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ORIGINAL ARTICLE

A PROSPECTIVE COMPARATIVE STUDY BETWEEN CLOSED MITRAL VALVOTOMY AND BALLOON VALVOPLASTY AS TREATMENT FOR RHEUMATIC NON CALCIFIC MITRAL STENOSIS

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ABSTRACT: BACKGROUND: Treatment of rheumatic mitral stenosis ranges from conservative medical management to closed mitral valvotomy and the more recent balloon mitral valvoplasty. This is a prospective study to compare the results of closed mitral valvotomy with percutaneous balloon valvoplasty in 100 cases (50 patients in each group) of rheumatic non-calcific mitral stenosis. **MATERIALS AND METHODS:** From November 2011 to March 2012, 50 patient underwent closed mitral valvotomy and another 50 had percutaneous balloon mitral valvoplasty. Balloon mitral valvoplasty was performed by Inoue technique and closed mitral valvotomy was carried out through standard anterolateral thoracotomy with transventricular gradual Tubbs dilatation. NYHA functional status, left atrial size, transmitral end diastolic gradient, mean diastolic gradient and mitral valve area were recorded. The results at the 4 day post procedure and the results at the 6 months follow up were compared. **RESULTS:** Residual atrial septal defect (ASD) was present in 6 patients at 6 month follow up after balloon mitral valvoplasty. Severe mitral regurgitation occurred in 3 cases of closed mitral valvotomy group as compared to 7 cases of balloon mitral valvoplasty group. Urgent mitral valve replacement was needed in 2 patient of balloon mitral valvoplasty group. There was single mortality in each group. **CONCLUSION:** No statistical significant difference between the result of closed mitral valvotomy and balloon mitral valvoplasty but better outcome obtained by closed mitral valvotomy. Hemodynamic and functional improvement was sustained through 6 month of follow up in both groups. Procedural cost of closed mitral valvotomy was significantly lower than the procedural cost of balloon mitral valvoplasty.

KEYWORDS: closed mitral valvotomy, balloon mitral valvoplasty, rheumatic non-calcific mitral stenosis.

I**NTRODUCTION:** Treatment of rheumatic mitral stenosis ranges from conservative medical management to closed mitral valvotomy and the more recent, minimally invasive balloon mitral valvoplasty. Improvement of symptoms after closed mitral valvotomy was demonstrated many years ago.[1-3] Refinement in technique and the routine use of metal dilator have produced sustained clinical improvement at low risk. Percutaneous balloon mitral valvoplasty evolved from balloon valvoplasty for pulmonary valve stenosis. This prospective study was designed to compare the result of closed mitral valvotomy with balloon mitral valvoplasty over a period of 6 months.

MATERIALS AND METHODS: From November 2009 to March 2010, 100 consecutive patients with rheumatic non-calcific mitral stenosis were assigned either closed mitral valvotomy or balloon mitral valvoplasty procedure according to their will, after informed consent, and financial condition. The study was approved by the institutional ethics committee.

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The mitral valve orifice area was determined by planimetry method on Doppler echocardiography. 50 patients underwent closed mitral valvotomy by standard transventricular Tubbs' dilatation. The Tubbs dilator was extended a minimum of 2.5cm and maximum of 3.5cm. Fifty patients underwent balloon mitral valvoplasty by the Inoue balloon technique.

Patient undergoing balloon mitral valvoplasty were managed by cardiologist in the cardiac care unit and those undergoing closed mitral valvotomy were managed in the post-operative intensive care unit. Post procedural two dimensional Echocardiography was performed on fourth post procedural day, with follow-up echocardiography after three month and six month.

Follow Up: All patients were kept on regular follow up with regular visits to the outpatient department. On follow up, the patients were also assessed for cardiac rhythm, New York Heart association (NYHA) functional class, medication and the presence or progression of the same or other valve lesion. Two patients out of 50 patients of closed mitral valvotomy group and 2 patients out of 50 balloon mitral valvoplasty group lost to follow up after one week. One more patient was lost for follow up, after 5 months of closed mitral valvotomy, because he met with an accident and died.

Cost: Procedure cost of closed mitral valvotomy was significantly lower than the procedure cost of balloon mitral valvoplasty. It was approximately Rs.25000/- for closed mitral valvotomy, compared to balloon mitral valvoplasty, which was approximately Rs. 75000/-.

Data Analysis: Statistical analysis of the data was performed using Microsoft Excel 2009 edition. Analysis of variance for repeated measures was used to assess baseline and follow-up date for change over time and for the effect of treatment. If the analysis of variance indicated statistical significance, it was followed by comparisons within groups by use of paired student's t test and comparison between groups by use of unpaired student's t test. All tests were two sided to adjust for multiple testing, a p value less than 0.05 were specified as indicating significance. Results are reported as mean ± standard deviation (SD).

RESULTS: Out of the 100 patients, 58 were female and 42 were male. Lowest age in closed mitral valvotomy group was 15 years and maximum age was 65 years. Lowest age in balloon mitral valvoplasty group was 12 years and maximum was 64 years (Table no.1). All the patient of balloon mitral valvoplasty and closed mitral valvotomy group had rheumatic non-calcific mitral stenosis. There was fall in transmitral end diastolic gradient and mean diastolic gradient in both groups of patient, determined by Doppler echocardiography fourth day after procedure.

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	Closed Mitral Valvotomy (CMV) (n=50)	Balloon Mitral Valvoplasty (BMV) (n=50)	
Personal Data			
Age (years)	30.16 ± 10.5 (15-65)	28.98 ± 11.62 (12-64)	
Sex (M:F)	M-17: F-33	M-25: F-25	
H/o Rheumatic heart disease	50	50	
Previous CMV	1	3	
Previous BMV	0	1	
Embolic episodes	1	1	
Symptoms			
Duration (years)	3.58 ± 3.55 (0.25-20)	4 ± 3.6 (0.5-18)	
Paroxysmal nocturnal dyspnoea	22	22	
Haemoptysis	7	7	
Palpitation	10	13	
NYHA Functional class (I/II/III/IV)	0/28/20/2	1/29/20/0	
Medications			
Digitalis	47	49	
Diuretics	50	50	
ECG findings			
Atrial fibrillation	12	13	
P mitrale	35	38	
Right axis deviation	30	33	
2D Echo findings			p value
Mitral valve area (cm^2)	0.81 ± 0.15 (0.5-1.2)	0.78 ± 0.15 (0.48-1.2)	>0.05
Mitral valve area <1 cm^2	46	49	>0.05
Left atrial size (mm)	45.2 ± 6.68 (31-64)	45.67 ± 6.58 (33-62)	>0.05
End diastolic gradient (mm of Hg)	5.88 ± 2.64 (2-13)	7.46 ± 3.71 (3-17)	>0.05
Mean diastolic gradient (mm of Hg)	16.38 ± 4.3 (9-27)	17.32 ± 5.63 (7-33)	>0.05
Tricuspid Regurgitation (Trivial/mild/moderate/severe)	6/24/12/8	8/12/13/17	
Mitral regurgitation (Absent/trivial/mild/moderate/ severe)	25/12/12/1/0	30/12/8/0/0	
Aortic regurgitation	17	10	
Echo score	6.7 ± 0.84 (4-9)	6.68 ± 0.76 (5-9)	

Table 1: Pre-procedural data

End diastolic gradient was 5.88±2.64mm Hg before closed mitral valvotomy and 7.46±3.7mmHg before balloon mitral valvoplasty. After closed mitral valvotomy and balloon mitral valvoplasty, they decreased significantly to 1.65±1.22 mm Hg and 1.99±1.2 mmHg respectively.

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Mean diastolic gradient before closed mitral valvotomy was 16.38±4.3 mmHg and before balloon mitral valvoplasty it was 17.32±5.63 mmHg. After closed mitral valvotomy and balloon mitral valvoplasty, mean diastolic gradient was 4.85±1.74mmHg and 5.54±1.48 mmHg respectively.

Mean left atrial (LA) size before closed mitral valvotomy and balloon mitral valvoplasty were 45.21±6.88 (mm) and 45.67±6.58 (mm), decreased to 39.71±5.92 (mm) and 40.02±5.64 (mm) respectively.

Mean mitral valve area before closed mitral valvotomy and balloon mitral valvoplasty were 0.81±1.5 (cm^2) and 0.78±0.15 (cm^2), after procedure it increased to 1.97±03.5 (cm^2) and 1.57±0.28 (cm^2) respectively. However there was no significant difference ($p>0.05$) attributable to the type of the procedure.

Thirty eight patients had post balloon mitral valvoplasty residual atrial septal defect at 4 day post procedure (Table no.2). At the end of the study there were six (13.6%) patients with residual atrial septal defect. No event of myocardial infarction occurred in either group. No event of re exploration occurred in closed mitral valvotomy.

At 6 months follow-up, improvement occurred in both groups (Table no.3). End diastolic gradient was 1.48± 0.654 mmHg in closed mitral valvotomy group and 1.76±0.84 mm Hg in balloon mitral valvoplasty group. Mean diastolic gradient was 4.32±1.01 mmHg in closed mitral valvotomy group and 4.72±1.16 mmHg in balloon mitral valvoplasty group ($p>0.05$).

Mean mitral valve area in closed mitral valvotomy group was 1.92±0.47cm^2 and was 1.54±0.25cm^2 in balloon mitral valvoplasty group ($p>0.05$). There was decrease in mean left atrial size after 4 day follow-up from 39.71±5.92 mm to 37.41±5.44 mm in closed mitral valvotomy group and from 40.02±5.64mm to 35.52±6.7mm after 6 month follow-up. There was no significant difference between the group at 4-day or 6-month follow-up ($p>0.05$).

	Closed Mitral Valvotomy (CMV) (n=48)	**Balloon Mitral Valvoplasty (BMV) (n=48)**	**p value**
Mitral Valve Area (cm^2)			
Mean	1.97±0.35	1.57±0.28	>0.05
1-1.5	7	27	
1.5-2	24	18	
>2	17	3	
Mitral regurgitation (Absent/trivial/mild/moderate/severe)	11/5/18/11/3	9/6/13/13/7	
Left atrial size (mm)	39.71±5.92	40.02±5.64	>0.05
End diastolic gradient (mm of Hg)	1.65±5.92	1.99±1.29	>0.05
Mean diastolic gradient (mm of Hg)	4.85±1.75	5.54±1.48	>0.05
Residual ASD	0	38	
NYHA Functional class (I/II/III/IV)	42/4/2/0	42/4/0/2	
Atrial fibrillation	7	5	
Myocardial infarction	0	0	
Hospital stay (days)	4.3±1.3	3.9±1.78	>0.05
Replacement needed	0	2	
Procedural expenditure (INR)	25000	75000	
Mortality	1	1	

Table 2: Result on post-operative day 4

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Post procedure mortality in closed mitral valvotomy was one, due to severe icterus and renal failure. This patient had preoperative icterus. After seventeen days of procedure she developed anuria and could not be saved in spite of vigorous try. One death occurred in balloon mitral valvoplasty group due to post procedure severe mitral regurgitation and pulmonary edema. Closed mitral valvotomy done on the patient with dextrocardia had good outcome.

Closed mitral valvotomy was done on two patients with 6 month pregnancy with good result and good fetal outcome. Urgent mitral valve replacement was needed in 2 patients of balloon mitral valvoplasty group after procedure. There was no need of mitral valve replacement in closed mitral valvotomy group.

At the 6 month follow-up, 42 patients out of 45 who had closed mitral valvotomy were in sinus rhythm and 3 were in atrial fibrillation. 40 patients were in NYHA class I, 1 was in class II and 3 were in class III (Table no.3). All patients were taking oral digoxin and diuretics. None had progression of mitral stenosis and Echocardiographic score.

	Closed Mitral Valvotomy (CMV) (n=48)	**Balloon Mitral Valvoplasty (BMV) (n=48)**	**p value**
Mitral valve area (cm^2)	1.92 ± 0.47	1.54 ± 0.25	>0.05
Left atrial size (mm)	37.41 ± 5.44	35.52 ± 6.7	>0.05
End diastolic gradient (mm of Hg)	1.48 ± 0.65	1.76 ± 0.84	>0.05
Mean diastolic gradient (mm of Hg)	4.32 ± 1.01	4.72 ± 1.16	>0.05
Residual ASD	0	6	
NYHA Functional class (I/II/III/IV)	40/5/3/0	36/7/5/0	
Atrial fibrillation	3	2	

Table 3: Result at the end of 6 months

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Figure.1: Mitral valve area (cm^2) preoperative, postoperative day 4 and 6 month's postoperative periods.

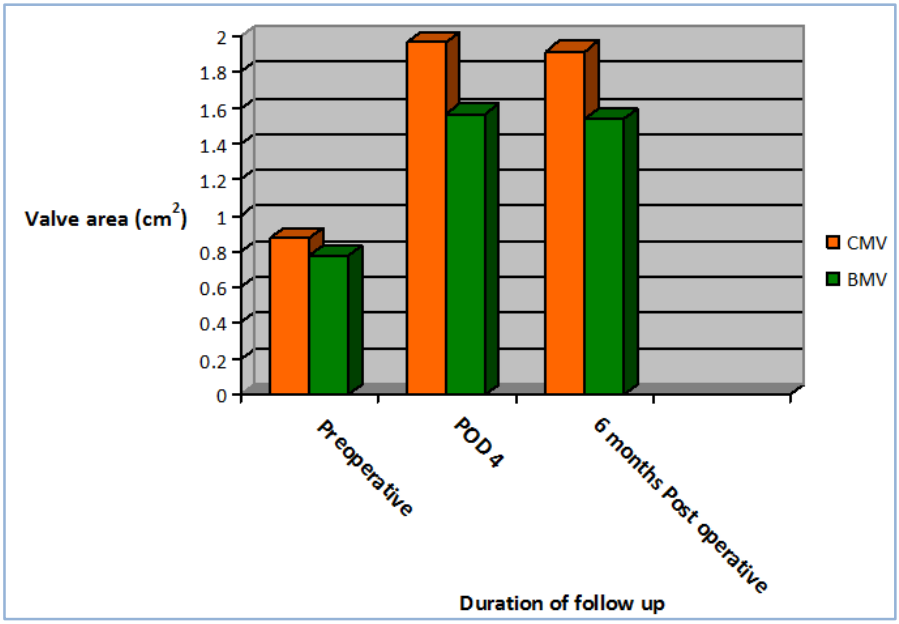

Figure 1

Figure 2: Left atrial size (mm) preoperative, postoperative day 4 and 6 months postoperative periods.

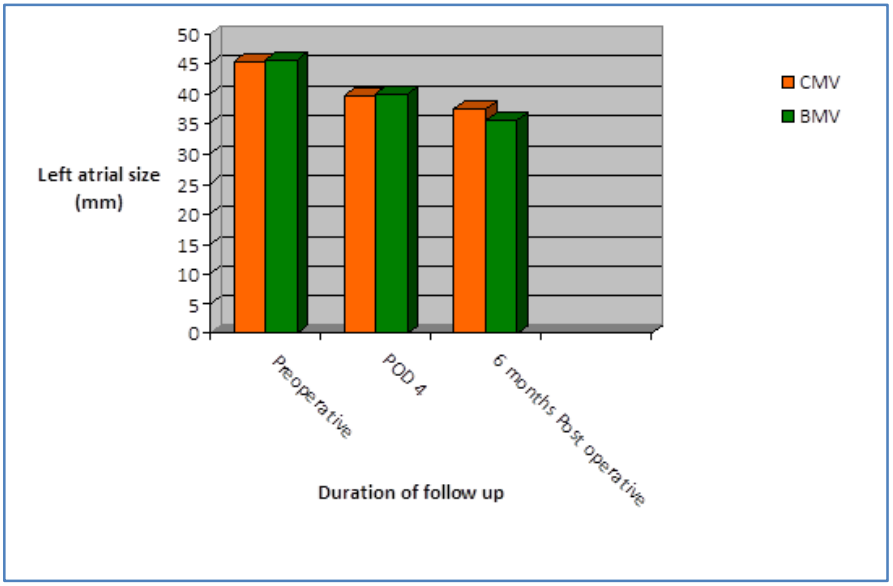

Figure 2

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Figure 3: Mean diastolic gradient (mm of Hg) preoperative, postoperative day 4 and 6 months postoperative periods.

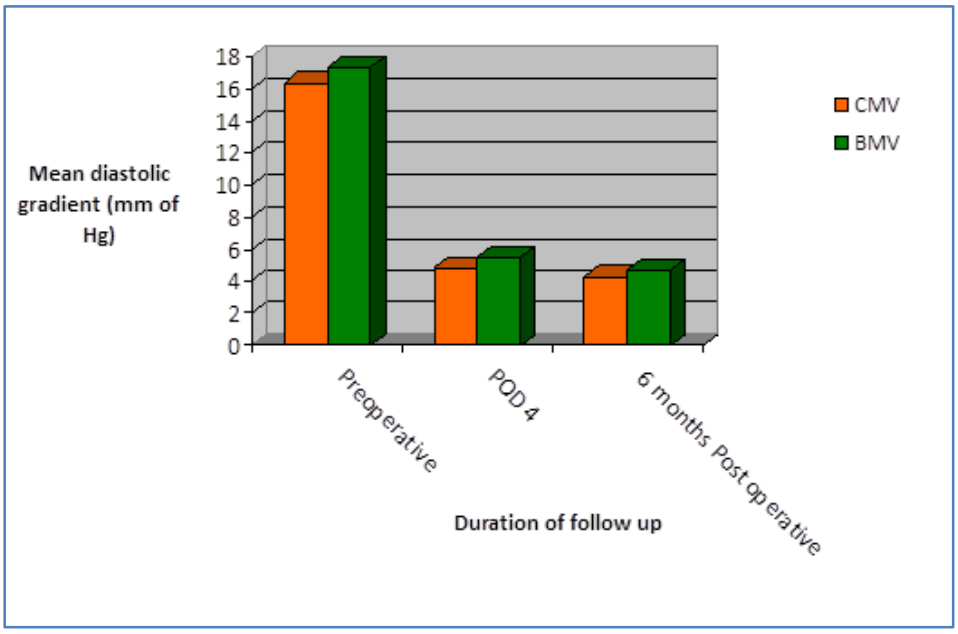

Figure 3

Figure 4: End diastolic gradient (mm of Hg) preoperative, postoperative day 4 and 6 months postoperative periods.

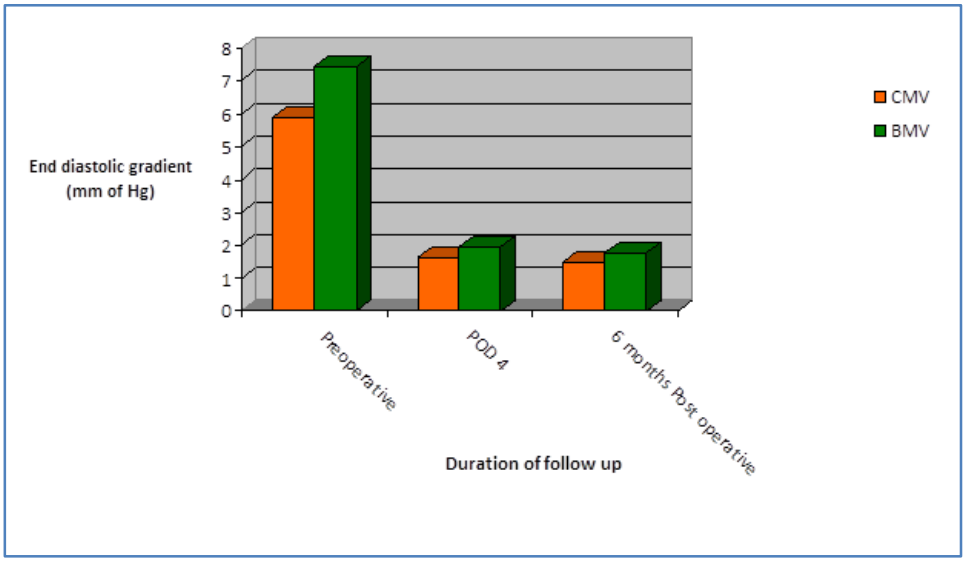

Figure 4

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Figure 5: NYHA Functional class in CMV group in preoperative, postoperative day 4 and 6 months postoperative periods.

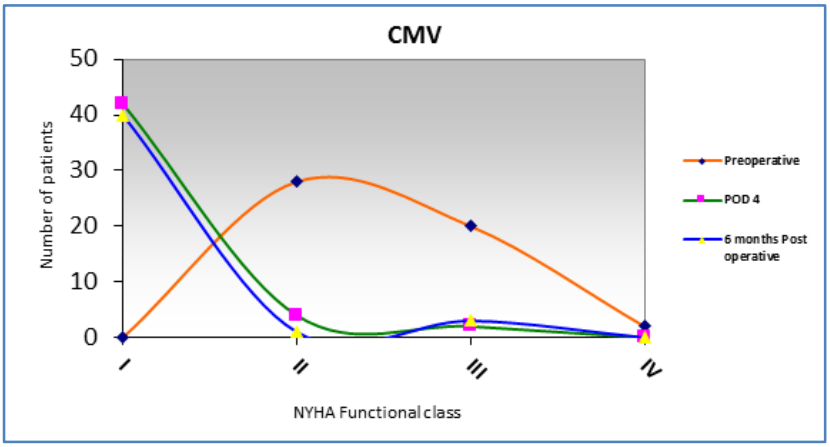

Figure 5

Figure 6: NYHA Functional class in BMV group in preoperative, postoperative day 4 and 6 months postoperative periods.

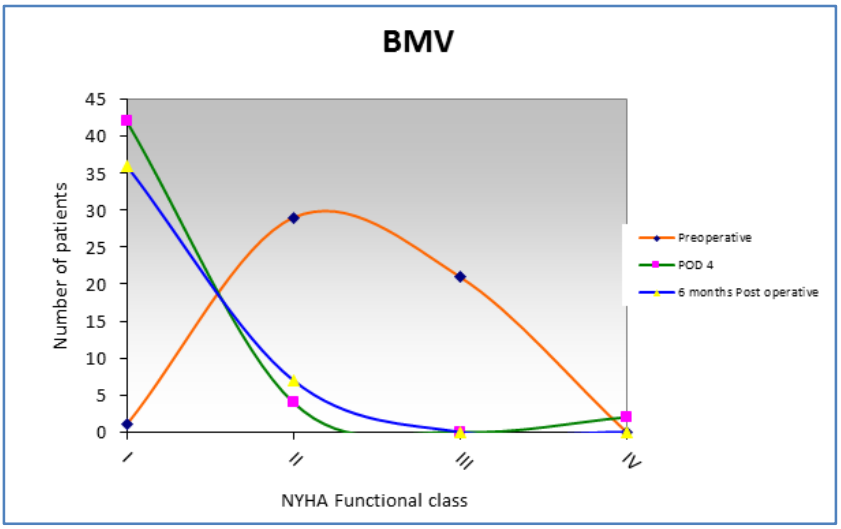

Figure 6

Of the patient undergoing balloon mitral valvoplasty, 42 were in sinus rhythm and 2 were in atrial fibrillation at 6 month follow-up. Thirty six patients were in NYHA class I and 7 were in class II. All these patients were taking oral digoxin and diuretics. Three patients who had mitral valve replacement were kept on oral anticoagulants to achieve an INR value between 3 and 3.5.

Of the closed mitral valvotomy group one patient had closed mitral valvotomy done previously. Three patients had closed mitral valvotomy and one patient had balloon mitral valvoplasty done previously in balloon mitral valvoplasty group.

DISCUSSION: A number of previous studies of closed mitral valvotomy and balloon mitral valvoplasty have been reported. Beg and Reyazuddin[4] reported favorable results after closed mitral

valvotomy in 45 cases of mitral stenosis in childhood and adolescence. The majority of their patients presented with dyspnea and palpitations. In a study by Gautam and Coulshed,[5] better long-term survival was noted for mitral valvotomy with the Tubbs dilator compared to finger splitting, and the presence of calcification at the time of valvotomy adversely affected survival. They concluded that closed mitral valvotomy gave good results before the onset of atrial fibrillation and congestive cardiac failure, and that all patients should have anti-coagulation.

In a randomized comparative study of the immediate and long-term results of balloon mitral valvoplasty and closed mitral valvotomy, both procedures were found to be comparable in respect of postoperative functional status, restenosis, and mitral valve areas.[6] Another report concluded that optimal results of balloon mitral valvoplasty can be expected in patients with sinus rhythm and pliable valves with no severe subvalvular disease identified by echocardiography who undergo dilatation with large effective balloon dilating areas.[7] Patients with sub-optimal results were more likely to have severe valve leaflet thickening and calcification on echocardiography.

Reporting cardiac catheterization after 8 months of follow-up in 92 patients, Turi and colleagues[8] found sustained improvement in a young population (mean age, 27 years) with a mean echo score of 7 and no difference in early or intermediate results between balloon valvoplasty and closed or open commissurotomy. Two dimensional echocardiography was used for assessment of mitral valve area, left atrial size, end diastolic gradient and mean diastolic gradient in this study.

Three mechanisms account for the results of balloon valvoplasty: commissural splitting; stretching of the commissural orifice; and cracking of valve leaflet calcification. Radiographic analysis of 15 operatively excised valves subjected to balloon dilatation demonstrated primarily commissural splitting, whereas an intraoperative study of the effects of balloon dilatation demonstrated a significant early benefit from commissural stretching.[9] Since fusion of the commissures is the typical etiology of mitral stenosis in young patients, commissural splitting provides exceptional results.[10]

In spite of the initial optimistic pronouncement that balloon mitral valvoplasty would significantly improve care for rheumatic valve disease in developing countries, the low cost and equally good results of closed mitral valvotomy make it the procedure of choice in many parts of the world where valvular heart disease is prevalent, and ours is no exception.[11] Closed mitral valvotomy is safer than the balloon mitral valvoplasty in midterm gravida patient as no hazard of radiation exposure to the fetus. No statistical significant difference between the result of closed mitral valvotomy and balloon mitral valvoplasty but better outcome obtained by closed mitral valvotomy (Table no. 2 and 3). The improvement in functional and hemodynamic status was sustained through 6 month of follow-up.

Largest mitral orifice area of 2.8cm^2 achieved by closed mitral valvotomy procedure as compare to balloon mitral valvoplasty (2.2cm^2). Procedural cost of closed mitral valvotomy is significantly lower than the procedure cost of balloon mitral valvoplasty (Table no. 2), although the duration of hospital stay was appreciably less in the balloon mitral valvoplasty patients. Mitral valve orifice area, transmitral end diastolic gradient, mean diastolic gradients, left atrial size and functional status, in both groups showed remarkable improvement at the 6-month follow-up (Fig.1,2,3,4) with no patient having recurrent mitral stenosis. Closed commissurotomy is the most common surgical procedure in most countries where rheumatic mitral stenosis is endemic, where there are limited facilities and resources; closed mitral valvotomy is by far the less costly procedure. Balloon mitral valvoplasty is a costly but less invasive procedure.

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