Indian Heart Journal 70 (2018) 685–689

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Original Article

Comparative study on maternal and fetal outcome in pregnant women with rheumatic heart disease and severe mitral stenosis undergoing percutaneous balloon mitral valvotomy before or during pregnancy

J.B. Sharma[a,*], Vikas Yadav[a], S. Mishra[b], A. Kriplani[a], Neerja Bhatla[a], Garima Kachhawa[a], Rajesh Kumari[a], Varnit Toshayan[a]

[a] Department of Obstetrics and Gynecology, AIIMS, New Delhi, India
[b] Department of Cardiology, AIIMS, New Delhi, India

ARTICLE INFO

Article history:
Received 26 May 2017
Accepted 8 January 2018
Available online 9 January 2018

ABSTRACT

Introduction: Mitral stenosis due to rheumatic heart disease is a common problem in India causing significant morbidity and mortality. We have compared the maternal and fetal outcome of women with severe mitral stenosis undergoing percutaneous balloon mitral valvotomy before or during pregnancy.
Methods: A total of 24 women of severe rheumatic mitral stenosis who underwent balloon mitral valvotomy before pregnancy (14 women, group 1) or during pregnancy (10 women, group 2) were included in the retrospective descriptive analysis.
Results: The mean age was 25.5 ± 3.6 yrs in group 1 and 25.7 ± 3.5 yrs in group 2. There was no difference in characteristics –primigravidas, time since diagnosis from pregnancy, NYHA (New York Heart Association) class and associated medical problems in the two groups. There was significant difference in cardiac events during pregnancy in the two groups. New York Heart Association class deterioration was observed in only 3(21.4% women in group 1) as compared to all (10; 100% women) in group 2($p < 0.001$). The incidence of arrhythmias and atrial fibrillation was not different in two groups. Obstetric events were similar in the two groups. Mode of delivery and caesarean section rate was also similar in the two groups. There was no significant difference in mean birth weights (2399.75 ± 601.8 gm vs. 2641.70 ± 580.6 gm), rate of fetal growth restriction, still birth and congenital malformation rates in the two groups.
Conclusion: Percutaneous mitral valvotomy for patients with severe mitral stenosis can be safely performed during pregnancy and has equivalent maternal and fetal outcomes as that performed before pregnancy.

1. Introduction

Rheumatic heart disease remains a common disease in developing countries like India with mitral stenosis (MS) being the most significant lesion.[1,2] It can cause significant maternal mortality (1%, 0.4% in NYHA class 1 and 2, 6.8% in NYHA class 3 and 4. Maternal morbidity is also high and related to severity of mitral stenosis being 26% in mild MS (mitral valve area >1.5 cm^2) to as high as 67% in severe MS (mitral valve area <1.0 cm^2).[3–5] Perinatal mortality and morbidity is also high in severe mitral stenosis and depending on functional class may be upto 30% in NYHA class 4 lesions.[6] Initially medical treatment is tried but interventional/surgical treatment is the definitive therapy. In current practice minimally invasive percutaneous mitral balloon valvuloplasty (PMBV) is the procedure of choice and has almost replaced the open surgical mitral valve commissurotomy.[5] Balloon mitral valvotomy has been observed to improve maternal and fetal outcome in severe MS during pregnancy[1,7–11]. Even long term obstetric outcome and development of children born to these women has been found to be good.[5] Lung and co-workers observed late results of PBMV in a series of 1024 patients while Fawzy and co-workers followed up patients of mitral balloon valvuloplasty for 19 years.[12,13] However, occurrence of pregnancy in a patient of MS undergoing PBMV adds another dimension. Esleves and co-workers reported immediate and long term follow-up of PBMV balloon mitral valvuloplasty in pregnant women with rheumatic mitral stenosis.[14] We report our results of a retrospective descriptive study on comparative maternal and fetal outcome in

* Corresponding author at: Department of Obstetrics and Gynecology, All India Institute of Medical Sciences, New Delhi, 110029, India.
E-mail address: jbsharma2000@gmail.com (J.B. Sharma).

https://doi.org/10.1016/j.ihj.2018.01.018

women with severe MS who underwent balloon mitral valvulotomy either before or during pregnancy.

2. Methods

It is a retrospective descriptive study on women of severe rheumatic MS who underwent percutaneous balloon mitral valvuloplasty (PBMV) either before or during pregnancy (due to symptoms of severe stenosis) over the previous 10 years (January 2007 to December 2016) in a tertiary referral center with facilities of high risk obstetrics, cardiology and cardiac surgery.

The patients were divided into two groups: Group 1: who had undergone PBMV before pregnancy while Group 2: who underwent PBMV during pregnancy due to development of severe disease necessitating surgery.

The characteristic of the women like mean age, obstetric history, time since diagnosis from pregnancy, NYHA classification and any associated medical problem were noted in all the women.

Cardiac events like deterioration of NYHA class, any arrhythmias, congestive cardiac failure, restenosis and atrial fibrillation were noted in all the patients and compared in the two groups. Use of cardiac medications like digoxin, diuretics and anticoagulants etc were also compared in the two groups.

Obstetric events like pre-eclampsia (high blood pressure with proteinuria), oligoamnios (scanty liquor), gestational diabetes mellitus (raised blood sugar during pregnancy), antepartum hemorrhage (bleeding per vaginum during pregnancy), intrahepatic cholestasis (raised bile acid and liver enzyme with pruritus during pregnancy), premature rupture of membranes and mode of delivery including vaginal delivery, instrumental delivery and cesarean section rate was noted and compared in the two groups.

Fetal outcome in the form of mean birth weight, fetal growth restriction, APGAR <8, still birth rate, congenital malformation rate and other neonatal complications were noted and compared in the two groups.

3. Statistical analysis

Data analysis was carried out using statistical software STATA version 12.0. Continuous variables were tested for normality assumptions using appropriate statistical tests. For the variables that were approximately to normal distribution descriptive statistics such as mean, standard deviation and the range values were calculated. For non- normal data median values were compared. Comparison of two group means were tested using student −t independent test. Categorical variables were expressed in terms of frequency and percent values. Frequency data by categories was compared using chi square test/Fischer exact test as appropriate. Two sided probabilities $P < 0.05$ was considered for statistical significance.

4. Results

A total of 24 women of severe MS were enrolled in the study. There were 14 women in group 1 who had undergone PBMV before pregnancy while there were 10 women in group 2 who underwent PBMV during the current pregnancy. PBMV in Group 1 was performed within last 4 years in all cases (mean 1–2 years). PBMV during pregnancy in Group 2 was performed in second trimester which is considered the safest period at surgery to perform any surgery due to least risk of miscarriage. The range of gestation age was 14 to 21 weeks, mean gestation age being 18.4 weeks. The characteristics of patients and their NYHA class,associated medical problems and mean blood pressure in the two groups are shown in Table 1. The mean age was similar in two groups ($p > 0.05$). The incidence of primigravida and multigravida was also similar in the

Table 1
Characteristics of women in the two groups.

S.no	Outcome	Group 1 PBMV done before pregnancy N= 14 (58.3%)	Group 2 PBMV done during pregnancy N = 10 (41.6%)	P value and Significance
1	Mean age	25.54 ± 3.68	25.70 ± 3.52	P > 0.05 NS
	<18	0	0	P > 0.05 NS
	18–35	14	10	P > 0.05 NS
	>35	0	0	P > 0.05 NS
2.	Obstetric history:			
	Primigravida	4(28.5)	4(40)	P > 0.05 NS
	Multigravida	10(71.4)	6(60)	P > 0.05 NS
	Previous abortions	4	1	P > 0.05 NS
3.	Time since diagnosis from pregnancy:			
	<10 yrs	12(85.7)	8(80)	P > 0.05 NS
	10–20 yrs	2(14.2)	0	P > 0.05 NS
	>20 yrs	0	0	P > 0.05 NS
	During pregnancy	0	2(20)	P > 0.05 NS
4.	NYHA class:		(After surgery)	
	NYHA 1	8(57.1)	7(70)	P > 0.05 NS
	NYHA 2	5(35.7)	3(30)	P > 0.05 NS
	NYHA 3	0	0	P > 0.05 NS
	NYHA 4	1(7.1)	0	P > 0.05 NS
5.	Associated medical problems:			
	Chronic HTN	0	0	P > 0.05 NS
	Anemia	0	0	
	LRTI	1(7.1)	0	
	Seizure disorder	0	0	
	Arthritis	1(7.1)	0	
	CVA	0	1(10)	
	Hepatitis/HIV	2(14.2)	0	
	Bronchial asthma	0	0	
	Beta thal trait	0	0	
6.	Mean blood pressure (mmHg)	81.5 ± 2.5	78.9 ± 2.8	P > 0.05 NS

LRTI:Lower respiratory tract infection, CVA:Cerebrovascular accident.

two groups ($P > 0.05$). There was no difference in time since diagnosis from pregnancy in the two groups. There was no significant difference in NYHA class in the two groups. Associated medical problems were also similar in the two groups. The various cardiac events and need of medications in the two groups are shown in Table 2. The status of mitral regurgitation and mitral valve area before and after PBMV is also shown in Table 2. There was significant difference in New York Heart Association classification deterioration in the two groups being seen in all 10 (100%) cases in group 2 as compared to only 3 (21.4%) in group 1 ($p < 0.001$). In fact the deterioration in NYHA was the reason for mitral valvotomy performed during pregnancy in many of them. There was no significant difference in use of cardiac medication like digoxin, diuretics and anticoagulants etc in the two groups as shown in Table 2.

The obstetrics events and mode of delivery in the two groups are shown in Table 3. There was no significant difference in the various obstetric events in the two groups. The mean gestation age was 38.4 weeks in group 1 and 39.2 weeks in group 2 and was similar ($P > 0.05$). History of previous cesarean section was seen in significantly higher no of cases in group 1 as compared to group 2.

Although incidence of cesarean section was higher in group 1 (50%) as compared to group 2 (10%), it was not statistically different ($p = 0.079$). rate of vaginal delivery and instrumental delivery was also similar in the two groups.

The fetal outcome in the two groups is shown in Table 4. The mean birth weight was similar ($p > 0.05$). Similarly, incidence of fetal growth restriction was also similar in the two groups. Similarly, incidence of APGAR <8, still birth rate, congenital anomalies and other neonatal complications were also similar in the two groups.

5. Discussion

Rheumatic heart disease remains the commonest cardiac disease during pregnancy in developing countries with MS being the most common lesion.[1,2] Pregnancy induced hyperdynamic circulatory changes cause an increase in left atrial pressure, increased risk of atrial fibrillation and left heart failure with pulmonary edema.[14,15] MS is classified according to the valve area, mild stenosis (<4 cm^2 but >1.5 cm^2); moderate stenosis (1.5–1 cm^2) and severe stenosis (< 1 cm^2). Pregnancy in women with mitral stenosis is associated with an increased maternal morbidity and adverse fetal outcome.[16] Ideally women with severe MS should be counseled pre-conceptionally and should not plan to become pregnant until the interventional correction with either balloon valvuloplasty or mitral valve replacement or valve repair as per the clinical situation is already undertaken.[14] In case of valve replacement surgery with mechanical valves, a lifelong anticoagulant therapy is mandated which is usually oral anticoagulant (warfarin). However, at the onset of pregnancy it needs to be changed to heparin in first trimester to avoid warfarin embryopathy.[14] Endocarditis prophylaxes is also required throughout pregnancy with penicillin.[14] However, in developing world many patients with heart disease present for the first time only during pregnancy. On the other hand in some patients significant MS is already known but they choose only medical management for the cardiac condition, and later they present with pregnancy.[14]

However, after presenting with pregnancy, in many severely symptomatic cases (especially with large *trans*-mitral gradients), an antenatal PBMV may be necessary and it is usually performed in second trimester.[14] PBMV is a minimally invasive interventional procedure which can be performed under local anesthesia with significantly fewer fetal complications and a reduction in fetal and neonatal mortality. [17] Jose and co-workers compared PBMV with open mitral valve commissurotomy and found it to be superior, safe and effective and more profitable for fetus than open procedure.[17] Many subsequent studies have confirmed the efficacy and superiority of PBMV during pregnancy in severe mitral stenosis.[7–13]

The results of the present study comparing mitral valvulotomy before and during pregnancy demonstrate similar maternal and fetal outcome in both the groups. However cardiac events were more common in mitral valvotomy performed emergently during pregnancy. Our results are similar to Malhotra and co-workers who also observed that mitral valve surgery before or during pregnancy did not significantly improve maternal and fetal outcome, but decreased adverse events like congestive heart failure and arrhythmias.[18]

5.1. Limitations

Sample size is small. It was not a randomized trial but a retrospective study and the comparison may not give true picture as valvotomy in second group was performed only for severe

Table 2
Cardiac events and need of medication in the pregnancy.

S.no	Outcome	Group 1 PBMV done before pregnancy N = 14(58.3%)	Group 2 PBMV done during pregnancy N = 10(41.6%)	P value and Significance
1.	Mitral Regurgitation	2(14.2)	2(20)	P > 0.05 NS
	Mitral valve area :			
	Before Surgery	0.96 ± 0.15	0.80 ± 0.2	P > 0.05 NS
	After Surgery	1.84 ± 0.30	1.75 ± 0.27	P > 0.05 NS
2.	Cardiac complications			
	A. Uneventful	11(78.5)	0	P=0.000 Sig
	B. Stuck valve	0	2(20)	p > 0.05 NS
	C. CCF	0	0	P > 0.05 NS
	D. Arrythmia	1(7.1)	0	P > 0.05 NS
	E. Restenosis	1(7.1)	0	P > 0.05 NS
	F. Nyha deterioration	3(21.4)	10(100)(before surgery)	P = 0.00 Sig
	G. AF	1(7.1)	0	P > 0.05 NS
Use of cardiac medication:				
	A. Digoxin	6(42.8)	1(10)	P = 0.172 NS
	B. Diuretic	8(57.1)	9(90)	P = 0.172 NS
	C. Beta blockers	6(42.8)	7(70)	P = 0.240 NS
	D. Anticoagulants	3(21.4)	0	P = 0.230 NS
	E. Anti hypertensive	0	0	P > 0.05 NS

CCF: Congestive cardiac failure, AF: Atrial fibrillation.

Table 3
Obstetric events and mode of delivery in the two groups.

S. no	Outcome	Group 1 PBMV done before pregnancy N = 14 (58.3%)	Group 2 PBMV done during pregnancy N = 10 (41.6%)	P value and Significance
1.	Obstetric events:			
	Anemia	1(7.1)	1(10)	P > 0.05 NS
	Pre eclampsia	0	0	P > 0.05 NS
	Oligoamnios	0	2(20)	P = 0.160 NS
	GDM	2(14.2)	0	P > 0.05 NS
	APH	0	0	P > 0.05 NS
	PROM	2(14.2)	0	P > 0.05 NS
	ICP	2(14.2)	1(10)	P > 0.05 NS
	Previous LSCS	6(42.8)	0	P = 0.024 Sig
	Post partum complication	1(7.1)	1(10)	P > 0.05 NS
	Mean gestation age	38.4 Weeks	39.2 Weeks	P > 0.05 NS
	Mode of delivery:			
	Vaginal:	7(50)	9(90)	P = 0.079 NS
	• Spontaneous	5	8	P > 0.05 NS
	• Induced	2	1	P > 0.05 NS
	• Use of forceps/ventouse	3	5	P > 0.05 NS
	LSCS :	7(50)	1(10)	P = 0.079 NS
	• Elective	3	0	P > 0.05 NS
	• Emergency	4	1	P > 0.05 NS

GDM:Gestational diabetes mellitus; APH: Antepartum hemorrhage; PROM:Premature rupture of membrane; ICP:Intrahepatic cholestasis of pregnancy; LSCS:Lower section caesarean section.

Table 4
Fetal outcome in the two groups.

S.no	Outcome	Group 1 PBMV done before pregnancy N = 14(58.3%)	Group 2 PBMV done during pregnancy N = 10(41.6%)	P value and Significance
1.	Fetal outcome:			
	Mean birth weight	2399.75 ± 601.8	2641.70 ± 580.6	P > 0.05 NS
	FGR	2(14.2)	2(20)	P > 0.05 NS
	LFD	0	1(10)	P > 0.05 NS
	Hyperbilirubinemia	0	1(10)	P > 0.05 NS
	NEC	0	0	P > 0.05 NS
	ROP	0	0	P > 0.05 NS
	BPD	0	0	P > 0.05 NS
	APGAR<8	4(28.4)	0	P = 0.144 NS
	Still birth	2(14.2)	0	P > 0.05 NS
	Congenital anomaly	2(14.2)	0	P > 0.05 NS

LFD: Large for dates; FGR: Fetal growth restriction; NEC: Necrotizingenterocolitis; ROP: Retinopathy of prematurity; BPD: Bronchopulmonary dysplasia.

symptomatic patients.It is recommended to perform larger study on more patients before generalization of these results.

6. Conclusion

In a patient with pregnancy and tight mitral stenosis, PBMV performed either before getting pregnant or at the time of pregnancy leads to equivalent maternal and fetal outcomes. However, there are more cardiac symptoms when PBMV was performed during the pregnacy. It implies that PBMV can be safely performed during the pregnancy with good maternal and fetal outcomes.

References

1. Vinayakumar D, Vinod GV, Madhavan S, et al. Maternal and fetal outcomes in pregnant women undergoing balloon mitral valvotomy for rheumatic mitral stenosis. *Indian Heart J.* 2016;68(6):780–782.
2. Vinaykumar M, Narula J, Reddy KS, et al. Incidence of rheumatic fever and prevalence of rheumatic heart disease in India. *Int J Cardiol.* 1994;43:221–228.
3. Perloff JK. Pregnancy and cardiovascular disease. In: Brauwald E, ed. *Heart Disease. A Textbook of Cardivascular Medicine.* 9th ed. :1843–1864.
4. Barbosa PJ, Lopes AA, Feitosa GS, et al. Prognostic factors of rheumatic mitral stenosis during pregnancy and puerperium. *Arq Bras Cardiol.* 2000;75:215–224.
5. Gulzare A, KurdiW. Niaz FA, et al. Mitral balloon valvuloplasty during pregnancy: the long term up to 17 years obstetric outcome and childhood development. *Pak J Med Sci.* 2014;30:86–90.
6. Safian RD, Berman AD, Sachs B, et al. Percutaneous balloon mitral valvuloplasty in a pregnant woman with mitral stenosis. *Catheter CardiovascDiagn.* 1988;15:103–808.
7. Mishra S, Narang R, Sharma M. Percutaneous transseptal mitral commissurotomy in pregnant women with critical mitral stenosis. *Indian Heart J.* 2001;53:192–196.
8. Nercolini DC, Bueno RRL, Guerios E, Tarastchuck JC, et al. Percutaneous mitral balloon valvuloplasty in pregnant women with mitral stenosis. *Cathe Cardiovasc Interv.* 2002;57:318–322.
9. Routray SN, Mishra TK, Swain S, et al. Balloon mitral valvuloplasty during pregnancy. *Int JGynecol Obstet.* 2004;85:18–23.
10. Sivadasanpillai H, Srinivasan A, Sivasubramoniam S, et al. Long-term outcome of patients undergoing balloon mitral valvotomy in pregnancy. *Am J Cardiol.* 2005;95:1504–1506.
11. Mangione JA, Lourenço RM, dos Santos ES, et al. Long-term follow-up of pregnant women after percutaneous mitral valvuloplasty. *Catheter Cardiovasc Interv.* 2000;50:413–417.

12. Iung BL, Garbarz E, Michaud P. Late results of percutaneous mitral commissurotomy in a series of 1024 patients: analysis of late clinical deterioration: frequency, anatomic findings and predictive factors. *Circulation*. 1999;99:3272–3278.
13. Fawzy ME. Long-term results up to 19 years of mitral balloon valvuloplasty. *Asian CardiovascThorac Ann*. 2009;17:627–633.
14. Deans CL, Uebing A, Stear P. *Cardiac Disease in Pregnancy. InStuddJ, TanSL, ChervenakFA*, vol. 17Edinburgh: Progress in Obstetrics and Gynecology Elsevier; 2006:164–182.
15. Desai DK, Adanlawo M, Naidoo DP, et al. Mitral stenosis in pregnancy:a five year experience at King Edward. *Br J Obstet Gynaecol*. 2000;107:953–957.
16. Malhotra M, Sharma JB, Tripathi R, et al. Maternal and fetal outcome in valvular heart disease. *Int J Gynecol Obstet*. 2004;84:11–16.
17. Jose A, deSouza M, Eulogio E, et al. Percutaneous balloon mitral valvuloplasty in comparison with pen mitral valve commissurotomy for mitral stenosis during pregnancy. *J Am Col Card*. 2001;37:900.
18. Malhotra M, Sharma JB, Arora P, et al. Mitral valve surgery and maternal and fetal outcome in valvular heart disease. *Int J Gynecol Obstet*. 2003;81:151–156.