Dyspnoea	**NYHA classification**	**No of subjects (%)**	**No of subjects (%)**	**Chi square- 7.52P value- 0.002**
	G0	16 (53.4%)	41 (82%)	
	G1	0	4 (8%)	
	G2	0	3 (6%)	
	G3	5 (16.6%)	2 (4%)	
	G4	9 (30%)	0 (0)	

Table 4: Distribution of subjects according to site of valve replacement

Site of valve replacement	Number of subjects (n=30)	%
Mitral	25	83.33%
Aortic	4	13.33%
Mitral + Aortic	1	3.33%
Total	30	100%

Table 5: Distribution of the study subjects based on model of valve replaced

Model of valve replaced	No subjects (n=30)	%
ATS	2	6.67%
Perimount Bi prosthetic valve	1	3.33%
St judes	16	53.33%
Sorin	3	10%
TTK chitra	9	30%
Total	31	100%

* In one subjects double valve replacement was done (**TTK chitra and St judes**)

Table 6: Distribution of the study subjects based on anticoagulants used in 1st, 2nd and 3rd trimester

Anticoagulant used	No of subjects		
	1st trimester	2nd trimester	3rd trimester
Warfarin only	26 (86.68%)	25 (83.33 %)	17 (56.67 %)
Warfarin plus heparin	1 (3.33%)	1 (3.33 %)	1 (3.33 %)
Heparin	2 (6.66%)	0	0
Aspirin	0	1 (3.33 %)	1 (3.33 %)
None	1 (3.33 %)	3(10 %)	11 (36.63 %)
Total	30 (100%)	30 (100%)	30 (100%)

Table 7: Distribution of the study subjects based on obstetric outcome (n=30)

obstetric outcome		Cases (n=30)	Control (n=50)	
		No of subjects (%)	No of subjects (%)	
ABORTION		9 (30 %)	0	Chi squar e- 3.0P value- 0.039
PRETERM	Normal delivery	5 (16.66 %)	7 (14 %)	
	LSCS	1 (3.33 %)	1 (2 %)	
FULL TERM	Normal delivery	8 (26.66 %)	25 (50%)	
	LSCS	7 (23.33%)	17 (34%)	
TOTAL		30 (100%)	50 (100%)	

Table 8: comparison with the maternal outcome

			maternal outcome				
		No of subjecs	Heart failure	Valve dysfunction	Atrial fibrillation	Ventricular fibrillation	Death
Age (in years)	20-25	8 (26%)	1	1	1	1	1
	26-30	20 (66.6%)	0	0	0	0	1
	>30	2 (6.6%)	0	0	0	0	1
Parity	primi	10 (33.3%)	1	1	0	0	1
	multi	20 (66.6%)	1	0	1	1	2
Int. between surgery and pregnancy	<1	5 (16.6%)	0	0	0	0	0
	1-5	10 (33.3%)	2	1	0	0	2
	6-10	13 (43.3%)	0	0	1	1	1
	>10	2 (6.66%)	0	0	0	0	0
Type of valve replacement	MVR	25 (83.3%)	1	0	1	1	2
	AVR	4 (13.3%)	0	0	0	0	0
	MVR+AVR	1 (3.33%)	1	1	0	0	1
anticoagulant	Warfarin	5 (16.6%)	1	0	0	0	1
	Warfarin+heparin	24 (80%)	0	0	1	1	2
	Heparin	1 (3.33%)	1	1	0	0	0

Table 9: comparison with the foetal outcome

		Foetal outcome						
		Term	Preterm	Abortion	IUD	Cong. anomalies	NICU	Death
Age (in years)	20-25	3	5	0	1	0	1	0
	26-30	7	3	6	0	0	1	0
	>30	4	1	1	0	0	0	0
Parity	Primi	8	3	5	0	0	1	0
	Multi	7	2	4	1	0	1	0
Int. between surgery and pregnancy	<1	1	1	1	0	0	0	0
	1-5	9	2	2	0	0	1	0
	6-10	5	2	2	1	0	1	0
	>10	0	1	3	0	0	0	0
Type of valve replacement	MVR	12	5	8	1	0	0	0
	AVR	3	0	0	0	0	2	0
	MVR+AVR	0	0	1	0	0	0	0
anticoagulant	Warfarin	0	0	5	0	0	0	0
	Warfarin+ heparin	15	6	3	2	0	2	0
	Heparin	0	0	1	0	0	0	0
Gestational age	<12	0	0	9	0	0	0	0
	13-20	0	0	0	0	0	0	0
	21-27	0	0	0	0	0	0	0
	28-32	0	0	0	1	0	0	0
	33-36	0	5	0	0	2	0	0
	>37	15	0	0	0	0	0	0

Summary

Present study entitled "A PROSPECTIVE STUDY OF PREGNANCY OUTCOME AFTER MECHANICAL VALVE REPLACEMENT" carried out in the department of obstetrics and gynaecology at the tertiary health care centre. It is a prospective observational case control study conducted at tertiary health institute over a period of 24 months from Oct 2017 to Sep 2019, 27 cases with 30 pregnancies with mechanical valve replacement admitted to emergency department and antenatal wards were enrolled. For control groups 50 pregnant cases of heart disease without Mechanical Valve Replacement matched with respect to age and parity were enrolled in the study. The cases and controls were selected on the basis of inclusion and exclusion criteria.

The study population was subjected to a detailed history taking including age of the patient, parity, LMP, gestational age, obstetric history, type of valvular lesion, type of valve replaced, period since valve replacement, type of the anticoagulation regime used with any if complications, personal history, present complaints were recorded from the patient followed by complete physical examination including general examination, cardiovascular and respiratory examination, obstetric and pelvic examination.

Information regarding the site of prosthetic valve along with the duration and type of valve used and the type of anticoagulation regime used in first, second and third trimester was reviewed from antenatal treatment records.

Maternal and perinatal outcome was analysed and compared with controls.

Data analysis was carried out by SPSS software version 24. The results were studied using appropriate statistical methods. Variables were compared by Pearson CHI- square test and tests of significance used and p value calculated. All p values were two- tailed and values <0.05 were considered statistically significant.

- Out of 30 pregnancies in 27 cases, 26.66% subjects were from 20 to 25 years of age followed by 66.67% in the age group of 26 to 30 years.
- From urban residence there were 66.67% cases and 74% controls and 33.33% cases and 26% controls were from rural residence.
- Multi gravidae were 66.67% cases and 33.33% were primi gravida.
- 66.6% subjects were obese and 6.7% subjects were morbidly obese, while 46% controls were obese. The association were the case and control for BMI was found to be statistically significant.
- Dyspnoea was present in 46.6% subjects of which 30% subjects had Grade 4 and 16.6% had Grade 3 dyspnoea according to NYHA classification. Among controls, grade 1 dyspnoea was seen in 8% subjects, grade 2 in 6% subjects and grade 3 dyspnoea was seen in 4% subject and the association between cases and control for dyspnoea classification was found to be statistically significant with the p value of 0.002.
- 83.3% (25/30) had Mitral valve replacement and 13.3%(4/30) had Aortic valve replacement and 3.3% (1/30) had double valve replacement (MVR+AVR).
- Mitral valve replacement was associated with poor outcome as compared with aortic valve replacement. 25 subjects who had Mitral valve replaced, 1 had heart failure, 1 had atrial fibrillation, 1 had ventricular fibrillation and 2 subjects died in this group. 4 subjects who had aortic valve replaced had no adverse outcome. Only 1 subject had both mitral and aortic valve replaced, suffered from heart failure, valve dysfunction and died.
- In the study 2/25 (8%) subject died with Mitral valve replacement and 1 subject died with double valve replacement.
- In the patients were mitral valve replacement was done there were 12 term deliveries, 5 pre term deliveries and 8 abortions and 1 Intra Uterine Death. The subjects in which aortic valve was replaced, there were 3 term deliveries and one NICU admission. One case who had double valve replacement had abortion.
- In the current study 16 subjects (53.33%) had St Judes used for replacement, 9 (30%) had TTK chitra, 3 (10%) had Sorin, two cases had ATS and one case had Perimount Bi prosthetic valve. In the present study there were 3 maternal deaths with St. Jude valve.
- In current study maximum 13 subjects (43.33%) had interval of 6 to 10 years between surgery and pregnancy, followed by 10 (33.33%) subjects with interval of 1 to 5 years, followed by 5 (16%) with an interval of less than 1 year and 2 (6.67%) had interval more than 10 years. The average time interval between valve replacement surgery and pregnancy is approx. 5.3 years.
- There was no case of warfarin embryopathy although study population received warfarin at a dose of $\leq$ 5mg/day. In the current study during 1st trimester 26 (86.66%) subjects were on warfarin only and there were 5 abortions
- Subjects in which heparin replaced warfarin as an anticoagulant, 1 had atrial fibrillation and 1 subject had ventricular fibrillation and 1 subject had valve thrombosis, 2 subjects died.
- Out of 25 subjects of mitral valve replacement, there were 12 term deliveries, 5 pre term deliveries and 8 abortions and 1 IUD. Out of the 4 subjects in which aortic valve was replaced, there were 3 term deliveries and one NICU admission and 1 patient had both mitral and arotic valve replaced and had abortion. The association between cases and control for fetal outcome was found to be significant with the p value of <0.001

CONCLUSION

We conclude that the patients with mechanical valves have a higher incidence of maternal complications and fetal loss than the healthy women of their age with comparable genetic and environmental backgrounds. Since pregnancy with mechanical valve replacement is very high risk pregnancy with significant maternal morbidity and mortality, early registration of ANC is required and management of these women requires the multiple disciplinary team throughout pregnancy. Maternal deaths and adverse haemodynamic events could be reduced if patients are better educated, counselled and compliant with preconception and antenatal care.

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