Balloon Mitral Valvotomy in Gestational Women with Symptomatic Mitral Stenosis

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Authors’ contributions

This work was carried out in collaboration among all authors. Author PKA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AK, KT, GR, SS and PR managed the analyses of the study. Author RBV managed the literature searches. All authors read and approved the final manuscript.

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Original Research Article

ABSTRACT

Background: Rheumatic valvular heart disease, commonly mitral stenosis, complicate 1% of pregnancies. Balloon mitral valvuloplasty (BMV) is an established treatment of rheumatic mitral stenosis. Aim of the study was to assess the safety and efficacy of Balloon mitral valvuloplasty in pregnant women with severe mitral stenosis.

Materials and Methods: 66 patients who failed to respond to medical therapy undergoing BMV during pregnancy were analysed in this retrospective study. Mitral valve area (MVA), transmitral Mean valve gradient (MVG), and mitral regurgitation (MR), Pulmonary artery pressure (PAP) were assessed before and 24 hours after the procedure by transthoracic echocardiography. Patients were followed up to one month post BMV and neonates were monitored for the adverse effect of radiation.

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**Results:** Mitral valve area increased from 0.83 ± 0.13 cm² to 1.38 ± 0.29 cm² (P = 0.007). Mean gradient mitral valve gradient decreased from 15.5 ± 7.4 mmHg to 3.36 ± 2.36 mmHg (P = 0.001). Pulmonary artery pressure decreased from 65.24 ± 17.9 to 50.45 ± 15.33 (P = 0.012). No maternal death, intrauterine growth restriction was observed.

**Conclusion:** Balloon mitral valvuloplasty has favourable immediate good outcomes for mothers and newborns.

**Keywords:** Balloon mitral valvuloplasty; mitral stenosis; pregnancy.

### 1. INTRODUCTION

Valvular heart diseases complicate 0.5 to 1.5 percent of all pregnancies [1]. Mitral stenosis is the most common form with increased pregnancy and delivery complications for both mother and neonate [2]. During pregnancy physiological hemodynamic changes of the circulation are the main cause of mitral stenosis decompen-sation [3]. The symptoms are poorly tolerated especially beyond the second trimester and in other cases may lead to frank heart failure [4,5]. Most pregnant women with mitral stenosis can be adequately treated with medical therapy and sometimes an invasive procedure is mandatory [6–9]. Before the introduction of percutaneous transluminal mitral commissurotomy(PTMC) surgical commissurotomy was the sole answer to pregnant women with refractory symptoms. The high mortality rate (1.8% to 33%) of surgery and favourable outcome of PTMC in relieving symptoms plus a lower risk of fetal death made PTMC more popular [10–15]. Prospective studies on PTMC and its effect on pregnancy outcome and neonate are needed. In this study, we aimed to investigate the clinical outcome of pregnant women undergoing PTMC and to assess the neonate condition after one month [16].

### 2. MATERIALS AND METHODS

A series of 66 pregnant women undergoing PTMC in Department of Cardiology, PSG Hospitals, Peelamedu, Coimbatore from September 2015 to October 2019 were analysed in this descriptive study. The study was approved by ethical committee.

#### 2.1 Inclusion Criteria

1. Patients with severe mitral stenosis.
2. Progressive symptoms during any trimester in spite of adequate medical therapy.
3. History of acute pulmonary edema during pregnancy.

#### 2.2 Exclusion Criteria

1) Severe mitral regurgitation.
2) Left atrial thrombus.

PTMC was performed using Accura balloon. Balloon diameters were chosen according to the patient’s height using Hung’s formula. Lead shields were used to protect the abdomen during the procedure limiting fetal radiation exposure. Fluoroscopy time was measured during the procedure. Heparin (80 IU/kg, intravenously) was administered twice during the procedure. Mitral valve area, transmtral valve gradient and severity of mitral regurgitation, PA pressures were measured before and 24 hours after the procedure and during long-term follow-up using two-dimensional echocardiography to evaluate the efficacy of the procedure. Transthoracic echocardiography was performed with a Philips HD7 machine with a 2.5 MHz probe, and images obtained in parasternal long and short axis and apical two- and four-chamber views. Mitral valve morphology was also evaluated before the procedure using criteria by Wilkins et al. [17] Mitral valve velocities were assessed with continuous-wave Doppler and mitral valve area was estimated from the planimetry method [18]. Mitral regurgitation was graded as mild, moderate, or severe according to jet length and area. Clinical follow-up after hospital discharge was accomplished by medical visits 1, 3, 6 months after discharge. Finally patients were scheduled to be visited every 6 months for lifetime and to report earlier if symptomatic [16].

All patients were advised injectable benzathine penicillin 12 lac units deep intramuscular once in 21 days. Moreover, all babies were examined after delivery for any malformation and their development was assessed after one month over telephone. Continuous variables are expressed in mean ± SD. Comparison between the groups

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was accomplished by Student’s two-tailed test. A P value of 0.05 was considered of statistical significance.

3. RESULTS

Demographic data are summarized in Table 1. Mean maternal age was 27 ± 5.4 years and mean gestational age was 22.8 ± 6.4 weeks. PTMC was performed successfully in all patients. After the procedure, mean MVA increased from 0.83 ± 0.13 cm² to 1.38 ± 0.29 cm² (P-value 0.007). Mean MVG significantly decreased from 15.5 ± 7.4 mmHg to 3.36 ± 2.36 mmHg (P-value 0.001). Also, a significant decrease in pulmonary artery pressure was detected from 65 ± 18 mmHg to 50 ± 15 mmHg (P = 0.012). Mean left atrial pressure decreased significantly from 28.3 ± 7.2 to 15 ± 5.45. No significant change occurred in left ventricular ejection fraction and left ventricular end diastolic volume before and after procedure (Table 2). Symptoms of heart failure improved in all patients, and none of them experienced NYHA class III or IV (Table 3). Mitral regurgitation in 12 patients changed from mild to moderate and in one case to severe after procedure and this patient was 2 weeks short of due and hence underwent simultaneous mitral valve replacement and lower abdomen cesarean section without any complications (Table 4). 3 patients developed cardiac tamponade during septal puncture, but all 3 underwent pericardiocentesis with successful completion of PTMC. No maternal death, abortion, or intrauterine growth retardation was reported. Total fluoroscopy time was 8 mins (average). Infants assessed after one month by paediatrician and all had normal growth and development which was verified over telephone [16].

![WILKINS SCORE](image1)

**Fig. 1. Wilkins score of study population**

![NYHA CLASS PRE PTMC](image2)

**Fig. 2. NYHA class pre PTMC**
Table 1. Baseline characteristics of study population

<table>
<thead>
<tr>
<th>Mean Maternal Weight (kg)</th>
<th>Mean Maternal height (cm)</th>
<th>Mean age (year)</th>
<th>Mean gestational age (weeks)</th>
<th>NYHA (1)</th>
<th>NYHA (11)</th>
<th>NYHA (111)</th>
<th>NYHA (IV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>48.5</td>
<td>150.4</td>
<td>27 ± 5.4</td>
<td>22.8 ± 6.4</td>
<td>2</td>
<td>24</td>
<td>30</td>
<td>10</td>
</tr>
</tbody>
</table>

Fig. 3. Nyha class post procedure

Fig. 4. Rhythm status

Table 2. Echocardiographic parameters

<table>
<thead>
<tr>
<th>Wilkins score</th>
<th>&lt;8</th>
<th>9-10</th>
<th>&gt;10</th>
<th>No Mitral regurgitation</th>
<th>Mild Mitral regurgitation</th>
<th>Moderate Mitral regurgitation</th>
<th>Thrombus confined to left atrial appendage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>28</td>
<td>32</td>
<td>6</td>
<td>24</td>
<td>36</td>
<td>6</td>
<td>2</td>
</tr>
</tbody>
</table>

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Pregnancy is characterized by a hyper dynamic state with significant change of hemodynamic especially between the 24th and 26th week of gestation and can explain decompensation in pregnant women with critical mitral stenosis [1,3]. However, most patients respond well to adequate medical therapy. In some cases, maximal clinical therapy is not enough and an invasive intervention is required. Surgical mitral commissarotomy was performed during pregnancy with precautions mainly due to the high mortality rates of mother and neonates. [15,17,18] Percutaneous mitral valvuloplasty was first performed in 1984. PTMC proved a safe procedure with outstanding results. However, studies with proper follow-up have not yet been fully described. The present study shows an excellent outcome for the patients after PTMC. After the successful procedure, most of the patients were in Functional Class I or II. In addition, there were no deaths related to the procedure. Echo cardiographic examinations also showed favourable results, with a significant increase in mitral valve area and decrease in transmitral gradients shortly after the procedure [16]. Only one case of severe mitral regurgitation was observed. The excellent results observed after PTMC in this study can be attributed to the young age of the group and suitable mitral valve morphology. These parameters are both important predictors of short and long term results [17,19]. There were neither maternal nor fetal deaths directly related to the procedure. No fetal abnormalities were found during examination and no clinical abnormalities could be associated with the use of radiation. Concerning the radiation exposure, the maximum safe radiation dose for the mother and the child has been established as 5 rads. Similar fluoroscopy time and the same protection used in other series, reported the total amount of received radiation to be approximately 0.5 rads, therefore far below the established limit. In summary, due to the favorable results observed, percutaneous mitral valvuloplasty can be considered the procedure of choice to treat pregnant women with mitral stenosis unresponsive to adequate medical therapy [16].
Table 5. Procedural indices

<table>
<thead>
<tr>
<th>Index</th>
<th>Pre procedure</th>
<th>Post procedure</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral Valve Orifice area (MVOA)</td>
<td>0.83 ± 0.14</td>
<td>1.39 ± 0.29</td>
<td>0.007</td>
</tr>
<tr>
<td>Mitral valve mean Gradient</td>
<td>15.55 ± 7.41</td>
<td>3.36 ± 2.36</td>
<td>0.001</td>
</tr>
<tr>
<td>Pulmonary artery pressure</td>
<td>65.24 ± 17.9</td>
<td>50.45 ± 15.33</td>
<td>0.012</td>
</tr>
<tr>
<td>Left atrial pressure</td>
<td>28.3 ± 7.2</td>
<td>15 ± 5.45</td>
<td>0.01</td>
</tr>
<tr>
<td>Left ventricular ejection fraction</td>
<td>51.97 ± 5.99</td>
<td>51.82 ± 5.7</td>
<td>0.01</td>
</tr>
<tr>
<td>No Mitral regurgitation</td>
<td>24 (15.8%)</td>
<td>13 (8.5%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Mild Mitral regurgitation</td>
<td>36 (23.7%)</td>
<td>40 (24%)</td>
<td>0.006</td>
</tr>
<tr>
<td>Moderate Mitral regurgitation</td>
<td>6 (4%)</td>
<td>12 (7.9%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Severe Mitral regurgitation</td>
<td>-</td>
<td>1 (0.6%)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Table 6. Changes in functional capacity

<table>
<thead>
<tr>
<th>New York Heart Association (NYHA) Class</th>
<th>0</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE PTMC</td>
<td>-</td>
<td>2</td>
<td>24</td>
<td>30</td>
<td>10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>POST PTMC</td>
<td>15</td>
<td>38</td>
<td>11</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. CONCLUSION

The present study shows a favorable immediate outcomes with BMV for gestational woman with symptomatic severe mitral stenosis [16].

CONSENT

As per international standard or university standard written patient consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

The study was approved by ethical committee.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

12. Palacios IG, Block PC, Wilkins T, Rediker DE, Daggett W. Percutaneous mitral


