Original Article

Maternal and fetal outcomes in pregnant women undergoing balloon mitral valvotomy for rheumatic mitral stenosis

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ARTICLE INFO

Article history:
Received 12 September 2015
Accepted 19 April 2016
Available online 20 May 2016

Keywords:
Mitral stenosis
Balloon mitral valvotomy
Pregnancy

ABSTRACT

Background: Rheumatic mitral stenosis constitutes a major cause of acquired heart disease complicating pregnancy in India. In the present study, we have studied the fetal and maternal outcomes of women undergoing balloon mitral valvotomy during pregnancy.

Methods and results: 48 pregnant ladies were included in this study in whom balloon mitral valvotomy was performed. The mean age of these patients was 25.7 ± 3.1 years. The mean gestational age was 23.5 ± 5.2 weeks (12–36 weeks). The procedure was successful in 48 patients (95.9%). Mean two-dimensional MVA increased from baseline value of 0.93 ± 0.17 cm² to 1.75 ± 0.27 cm² (p value <0.0001). Pre-procedure peak pulmonary artery pressure was 43.05 ± 15.88 mmHg, which decreased 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). Mean fluoroscopy time was 6.4 ± 1.2 min. There was no maternal mortality in our study. One procedure had to be abandoned, because of failed septal puncture. 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 8 (16.7%) underwent cesarean section for obstetric indications. One of the patients had abortion on the second day of the procedure.

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 mitral stenosis.

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1. Background

Rheumatic mitral stenosis constitutes a major cause of acquired heart disease complicating pregnancy in India.1 Symptomatic worsening occurs during pregnancy because of increased hemodynamic burden associated with pregnancy, which includes increased blood volume, heart rate, mean left atrial pressure, and pulmonary venous pressure which can precipitate pulmonary edema.2–5 Medical treatment alone may not be sufficient in these patients and relief of mitral obstruction is often required. Treating these patients with surgical valvotomy has shown to have adverse fetal outcomes.7–10 Balloon mitral valvotomy (BMV)6 is an alternative option in this situation. In the present study, we have examined the fetal and maternal outcomes of women undergoing BMV during pregnancy.

2. Methods

Data were collected prospectively on the fetal and maternal outcomes in pregnant women undergoing BMV for symptomatic mitral stenosis, between 1998 and 2013. Patients with severe mitral stenosis on echocardiographic evaluation were planned for BMV. The criteria were:

- Two-dimensional echocardiography (2D ECHO) mitral valve area (MVA) by planimetry ≤1.0 cm²
• Mean trans-mitral diastolic gradient >10 mmHg
• Resting pulmonary artery systolic pressure >50 mmHg.

Patients with symptomatic mitral stenosis and mitral valve area between 1 and 1.5 cm² were also included.

Patients with more than mild mitral regurgitation (moderate mitral regurgitation) and left atrial/left atrial appendage clot were excluded.

Full clinical evaluation was done in all patients by assessing functional class, pliability of the mitral valve, and presence of audible mitral regurgitation. All the included patients underwent a comprehensive transthoracic echocardiographic evaluation. Assessment of the mitral valve was done with special attention to the mitral valve morphology, commissural calcification, severity of subvalvar pathology, and severity of mitral regurgitation to determine the suitability for BMV. Mitral valve area was assessed by planimetry using standard technique. Transmitral gradient and peak pulmonary artery pressures were assessed using Doppler technique. Left atrial mean pressure and transmirtal gradient were recorded before and after balloon dilatation.

Two-dimensional and color Doppler echocardiography was performed within 24 h after the procedure to assess the 2D MVA by planimetry, transmitral gradient, severity of mitral regurgitation, and peak pulmonary artery pressure. (Within 24 h post-procedure, 2D MVA was calculated by planimetry and transmitral gradient, severity of mitral regurgitation, and peak pulmonary artery pressure estimated using Doppler echocardiography.) The procedure was considered successful when

• there was more than 50% increase in 2D MVA from baseline
• no significant post-procedural increase in mitral regurgitation with an absolute 2D MVA greater than 1.5 cm².

The symptomatic statuses of the patients were also assessed post-procedure. Patients were followed up for one year and regular antenatal evaluation was advised including ultrasonography for assessment of fetal growth. Cesarean section was advised for any obstetric indication. Clinical and echocardiographic evaluation was repeated post-delivery.

2.1. Statistical analysis

All data were expressed as mean (standard deviation, SD). The pre- and post-BMV data 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. Baseline characteristics 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). One patient had to be included at 36th week of gestation as she presented for the first time in the third trimester. Another patient at 12 weeks of gestation was included because she presented with class III symptoms, orthopnea and PND in spite of optimal medication. 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%) of the 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 cm² to 1.75 ± 0.27 cm² (p value <0.0001). The pre-procedural peak pulmonary arterial pressure (43.05 ± 15.88 mmHg) decreased to 22.31 ± 6.36 mmHg (p value <0.0001). Pre-BMV peak mitral valve gradient assessed by Doppler echocardiography was 26.22 ± 5.95. Based on hemodynamic data, 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 was 6.4 ± 1.2 min. There was no maternal mortality in this study. The procedure was successfully completed in 48 patients (95.9%); one procedure had to be abandoned, because of failure to puncture the septum due to marked bulge of the inter atrial septum. This patient had to undergo surgical valvotomy. Cardiac tamponade 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 stable and 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.

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.

4. Discussion

Rheumatic mitral stenosis is the most common cardiovascular disease complicating pregnancy in developing countries. 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. In a study conducted by Mishra et al.11 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 of 24.84 ± 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

| Table 1 |
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| Baseline characteristics of pregnant women who underwent BMV (n = 49). |
| Age | 25.68 ± 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 cm² |
| Atrial fibrillation | 14 (28.5%) |

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

| Table 2 |
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| Echocardiographic and hemodynamic data before and after BMV. |
| | Pre-BMV (mean ± SD) | Post-BMV (mean ± SD) |
| 2D MVA | 0.93 ± 0.17 cm² | 1.75 ± 0.27 cm² |
| LA mean pressure | 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) | II–I (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.
improvements in NYHA class. There was no maternal mortality in both the studies. Singh et al.\textsuperscript{12} 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\textsuperscript{2} to 1.82 ± 0.25 cm\textsuperscript{2}. No maternal mortality or abortion occurred during this study. Harikrishnan et al.\textsuperscript{13} \((n = 36)\) 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 caesarean sections. The mean fluoroscopy time in the study of Harikrishnan et al. was 5.4 ± 5.8 min which were comparable to the present study. Gupta et al.\textsuperscript{14} 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.\textsuperscript{15} They performed BMV in 40 pregnant women and 39 of them had successful outcome. After a mean follow-up of 36 ± 15 months, 38 babies maintained normal growth and development except for a single death of a baby at 7th month due to pneumonia. Kinsara\textsuperscript{16} conducted a follow-up study in 20 pregnant women who had BMV during pregnancy. Their offspring had mean age of 63 ± 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 was an 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 mitral stenosis.

Conflicts of interest

The authors have none to declare.

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