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RESEARCH ARTICLE

PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY DURING PREGNANCY: ITS OUTCOME AND APGAR SCORE

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ABSTRACT

Objectives:The present study was performed to determine the outcome of percutanous balloon mitral valvotomy in pregnant patients either with severe MS (MVA ≤ 1.0 cm^2, with or without symptoms),or symptomatic moderate MS (MVA 1.0 cm^2 to 1.5 cm^2).

Methods: From January 2002 to January 2015, 84 pregnant women with mitral stenosis (MS) underwent BMV. We retrospectively analyzed the pregnancy outcomes, Apgar score of the neonates born to mother after BMV in a pregnant patients with mitral stenosis (MS).

Results: All patients underwent clinical, electrocardiography and echocardiography evaluations before the procedure. BMV resulted in a significant increase in mitral valve area (MVA) from 0.92 ± 0.2 to 2.06 ± 0.3 cm^2 ($p<0.0001$). Mean gestational age (GA) at BMV was 22.43 ± 5.70 and that at delivery was 37.39 ± 2 weeks. Full-term births, either vaginal or cesarean, were observed in 56 (66.67%) pregnancies whereas 24 (28.57%) had preterm delivery. Three patients had abortions and there was one macerated still-birth. There were no embolic events or death related to the procedure. Out of 81 live newborns, 74 (91.36%) newborns had normal birth weight (≥ 2.5 kg). Mean Apgar scores at 1, 5 and 10 minutes after birth were 5.98 ± 0.68, 6.98 ± 0.72, and 8.23 ± 0.45 respectively. Five-minute Apgar score below 7 was found in 19 (23.46%) newborns.

Conclusion: BMV is safe and effective intervention for MS during pregnancy with favorable pregnancy and short-term neonatal outcomes.

INTRODUCTION

Prevalence of heart disease in pregnancy ranges from nearly 1% to 3% and is responsible for 10% to 15% of maternal mortality (1). Rheumatic valvular heart disease (RVHD), complicating pregnancy is a concern in developing countries like India (1-3). Mitral stenosis is the most common encountered disease and is an important contributor to the mortality in pregnant women (1, 4, 5). In mitral stenosis with valve area ≤1.5 cm^2, the mortality in pregnancy reaches to about 5% (5). Valve intervention during pregnancy is recommended in symptomatic cases despite optimal medical management, persistent symptomatic stage IV heart failure or hemodynamic deterioration in stage III and IV heart failure (6). Percutaneous balloon mitral valvuloplasty (BMV) is the method of choice in patients with non-calcific valves without sub-valvular thickening or significant mitral regurgitation (5). Procedural complexities and hazards of radiation during BMV demand a good interventional experience in pregnant patients (7). In view of lack of literature on BMV in pregnancy and its effect on pregnancy and neonatal outcome in India, we retrospectively evaluated outcome in patients who had undergone BMV at a tertiary care institution.

METHODS

We reviewed the health records of patients with rheumatic mitral stenosis who had undergone BMV during pregnancy at Tertiary care institute from January 2002 to January 2015. Eighty-four pregnant women had undergone BMV during this period. As per hospital protocol, clinical (cardiac and

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obstetric), electrocardiography (ECG) and echocardiography (ECHO) evaluations were performed for all patients before the procedure. We had taken institutional ethical clearance for the study.

Severity of mitral stenosis was assessed using 2-dimensional and Doppler ECHO with special emphasis on mitral valve morphology (using the echocardiographic mitral valve score described by Wilkins *et al*) and valve area was measured by 2D Planimetry (8). Mean diastolic mitral gradient, and severity of MR were assessed before and after BMV.

All patients who underwent BMV had either severe MS (MVA ≤ 1.0 cm^2, with or without symptoms), or symptomatic moderate MS (MVA 1.0 cm^2 to 1.5 cm^2). All patients had favorable valve morphology (Wilkins score ≤8). Patients with moderate to severe mitral regurgitation (MR) at baseline, severe aortic or tricuspid valve disease that requires surgery, recent thromboembolic stroke, echocardiographically confirmed presence of left atrial thrombi, moderate to severe MS with unsuitable valve morphology (Wilkins score >8) were excluded from BMV.

BMV Procedure

All patients had to sign an informed consent, before being submitted to BMV using the Inoue balloon. BMV was performed in the fasting state. Patients' abdomen and pelvis were shielded with a folded 5-mm lead shield throughout the procedure. To reduce the duration of fluoroscopy and total procedure time, only important hemodynamics were assessed including transmitral pressure gradient, pulmonary artery pressure and left atrial pressure during the procedure. Fluoroscopy was used only during trans-septal puncture and balloon inflation. Heparin *(*100-150 IU/Kg of body weight) was injected intravenously after trans-septal puncture. Stepwise mitral valve dilatation was performed and was supplemented with Doppler ECHO to determine mitral valve area (MVA), mean gradient and the degree of MR after each inflation .The reference size (RS) is calculated according to the simple formula : patient height (in cm) is rounded to the nearest zero and divided by 10, and 10 is added to the ratio to yield the RS (in mm); e.g., if height = 158cm,then RS=10+10=26mm. At the end, occurrence of inter-atrial communication and severity of MR were assessed by color Doppler technique.

Successful optimal outcome was defined as a final post-BMV MVA of ≥ 1.5 cm^2 or an increase in MVA of > 25% compared with the MVA at baseline in the absence of severe MR. After the procedure, patients were transferred to intensive cardiac care unit and monitored. Clinical, 2-dimensional, and Doppler echocardiographic studies were repeated 24 to 48 hours after BMV in all cases.

Data from medical records department was procured and was evaluated for pregnancy and neonatal outcome. Apgar score was used to assess neonatal outcome (table 1).The test is generally done at one and five minutes after birth, and may be repeated later if the score is and remains low. Scores 7 and above are generally normal, 4 to 6 moderately depressed, and 3 and below are generally regarded as severely depressed.

Table 1 Apgar score

	O point	1 point	2 point
Activity(Muscle tone)	Absent	Arms and leg flexed	Active movement
Pulse	Absent	Below 100 bpm	Over 100 bpm
Grimace (reflex irritability)	Faccid	Some flexion of Extremities	Active motion (sneeze, cough, pull away)
Apperance (skin color)	Blue , pale	Body pink Extremites blue	Completely pink
Respiration	Absent	Slow ,irregular	Vigorous cry

Severely depressed 0-3 , Moderately depressed 4-6, ,Excellent condition 7-10

Statistical analysis

Descriptive analysis was performed for all clinical data. Continuous data variables are expressed as mean ± SD, and categorical variables are expressed as percentages. Paired Student's *t*-test was used to compare continuous variables.

RESULTS

Demographic characteristics

Maternal demographic and pregnancy characteristics are described in table 2. Mean age of the pregnant women (n=84) was 25.21 years (range: 18-36 years) with highest numbers of patients in the age group of 18 - 25 years. Most pregnancies were either second gravida (42.86%) or primigravida (36.90%). Only one twin pregnancy was noted among 84 patients.

Table 2 Maternal characteristics (n=84)

Characteristics	Observation [n, (%)]
Age (Years) (N=84)	
Mean maternal age (Mean ± SD)	25.21 ± 7.66
18-25	57 (67.86)
26-30	19 (22.62)
31-35	6 (7.14)
> 35	2 (2.38)
Gravida (N=84)	
G1	31 (36.90)
G2	36 (42.86)
G3	14 (16.67)
> G3	3 (3.57)
Pregnancy by number of fetus	
Singleton pregnancy	83 (98.81)
Twin pregnancy	1 (1.19)

Intervention Procedure Characteristics

Mean gestational age at the intervention was 22.43 weeks (table 3). In majority of the patients, the intervention was done in second trimester (84.52%). One patient had undergone BMV in first trimester who underwent planned medical termination of pregnancy (MTP). MVA was significantly improved after BMV (baseline: 0.92 ± 0.2 cm^2; post-BMV: 2.06 ± 0.3 cm^2, p<0.0001) (figure 1). In most patients Inoue balloon size was number 26 mm (61.90%) followed by number 24 mm (38.10%).

Table 3 Balloon mitral valvuloplasty (BMV) associated characteristics in pregnancies

Characteristics	Observation
Gestational age at BMV (weeks)[a]	22.43 ± 5.70
Antenatal trimester	
First	1 (1.19)
Second	71 (84.52)
Third	12 (14.29)
Wilkins score[a]	6.82 ± 0.75
6	30 (35.71)
7	41 (48.81)
8	13 (15.48)
Balloon size	
24 mm	32 (38.10)
26mm	52 (61.90)

[a] Mean ± SD, BMV-Balloon mitral valvuloplasty

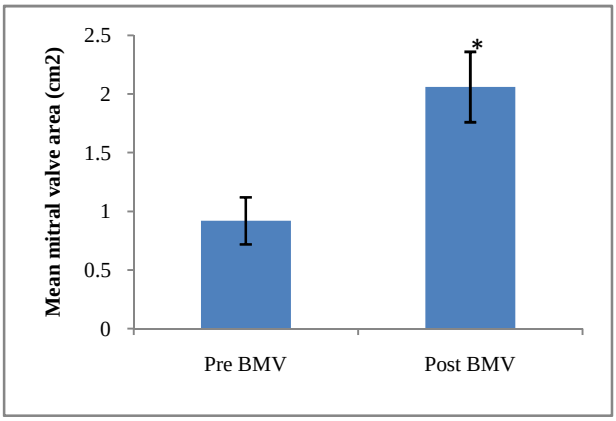

Figure 1 Mitral valve area before and after BMV

*P<0.0001 compared to pre-procedure mitral valve area, BMV-Balloon mitral valvuloplasty

No grade III or IV MR was observed post-BMV after 24 to 48 hours. Post-BMV, grade-I and grade-II MR was observed in 41.67% and 7.14% patients respectively. Pulmonary edema (2.38%), pneumonia (3.57%) and post-procedural delivery within 24 hours (1.19%) were some of the complications observed (table 4). No cases of systemic embolism or death of any pregnant patient occurred.

Table 4 Complications associated with BMV

Complications	N (%)	
Change in mitral regurgitation	Pre BMV	Post BMV
No regurgitation	30 (35.71)	18 (21.43)
Trivial	25 (29.76)	25 (29.76)
Grade 1	27 (32.14)	35 (41.67)
Grade 2	2 (2.38)	6 (7.14)
Pulmonary edema	2 (2.38)	
Pneumonia	3 (3.57)	
Post-procedure delivery (in < 24 hours)	1 (1.19)	

Pregnancy and Neonatal outcomes

Pregnancy Outcomes

Table 5 provides details of pregnancy and neonatal outcomes. Almost two third pregnancies 56 (66.67%) reached to full-term (≥ 37 weeks) whereas preterm delivery was observed in 24 (28.57%) of the patients. There were 3 cases where the pregnancy was prematurely terminated; one patient had spontaneous abortion and the other two underwent planned MTP. There was one case of macerated still-birth at 36 weeks. In this case, intervention was performed at 20 weeks of gestation. The mode of delivery was vaginal in 55% and by cesarean section in 45% of pregnancies with live-births.

Table 5 Pregnancy and neonatal outcomes

Characteristics	Observation [n, (%)]
Pregnancy outcomes (n=84)	
Gestational age at delivery (weeks)[a]	37.39 ± 2
Full term birth (≥ 37 weeks)	56 (66.67)
Preterm birth (< 37 weeks)	24 (28.57)
Abortions[b]	3 (3.57)
Still-birth	1 (1.19)
Mode of delivery for live births (N=80)	
Vaginal	44 (55.00)
Caesarean section	36 (45.00)
Outcomes of live neonates (n=81)	
Birth weight (Kg)	
≥ 2.5	74 (91.36)
< 2.5	7 (8.64)
APGAR score of newborns (n=81)[a]	
1 minute	5.98 ± 0.68
5 minute	6.98 ± 0.72*
10 minute	8.23 ± 0.45#
5-minute APGAR score	
< 7	19 (23.46)
≥ 7	62 (76.54)
Gestational age of neonates with 5-minute APGAR score below 7	
Gestational age[b]	37.3 ± 1.26
< 37 weeks	7 (36.84)
≥ 37 weeks	12 (63.16)

[a] Mean ± SD; [b] Medical termination (n=2); Spontaneous (n=1); *p<0.0001 compared to 1-minute Apgar score, #p<0.0001 compared to 5-minute Apgar score.

Neonatal outcomes

In total, 81 live-births were observed including one twin pregnancy. In most newborns (91.36%), birth weight of 2.5 kg or more was observed. In the twin pregnancy, both babies had low birth weight (1.8 and 1.6 kg in each). Mean (SD) APGAR score at 1, 5 and 10 minutes were 5.98 (± 0.68), 6.98 (± 0.72) and 8.23 (± 0.45) respectively with statistically significant differences between 1 and 5 minute score as well as 5-minute and 10-minute Apgar score (p<0.0001 for both comparisons). Among newborn babies, 23.46% had Apgar score below 7.

DISCUSSION

Rheumatic heart disease still remains a major cause of cardiovascular (CV) mortality for valvular heart disease in pregnancy. Konar *et al*. reported mitral stenosis as the most common VHD in pregnancy (9). In experienced hands, BMV is the recommended intervention for pregnancy-associated mitral stenosis (10). BMV is performed in second trimester in majority of patients since organogenesis is mostly complete by first trimester. Hazards of radiation are also lesser with higher gestational age. In this present study is backed by finding that mean gestational age at intervention is 22.43 ± 5.70 weeks. Similarly Lee *et al*. reported a mean gestational age of 24 ± 4.2 weeks at the time of BMV (11). Second trimester is the suitable time for such intervention which was evident in our study as 84.52% undergone BMV in second trimester with favorable outcome. In this present study only one patient was operated successfully in first trimester since patient had to undergo MTP. Because of the risks involved with MTP in heart disease, BMV was performed in first trimester in this patient.

BMV is less invasive and equally safe and effective as compared to trans-ventricular mitral commissurotomy (TVMC) (9). In this present study our findings, BMV can be a safe and effective alternative to TVMC, as indicated by the significant increase in MVA post BMV. Similar result was reported by Esteves *et al* (12) with increase in MVA from 0.9 ± 0.2 to 2.0 ± 0.3 cm2 (p <0.001). Similar results were also reported by Nercolini *et al* with a significant increase of MVA from 1.17 ± 0.26 to 2.06 ± 0.41 cm^2 post-BMV (13) .Successful outcomes with BMV during pregnancy have been reported by multiple studies (14-15). Additionally, de Souza *et al*. demonstrated 95% success rate with BMV in comparison to open mitral valve commissurotomy in pregnant women (16). These observations strengthen the fact that BMV is a successful intervention for MS in pregnancy. The Inoue balloon size of 26mm was used in most cases providing better results in BMV. It is associated with lesser degrees of mitral regurgitation as is evident in present study (17). Only grade I (41.67%) and grade II (7.14%) MR was observed with no patients developing severe forms of MR.

Radiation exposure during BMV is a significant concern that can result in adverse neonatal outcomes. Major negative effects of radiation include mental retardation, malformed organs and malignancies like leukemia (11). Covering the abdomen with lead sheet to reduce radiation exposure is common practice followed at our institution. Most deliveries were full term extending beyond 37 weeks of gestation suggests a good outcome in terms of uneventful pregnancy after BMV. Esteves *et al* also reported a similar mean gestational age at delivery of 38 ± 1 weeks (12).

Effect of heart disease, procedural intervention or radiation was not evident on fetal growth since 91.36% had birth weight of 2.5 kg and above. This finding is well supported by observation of Esteves *et al* with 88% newborns having normal birth weight at delivery (12).

Newborn babies with lower five minute Apgar scores may suffer from adverse short-term and long-term cognitive outcomes and developmental delay (18). Mean score at five minutes was near 7. A large cohort study of 10,29,207 live births suggests that low Apgar (0-3) at 5-minutes had adjusted relative risk of 359.4 for early neonatal death, 30.5 for late neonatal death and 50.2 for infant death. With moderate Apgar scores (4-6), similar association was observed but with lower magnitude (19). Further with 5-minute Apgar score of 7 and above, neonatal and post-neonatal death rate is reduced with progressively increasing gestational age (20). The present study finding is further supported by different reports (21- 23). Thus it is imperative to conclude that babies born at our set up had overall low risk of early/late neonatal and infant mortality. We found mean Apgar score above 6.98 ± 0.72 at 5 minutes and 8.23 ± 0.45 at 10 minutes. In Indian newborn babies, Misra *et al* found no significant differences for scores at 5 and 10 minutes and outcomes studied. They reported that score of 6 at 5 minutes or 10 minutes had similar outcomes in terms of neurodevelopmental outcome and neonatal mortality (24). We found 5-minute score below 7 in 23.46% of newborns of which only 7 were born prematurely. Going by literature evidence we predict overall good neonatal and infantile outcome of these infants (20-23). No neonatal deaths were observed in this present study. Fawzy *et al*. in long term follow up of babies born in patients undergoing balloon valvotomy found no neurodevelopmental abnormalities (mean follow up 5.1 ± 2.8 years) suggesting good long-term neonatal outcomes with BMV (14).

Study limitations

Being retrospective in nature, this study had limitation in terms of limited availability of clinical data, hemodynamic data and fluoroscopy time. Our study provides immediate pregnancy and neonatal outcomes. Long term outcomes are difficult to assess and comment on, since no further data of women and neonates was available. Restenosis rate is also difficult to assess since no follow-up is available.

CONCLUSION

Our study is the one of its kind that provides Indian data on outcomes of BMV during pregnancy in relation with apgar score. BMV resulted in significant improvement in mitral area with no adverse outcome on pregnancy. Minimal complications rates with no systemic embolisms or deaths observed points to good experience with BMV at our set up. Good neonatal outcomes were seen, as suggested by higher birth weight and 5-minute and 10-minute Apgar scores. Taking into account these scores, we predict better long term outcomes in newborns born after BMV at our set up. Thus our observations suggest that BMV serves as a safe and less invasive intervention than mitral valve replacement for valvular heart disease during pregnancy as thoracotomy and risk of general anaesthesia are avoided. With no contraindications, BMV should be the preferred choice for mitral stenosis intervention during pregnancy.

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