

Immediate Outcome of Balloon Mitral Valvuloplasty with JOMIVA Balloon during Pregnancy

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ABSTRACT

Introduction: Rheumatic mitral stenosis is the most common Valvular Heart Disease encountered during pregnancy. Balloon Mitral Valvuloplasty (BMV) is one of the treatment option available if the symptoms are refractory to the medical management and the valve anatomy is suitable for balloon dilatation. BMV with Inoue balloon is the most common technique being followed worldwide. Over the wire BMV is a modified technique using Joseph Mitral Valvuloplasty (JOMIVA) balloon catheter which is being followed in certain centres.

Aim: To assess the immediate post procedure outcome of over the wire BMV with JOMIVA balloon.

Materials and Methods: Clinical and echocardiographic parameters of pregnant women with significant mitral stenosis who underwent elective BMV with JOMIVA balloon in our institute from 2005 to 2015 were analysed retrospectively. Severity of breathlessness (New York Heart Association Functional Class), and duration of pregnancy was included in the analysis. Pre procedural echocardiographic parameters which included severity of mitral stenosis and Wilkin's scoring were analysed. Clinical, haemodynamic and echocardiographic outcomes immediately after the procedure were analysed.

Results: Among the patients who underwent BMV in our Institute 38 were pregnant women. Twenty four patients (63%) were in New York Heart Association (NYHA) Class III. All of them were in sinus rhythm except two (5%) who had atrial

fibrillation. Thirty four patients (89.5%) were in second trimester of pregnancy at the time of presentation and four (10.5%) were in third trimester. Echocardiographic analysis of the mitral valve showed that the mean Wilkin's score was 7.3. Mean mitral valve area pre procedure was 0.8 cm². Mean gradient across the valve was 18 mmHg. Ten patients (26.5%) had mild mitral regurgitation and none had more than mild mitral regurgitation. Thirty six patients had pulmonary hypertension as assessed by tricuspid regurgitation jet velocity. All of them underwent BMV with JOMIVA balloon. Post procedure mean mitral valve area was 1.7 cm² as assessed by echocardiography. Post procedure mean gradient across the mitral valve as assessed by echocardiography was 5 mmHg. Two patients had moderate to severe mitral regurgitation after the procedure and the rest had either no mitral regurgitation or mild mitral regurgitation after the procedure. None of the patients warranted mitral valve replacement after BMV. No patients had any manifestations of systemic embolism like cerebrovascular accident or limb ischemia after the procedure. None of the patients had preterm delivery or adverse fetal outcome during index hospitalisation.

Conclusion: Over the wire BMV is safe and effective method during pregnancy. The results are comparable to that of Inoue technique. BMV offers a good symptomatic improvement in pregnant women presenting with symptoms of pulmonary congestion because of Rheumatic mitral stenosis.

Keywords: Mitral valve, Stenosis, Valvular heart disease

INTRODUCTION

Rheumatic mitral stenosis is the most common acquired Valvular Heart Disease encountered during pregnancy [1,2]. Moderate or severe mitral stenosis during pregnancy poses a challenge to the clinician since it can increase maternal as well as fetal morbidity and mortality [1,2]. The rate of fetal growth restriction and preterm birth rises with the severity of mitral stenosis from 14% in pregnant patients with mild mitral stenosis, to 28% and 33% in pregnant patients with moderate and severe mitral stenosis [3-5]. Heart failure occurs frequently in pregnant women with moderate or severe mitral stenosis (area <15.cms²) during second or third trimester [3-5]. Closed or open mitral valvotomy during pregnancy is associated with significant maternal and fetal morbidity and mortality [6-8]. BMV is the preferred treatment in pregnant women presenting with severe mitral stenosis if the symptoms are not controlled with medications and the valve anatomy is suitable [8-11]. Safety and efficacy of BMV during pregnancy is proven [9-11]. BMV is commonly done with Inoue balloon [12]. Over the wire BMV is a modified technique using JOMIVA balloon catheter and is being followed in certain centres [13,14]. There are studies assessing the short term and long term

outcomes of BMV using JOMIVA balloon [13,14]. There are no studies assessing the safety and efficacy of over the wire BMV during pregnancy. In this study we have assessed the immediate post procedure outcome of over the wire BMV during pregnancy.

MATERIALS AND METHODS

Clinical and echocardiographic parameters of pregnant women with significant mitral stenosis who underwent elective BMV with JOMIVA balloon in PSG Institute of Medical Sciences and Research, Tamil Nadu, India between 2005 to 2015 were analysed retrospectively. Patients who underwent emergency BMV and patients who were on mechanical ventilation were excluded. Severity of breathlessness (New York Heart Association Functional Class), duration of pregnancy were included in the analysis. Pre procedural echocardiographic parameters were analysed which included severity of the mitral stenosis as assessed by 2 dimensional mitral valve area, morphological analysis of the valve and Wilkin's scoring (valvular calcification, thickness, mobility and subvalvular disease) [15]. Clinical (New York Heart Association Functional Class) and echocardiographic outcome which included 2 dimensional mitral

valve area, pressure gradient across the mitral valve area and severity of mitral regurgitation after the procedure were analysed. Severity of pre procedural mitral regurgitation was noted. Mitral regurgitation was graded as mild, moderate and severe when the jet area occupies less than 20%, 20-40% and more than 40% of left atrium respectively. Width of vena contracta was also used to classify the severity of mitral stenosis, when it is less than 0.3 cm, 0.3-0.7 cm, more than or equal to 0.7 cm classifies mitral regurgitation as mild, moderate and severe respectively [16].

Procedure

Femoral arterial and venous access were taken. Atrial septal puncture was done with Brockenbrough technique [17]. A Mullin sheath and dilator was tracked inside the left atrium. Subsequently a Swan Ganz catheter was taken inside the left atrium through the Mullin sheath [18]. Mitral valve was crossed with the Swan Ganz catheter. A support wire was taken across the mitral valve through the Swan Ganz catheter. An appropriate sized JOMIVA balloon catheter was taken across the mitral valve over the support wire and the valve was dilated.

STATISTICAL ANALYSIS

Data was analysed using the statistical package for the social sciences (WINDOW VERSION 12.0; SPSS). Continuous variables were presented as mean and standard deviation. Categorical variables were expressed as percentages.

RESULTS

Among the patients who underwent BMV in our Institute between 2005 and 2015, 38 were pregnant women. All 38 patients were included in the analysis. All patients underwent BMV with JOMIVA balloon. Baseline clinical and echocardiographic parameters are shown in [Table/Fig-1]. Mean age at the time of the procedure was 25 years. Twenty four patients (63%) were in NYHA Class III at the time of presentation in spite of medications. Ten patients (26.5%) were in NYHA class II and four (10.5%) were in NYHA class IV. Among the patients who underwent BMV all of them were in sinus rhythm except two (5%) who had atrial fibrillation at the time of the procedure. Thirty four patients (89.5%) were in second trimester of pregnancy at the time of presentation and 4 (10.5%) were in third trimester.

Baseline echocardiographic parameters of the patients are shown in [Table/Fig-1]. Echocardiographic analysis of the mitral valve showed that the mean Wilkin's score was 7.3. None of the patients had left atrial cavity or appendage thrombus. Mean mitral valve area pre procedure was 0.8 cm². Mean gradient across the valve was 18 mmHg. Twenty eight patients (73.5%) did not have mitral regurgitation at the time of presentation. Ten patients (26.5%) had mild mitral regurgitation and none had more than mild mitral regurgitation. Thirty six patients (94.7%) had pulmonary hypertension as assessed by tricuspid regurgitation jet velocity.

All of them underwent BMV with JOMIVA. Pre and post procedure echocardiographic and catheterisation haemodynamic parameters are shown in [Table/Fig-2]. Mean mitral valve area as assessed by echocardiography after the procedure was 1.7 cm². Mean gradient across the mitral valve after the procedure as assessed by echocardiography was 5 mmHg.

Procedure related complications are shown in [Table/Fig-3]. Only two patients had moderate to severe mitral regurgitation after the procedure and the rest had either no mitral regurgitation or mild mitral regurgitation after the procedure. Symptomatic improvement was noted in all of the patients except two. Requirement of medications like diuretics reduced after the procedure in all of the patients except those two. Two patients had persistent breathlessness after the procedure which could be managed medically with diuretics. None of the patient warranted mitral valve replacement after BMV. No patients

Age (mean)	25±6yrs
New York Heart Association Functional Class	
II	10 (26.5%)
III	24 (63%)
IV	4 (10.5%)
Sinus Rhythm	36 (95%)
Atrial Fibrillation	2 (5%)
Duration of pregnancy	
Second trimester	34 (89.5%)
Third trimester	4 (10.5%)
Echocardiographic parameters	
Wilkin's score (mean)	7.3
Thickness (mean)	2.1
Mobility (mean)	2.1
Calcification (mean)	1.6
Sub valvular apparatus (mean)	1.5
Mitral valve area (mean)	0.82±0.3cm ²
Mitral stenosis gradient (mean)	18 mmHg
Pre-existing mitral regurgitation (MR)	
No MR	28 (73.5%)
Mild MR	10 (26.5%)
Pulmonary hypertension	36 (94.7%)

[Table/Fig-1]: Baseline clinical and echocardiographic characteristics of pregnant women who underwent Balloon Mitral Valvuloplasty with JOMIVA balloon.

Echocardiographic Parameters	Pre Procedure	Post Procedure
Mitral Valve Area	0.8±0.3 cm ²	1.7±0.4 cm ²
Moderate to severe mitral regurgitation	Nil	2
Mitral stenosis gradient (Mean)	18±8 mmHg	5±2 mmHg
Catheterisation Parameters		
Left Atrial mean	26±7 mmHg	9±2 mmHg
Mitral stenosis gradient (mean)	16±4 mmHg	4±3 mmHg
Pulmonary arterial Systolic pressure (mean)	50±12 mmHg	36±10 mmHg

[Table/Fig-2]: Echocardiographic and catheterisation haemodynamic parameters pre and post procedure.

Post procedure Complications	Number of Patients
Significant worsening of mitral regurgitation	2
Embolic complications	Nil
Pericardial effusion	Nil
Requirement of emergency Mitral valve replacement	Nil
Access site complications	1
Fetal complications during index hospitalisations	Nil

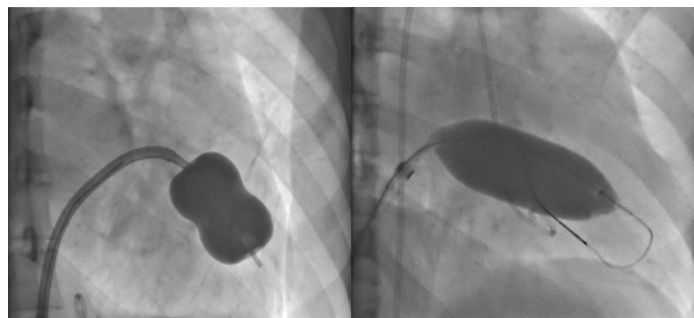
[Table/Fig-3]: Showing the list of complications of Balloon Mitral Valvuloplasty in pregnant women.

had any manifestations of systemic embolism like cerebrovascular accident or limb ischemia. None of the patients had preterm delivery or adverse fetal outcome during index hospitalisation. One patient had minor groin hematoma at the access site which was managed with mechanical compression.

DISCUSSION

Pregnant women with haemodynamically significant mitral stenosis and significant breathlessness have an estimated mortality rate of 5 to 15% [6]. Closed mitral valvotomy has a mortality rate of less than 2%, fetal mortality of 1.2 to 8% and a miscarriage rate of 5 to 15% [7]. Open valvotomy has a fetal mortality rate of 37.9% [8]. In view of high morbidity and mortality associated with the open surgical procedures, BMV has become the preferred treatment modality in pregnant women presenting with haemodynamically significant

mitral stenosis with valve anatomy suitable for balloon dilatation [8]. Over the wire BMV with JOMIVA balloon was shown to be a cost-effective alternative to the widely followed Inoue technique [13,14]. JOMIVA balloon catheter is different from Inoue balloon in a way that it is a cylindrical balloon and not a dumbbell shaped balloon [Table/Fig-4].



[Table/Fig-4]: Images showing Inoue balloon (left) with a central waist when inflated and JOMIVA balloon (right) which is cylindrical when inflated.

Baseline characteristics of pregnant women who presented with significant mitral stenosis shows that most of the patients were in sinus rhythm except two who were in atrial fibrillation. Low prevalence of atrial fibrillation in pregnant women presenting with mitral stenosis in our study is similar to other studies where a similar data was noted [10]. This could be explained by the age of these patients at presentation. Pre-existing mitral regurgitation was documented in 10 patients. The valve morphology as assessed by Wilkin's scoring shows that mean score was 7.3 which indicate that most of the patients had a low risk valve for complications during balloon dilatation.

Procedural success as defined by a reduction in mitral valve gradient less than 50% of the pre BMV gradient, valve area more than or equal to 1.5 cm² and no significant increase in mitral regurgitation was noted in 90% of the patients. This was similar to the results obtained with Inoue balloon where the procedure success was documented in 90-95% of the patients [8].

Moderate to severe mitral regurgitation as assessed by echocardiography was documented in two (5%) patients in our study. This is similar to the data published earlier with Inoue balloon where significant increase in mitral regurgitation was documented in 4% of the patients [8]. No patient warranted emergency or elective mitral valve replacement in our study. Long term efficacy of BMV during pregnancy, safety in terms of long term effect of radiation during fetal life is also proven [11].

LIMITATION

Number of patients included in this study was less; it may not represent the entire set of patients who undergo BMV with JOMIVA balloon during pregnancy.

CONCLUSION

Over the wire BMV with JOMIVA balloon is safe and effective method of BMV during pregnancy. The results with JOMIVA balloon are comparable to that of Inoue technique. Incidence of post procedure mitral regurgitation after BMV with JOMIVA balloon is comparable with Inoue technique. Pregnant women presenting with symptoms of pulmonary congestion refractory to the medical management has good symptomatic improvement with BMV.

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