MITRAL BALLOON VALVOTOMY IN PREGNANT WOMEN: LONG-TERM FOLLOW-UP

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Aim: To study the immediate and long-term results of mitral balloon valvotomy (MBV) in pregnant patients with severe mitral stenosis. Methods and Results: 19 patients with severe, symptomatic (NYHA class III/IV) mitral stenosis were submitted to Inoue MBV during the second trimester of their pregnancy, and all but one were followed-up for 6 to 98.3 (42.6 ± 29.4, mean ± standard deviation) months. The procedure was successful in all patients. Immediately after valvotomy, the mitral valve area (Doppler) increased from 0.88 ± 0.17 cm² to 1.97 ± 0.36 cm² (P < 0.0001) and the transmitral gradient decreased from 16.2 ± 7.1 to 5.6 ± 1.7 mm Hg (P < 0.0001). Four patients had mild worsening of mitral regurgitation and six developed insignificant interatrial communication immediately after MBV. There was no other morbidity or mortality. All patients had uneventful pregnancies, with improvement in NYHA class. Seventeen had normal delivery and one had cesarean section on the 36th week that resulted in stillbirth. No developmental abnormalities were detected. On long-term follow-up, the Doppler mitral valve area was 1.64 ± 0.44 cm² and restenosis developed in three patients (16.7%). One baby died at one week of sudden infant death syndrome and another at eight months of age of pneumonia. All other children maintained normal growth, development and speech for their age. Conclusion: MBV provides satisfactory immediate relief long-term outcome to pregnancies with severe mitral stenosis.

Key words: Mitral stenosis, pregnancy, mitral balloon valvotomy.

OPEN OR CLOSED SURGICAL COMMISSUROTOMY IS the established method of treatment for patients with severe mitral valve stenosis (MC) during pregnancy. Although the maternal mortality is low, fetal morbidity and mortality are considerably high with either closed (6% to 12%) or open mitral commissurotomy (9% to 29%) performed during pregnancy. 1-4 Several previous reports on the immediate effects of mitral balloon valvotomy (MBV) in pregnant women have shown favorable results.5-12 The use of the Inoue balloon with its attendant shorter fluoroscopy time, in addition to the use of abdominal shields, have probably reduced the radiation hazards to the mother and the baby. This report describes the long-term outcome of MBV on the mothers, and its effect on subsequent pregnancies.

Methods

Between December 1989 and December 1997, 407 patients underwent MBV for severe mitral stenosis in our institution. Nineteen of them, aged 30.3 ± 8.1 years, were pregnant and their period of amenorrhea was 6.5 ± 2 months. All patients had severe mitral stenosis, 15 were in New York Heart Association (NYHA) functional class III, and four were in class IV. At the time of valvotomy, 16 patients were in normal sinus rhythm and three were in atrial fibrillation. All patients were submitted to two-dimensional and Doppler echocardiographic assessment, with special emphasis on mitral valve morphology, using the echocardiographic mitral valve score described by Wilkins et al.13 Seventeen

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MBV IN PREGNANT WOMEN

patients had favorable mitral valve morphology for valvotomy (score: S; 8), and two patients had an unfavorable morphology (scores: 9 and 10). The mitral valve area was measured by the Doppler pressure half-time method before and immediately after MVB, and repeated annually thereafter; by 2-D echo before MBV and at follow-up, and invasively before and immediately after MBV. The indications for MVB included the presence of severe symptomatic mitral stenosis, refractory to medical therapy, with mitral valve area of: S; 1.2 cm². Eight patients had direct access to this hospital where they were attending regular cardiology outpatient clinics prior to their current pregnancy. These patients were co-managed with obstetric consultants throughout the pregnancy, and the babies were periodically assessed by our pediatricians. The remaining 11 patients had been referred to us from other hospitals at some point during their pregnancy in order to be submitted to MVB. Following MVB, they were returned to the care of the referring hospitals where they had their delivery. Ten of these patients had periodic clinical and echocardiographic follow-up evaluation in our outpatient clinics and one was lost to follow-up. However, because of regulations regarding access to our hospital for tertiary medical care, the babies of these 10 women had their pediatric follow-up in the hospitals where they were born. Information regarding the physical and mental development of the children was gathered when, in response to our request, they were brought along with their mothers in a joint outpatient clinic visit.

Mitral Balloon Valvotomy Procedure

After signing an informed consent, all patients were submitted to MBV using the Inoue balloon as previously described.8 The abdomen and pelvis were totally shielded with a folded 5 mm lead shield throughout the procedure. Left ventricular angiography was not performed. In order to reduce the fluoroscopy and total procedure time, only important hemodynamics were assessed, including mitral valve area, mean transmural pressure gradient and pulmonary artery pressure and left atrial pressure. Fluoroscopy was used only during transseptal puncture and balloon inflation. Heparin (150 IU/kg of body weight) was injected intravenously after transseptal puncture. Stepwise mitral valve dilatation was performed and supplemented with Doppler echo cardiography to determine mitral valve area, mean gradient and the degree of mitral regurgitation following each inflation. At the end of the procedure, the occurrence of interatrial communication was evaluated by color Doppler technique, and protamine sulfate was administered intravenously to reverse the effect of heparin.

One patient was lost to follow-up. In the remaining 18 patients, clinical and echocardiographic assessments were performed six months after MBV, and annually thereafter for a period of 6 to 98.3 months. The follow-up results presented are those of the last follow-up assessment for each patient.

Data were analyzed by the paired Student t-test, using the Microsoft EXCEL statistical package, and presented as mean ± standard deviation. The level of statistical significance was set at P < 0.05.

Results

Immediate Hemodynamics

Mitral balloon valvotomy was successful in all patients. Immediately after the procedure, there was a significant (P < 0.0001) increase in mitral valve area when calculated both invasively (from a baseline of 0.75 ± 0.21 to 1.61 ± 0.54 cm² immediately after valvotomy), and by Doppler (from 0.88 ± 0.17 to 1.97 ± 0.36 cm², respectively) (Table 1). At the same time, the catheter-determined transmitral mean pressure gradient decreased from 18.1 ± 6.9 mm Hg to 6.1 ± 2.0 mm Hg, the systolic pulmonary artery pressure from 61.7 ± 17.7 mm Hg to 48.2 ± 15.4 mm Hg, and the mean left atrial pressure from 25.6 ± 5.9 mm Hg to 13.3 ± 4 mm Hg (P < 0.0001 for all three comparisons). Similar reductions were noted immediately after valvotomy in Doppler-determined mean pressure gradient and systolic pulmonary artery pressure, as shown in Table 1. In three patients, mitral regurgitation increased by 1 degree and in one patient by 2 degrees.

Six patients developed small interatrial communications, seen by color-Doppler but undetectable by oximetry. No peripheral vascular complications, thromboembolic events, cardiac tamponade or deaths occurred. The fluoroscopy time was 15 ± 14 min and the total procedure time was 91 ± 39 min.

Pregnancy Outcome

All 18 patients with follow-up had uneventful pregnancies. Sixteen patients has unassisted,
Long-term Follow-up of the Babies

Of the 19 babies born alive, one died subsequently at one week of age from sudden infant death syndrome and another at eight months of age from severe pneumonia. All remaining 17 children had normal physical examination without any dysmorphic features, and all maintained normal growth, development and speech throughout the period of follow-up. Repeated, periodic laboratory assessments including complete blood count, urinalysis and renal and hepatic function tests remained normal in the eight children born in the hospital.

Discussion

Pregnancy induces hemodynamic disturbances, mainly by increasing the intravascular volume by 30% to 50% over non-pregnant levels, a process that starts on the 8th week onwards and reaches a plateau towards the 3rd trimester. This hemodynamic burden, in conjunction with the physiologic increase of heart rate in pregnancy, results in an increase in transmural gradient and left atrial pressure, which may lead to acute pulmonary edema even in patients with moderate mitral stenosis. Although patients with cardiac diseases are generally expected to experience a symptomatic increase by one NYHA class during pregnancy, this functional assessment may at times be deceptive because some patients either over- or underestimate their symptoms or limit their physical activity during pregnancy. However, when clinical assessment is complemented by accurate echocardiographic evaluation, the pregnancy outcome in such patients is usually predictable. Thus, without intervention, the maternal mortality for patients with mitral stenosis who are in NYHA class I and II is 0.4% and significantly higher (6.8%) for those in NYHA class III and IV, particularly during labor and delivery. Although both surgical commissurotomy and mitral balloon valvuloplasty have been shown to yield similarly favorable immediate and late results, the maternal mortality associated with the latter procedure has been reported to be 1.7% to 3% as compared with no mortality with the former. Moreover, surgical commissurotomy is associated with significantly higher fetal mortality ranging from 5% to 15%, whereas only one fetal death has so far been reported implicating MBV during pregnancy.

All 19 patients in this retrospective analysis experienced immediate improvement in their functional status. In the 18 patients who were followed up, this improvement continued throughout the remainder of the pregnancy, ending in an uncomplicated delivery. All but three of these patients maintained this symptomatic improvement throughout a long follow-up period, and seven of them had similarly uneventful subsequent pregnancies. The three exceptions pertained to patients who developed mitral valve restenosis dealt with by repeated MEV in one case, and by mitral valve replacement with bioprosthesis in the other two cases. Two of these three patients had unfavorable initial mitral anatomy, with a Willans score exceeding 8.

It is generally accepted that radiography of areas remote from the fetus is relatively safe, provided there is good collimation and proper shielding. With these precautions the estimated amount of radiation received by the fetus in the course of a typical MBV falls below the maximal allowed safe dose of 5 rad.

There are no reports in the English literature on the long-term effects of radiation received by fetuses during MEV of their pregnant mothers, but reports on the immediate outcome included no evidence of malformation. In our series of 19 babies born alive, no malformation, in particular microcephaly, or major abnormalities in birth weight were observed. For up to eight years of follow-up, 17 of these children grew normally and achieved their expected height and weight. No features of mental retardation were detected and none developed leukemia or other neoplasms. Nevertheless, because follow-up data from the nine children born in other hospitals are incomplete, no firm statement regarding the long-term effect of MBV on the offspring can be made.

Although most clinical and hemodynamic outcomes of the Inoue balloon and the double balloon methods of MBV have been similar, the former has consistently been associated with shorter fluoroscopy and total procedure times. It is, therefore, plausible to assume that the Inoue balloon method would decrease both the hazard of fetal radiation and the likelihood of a significant reduction in placental perfusion associated with the supine hypotensive syndrome of pregnancy.
Conclusions

Balloon mitral valvotomy by the Inoue technique for severe mitral valve stenosis during pregnancy yields satisfactory clinical and hemodynamic immediate results and long-term outcome.

References