

# Percutaneous Balloon Mitral Valvuloplasty in Comparison With Open Mitral Valve Commissurotomy for Mitral Stenosis During Pregnancy

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<b>OBJECTIVES</b>	We sought to compare the maternal and fetal outcomes of patients with severe mitral stenosis submitted to percutaneous balloon dilation versus open mitral valve commissurotomy (MVC) during pregnancy.
<b>BACKGROUND</b>	Heart failure in patients with mitral stenosis complicating pregnancy is a common problem in developing countries. Since 1984, percutaneous dilation of the mitral valve using a balloon catheter has become a therapeutic alternative to open heart surgery. Although the efficacy of percutaneous mitral valve balloon dilation is well established, its results have never before been compared with the results of commissurotomy during pregnancy.
<b>METHODS</b>	We compared the clinical and obstetric complications in 45 women who were treated with percutaneous mitral valve balloon dilation (group I, n = 21; from 1990 to 1995) or open MVC (group II, n = 24; from 1985 to 1990) for severe heart failure due to mitral stenosis during pregnancy.
<b>RESULTS</b>	In our study, percutaneous balloon dilation of the mitral valve had a success rate of 95% (Gorlin formula) and 90.5% (echocardiographic "pressure half-time" method), as demonstrated by the final mitral valve area achieved. This improvement was followed by a marked decrease in the mitral valve gradient, left atrial pressure and mean pulmonary artery pressure. Patients in both groups had similar improvements in symptoms. Patients who underwent percutaneous balloon dilation had significantly fewer fetal complications, with a reduction in fetal and neonatal mortality (1 death in group I vs. 8 in group II, p = 0.025).
<b>CONCLUSIONS</b>	Percutaneous balloon mitral valvuloplasty is safe and effective and appears to be preferable for the fetus, compared with open MVC during pregnancy. (J Am Coll Cardiol 2001;37:900-3) © 2001 by the American College of Cardiology

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The safety and efficacy of percutaneous balloon mitral valvuloplasty (PBMV) has been reported by several investigators (1,2). In patients with mitral stenosis and a pliable valve anatomy, PBMV has been shown to be equivalent to either closed or open mitral valve commissurotomy (MVC) (3-5).

Patients with mitral stenosis complicating pregnancy represent a common health problem in the developing world (6). These women frequently present with worsening symptoms, often necessitating prolonged periods of bed rest and hospitalization, despite optimization of clinical treatment (7).

Before the introduction of PBMV in 1984 (1), MVC was the only treatment available for patients with refractory symptoms of heart failure. Although performing this procedure during pregnancy does not add risk for the mother, the fetal risk is increased (fetal mortality 6% to 33%) (8-10). This increase in fetal mortality may be due to either the effects of general anesthesia, thoracotomy or extracorporeal circulation. In contrast, PBMV during pregnancy has been

reported without fetal loss and may be the preferred modality of treatment in this subset of patients (11-15). However, no study has shown the superiority of PBMV over open MVC during pregnancy.

## METHODS

From January 1985 to August 1995, a total of 45 consecutive pregnant women underwent MVC in our institution for control of symptoms of mitral stenosis. All patients were in New York Heart Association functional class III or IV despite hospital admission and intensive medical therapy. Twenty-one patients were submitted to balloon mitral valvuloplasty (group I) and 24 were submitted to MVC (group II). The first 24 patients (from 1985 to 1990) underwent open MVC, and the following 21 patients (from 1990 to 1995) underwent a percutaneous procedure.

All patients who had MVC or PBMV between 1985 and 1995 were included. Patients in functional class III or IV heart failure were admitted and treated with an intravenous diuretic agent, digitalis or, occasionally, beta-blockers.

Two-dimensional echocardiograms were obtained in all patients treated by balloon valvuloplasty, whereas M-mode echocardiograms were used for the analysis of the mitral valve anatomy in the surgical group, because two-

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**Abbreviations and Acronyms**

MVC = mitral valve commissurotomy  
 PBMV = percutaneous balloon mitral valvuloplasty

dimensional echocardiography was not available at our institution before 1990.

**Clinical indications.** The indication for valvuloplasty included severe heart failure despite intensive medical treatment. All patients presented with severe orthopnea or pulmonary edema despite treatment with a high dose of diuretic agents (furosemide, 80 mg to 240 mg/day). Patients treated medically who returned to functional class II were excluded. In most cases, the interventions were done on an urgent basis because of clinical deterioration. In the surgical group, visual inspection of the mitral valve apparatus was used for deciding between mitral valve replacement or commissurotomy. Mitral valve commissurotomy was performed in cases of predominant commissural fusion, little or no calcification and absence of major deformities of the mitral valve. Eight patients submitted to mitral valve replacement were not analyzed in this study. Of these, five had mitral stenosis as a predominant lesion, but the mitral valve apparatus was not suitable for commissurotomy (either PBMV or mitral valve surgery) because of severe deformity, with a Block echocardiographic score >11; and three had significant concomitant mitral regurgitation.

Patients were submitted to balloon valvuloplasty when the two-dimensional echocardiogram revealed severe mitral stenosis with minimal or absent mitral regurgitation, a mitral valve score <10 and the absence of detected atrial thrombus (16).

All patients were followed after the procedure, as well as during the gestational period, puerperium and delivery.

**Procedure.** Mitral valve commissurotomy was performed under general anesthesia and extracorporeal circulation with continuous flow. Mild hypothermia (32°C), partial hemodilution and blood cardioplegia in the aortic root were used. High flow and high pressure cardiopulmonary bypass were used and adjusted according to fetal heart rate monitoring. Heparin was given to maintain an activated coagulation time between 250 and 300 s. The surgical procedure was undertaken with the patient lying supine with the lower part of the body tilted to the left, with the use of a cushion, to minimize inferior vena cava compression by the uterus. After visual inspection, the commissures were incised. Fused chordae separation and splitting of the underlying papillary muscle were done as needed. The technique used by our surgeons was very similar to that reported by other surgeons in recent reviews of cardiac surgery during pregnancy (10).

Percutaneous balloon mitral valvuloplasty was performed in the catheterization laboratory, and a plumb abdominal and pelvic shield was used. All of the procedures were done under local anesthesia by a transseptal, anterograde tech-

**Table 1.** Data of Patients Submitted to Mitral Balloon Valvuloplasty and Mitral Valve Commissurotomy

	PBMV (n = 21)	MVC (n = 24)	p Value
Age (yrs)	24.6 ± 4.8	27.4 ± 5.2	0.06
Gestational age (weeks)	25.2 ± 7.2	22.6 ± 6.6	0.23
NYHA functional class (n)			
III	17	20	1.0
IV	4	4	1.0
Heart rate (beats/min)	78.4 ± 8.7	74.7 ± 10.0	0.20
Atrial fibrillation (n)	0	1	1.0
Medical therapy before procedure (n)			
Diuretics	21	24	1.0
Digoxin	18	20	1.0
Beta-blocker	7	6	0.74
Medical therapy after procedure (n)			
Diuretics	17	20	0.85
Digoxin	18	20	1.0
Beta-blocker	3	4	0.83

Data are presented as the mean value ± SD or number of patients.

MVC = mitral valve commissurotomy; NYHA = New York Heart Association; PBMV = percutaneous balloon mitral valvuloplasty.

nique, as described by Inoue et al. (1). Three vascular accesses were obtained: the right jugular vein for the introduction of a Swan-Ganz catheter, the left femoral artery for the introduction of a pigtail catheter and the right femoral vein for the dilation catheter. Hemodynamic variables, including the Gorlin valve area, were obtained before and after each balloon inflation. To minimize radiation exposure, contrast ventriculograms were not performed. Transthoracic echocardiography and Doppler echocardiography were performed 48 h after the procedure to assess the mitral valve area and the presence and magnitude of mitral insufficiency. The dilation was considered successful if the mitral valve area increased to >1.5 cm<sup>2</sup>, without significant mitral insufficiency. An increase in the mitral valve area of 25%, with a final area <1.5 cm<sup>2</sup> was considered a partial success.

Data from the patients in the surgical group were obtained by a review of medical records, whereas the data from patients in the balloon dilation group were collected prospectively.

**Statistical analysis.** The Student *t* test was used for the comparison of continuous variables between group I (PBMV) and group II (MVC) and between pre- and postvalvuloplasty in each group. The Fischer exact test was utilized for comparison of the demographic data between the two groups. A value *p* < 0.05 was selected as the level of statistical significance.

**RESULTS**

As shown in Table 1, both groups were comparable in terms of demographic data. The patients in both groups were young, in the second trimester of pregnancy and highly symptomatic. Atrial fibrillation was rare. Heart rates were relatively low in both groups, and these were measured in

**Table 2.** Hemodynamic Data of Patients Before and After Percutaneous Balloon Mitral Valvuloplasty

	Before PBMV	After PBMV	p Value
Left atrial pressure (mm Hg)	21.4 ± 8.9	9.5 ± 3.4	<0.0001
Right atrial pressure (mm Hg)	12.0 ± 2.8	10.2 ± 3.1	0.06
Transmitral valvar gradient (mm Hg)	15.9 ± 8.6	4.7 ± 3.3	<0.0001
Mean pulmonary artery pressure (mm Hg)	38.2 ± 15.6	21.2 ± 8.3	<0.0001
Cardiac index (liters/m per m <sup>2</sup> )	3.1 ± 0.5	3.4 ± 0.5	0.03
Mitral valve area by Gorlin formula (cm <sup>2</sup> )	1.04 ± 0.25	2.16 ± 0.37	<0.0001
Mitral valve area by echocardiography (cm <sup>2</sup> )	0.96 ± 0.15	1.84 ± 0.30	<0.0001

Data are presented as the mean value ± SD.  
PBMV = percutaneous balloon mitral valvuloplasty.

the surgical group just before the operation from data obtained from nurses' notes. In all cases, the heart rates represent the status of the patient after prolonged bed rest and diuretic therapy.

Percutaneous balloon mitral valvuloplasty was successful in 95% of patients, as evaluated by the Gorlin formula in the catheterization laboratory, and in 90.5%, as evaluated by the pressure half-time method 48 h after the procedure. Two patients had partial success in that their mitral valve area did not increase to >1.5 cm<sup>2</sup>. Pre- and post-PBMV hemodynamic data for these patients are shown in Table 2.

In the group treated with PBMV, "de novo" mild mitral regurgitation developed in four patients. One patient with mild MR before the procedure developed moderate insufficiency. There were no severe complications, including cardiac perforation, tamponade or embolization.

There was only one death in the entire group of patients, and that was in the surgical group. There was a significant improvement of symptoms in all except one patient in the surgical group, in whom heart failure persisted until the end of pregnancy. All other patients were in functional class I or II at the end of pregnancy and puerperium. There was no statistically significant difference in functional class in follow-up after the procedure when the groups were compared.

**Fetal and neonatal complications.** In group I (PBMV), there was only one neonatal death in a premature child with an esophageal malformation. No fetal death occurred in group I. In contrast, there were six fetal and two neonatal deaths in group II (surgical group). The difference in the combined occurrence of fetal and neonatal deaths was significant when the groups were compared (1 vs. 8, respectively;  $p = 0.025$ ) (Table 3). Fetal deaths occurring up to 24 h after the operation and PBMV were 0 and 5, respectively ( $p = 0.051$ ). In the five patients operated on after 1990 for mitral stenosis without a pliable valve, a porcine mitral valve prosthesis was used, and there were three fetal losses. In the three patients who were submitted to mitral valve replacement for mitral regurgitation, there was one fetal loss.

**Table 3.** Neonatal and Fetal Mortality

Mortality	PBMV n (%)	MVC n (%)
Yes	1 (4.8%)	8 (37.9%)*
No	20 (95.2%)	16 (62.1%)
Total	21 (100%)	24 (100%)

\* $p = 0.025$  by the Fisher exact test.  
Abbreviations as in Table 1.

## DISCUSSION

Mitral stenosis is highly prevalent in developing countries. In Brazil, rheumatic heart disease is responsible for 50% of the cardiac complications during pregnancy, and mitral stenosis is the most important lesion in 75% of these patients (17). Most of these women have worsening of their symptoms, reaching functional class III or IV by the second or third trimester of pregnancy. Clinical management is often difficult and requires prolonged periods in the hospital.

In cases of uncontrolled heart failure, MVC was the only treatment option before the advent of PBMV. Although this surgery carries a low risk for the mother, it carries a substantial risk of fetal mortality (10,18,19), especially when open MVC is performed. In our institution, closed MVC was abandoned because of the better functional results of open MVC under extracorporeal circulation and direct valve visualization.

Several reports have reported the favorable results of PBMV performed during pregnancy, with immediate hemodynamic success and clinical benefit, consequent to the increase of mitral valve area (11-15). The hazards of X-ray exposure can be minimized by avoiding the procedure during the first half of pregnancy (period of organogenesis) and by appropriate shielding of the mother's abdominal and pelvic regions (15). We compared both modalities of treatment in a selected group (pregnant women with severe mitral stenosis and mitral valve anatomy suitable for commissurotomy, either percutaneously or by operation). The demographic data of both groups were very similar, and the indications for the procedure remained unchanged during the entire study period.

This study shows that PBMV appears to be a better alternative than surgical repair owing to a significant reduction in fetal and neonatal mortality. To provide more solid evidence, a definitive conclusion based on a randomized trial is desired, but a study such as this is not feasible. Thus, we believe that PBMV should be considered the treatment of choice for severe mitral stenosis complicating the course of pregnancy in patients with a favorable valve anatomy.

**Study limitations.** This study has several limitations inherent to the retrospective analysis of the surgical group. Also, the two groups were compared in different intervals, during which improvements in patient care could have favored the outcome of the group treated by PBMV. However, the two groups were similar clinically at the time of their procedures; the indication for the interventions remained unchanged,

and there were no major surgical or clinical advancements that, in our view, could have resulted in better fetal protection if MVC had been performed earlier.

There were also differences in the preoperative evaluation of patients between the two groups. Patients treated surgically were evaluated preoperatively by M-mode echocardiography. A detailed two-dimensional echocardiogram of the heart is mandatory in the proper evaluation of PBMV, but not for open mitral valve surgery. Furthermore, two-dimensional echocardiography was not available before 1990 at our hospital. In addition, a hemodynamic assessment was not done preoperatively in the surgical group because of pregnancy.

Finally, beta-blockers were infrequently used, and their use in small doses could have, theoretically, improved the patients' clinical status. However, the use of high doses of beta-blockers may not be safe, as it can increase the risk of abortion and premature birth (20).

**Conclusions.** This study strongly supports the role of PBMV as the treatment of choice for refractory congestive heart failure in pregnant women with mitral stenosis and a favorable mitral valve anatomy.

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