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Study of Effectiveness and Safety of Percutaneous Balloon Mitral Valvulotomy for Treatment of Pregnant Patients with Severe Mitral Stenosis

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Abstract: ***Introduction: Mitral stenosis is the commonest cardiac valvular lesion In pregnant women. When it is present in severe condition itleads to maternal and fetal morbidity and mortality. In mitral stenosis pregnancy can lead to development of heart failure. Aim: To evaluate the safety and efficacy of balloon mitral valvulotomy (BMV) in pregnant females with severe mitral stenosis. Materials and Methods: A total of 49 pregnant patients who underwent Balloon Mitral Valvulotomy were included in the study fromJuly2015 to July 2017. Mean age of these of these patients was 25.7 +- 3.1 years. Clinicalfollow-up during pregnancy was done every 3 months until delivery and after delivery. The mean follow up time after BMVwas 6.72±0.56 months. Results: From the 49 pregnant females 24 (46.67%) and 25 (53.3%) patients underwent BMV during the third and second trimester of pregnancy respectively. The mean mitral valve area was increased from 0.93 +-0.17 cm to 1.75 +-0.27 cm(p<0.0001) immediately after BMV. Preprocedure peak pulmonary artery pressure was 43.05 ± 15.88 mmHg, whichdecreased to 22.31 ± 6.36 mmHg (p value <0.0001). Hemodynamic data showed pre-BMV left atrial mean pressure of 29.6 ± 6.6 mmHg, which decreased to 13.7 ± 4.8 mmHg after the procedure (p value <0.0001) but remained very much unchanged at 6.72 month period of follow-up. There was no maternal mortality in our study. One of the patients developed cardiac tamponade and another patient developed severe mitral regurgitation, which were managed medically. The patient who developed severe mitral regurgitation later underwent mitral valve replacement. Post-procedure follow-up showed an improvement in NYHA status by at least one class in 81.3% of patients. Thirty-nine (81.3%) patients had a term normal vaginal delivery and 9(16.7%) underwent cesarean section for obstetric indications. One of the patients had abortion on the second day of the procedure. Conclusion: During pregnancy BMV technique is safe and effective in patients with severe mitral stenosis. This results in marked symptomatic relief and hemodynamic improvement along with long term maternal and fetal outcomes.***

Keywords: Cardiac abnormalities, Cardiac valvular, Morbidity and mortality

1. Introduction

Mitral stenosis is the commonest cardiac valvular lesionin pregnant women. Cardiovascular events such as arrhythmia, hypertension and heart failure is responsible for the complication in pregnant women with heart diseases. Obstetricand neonatal complications are seen more frequently in pregnant women with heart disease in compare to those without heart disease. Worldwide, prevalence of rheumatic heart disease is decreasing but still it is accounted as most important cause of valvular problems, in which mitral stenosis is the commonest lesion. When mitral stenosis is present in severe condition it results into significant risk of morbidity and mortality for both mother and foetus. In adults, mitral stenosis occurs usually due to a post-rheumatic inflammatory and degenerative disease that fuses the mitral commissures and thickens the chordae. It is one of the most frequently encountered cardiac abnormalities in woman of child bearing age, accounting for nearly 90% of the cases of rheumatic heart disease associated with pregnancy.

Maternal mortality from mitral stenosis is approximately 1%, and rises up to almost 7% in patients with severe impairment. Surgery carries a substantial risk of fetal mortality and morbidity. Valve replacement is associated with high rates of fetalloss (23%) and maternal mortality (2.5%), due to complications of coagulation/anticoagulation [2]. Percutaneousballoon valvulotomy is an alternative to surgery and should be considered as a treatment-of-choice in patients with mitralstenosis who remain symptomatic despite adequate medical therapy. The aim of investigation was to evaluatethe effectiveness and safety of percutaneous mitral valvulotomy for the treatment of pregnant patients with mitral stenosis.

2. Materials and Methods

Study design and patient population

We conducted a prospective study to evaluate the outcomes of percutaneous mitral valvulotomy in pregnantpatients with mitral stenosis. Between July 2015 and july 2017, 49 pregnant patients with mitral stenosis underwentballoon mitral valvulotomy (BMV) at our center. BMV was performed in pregnant women with mitral stenosis with following inclusion criteria:

1) Severe or moderate mitral stenosis with valve area 1.0 cm or less with New York Heart Association (NYHA) functional class II, III or IV.
2) Pliable mitral valve.
3) Gestational age of 20 weeks after the first trimester of pregnancy.
4) Absence of more than grade II/IV mitral regurgitation.
5) Absence of left atrial/left atrial appendage clot.

The patients with moderate mitral regurgitation (grade II/IV) at baseline, echocardiographically confirmed presence of left atrial thrombus, severe aortic or tricuspid valve disease that required surgery, recent thromboembolic stroke, acute infection processes, and asymptomatic moderate to severe mitral stenosis were excluded from the study. All patients underwent detailed transthoracic echocardiographic (TTE) assessment, including 2-dimensional imaging, Doppler studies, and color-flow mapping. The suitability of the valve

for BMV was assessed by morphology of the mitral valve, presence of calcium in the valve commissures, severity of subvalvar pathology, and presence of mitral regurgitation. Transoesophageal echocardiography(TEE) was performed in patients with atrial fibrillation and in those with a suspicion of left atrial clot on transthoracicechocardiography. All subjects gave informed consent, and the risk associated with the procedure was explained, including the risks related to radiation exposure to the fetus. The protocol of the study was reviewed and approved by institutional ethics committee. BMV was performed in the fasting state in the catheterization laboratory. To limit fetal radiation exposure, abdominal and pelvic lead shielding of patients was done (thickness 0.5 mm) from the diaphragm to pubic symphysis, and contrast left ventriculography was not performed. Fluoroscopy was used only when absolutely necessary. The percutaneous Inoue balloon technique was chosen.

Surgical technique and data collection

All BMV procedures were performed under local anaesthesia using the trans-septal, anterograde left-sided cardiac approach. Patients underwent heparinization (100U/kg) after trans-septal puncture. Maximum balloon size possible was determined according to patient's height. Left atrial pressure was recorded before and after the procedure. Stepwise dilatations of 0.5 mm. Echocardiography was performed in the catheterization laboratory to assess the splitting of the commissures. Procedural success was defined as an increase in mitral valve area of 50% over the baseline or a valve area of >1.5 cm , with no significant increase in mitral regurgitation (>2 grades). Clinical follow-up was accomplished by hospital visits every 3 and 6months after the procedure until delivery. After BMV, all patients were followed up for fetal growth and wellbeing. Clinical and echocardiographic evaluation was performed in all patients at follow-up. After delivery, patients were called forevaluation after 3 and 6 months. The mean follow up time after BMV was 6.73±0.56 months.

Statistical Analysis

All data were expressed as mean (standard deviation, SD). The pre- and post-BMVdata were compared using *t* test. A *p* value of <0.05 was considered statistically significant.

3. Results

There were 49 patients during the period who qualified for BMV. Baselinecharacteristics are shown in Table 1. Mean age of the patient was 25.7 ± 3.1 years. Mean gestational age was 23.5 ± 5.2 weeks (12–36 weeks). Symptomatic status varied from New York Heart Association (NYHA) functional class II–IV (mean 2.5 ± 0.6). Sinus rhythm was noted in 35 (71.43%) ofthe patients. Fourteen patients (28.57%) had atrial fibrillation. The procedure was successful in 48 patients. Mean two-dimensional MVA increased from baseline value of 0.93 ± 0.17 cm to 1.75 ± 0.27 cm (*p* value <0.0001). The pre-procedural peak pulmonary arterial pressure (43.05 ± 15.88 mmHg) decreased to22.31 ± 6.36 mmHg (*p* value <0.0001). Pre-BMV peak mitral valve gradient assessed by Doppler echocardiography was 26.22 ± 5.95. Based on hemodynamicdata, it was found that the pre-BMV left atrial mean pressure (29.6 ± 6.6 mmHg),reduced to 13.7 ± 4.8 mmHg after the procedure (*p* value <0.0001). Table 2 shows the pre-BMV and post-BMV comparison. The mean fluoroscopy time was6.4 ± 1.2 min. There was no maternal mortality in this study. The procedure was successfully completed in 48 patients (95.9%). Cardiactamponade developed in a patient who underwent a successful valvotomy, and it necessitated a surgical repair of the rent. This patient went on to have a term normal delivery. One patient who developed severe mitral regurgitation was managed medically since she was hemodynamically and symptomatically stableand she also had a normal vaginal delivery subsequently. This patient underwent elective mitral valve replacement later. Post-procedure follow-up showed an improvement in NYHA status by at least one class in 81.3% of patients.

Table 1: Baseline characteristics of pregnant women who underwent BMV (*n* = 49).

Age	25.69 ± 3.08 (21–33)
Gestational age at which BMV is performed	23.5 ± 5.2 weeks
NYHA class	
II	24 (50%)
III	22 (45%)
IV	2 (4.0%)
2D MVA	0.93 ± 0.17 cm
Atrial fibrillation	14 (28.5%)

BMV, balloon mitral valvotomy; MVA, mitral valve area.

Table 2: Echocardiographic and hemodynamic data before and after BMV

Pre-BMV (mean ± SD)	Post-BMV (mean ± SD)
2D MVA	0.93 ± 0.17 cm 1.75 ± 0.27 cm
LA mean preassure	29.57 ± 6.55 mmHg 13.68 ± 4.77 mmHg
PAP	43.05 ± 15.88 mmHg 22.31 ± 6.36 mmHg
NYHA class	II–IV (2.5 ± 0.6) I–II (1 ± 0.5)
Peak mitral valve gradient	26.22 ± 5.95 mmHg 10.4 ± 3.42 mmHg

BMV, balloon mitral valvotomy; LA, left atrium; PAP, peak pulmonary artery pressure; SD, standard deviation.

Thirty-nine (81.3%) patients had a term normal vaginal delivery and eight (16.7%) had cesarean section for obstetric indications. One patient had an abortion on the second day post-procedure.

Baseline and demographic details of 49 patients with mitral stenosis who underwent balloon mitral valvulotomy, Short-term follow-up information was available in 48 of 49 of the total patient population (90%). One patient was lost to follow up. The mean follow up duration was 6.72±0.56 months. Mean diastolic gradients had decreased significantly after the procedure ($p<0.001$) but remained very much unchanged at 6-month follow-up compared with post procedure values.

Two patients had an increase in mitral regurgitation by 2 grades. The mean mitral valve area was 0.93 ± 0.17 cm before BMV and increased to 1.75 ± 0.27 cm ($p<0.0001$) immediately after BMV . At about 6-month follow-up, the mean mitralvalve area decreased from 1.75 to 1.6

About 83.4% of patients had fluoroscopy time between 2 to 6 minutes, while five (16.66%) patients had fluoroscopy time more than 8 minutes. The mean fluoroscopy time of the whole group was 6.44 ± 1.16 min. We did not calculate radiation exposure in any of the patient. Short term follow up information was available in 48 of 49 of the total patient population (98%). Three patients were lost to follow up. The mean follow up duration was 6.72±0.56 months.

There was one abortions, No still births or neonatal deaths. Mean birth weight was 2.52± 0.35 kg (range: 1.25 to 3.25). Seven (23.33%) babies were having birth weight less than 2.5 kg. There were no clinically evident congenital malformations in any of the patients. All children had normal mental development with normal development milestones.

4. Discussion

Marked hemodynamic changes and the increased cardiac output have their adverse effects during pregnancy, and can lead to worsening of symptoms by approximately 30 weeks of gestation, during labor and after delivery. Maternal mortality is approximately 1% in untreated patients and depends on the functional class of patients during pregnancy. Studies have shown that open surgical procedures during pregnancy carry an adverse fetal and maternal outcome. Medical management alone does not give adequate symptomatic relief or prevent an adverse outcome. In this context, BMV performed during pregnancy is found to be safe and provides excellent symptomatic relief. Ina study conducted by Mishra et al. in All India Institute of Medical Sciences, India (n = 85), a success rate of 94.1% was noted when BMV was performed in severe mitral stenosis patients of NYHA class III–IV, at a mean gestational age of24.84 ± 4 weeks. In the present study, majority of patients were in NYHA functional class II–III and the success rate was 98%. In both groups, patients had excellent symptomatic relief and improvements in NYHA class. There was no maternal mortality in both the studies. Singh et al. from Jayadeva Institute of Cardiovascular Research, Bengaluru, India studied outcome in 58 pregnant patients with mean gestational age of 26.53 ± 5.2 weeks. They reported a success rate of 91% and increase in mean 2D MVA from 0.87 ± 0.14 cm to1.82 ± 0.25 cm . No maternal mortality or abortion occurred during this study. Harikrishnan et al. (n = 36) reported a procedural success rate of 97.2% and an excellent symptomatic improvement. There was no maternal mortality in this study, though 3 preterm deliveries were reported. In the present series, 39 (79.3%) patients had term normal vaginal deliveries and 8 (16.7%) had caesarian sections. The mean fluoroscopy time in the study of Harikrishnan et al. was 5.4 ± 5.8 minwhich were comparable to the present study. Gupta et al. evaluated the safety and efficacy of BMV in 40 pregnant women with rheumatic mitral stenosis. Thirty nine patients underwent a successful procedure. Eleven patients in whom BMV was performed before 20 weeks of gestation underwent medical termination of pregnancy. Out of the 29 women who continued pregnancy, one patient developed preterm labor and one had a stillbirth. There was no maternal mortality in this study. Mean fluoroscopy time was 7.8 ± 1.8 min. Routray et al. have studied patients undergoing BMV during pregnancy and the long-term effects on child development in them. They performed BMV in 40 pregnant women and 39 of them had successful outcome. After a mean follow-up of 36 ± 15 months, 38babies maintained normal growth and development except for a single death of a baby at 7th month due to pneumonia. Kinsara conducted a follow-up study in 20pregnant women who had BMV during pregnancy. Their offspring had mean age of63 ± 39 months (range 6–98). All had normal growth and development as assessed by standard development charts and laboratory tests. The above studies show that BMV done during pregnancy had no major adverse effects on the fetus and postnatal growth and development of the offspring. In the present study, out of 49 patients, 47 had a successful procedure with mean fluoroscopy time of 6.44 ± 1.16 min. There were no preterm delivery, but there wasan abortion following the procedure. We found excellent symptomatic relief following the procedure without an increased risk of maternal mortality. These results are consistent with previous studies and show that performing BMV during pregnancy in symptomatic mitral stenosis patients is safe and effective with good fetal and maternal outcomes.

5. Conclusion

Percutaneous mitral valvotomy during pregnancy is safe and provides excellent symptomatic relief and hemodynamic improvement. This should be considered as the treatment of choice when managing pregnant women with severe mitralstenosis.

6. Conflicts of interest

The authors have none to declare.

7. Financial or Other Competing Interests

None

References

[1] Gulraze A, Kurdi W, Niza FA, Fawzy ME. Mitral balloon valvuloplasty during pregnancy: The long term up to 17 years obstetricoutcome and childhood development. Pak J Med Sci. 2014;30(1):86–90. [PMC free article] [PubMed]
[2] Presbitero P, Boccuzzi GG, de Groot CJM, Roos-Hesselink JW. The ESC Textbook of Cardiovascular Medicine. Oxford: BlackwellPublishing; 2006. Pregnancy and heart disease. In: Camm AJ, Luscher TF, Serruys PW, eds; pp. 607–24.
[3] Routray SN, Mishra TK, Swain S, Patnaik UK, Behera M. Balloon mitral valvuloplasty during pregnancy. Int J Gynaecol Obstet.2004;85(1):18–23. [PubMed]
[4] Nercolini DC, BuenoRdRL, Eduardo Guerios E, Tarastchuk JC, Pacheco AL, Andrade PMP, et al. Percutaneous mitral balloonvalvuloplasty in pregnant women with mitral stenosis. Catheterization and Cardiovascular Interventions. 2002;57(3):318–22. [PubMed]
[5] Bouchahda N, Hassine M, Mechri I, Mahjoub M, Dridi Z, Betbout F, et al. Emergent balloon mitral valvotomy in pregnant womenpresenting with refractory pulmonary edema. The Egyptian Heart Journal. 2014;66:11.
[6] Mangione JA, Lourenco RM, Dos Santos ES, Shigueyuki A, Mauro MF, Cristovao SA, et al. Long term follow-up of pregnant womenafter percutaneous mitral valvuloplasty. Catheterization and Cardiovascular Interventions. 2000;50:413–17. [PubMed]
[7] Kalra GS, Arora R, Khan JA, Nigam M, Khalillulah M. Percutaneous mitral commissurotomy for severe mitral stenosis duringpregnancy. CathetCardiovascDiagn. 1994;33(1):28–30. [PubMed]
[8] Farhat MB, Gamra H, Betbout F, Maatouk F, Jarrar M, Addad F, et al. Percutaneous balloon mitral commissurotomy during pregnancy.Heart. 1997;77(6):564–67. [PMC free article] [PubMed]
[9] Gupta A, Lokhandwala YY, Satoskar PR, Salvi VS. Balloon mitral valvotomy in pregnancy: maternal and fetal outcomes. J Am CollSurg. 1998;187(4):409–15. [PubMed]
[10] Mishra S, Narang R, Sharma M, Chopra A, Seth S, Ramamurthy S, et al. Percutaneous transseptal mitral commissurotomy in pregnantwomen with critical mitral stenosis. Indian Heart J. 2000;53(2):192–96. [PubMed]
[11] Fawzy ME, Kinsara AJ, Stefadouros M, Hegazy H, Kattan H, Chaudhary A, et al. long-Term outcome of mitral balloon valvotomy inpregnant women. J Heart Valve Dis. 2001;10(2):153–57. [PubMed]
[12] De Souza JA, Martinez EE, Ambrose JA, Alves CM, Born D, Buffolo E, et al. Percutaneous balloon mitral valvuloplasty incomparison with open mitral valve commissurotomy for mitral stenosis during pregnancy. J Am CollCardiol. 2001;37(3):900–03.[PubMed]
[13] Cheng TO. Percutaneous Inoue balloon valvuloplasty is the procedure of choice for symptomatic mitral stenosis in pregnant women.Catheterization and Cardiovascular Interventions. 2000;50(4):418. [PubMed]
[14] Sivadasanpillai H, Srinivasan A, Sivasubramoniam S, Mahadevan KK, Kumar A, Titus T, et al. Long-term outcome of patientsundergoing balloon mitral valvotomy in pregnancy. Am J Cardiol. 2005;95(12):1504–06. [PubMed]
[15] Ribeiro PA, Fawzy ME, Awad M, Dunn B, Duran CG. Balloon valvotomy for pregnant patients with severe pliable mitral stenosisusing the Inoue technique with total abdominal and pelvic shielding. Am Heart J. 1992;124(6):1558–62. [PubMed]
[16] Patel JJ, Mitha AS, Hassen F, Patel N, Naidu R, Chetty S, et al. Percutaneous balloon mitral valvotomy in pregnant patients with tightpliable mitral stenosis. Am Heart J. 1993;125(4):1106–09. [PubMed]
[17] Lung B, Cormier B, Elias J, Michel PL, Nallet O, Porte JM, et al. Usefulness of percutaneous balloon commissurotomy for mitralstenosis during pregnancy. Am J Cardiol. 1994;73(5):398–400. [PubMed]
[18] Kinsara AJ, Ismail O, Fawzi ME. Effect of balloon mitral valvoplasty during pregnancy on childhood development.Cardiology.2002;97(3):155–58. [PubMed]
[19] Fawzy ME, Hegazy H, Shoukri M, El Shaer F, ElDali A, Al-Amri M. Long-term clinical and echocardiographic results aftersuccessful mitral balloon valvotomy and predictors of long-term outcome. Eur Heart J. 2005;26(16):1647–52. [PubMed]