

Percutaneous Transluminal Mitral Commissurotomy using Inoue Balloon in Iraqi population

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Summary:

Background: Mitral stenosis (MS) is the most common valve disease in developing countries and there are many ways to deal with this condition. The aim of this study was to evaluate the immediate results of percutaneous transvenous mitral commissurotomy (PTMC) in patients with severe symptomatic rheumatic mitral stenosis.

Patients and Methods: From May 2006 to August 2007, 58 patients (17 male, 41 female) with age range (16-57) years, underwent PTMC in Ibn AL- Bitar Hospital for Cardiac Surgery. All the patients were symptomatic, their MVA ≤ 1.5 cm² with NYHA class II-IV. Clinical evaluation and echocardiographic examination were carried out before and after PTMC, mitral valve structures were assessed using Wilkins score. The procedure was performed under local anesthesia, using the step-wise Inoue balloon technique with the antegrade transvenous approach.

Results: The procedure was successful in 51(88%) of the patients and unsuccessful in the remaining 7(12%) patients. Successful result was defined as post procedure mitral valve area (MVA) ≥ 1.5 cm² as assessed by echocardiography and no mitral regurgitation (MR) >2 according to sellers classification. Mitral valve area increased from 0.93 ± 0.2 to 1.84 ± 0.2 cm² after the procedure ($P < 0.001$) as measured by echocardiography. Severe MR was observed in 1(1.7%) patients, while new mild - moderate MR have been detected in 9(17.6%) patients. Symptomatic improvement was seen in all patients who underwent successful PTMC. There were no procedure related deaths, tamponade or the need for emergent mitral valve replacement.

Conclusion: percutaneous transvenous mitral commissurotomy by Inoue balloon technique is safe and effective procedure for patients with severe and symptomatic rheumatic MS. The ideal candidate are those patients with pliable valve, but still most of patients with relatively high Wilkins echo score can get considerable benefit.

Keywords: PTMC, mitral, Inoue.

Fac Med Baghdad
 2009; Vol.51, No1
 Received May, 2008
 Accepted June, 2008

Introduction:

Rheumatic heart disease continues to be endemic in developing countries where mitral stenosis (MS) is the most common valve disease. Although the prevalence of rheumatic heart disease has greatly decreased in western countries, it continues to represent an important clinical entity (1). Treatment options for patient with MS include medical therapy for those with minor symptoms and mild - moderate MS and percutaneous or surgical interventions for those patient with more severe symptoms and moderate - severe MS. Surgical approach include closed commissurotomy, open commissurotomy and mitral valve replacement, while percutaneous approach can

be done either through metallic commissurotomy or balloon valvuloplasty using either the double balloon or Inoue balloon technique. (2)

Inoue balloon catheter is a double lumen catheter that has a 12 F tube shaft as shown in figure -1-. The inner lumen of the catheter (a) permits pressure measurement, blood sampling, or insertion of a metal tube, a guidewire, or a stylet. The outer lumen connects proximally with a two-way stopcock (b), used to connect the catheter to an inflation /deflation syringe and a vent (c) used to discard air by injection of a dilute contrast medium, and distally with a balloon mounted at the end of the shaft. The balloon is made of double layers of latex tubing and one layer of nylon micromesh between the latex layers, the Inoue balloon comes in 4 sizes (24,26,28,30 mm). (2,3,4)

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Patients and methods:

From May 2006 to August 2007, 58 patients (17 male, 41 female) with age range (16-57) years, underwent PTMC in Ibn AL- Bitar Hospital for Cardiac Surgery. All the patients were symptomatic, their MVA $\leq 1.5 \text{ cm}^2$ with NYHA class II-IV. Clinical evaluation and echocardiographic examination were carried out before and after PTMC, mitral valve structures were assessed using Wilkins score 5. Transesophageal echocardiography (TEE) was carried out before PTMC for patients with AF, history of systemic embolism or when left atrium is not properly visualized by transthoracic echocardiography (TTE). After obtaining an informed consent from the patients, the procedure was performed under local anesthesia, using the step-wise Inoue balloon technique with the antegrade transvenous approach. Right and left catheterization was performed, trans-septal puncture was done using a Brockenbrough needle and Mullins sheath, standard haemodynamic measurements of the right and left heart pressures including simultaneous measurement of left atrial and left ventricular pressure and mean mitral gradient were obtained before and immediately after PTMC. Left ventriculography was performed before and after PTMC to assess the presence and severity of MR, using seller's classification. PTMC was monitored by TTE with special attention to detect a new or increasing MR. Procedure related deaths were defined as those occurring during the PTMC procedure and those occurring from complications directly related to the procedure. Emergency mitral valve replacement (MVR) was defined as a MVR procedure performed within 24 hours of PTMC. (6). PTMC was considered successful if post dilatation MVA $\geq 1.5 \text{ cm}^2$ and MR < 3 sellers grade, and the results considered suboptimal if the post procedure MVA $< 1.5 \text{ cm}^2$ (7, 8) Symptomatic improvement was defined as reclassification by one or more NYHA functional classes. (2). Clinical evaluation to assess the improvements in symptoms and exercise tolerance was accomplished by either direct interview at the hospital or trans-telephonic about 2 weeks post procedure. Statistical analysis was performed by using a student t-test, significance was taken for P-value < 0.05 .

Results:

The total number of patients were 58, the procedure was successful in 51 (88%) of them, and unsuccessful in the remaining 7(12%) patients, due to failure in crossing the mitral valve with balloon catheter in 1(1.7%) patient, development of severe MR in another patient and the results were suboptimal in 5(8.6%) patients (table-1-). Baseline characteristics of patients with successful procedure are shown in table -2-. The mean age was 33.16 ± 8.4 year, female constituted 68.6% of the studied population. Three (5.8%) patients were pregnant. The rhythm was AF in (23.5%) and the

mean echo score was $8.78\% \pm 1.12$ (range 7-12). Baseline characteristics of patients with unsuccessful procedure nearly mimic those for patients with successful procedure except for the high Wilkins score (11-12) and more commissural calcifications. Mitral valve area increased significantly from (0.93 ± 0.2) to $(1.84 \pm 0.2) \text{ cm}^2$ ($p < 0.0001$) as measured by 2D echo and from (0.93 ± 0.19) to $(1.82 \pm 0.2) \text{ cm}^2$ as measured by Doppler echo (table -3-). Mitral regurgitation (as measured by echo) was absent after the procedure in 34 (66.6%) patients and was recorded as grade 1 in 16 (31.37%) patients, half of them (15.6%) due to development of new MR (statistically significant), and preexisted from baseline in the other half. Only 1(1.96%) patient developed new grade II MR (table -3-). Left atrial pressure and mean mitral gradient decreased significantly ($p < 0.0001$) from (25.57 ± 7.6) to $(12.6 \pm 3.8 \text{ mmHg})$ and from (13.96 ± 6.6) to $(3.6 \pm 2 \text{ mmHg})$ respectively as measured by catheter (table-4-). The incidence of major complications (severe MR and systemic embolism) were 3.9%, atrial septal defect was detected by echo color flow mapping in 10 (17%) patients. There were no procedure related deaths, tamponade or the need for emergency MVR (table -5-). Symptomatic improvement was seen in all patients in whom the dilatation was successful. Prior to the procedure, 43(84.3%) patients were classified as NYHA class III, while majority of patients (80 %) reclassified as NYHA class I after the procedure (figure -2- and -3-).

Discussion:

Since the advent of PTMC in 1984, many studies have established this as a safe and effective technique to relieve rheumatic MS (9, 10, 11). In this study the procedure was successful in 51(88%) patients, a result that is consistent with the result obtained by Bernard Lung et al (89.5%) (12). Technical failure was noticed in 1(1.7%) patient, owing to failure in crossing the MV with balloon an event that is mentioned by Inoue and associate among the most common causes of technical failure (2). The study reported a significant increase in MVA ($P < 0.0001$) from (0.93 ± 0.2) to $(1.84 \pm 0.2 \text{ cm}^2)$ which simulate results of many other studies like those conducted by Inoue et al (13), Mohammad Eid fawzi et al (14) and Palacios et al (6) as shown in table- 6 -. Severe pulmonary hypertension is present in a large proportion of patients with severe MS, and many previous studies proved the immediate decrease of systolic pulmonary artery pressure with further substantial regression occurring over time, this finding is consistent with our results and observations (15,16,17)

Several authors (2,14) have documented the significant reduction in LA size and pressure following successful mitral valvuloplasty, supporting our results of a significant ($P < 0.0001$) declining of LA diameter and pressure after the procedure (table 3 & 4).

Mitral regurgitation remains one of the important factors that affect patient selection to undergo PTMC and one of the significant complications of the procedure. Severe MR is related mostly to noncommissural leaflet tearing or chordal rupture, leaflet tears are largely unpredictable and unpreventable, while chordal rupture can be minimized by careful technique. (4) Mild commissural MR, defined as MR that originated from medial or lateral commissures on color flow imaging, was frequently observed in patients with successful immediate results and was an independent factor associated with significantly higher restenosis-free survival rate after PTMC.18

The study documented the development of new mild-moderate MR in 9 (17.6%) patients in whom 8(15.6%) was grade I and 1(1.96%) grade II ,while Inoue et al (13)observed mild –moderate MR in 28%.We documented severe MR in 1(1.96%) patient, due to leaflet tear; she was a pregnant woman in her 2nd trimester and she tolerated the new sequence relatively well with no significant haemodynamic deterioration, Igor et al recorded severe MR in(3.4%) while Bernard Lung et al(8) noticed severe MR in (4.1%).

Echo score was 11 in 6 (11.7%) patients, with post procedure mean MVA $1.68 \text{ cm}^2 \pm 0.1$ for these patients indicating that even patients with relatively high echo score (up to 12) can get considerable benefit. Following the procedure new atrial septal defects was seen in 10 (17%) patients, in all of these cases the magnitude of the shunt was small and posed no haemodynamic or clinical consequences at the present time, however this percentage is greater than that recorded by Inoue et al (12%)(13) and less than that recorded by Mohammad Eid et al(23%).(14)

Interestingly we observed improvement in LV systolic function (as determined by echo) after the procedure in those few patients with preexisting LV systolic dysfunction when they were seen 3 months later during follow up period , this observations consistent with data from Goto S. and associates.(19)

Tables and Figures

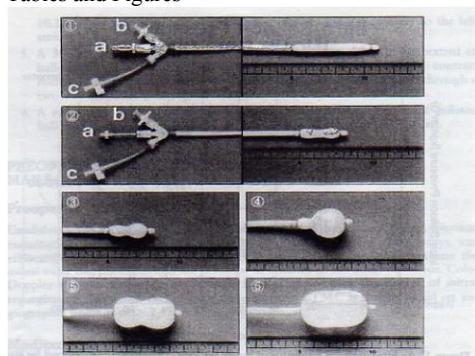


Figure-1- Inoue balloon catheter

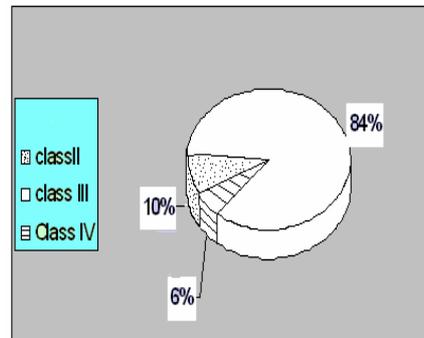


Figure (2) pre PTMC cardiac function NYHA class of patients with successful procedure.

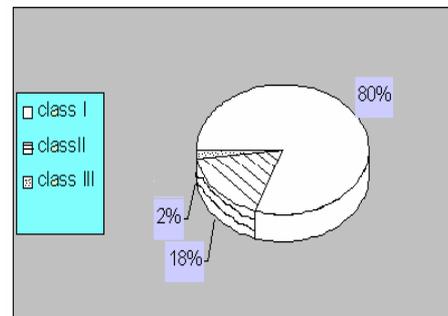


Figure (3) post PTMC cardiac function NYHA class of patients with successful procedure

Table-1- General results of PTMC

Total number	58	100%
Successful	51	88%
Unsuccessful		
Technical failure	1	1.7%
Suboptimal results	5	8.6%
≥ 3 grade mitral regurgitation	1	1.7%

Table (2) Baseline characteristics of patient with successful procedure

variable	value	percentage
Age (years)	Range=16-57	mean=33.16 ± 8.43
Gender (male/female)	16/35	31.4%/68.6%
NYHA	Class 1	0
Functional class	Class 2	5
	Class 3	43
	Class 4	3
Rhythm" AF"	12	23.5
Emboic history	4	7.8
Previous commissurotomy	Percutaneous	0
	Closed	1
Pregnant patients	open	0
		3
Echo score	Range 7-12	Mean=8.78 ± 1.12

Table (3): baseline and post procedure echocardiographic data of patients with successful procedure

parameter	before	after	p-value
2D echo MVA" cm2	0.93 ± 0.2	1.84 ± 0.2	<0.001
Doppler MVA "cm2"	0.93 ± 0.19	1.82 ± 0.2	<0.001
Doppler mean gradient "mmHg"	16.65 ± 7.5	5.47 ± 2.94	<0.001
LA dimension	50.4 ± 6.8	47.1 ± 5.96	<0.001
Systolic pulmonary artery pressure"mmHg"	61.372 ± 22.67	39.117 ± 14.121	<0.001
Mitral regurgitation	Absent	43(84.3%)	34 (66.6%)
	Grade 1	8 (15.6%)	16 (31.37%)
	Grade 2	0	1 (1.96%)
	Grade 3	0	0
	Grade 4	0	0

Table (4) baseline and immediate catheter hemodynamic data of patients with successful procedure.

parameter	before	after	p-value
LA pressure "mmHg"	25.57 ± 7.6	12.63 ± 3.8	<0.001
Mitral valve gradient "mmHg"	13.96 ± 6.6	3.6 ± 2	<0.001
Mitral regurgitation	Absent	44(86.2%)	35(68.6%)
	Grade 1	7 (13.7%)	15 (29.4%)
	Grade 2	0	1(1.96%)
	Grade 3	0	0
	Grade 4	0	0

Table (5) procedure related complications

ASD	10	17%
MR Grade 3 and more	1	1.7
Systemic embolism	1	1.7
Arrhythmia"AF"	1	1.7
Tamponade	0	0
Emergency MVR	0	0
death	0	0

Table (6) comparison of our study results with other similar studies:

parameter	Our study	Inoue et al "Japan"	Mohammed Eid Fawzy "Saudi Arabia"	Palacios et al "USA"
Doppler MVA "cm2"	before	0.93 ± 0.2	1.13 ± 0.02	0.9 ± 0.3
	After	1.84 ± 0.2	1.97 ± 0.04	1.9 ± 0.7
MV gradient "mmHg"	Before	16.65 ± 7.5	11.9 ± 0.27	14 ± 6.0
	after	5.47 ± 2.94	5.5 ± 0.14	5.4 ± 2

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