

# The Outcomes of PBMV in Pregnancy, and When is the Best Time?

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**Background:** Percutaneous balloon mitral valvuloplasty (PBMV) is considered the most suitable option for managing symptomatic severe mitral valve stenosis (MS) during pregnancy with favorable anatomy. We do not know the best time to perform PBMV during pregnancy to achieve the best maternal and fetal outcomes. Therefore, we conducted this study to clarify the best procedure timing.

**Methods:** This prospective, observational, single-center study involved 44 pregnant patients suffering from symptomatic MS who underwent PBMV from May 2017 to May 2020. A detailed history is taken, full clinical examination, laboratory assessment, 2 D echocardiography, and follow-up during the hospital stay and monthly until labor.

**Results:** We found that the mean mitral valve area (MVA) had significantly increased from  $1.12 \pm 0.24$  to  $2.09 \pm 0.46$  cm<sup>2</sup> ( $P < 0.001$ ). The mean pressure gradient across the mitral valve reduced from  $17.22 \pm 5.55$  to  $8.94 \pm 3.75$  mmHg ( $P < 0.001$ ). The procedures were successful in 91% of the patients. Regarding obstetric outcomes, the incidence of preterm labor, fetal death, and composite adverse outcomes was significantly lower in patients who had the procedure during the second trimester than those who had the procedure during the third trimester. All preterm deliveries and intrauterine fetal deaths occurred at least 21 days after PBMV. The patients showed a statistically significant improvement in NYHA functional classification.

**Conclusion:** We can conclude that PBMV performed in pregnant patients is an effective and safe treatment modality, and we observed better obstetric outcomes achieved with early intervention during the second trimester.

**Keywords:** rheumatic heart disease, mitral stenosis, PBMV, pregnancy, obstetric outcomes

## Introduction

Rheumatic MS is a leading cause of acquired cardiovascular disease that complicates pregnancy. The increased hemodynamic burden related to pregnancy causes symptomatic deterioration, including higher blood volume, heart rate, mean left atrial pressure, and pulmonary venous pressure, which might induce pulmonary edema. Palpitation, chest discomfort, thrombosis, hepatomegaly, ascites, and edema are frequent signs of mitral stenosis.<sup>1</sup> It is linked to bad maternal outcomes such as arrhythmia, pulmonary edema, and thromboembolism, as well as bad neonatal outcomes such as intrauterine growth retardation, preterm delivery, low birth weight, and neonatal or fetal death.<sup>2</sup>

Despite the availability of various non-invasive diagnostics, echocardiography is the preferred imaging method to evaluate MS patients.<sup>3</sup> MS treatment options include medical therapy, PBMV, and surgery. In symptomatic individuals, medical therapy is the primary line of treatment. PBMV is a minimally invasive technique that can be used in both symptomatic and asymptomatic MS patients. Surgical management is suggested when PBMV is contraindicated in moderate-to-severe MS because of mitral regurgitation (MR).<sup>4</sup> We do not know the best time to perform PBMV during pregnancy to achieve the best maternal and fetal outcomes. Therefore, we conducted this study to clarify the best procedure timing.

## Methods

### Design of the Study

From May 2017 to May 2020, we conducted our study on 44 pregnant patients with a symptomatic moderate-to-severe Rheumatic MS with a mean age of  $29.51 \pm 6.22$  years, who underwent PBMV at the Cardiology Unit of the Sohag University Hospitals. All participants provided written informed consent prior to participating in the study. The study protocol conformed to the ethical guidelines of the 1975 Helsinki Declaration. The ethics committee of the Sohag Faculty of Medicine approved the study protocol [https://medsohagedu-my.sharepoint.com/:b:/g/personal/ahmed\\_hussien\\_med\\_sohag\\_edu\\_eg/Ee1vaCiHnH5FgLK\\_VUjr0aMBOPI98CGEXSXW2K7tnSEfVw?e=5nmBLL](https://medsohagedu-my.sharepoint.com/:b:/g/personal/ahmed_hussien_med_sohag_edu_eg/Ee1vaCiHnH5FgLK_VUjr0aMBOPI98CGEXSXW2K7tnSEfVw?e=5nmBLL). All participants gave informed written consent.

A full clinical and obstetric evaluation, electrocardiogram, transthoracic echocardiogram, and transesophageal echocardiography were done for all patients. The assessment of the severity of MS was done pre- and post-procedure using 2D and Doppler echocardiography. Valve area, mean transvalvular pressure gradient, degree of mitral regurgite (MR) if present and valvular morphology were also assessed.

We included all patients fulfilling the criteria for being suitable for PBMV: 1) patients with New York Heart Association (NYHA) functional classification III or IV despite receiving optimum medical therapy; 2) echocardiographic assessment revealed moderate-to-severe MS with less than grade III mitral regurgitation; and 3) all patients exceeding their first trimester after 14 weeks of gestational age.

Evaluation of obstetric and fetal outcomes was done before, and immediately after the procedure, during the hospital stay, and monthly until delivery.

Patients with left atrial (LA) appendage thrombus by transesophageal echocardiographic assessment, acute rheumatic activity, the presence of coexisting infection, those with highly unfavorable mitral valve morphology, multi-valvular affection, the presence of massive or bi-commissural calcification, hypertension, or gestational diabetes were excluded.

Patients with a high MV score ( $>8$ ) without the presence of significant commissural calcification, including 12 patients were referred for PBMV because they are considered to be at increased risk of cardiac surgery.

After consultation with senior obstetricians and inhibiting uterine contraction, patients received indomethacin (40 mg) rectal suppository 6 hours pre-procedure. For ensuring fetal safety and limited radiation exposure, we omitted left ventriculography. Fluoroscopy was used only when necessary. The patient's abdomen and pelvis were shielded with a folded 5-mm lead Apron shield throughout the procedure.

For all patients, PBMV was done using the Inoue balloon technique. Septostomy & Trans septal catheterization with an 8F Mullins transseptal dilator and then transseptal left-sided catheterization were done in a standard method then anterograde mitral commissurotomy. Maternal outcomes were recorded through assessment of standard hemodynamics, including trans-mitral pressure gradient and pulmonary artery systolic pressure, throughout the procedure. All hemodynamic measurements were obtained both before and immediately after PBMV. Heparin was given (100 IU/kg of body weight) after the transseptal puncture. The Color Doppler technique was used to assess interatrial communication and the severity of MR. The size of the balloon was selected according to the patient's body surface area modulated by the valve anatomy and confirmed the selection of the balloon size was by directly measuring the mitral annular diameter using 2-dimensional echocardiography. The maneuver is considered successful when meeting the criteria of the definition of optimal results referred to by "Block & Palacios",<sup>5</sup> In which a decrease in the transmitral pressure gradient of  $<10$  mmHg, post-procedural MVA of  $\geq 1.5$  cm<sup>2</sup>, and an increase in MVA of  $>25\%$  compared to MVA before dilatation.

Finally, patients were transferred to the intensive care unit of the cath lab for monitoring with full obstetric reassessment. 2D and Doppler echocardiographic evaluations were done 24 hours after PBMV.

The mode of delivery was decided based on obstetric indications, and a senior pediatrician assessed neonatal outcomes.

### Analysis of Data

Data were analyzed using SPSS version 20. We performed the test of normality for the provided data (Shapiro–Wilk test), the p-value was  $>0.05$ , so the data were normally distributed, and we used a *t*-test. We analyzed Quantitative data

using the Student's *t*-test to compare the means between groups. Qualitative data were compared using the Chi-square test and we used Fisher's exact correction when the expected cell count is less than 5. A paired sample *t*-test or Marginal homogeneity test was used to assess the significance between means when we compare paired samples. A P-value less than 0.05 is considered significant.

## Results

As regards demographic and baseline characteristics, we found that the mean age of participating patients was  $29.51 \pm 6.22$  (21–35 years). Forty patients were in class III NYHA functional classification and four patients were in class IV. The mean gestational age was  $23.27 \pm 7.11$  weeks. The echocardiography score using Wilkin's score showed 12 patients (27.3%) had Wilkin's  $>8$  (range 9–11) without the presence of significant commissural calcification (Table 1).

As regards the procedure outcomes, the procedure significantly increased the presence of or the grade of MR (Table 2). Post-procedure, there was a significant decrease in the mean pulmonary artery systolic pressure (PASP), the mean LA pressure, and the mean transvalvular pressure gradient. The mean (MVA) was  $1.12 \pm 0.24 \text{ cm}^2$  and had significantly increased to  $2.09 \pm 0.46 \text{ cm}^2$  after balloon dilatation ( $P < 0.001$ ) (Tables 3).

**Table 1** Demographic and Baseline Data of Studied Patients

		Cases (N=44)	
Age (years)	Mean +SD	$29.51 \pm 6.22$	
	Range	21–35	
Gestational age (weeks)	Mean +SD	$23.27 \pm 7.11$	
	Range	(16–30)	
NYHA classification	III	40	90.9%
	IV	4	9.1%
Prior surgical open commissurotomy		5	11.4%
Atrial fibrillation		4	9.1%
Sinus rhythm		40	90.9%
Wilkin's score	$\leq 8$	32	72.7%
	$> 8$	12	27.3%

**Abbreviations:** N, number; SD, standard deviation; NYHA, New York Heart Association.

**Table 2** Mitral Regurge Before and After the PBMV Procedure

		Before (N=44)	After (N=44)	P value
		No (%)	No (%)	
Mitral regurge	No	28 (63.6%)	16 (36.8%)	$<0.001^*$
	Grade I	12 (27.2%)	22 (50%)	
	Grade II	4 (9%)	6 (13.6%)	

**Notes:** P value, probability value; \*Statistically significant.

**Abbreviations:** MR, mitral regurge; N, number; SD, standard deviation; PBMV, percutaneous balloon mitral valvuloplasty.

**Table 3** Echocardiographic Parameters Before and After the PBMV Procedure

	Before (N=44)	After (N=44)	P value
	Mean +SD	Mean +SD	
<b>Pulmonary artery systolic pressure</b> (mmHg)	55.43 ± 23.4	33.63 ± 11.40	<0.001*
<b>LA pressure</b> (mmHg)	25.16 ± 7.10	11.27 ± 4.61	<0.001*
<b>Trans-valvular pressure gradient</b> (mmHg)	17.22 ± 5.55	8.94 ± 3.75	<0.001*
<b>Mitral valve area</b> (cm <sup>2</sup> )	1.12 ± 0.24	2.09 ± 0.46	<0.001*

**Notes:** P value, probability value; \*Statistically significant.

**Abbreviations:** cm<sup>2</sup>, cubic centimeter; LA, left atrium; mmHg, millimeter mercury; N, number; SD, standard deviation; PBMV, percutaneous balloon mitral valvuloplasty.

**Table 4** NYHA Functional Classification Before and After PBMV Procedure

		Before (n=44)	After (n=44)	P value
		No (%)	No (%)	
<b>NYHA Class</b>	<b>I</b>	0	6 (13.6%)	<0.001*
	<b>II</b>	0	35 (79.5%)	
	<b>III</b>	40 (90.9%)	3 (6.9%)	
	<b>IV</b>	4 (9.1%)	0	

**Notes:** P value, probability value; \*Statistically significant.

**Abbreviations:** N, number; SD, standard deviation.

MVA increased to > 25% in all patients without the occurrence of a significant degree of MR. Four patients showed a >25% increase in MVA; however, the final area was still <1.5 cm<sup>2</sup>. Therefore, we achieved a 91% success rate. The patients showed a statistically significant improvement in NYHA functional classification (Table 4).

The mean procedural time was 50.24 ± 16.11 minutes with a range from 20 to 120 minutes. There were no reported major complications such as pericardial effusion and consequent tamponade, severe MR, thrombotic or embolic events and death.

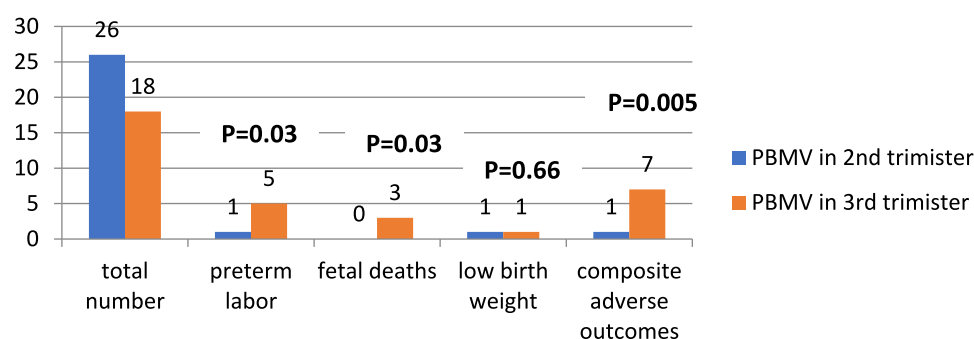
Regarding obstetrics outcomes, the incidence of preterm labor was significantly lower in patients who had the procedure during the second trimester compared to those who had the procedure in the third trimester (p values = 0.03), while the incidence of low birth weight showed no significant difference. The incidence of intrauterine fetal deaths was significantly lower in patients who had the procedure during the second trimester compared to those who had the procedure in the third trimester (p values = 0.03). The incidence of composite adverse outcomes was significantly lower in patients who had the procedure during the second trimester compared to those who had the procedure in the third trimester (p values = 0.005) (Table 5, Figure 1).

**Table 5** Procedure Adverse Outcomes During the Second and Third Trimesters

<b>Obstetric and Fetal Outcomes</b>	<b>PBMV Performed During 2nd Trimester (N=26)</b>	<b>PBMV Performed During 3rd Trimester (N=18)</b>	<b>P-value</b>
	No (%)	No (%)	
<b>Preterm labor</b>	1 (3.85%)	5 (27.78%)	0.034
<b>Dead fetus</b>	0 (0%)	3 (16.67%)	0.031
<b>Low birth weight</b>	1 (3.85%)	1 (5.56%)	0.66
<b>Composite adverse outcome</b>	1 (3.85%)	7 (38.89%)	0.005

**Notes:** P value, probability value; \*Statistically significant.

**Abbreviations:** N, number; PBMV, percutaneous balloon mitral valvuloplasty.



**Figure 1** Post procedure adverse obstetric outcomes during the second and third trimesters.

All preterm deliveries and intrauterine fetal deaths occurred at least 21 days after PBMV, and so the obstetric complications mostly were not related to our procedure. All patients were delivered by cesarean section and no obstetric complications were observed.

## Discussion

The changes in hemodynamics that occur during pregnancy may be considered a normal physiological adaptation to the 15–20% elevation in fetal oxygen consumption.<sup>7</sup> The first trimester shows a 60% increase in blood volume above the non-pregnant.<sup>3,6–8</sup> The Cardiac output (COP) starts to increase during the first trimester, reaching a peak of 30–45% over resting in non-pregnant women around the 20th-week gestation.<sup>2,3</sup> Increased COP is related to reduced systemic vascular resistance, resulting in lower or no change in blood pressure and a wide pulse pressure range.<sup>3,7,8</sup> An increase of about 10–20 beats/min of mean heart rate when reaching the term.<sup>7,8</sup> Other cardiovascular changes occur during delivery due to increased demands. Pain during uterine contraction and the increased venous return from these contractions represents another 20% increase in COP.<sup>7</sup> Another large amount of fluid shifts occurs during the postpartum period, normal pregnant women may have an elevation in COP reaching up to 65% immediately after delivery.<sup>6</sup> The hemodynamic stress associated with pregnancy leads to decompensation of asymptomatic patients, especially those with moderate-to-severe MS.<sup>9,10</sup>

PBMV is considered the treatment of choice for MS during pregnancy if the anatomy is favorable. In our study, the mean gestational age was  $23.27 \pm 7.11$  weeks at the time of PBMV, which was comparable to the previously published studies showing a range of 21–25 weeks, but different from a study conducted in India by Vijayvergiya R, who reported a mean gestational age  $29.5 \pm 6.68$  weeks.<sup>11</sup> The safety and effectiveness of PBMV during pregnancy have been shown by great clinical and hemodynamic outcomes.<sup>11–35</sup> It is considered an excellent and beneficial procedure in many studies with a success rate of 82–94% and in some instances it reaches up to 100% of the patients.<sup>11,32–37</sup> Similar results were found in our study, as we achieved a 91% success rate with a significant improvement in MVA and decreased transvalvular gradient and pulmonary artery pressure.

The incidence of occurrence of major complications was considerably low ranging from 0% in a study conducted by Fawzy et al<sup>38</sup> up to 9% in a study conducted by Ben Farhat et al<sup>12</sup> and continues to decrease as expertise in this procedure improves with time. Similar results were achieved in our study, as the major unfavorable outcomes were 0%.

According to the time of the procedure, whether in the second or third trimester of pregnancy. We found a significant difference in obstetric outcomes. The incidence of preterm labor, fetal death, and composite adverse outcomes was significantly lower in patients who had the procedure during the second trimester than those who had the procedure in the third trimester (p values = 0.034, 0.031, and 0.005, respectively). While the incidence of low birth weight shows no significant difference. While Vijayvergiya et al<sup>11</sup> found no statistically significant difference in the incidence of preterm labor, fetal death, or low birth weight in patients performed the procedure before 24 weeks of pregnancy compared to those who had the procedure after 24 weeks. But we considered the third trimester to start after 28 weeks of pregnancy, not after 24 weeks, that may have an impact on the different results. Other studies reported the adverse obstetric outcomes happened mainly during the third trimester that matches with our results.<sup>33–35</sup> All preterm deliveries and

intrauterine fetal deaths occurred at least 21 days after PBMV, and so the obstetric complications mostly were not related to our procedure.

## Strengths of Our Study

To our knowledge, no previous study assessed the best time to perform PBMV to achieve the best maternal and fetal outcomes.

## Limitations of Our Study

Our study has some limitations to be considered. Firstly, the relatively small number of patients limited the comparative data analysis of those collected in the current study. Secondly, we have no control group because it is non-ethical to leave pregnant women with significant symptomatic MS without intervention. Finally, data comparing PBMV in pregnant women in the second trimester versus those performed late in the third trimester are lacking, therefore comparing our data with other similar studies is not possible.

## Conclusion

We can conclude that PBMV performed in pregnant patients is an effective and safe treatment modality, and we observed better obstetric outcomes achieved with early intervention during the second trimester.

## Abbreviations

COP, cardiac output; LA, left atrium; MR, mitral regurge; MS, mitral stenosis; MVA, mitral valve area; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; PBMV, percutaneous balloon mitral valvuloplasty.

## Declarations

- Ethics approval and consent to participate: All subjects provided written informed consent to participate in the study. The study protocol was approved by:
  1. Medical Research Ethics Committee, Sohag Faculty of Medicine, Sohag University. The committee reference number is not applicable. Date of approval, May 2017.
- Availability of data and materials: the datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.
- Authors' contributions: All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors report no conflicts of interest for this work.

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