Abstract

Objectives: We sought to compare the maternal and fetal outcomes of patients with severe mitral stenosis submitted to percutaneous balloon dilation using inoue versus Multi-track balloons during pregnancy.

Background: Heart failure in patients with mitral stenosis complicating pregnancy is a common problem in developing countries. Since 1982, percutaneous dilation of the mitral valve using a balloon catheter has become a therapeutic alternative to open or closed heart surgery. Although the efficacy of percutaneous mitral valve balloon dilation is well established with inoue balloon, its comparison with Multi-track balloon during pregnancy is needed.

Methods: We compared the clinical and obstetric outcomes in 486 women who were treated with percutaneous mitral valve balloon dilation Multi-track (group I, 243 patients) or inoue balloon (group II, 243 patients) for heart failure (NIHA classII ,III,and IV) due to mitral stenosis during pregnancy.

Results: In our study, percutaneous balloon dilation of the mitral valve had a success rate of 99.1% as regard safely completed procedure and a rate of 94.4% for group I and 92.9% for group II 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 pulmonary artery pressure and increase of mitral valve area by planimetry. Patients in both groups had similar improvements in symptoms. Patients who underwent percutaneous balloon dilation had no significant difference fetal complications, with no maternal mortality (2 fetal death in group I vs. 1 deaths in group II, p >0.05).Patients who underwent percutaneous balloon dilation had no significant difference fetal complications, with no maternal mortality (2 fetal death in group I vs. 1 deaths in group II, p >0.05).

Conclusions: Percutaneous balloon mitral valvuloplasty is safe and effective and appears to appropriate using either inoue or Multi-track balloons during pregnancy.

Introduction:

Cardiovascular physiology of pregnancy: Normal pregnancy is related with an increment of 30 to 50 percent in blood volume and a comparing expansion in heart yield. These builds start during the primary trimester; the levels top by 20 to 24 weeks of pregnancy and afterward are either supported until term or diminishing. Simultaneously, the pulse increments by 10 to 20 beats each moment, the stroke volume increments, and there is a generous decrease in fundamental vascular obstruction, with diminishes in circulatory strain. During work, heart yield builds; the pulse increments with uterine compressions. Following conveyance, the heart filling pressing factor may increment drastically due to the decompression of the vena cava and the arrival of uterine blood into the foundational flow. The cardiovascular variations related with pregnancy relapse by roughly a month and a half after conveyance.1 Mitral stenosis is the most usually experienced valvular injury in Pregnancy 2,3,4,5 and is caused in practically all cases by rheumatic heart disease. Although rheumatic MS is regularly joined by some level of mitral spewing forth (MR),2,5 pregnancy-related hemodynamic and suggestive issues are pre-predominantly because of valve stenosis. The pressing factor inclination across the limited mitral valve may significantly increment during pregnancy auxiliary to the physiological ascent in pulse and stroke volume, which prompts an expansion in left atrial pressing factor and subsequently to the turn of events or deteriorating of indications, including dyspnea, diminished exercise limit, orthopnea, paroxysmal nighttime dyspnea, and pneumonic edema. Expanded left atrial pressing factor can likewise bring about atrial arrhythmias 2, 3, 6, which may prompt a further speed increase of ventricular rate and subsequently to extra hemodynamic declining and suggestive deterioration7 .The first to perform percutaneous mitral commissurotomy (PBMC) as an option in contrast to a medical procedure was in mid 1980. The great outcomes got with the method have prompted its expanding overall use and its situating as the second most significant strategy in the field of interventional cardiology 8. The wellbeing and adequacy of percutaneous inflatable mitral valvuloplasty (PBVM) has been accounted for by a few agents. In patients with mitral stenosis and a flexible valve life systems, PBVM has been demonstrated to be identical to either shut or open mitral valve commissurotomy 9. In patients who gave extreme side effects during pregnancy, fruitful percutaneous inflatable mitral valvuloplasty performed during the subsequent trimester has been related with typical resulting conveyances and brilliant fetal results 10. Dangers to the embryo related with openness to radiation might be diminished by keeping away from openness to radiation during the primary portion of pregnancy 11. Pregnant ladies who are to be presented to radiation ought to have the uterus safeguarded and ought to be educated about the potential dangers.

Methods:

From June 2000 to August 2014, a total of 396 consecutive pregnant women underwent PBMV in the National Heart Institute (Egypt) for control of symptoms of mitral stenosis and to achieve safe delivery.

Clinical indications: The indication for valvuloplasty included severe heart failure despite intensive medical treatment. All patients in the mid or third trimester presented with severe dyspnea, orthopnea or pulmonary edema despite treatment with a diuretic agents (furosemide, 80 - 160 mg/day) and beta blockers metoprolol (50-100 mg/day). Patients treated medically who returned to functional class I were excluded, also patients with large left atrial appendage thrombus, severe mitral regurgitation or mitral valve...
score > 10 by Wilkins score were excluded.

**Study population:** Percutaneous balloon mitral dilation (PBMD) was performed in 396 pregnant patients with rheumatic mitral stenosis. (PBMD) was completed in 193 patients for group I using Multi-Track balloon and 193 patients using Inoue balloon (Group II). The selection of patients for each group was at random. All patients had severe symptomatic mitral stenosis with NYHA functional class > II, and echocardiographic mitral valve area (MVA) < 1.5 cm².

**Exclusion criteria:** Associated mitral regurgitation > grade II, associated aortic valve disease that needs surgical correction, acute rheumatic activity or infective endocarditis, history of recent thromboembolic events < 2 months and left atrial thrombus on TEE performed within 24h before the procedure. Written informed consent was obtained from all patients. All patients were subjected to the following: Careful history and clinical examination, resting 12-lead ECG, trans-thoracic and trans-esophageal echocardiography. Two-dimensional echocardiography (2D echo) and Doppler echocardiographic studies were performed 1-2 days before the procedure using commercially available equipment (Hewlett-Packard Unit Sonos 2500 and 5500). In addition to the mean transmirtal valve gradient, the MVA was calculated from the Doppler study using the pressure half-time method and also by planimetry using the short axis 2D echo view. Pulmonary artery systolic pressure was estimated by continuous wave Doppler echocardiography using the modified Bernoulli equation [4x(peak tricuspid regurgitant jet velocity²)] with 10 mmHg added for the estimated right atrial pressure within two weeks later. The morphologic features of the mitral valve were semi quantitated according to the mitral echocardiographic score (MES) as described by Wilkins et al.12. Scoring ranging from 0 to 4 was assigned to represent each of four morphologic characteristics, namely, leaflet thickening, leaflet mobility, subvalvular thickening and calcification. Subvalvular thickening was classified into four grades: 1) Minimal thickening just below the mitral leaflets, 2) Thickening of the chordae structures extending up to one third of the chordal length, 3) Thickening extending to the distal third of the chordae and 4) Extensive thickening and shortening of all chordal structures extending down to the papillary muscles.

Several parameters were measured as indicators for successful mitral valvuloplasty including; mitral valve area, Pulmonary artery pressure and mean diastolic pressure gradient across mitral valve, in addition to the mitral valve morphology and scoring. Percutaneous mitral valvuloplasty was performed for the two groups according to selected procedure to each group with same criteria for stopping any procedure; when complete opening of the commissures achieved with resulting valve area > 1.5 cm² or the appearance of MR > I/IV. Immediate assessment and post delivery after the procedure was done for each patient, including: Clinical assessment, Local (groin) or systemic complications of the procedure, detailed echocardiographic and Doppler assessment. Careful evaluation of the baby to assess for mode of delivery, any peri-natal complications and maternal obstetric outcome.

**Procedure:** 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 technique, unique, as described by Inoue et al 8. Two vascular accesses were obtained: the left femoral artery for the introduction of a pigtail catheter and the right femoral vein for the dilation catheter. Hemodynamic variables, including the left atrial pressure, transmitral gradient and presence or absence of V wave in pressure tracing, were obtained before and after each balloon inflation. To minimize radiation exposure, contrast ventriculograms were not performed. Transthoracic echocardiography and Doppler echocardiography were performed 48h 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 more than 1.5 cm², without significant mitral insufficiency, well splitting of both mitral valve commissures or at least one, and an increase in the mitral valve area of 25%, with a final area, 1.5 cm² was considered a partial success. Statistical analysis. The Student t test was used for the comparison of continuous variables between group I and group II and between pre- and post valvuloplasty in each group. 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. Percutaneous balloon mitral valvuloplasty was successful in 100% of patients. Five patients had partial success in that their mitral valve area did not increase to > 1.7 cm², three in group I and two in group II. A Pre- and post-PBMD hemodynamic data for these patients are shown in Table 2. De novo mild mitral regurgitation developed in twenty patients five in group 15 and 5 in group II. Ten patient with mild MR before the procedure developed moderate insufficiency (group I) and 6 patients in group II. There were no severe complications, including cardiac perforation, tamponade or embolization.

There was only three fetal death in the entire patients, one may be not related to the procedure it was a lady with twin pregnancy she had uterine contractions less than one hour after the procedure one fetus was macerated the other was diagnosed as stillbirth. There was a significant improvement of symptoms in all patients. All 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 (PBMD), there was only two neonatal death, one fetal death occurred in group II. The difference in the combined occurrence of fetal death was not significant when the groups were compared (Table 3).

**Discussion**

Mitr stenosis is highly prevalent in developing countries. 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 PBMC. Although this surgery carries a low risk for the mother, it carries a substantial risk of fetal mortality 13,14,17. Patients with severe MS who are symptomatic before conception will not predictably tolerate the
hemodynamic weight of pregnancy and ought to be considered for percutaneous inflatable mitral valvotomy before origination, given the valve is anatomically appropriate. Patients with extreme MS who foster NYHA practical class III-IV side effects during pregnancy ought to go through percutaneous inflatable valvotomy 20. A few reports have announced the positive aftereffects of PBMC performed during pregnancy, with prompt hemodynamic achievement and clinical advantage, subsequent to the increment of mitral valve region 15,16,18,19. The risks of X-beam openness can be limited by staying away from the system during the main portion of pregnancy (time of organogenesis) and by proper safeguarding of the mother's stomach and pelvic districts 19. The Multitrack framework is a new variation of the twofold inflatable procedure was presented by Bonhouffer P. in 1995. We thought about the two modalities of treatment in a chose bunch (pregnant ladies with serious mitral stenosis and mitral valve life structures appropriate for commissurotomy, utilizing either Multitrack or Inoue inflatables). The segment information of the two gatherings were practically the same, and the signs for the technique stayed unaltered during the investigation time frame. The prompt consequences of inflatable mitral commissurotomy in youthful were better compared to in Inoue bunch with a critical bigger mitral valve region, in any case, there was no measurably huge between bunch contrasts in a large portion of the hemodynamic factors or system complications. This study shows that PBMD gives off an impression of being similarly powerful in the two gatherings.

Conclusions: This study strongly supports the role of PBMC as the treatment of choice for refractory congestive heart failure in pregnant women with mitral stenosis and a favorable mitral valve anatomy with either Inoue or Multi-track technique.