

PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY DURING PREGNANCY LONG TERM FOLLOW-UP

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Aims: To study the immediate and long-term results of percutaneous balloon mitral valvuloplasty (PBMV) in pregnant patients with severe mitral stenosis.

Setting: Patient selected from cases performed at King Khalid University Hospital, Riyadh, Saudi Arabia.

Patients and Methods: 17 patients with severe, symptomatic (NYHA Class I mitral stenosis) were submitted to Inoue PBMV during the second trimester of their pregnancy and all were followed up for 9 to 95.3 (42.6 ± 29.4, mean ± standard deviation) months.

Results: The procedure was successful in all patients. Immediately after valvuloplasty, the mitral valve area (Doppler) increased from 0.85 ± 0.19 cm to 1.96 ± 0.32 cm (P<0.0001) and the transmitral gradient decreased from 17.2 ± 6.1 to 6.5 ± 1.6 mmHg (P<0.0001). Three patients had mild worsening of mitral regurgitation and 4 developed insignificant interatrial communication immediately after PBMV. There was no other morbidity or mortality. All patients had uneventful pregnancy with improvement in NYHA Class. Sixteen had normal delivery and one had caesarean delivery on the 37th week. No developmental abnormalities were detected. On long-term follow-up the Doppler mitral area was 1.74 ± 0.43 cm and restenosis developed in 3 patients (17.6%). One baby died at 9 months of age of pneumonia. All other children maintained normal growth development and speech for their age.

Conclusion: For pregnant women with severe mitral stenosis, PBMV provides good immediate relief of symptoms and a good long-term outcome. There were no developmental abnormalities detected during follow-up of the babies.

Keywords: Mitral stenosis, pregnancy, percutaneous mitral balloon valvuloplasty

Introduction

PERCUTANEOUS BALLOON mitral valvuloplasty (PBMV) is now the treatment of choice for many patient with symptomatic mitral stenosis.

Numerous large series have reported excellent short, medium and long term outcomes,¹⁻⁵ with a low incidence of serious complications.⁶ Randomized trials comparing balloon valvuloplasty with the surgical alternatives of open or closed

commissurotomy have demonstrated an equivalent outcome.⁷⁻⁸ Open or closed surgical commissurotomy is the established method for patients with severe mitral valve stenosis during pregnancy. Although the maternal mortality is low, fetal morbidity and mortality are considerably high with either closed (6 - 12%) or open mitral commissurotomy (9-29 %) performed during pregnancy.⁹⁻¹² Several reports of the immediate effect of mitral balloon valvuloplasty in pregnant women have shown favorable results.¹³⁻²⁰ This report describes the long-term outcome of PBMV on the mother, foetus and its effect on subsequent pregnancies.

Methods

Between January 1992 to January 2002, 207 patients underwent PBMV at King Khalid University Hospital. Seventeen (aged 29.2 ± 7.3 years) were

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pregnant and their period of amenorrhea was 6.4 ± 1.2 month. All patients had severe mitral stenosis, refractory to medical therapy. Thirteen patients were in New York Heart Association (NYHA) functional class III and 4 were in class IV. All patients were followed-up at our hospital for their pregnancy. Fourteen patients were in normal sinus rhythm and 3 were in atrial fibrillation. All patients were subjected to two dimensional echocardiographic assessment, Doppler and transesophageal echocardiogram to exclude left atrial clot. Mitral valve morphology was assessed using the echocardiographic mitral valve score described by Wilkins.²¹ Fourteen patients had favorable mitral valve morphology (score ≤ 8) and 3 patients had an unfavorable morphology (score 9 - 10). The mitral valve area was measured by planimetry and by the Doppler pressure half-time method before and immediately after PBMV. These measurements were repeated once six months later and then annually. The area was measured invasively before and immediately after PBMV. The inclusion criteria were the presence of severe mitral stenosis with mitral valve area ≤ 1.2 cm², acceptable echocardiographic score ≤ 10 , mitral regurgitation \leq grade II, absence of left atrial clot and absence of severe tricuspid regurgitation with severe pulmonary hypertension. Post valvuloplasty all patients were followed at our hospital, and post delivery all babies were followed at the paediatric clinic for physical and mental development.

Mitral balloon valvuloplasty procedure

After signing the consent, all patients were subjected to PBMV, using the Inoue balloon, after the middle of the 2nd trimester (6.4 ± 1.2 months) when most hemodynamic changes are expected to occur. The abdomen and pelvis were completely shielded with a folded 5-mm lead shield throughout the procedure. Left ventricle and right side angiography was not performed. Only important hemodynamic parameters were assessed, including mitral valve area, mean transmitral pressure gradient, pulmonary artery pressure and left atrial pressure. Fluoroscopy was used only during transeptal puncture and balloon inflation. Heparin (150 unit/kg of body weight) was injected intravenously after transeptal puncture. Stepwise, mitral valve area dilatation was performed and Doppler echocardiography was used to determine mitral valve area, mean gradient and the degree of mitral

regurgitation following each inflation. The occurrence of interatrial communication was detected by colour Doppler technique at the end of the procedure. Protamin sulphate was administered intravenously to reverse the effect of heparin.

Follow-up

All patients were followed-up from 9 to 95.3 months (42.6 ± 29.4) mean \pm standard deviation. Clinical and echocardiographic assessment was done at 6 months after PBMV and annually thereafter.

Statistical Analysis

Data were analyzed by the paired student t-test using the Microsoft Excel statistical package and presented as mean \pm standard deviation. The level of statistical significance was set at <0.05 .

Table 1: Patient's characteristics

Patient's characteristics:

Total number of patients: 17

Age: 29.2 ± 7.3 years.

Symptomatic class:

Class III: 13

Class IV: 4

Gestational age: 6.4 ± 1.2 month.

Rhythm:

Sinus rhythm: 14 patients.

Atrial fibrillation: 3 patients.

Echo score:

≤ 8 : 14

9 - 10: 3

Degree of mitral regurgitation:

No MR: 12

Mild MR: 5

Results

Table 1 shows patient characteristics. All patients had a successful procedure. Immediately after PBMV there was a significant ($P < 0.0001$) increase in mitral valve area calculated invasively (from 0.73 ± 0.24 to 1.72 ± 0.35 cm²) and by Doppler (0.86 ± 0.16 to 1.94 ± 0.32 cm²) (Table 2). At the same time, the mean gradient across the mitral valve measured by the catheter decreased from 18.4 ± 6.7 mmHg to 6.2 ± 2.1 and by Doppler for $17.2 \pm$



Table 2

<u>Mitral valve area cm²</u>	Baseline	Immediate	Follow-Up
Catheter	0.73 ± 0.24	1.72 ± 0.35	
2D Echo	0.82 ± 0.15		1.74 ± 0.84
Doppler	0.86 ± 0.16	1.94 ± 0.32	1.76 ± 0.42
<u>Mean Gradient Across Mitral valve (mmHg):</u>			
Catheter	18.4 ± 6.7	6.2 ± 2.1	
Doppler	17.2 ± 6.9	5.7 ± 1.8	5.8 ± 2.7
<u>Mean left atrial Pressure (mmHg):</u>			
Catheter	2.4 ± 5.6	13.7 ± 4.2	
<u>Systolic pulmonary Arterial pressure (mmHg):</u>			
Catheter	62.1 ± 18.7	47.2 ± 15.6	
Doppler	60.4 ± 21.6		36.1 ± 13.4

6.9 to 5.7 ± 1.8 mmHg, and the mean left atrial pressure from 24 ± 5.6 to 13.7 ± 4.2 (Table 2). The systolic pulmonary artery pressure decreased from 62.1 ± 18.7 mmHg to 47.2 ± 15.6 by the catheter measurement. In 3 patients mitral regurgitation had increased (in 2 patients by 1 degree and in one patient by 2 degrees). Four patients developed small interatrial communication seen by colour Doppler but undetectable by oximetry. There were no complications as no patient developed initiation of uterine contraction, maternal arrhythmia leading to foetal distress, thromboembolic event, cardiac tamponade, vascular complication or death. Fluoroscopy time was 16 ± 14 minutes and total procedure time was 72 ± 38 minutes.

Pregnancy outcome

All 17 patients had uneventful pregnancies. 16 patients delivered normally and 1 patient had a caesarean delivery on the 37th week. No baby had development abnormalities at birth.

Long-term follow-up of the mothers

All 17 patients were followed up for 9 to 95.3 (42.6 ± 29.4) (mean ± standard) months. Seven had other uneventful pregnancies. One had 4 subsequent pregnancies. Three patients (17.6%) developed restenosis (2 patients were redilated successfully and 1 patient had mitral valve replacement). The other 14

patients remained stable in NYHA Class I - II with a follow-up mitral valve area of 1.74 ± 0.48 cm² by two-dimensional echocardiogram and 1.76 ± 0.42 cm² by Doppler. No interatrial communication was detected by colour Doppler at follow-up.

Long-term follow-up of the babies

Sixteen babies maintained normal growth, development and speech through the period of follow-up. One baby died with pneumonia at 9 months of age. Repeated periodic assessment by laboratory tests including complete blood count, urine analysis and renal, hepatic profile remained normal.

Discussion

The pressure gradient across the narrowed mitral valve may increase greatly secondary to the physiological increase in heart rate and blood volume of pregnancy.²² Cardiac output during pregnancy is estimated to exceed the output during the non-pregnant state by 30 to 50 percent.²²⁻²⁴ It begins to rise around the fifth week and peaks between the middle of the second and the third trimesters when it plateaus. The rise in heart rate peaks during the third trimester with an average increase of 10 to 20 beats/minute.^{24,25}

Without intervention, the maternal mortality for patients with severe mitral stenosis who are in NYHA Class I and II is (0 - 4%) and is significantly



higher (6 - 8%) for those in NYHA Class III and IV, particularly during labour and delivery.^{26,27} Perinatal mortality is between 15 - 20%.²⁸ PBMV has been reported by Iung B et al²⁹ on 100 pregnant patients to be a safe and effective treatment to improve the mother's hemodynamic status and it is well tolerated by the fetus. There are case reports describing a successful outcome using transesophageal echocardiographic guidance alone.

In our study, PBMV was done for patients with an acceptable echocardiographic score. However, Prendergast et al³⁰ stated in their review that although we have no randomized study available in the sub-group of patients with non-pliable calcified mitral valve, it is now accepted that a favourable clinical and procedural outcome may be predicted in many subjects depending on the precise assessment of commissurotomy morphology and a number of clinical and procedural variables.

The risk of exposing the fetus to radiation may be minimized by adequate lead shielding of the abdomen and good collimation.^{15,17} In addition, the timing for the procedure was done after the middle of the second trimester where the effect of exposure to radiation is minimal.³¹ There are no reports on the long-term effects of radiation received by the fetuses during PBMV. In our study, we followed 17 babies born alive with no malfunction, in particular microcephaly or major abnormalities in birth weight. For up to 9 years of follow-up, the children grew normally and achieved their expected height and weight. No features of mental retardation were detected and none developed leukaemia or other neoplasm.

Gamra et al³² reported on 58 pregnant women with severe mitral stenosis who underwent a successful PBMV. At a mean follow-up of 71 ± 35 (8 - 120) months, 45 (76%) babies were only evaluated physically and mentally. There was no evidence of radiation side effects up to six years follow-up. Our follow-up was better and for a longer period.

Conclusion

Percutaneous balloon valvuloplasty using the Inoue technique for severe mitral valve stenosis during pregnancy provided good immediate relief and long-term outcome to patients and there were no developmental abnormalities detected during follow-up of the babies. The risk of radiation was minimized by doing the procedure after the middle of the second

trimester and by adequate shielding of the abdomen and good collimation.

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