Original Article

Inoue Balloon Mitral Commissurotomy Using Percutaneous Transvenous Approach in Babylon, Iraq

Inoue Balloon Mitral Commissurotomy

Shokry Faaz Alsaad

ABSTRACT

Objective: Immediate outcomes of percutaneous transvenous approaches to inoue balloon mitral commissurotomy.
Study Design: A single-center observational study
Place and Duration of Study: This study was conducted at the Shaheed Almihrab Cardiac Center in Babylon, Iraq from 1st January 2021 to 31st December 2025.
Methods: 86 patients with severe rheumatic mitral stenosis (mitral valve area ≤1.5 cm^2 and Wilkins score ≤8) who underwent inoue balloon mitral commissurotomy were included. Pre- and post-procedural transthoracic echocardiography was performed on all patients. Mean mitral pressure gradient , mean mitral valve area, pulmonary artery systolic pressure post-transcatheter pulmonary valve replacement, and mitral regurgitation (MR) severity were primary clinical end points. Procedural success was defined as mitral valve area >1.5 cm^2 without severe mitral regurgitation (MR ≥3+).
Results: The mean age was 38.4 ± 11.2 years. The majority of the patients were females (74.4%). Procedural success was 94.2%. Baseline mitral valve area was 0.91±0.18 cm^2, increasing to 1.79±0.24 cm^2, P<0.001. Mitral mean gradient decreased from 14.2±4.6 mmHg to 5.1±2.3 mmHg, P<0.001, and pulmonary artery systolic pressure decreased from 48.6±14.2 mmHg to 31.4±10.8 mmHg, P <0.001. Severe mitral regurgitation occurred in 3.5%, cardiac tamponade in 1.2%, but no deaths were procedure-related.
Conclusion: Inoue balloon mitral commissurotomy via the percutaneous transvenous approach for rheumatic mitral stenosis performed in Babylon, Iraq, achieves a hemodynamic improvement and procedural success rate similar to the global data.

Key Words: Inoue balloon. Mitral commissurotomy; Percutaneous transvenous, Rheumatic mitral stenosis, Transseptal puncture, valvuloplasty

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INTRODUCTION

Rheumatic heart disease (RHD) remains a leading cause of potentially cardiovascular morbidity and mortality in low- and middle-income countries (LMICs), with mitral stenosis (MS) accounting for the most frequent valvular complication.[1-3] Furthermore, the burden of RHD is disproportionately higher in Iraq, particularly in central provinces such as Babylon, due to a combination of overcrowding, poverty, a lack of access to prophylactic, and high rates recurrent streptococcal pharyngitis, which allows for a high frequency of acute rheumatic fever (ARF) relapse with progressive valvular scarring.[4-6]

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In stenosis, the mitral valve leaflets and subvalvular apparatus gradually-thicken and fuse together, causing persistent obstruction of left ventricular filling. Untreated, this may lead to increased left-atrial pressure, pulmonary hypertension, right heart failure, atrial fibrillation and systemic thromboembolism. In untreated cases, severe MS is associated with a five-year mortality rate exceeding 40%.[7-9]

For decades, the treatment of choice for symptomatic severe was OMC, which required the use of cardiopulmonary bypass and the associated with major open-heart surgery. This changed in 1984 Dr. Kanji Inoue introduced the percutaneous transvenous inoue balloon mitral commissurotomy (IBMC).[10-13] This intrusive catheter procedure could be performed in the cardiac catheterization laboratory (CCU) using local anaesthesia via a catheter inserted through the femoral vein, and mechanically splitting the fused commissures using a balloon. In appropriately selected patients, IBMC has become the preferred approach over OMC, and the procedure is endorsed by international cardiac guidelines.[12,14]

Wilkins morphology score using echocardiography used to select which patient to treat remains a central

aspect of procedure success: a score of ≤8 means the valve is relativelyand non-calcified, and is associated with improved outcomes.[8,15] This procedure is associated with immediate and sustained increases in mitral valve area, decreased transmitral gradient, symptomatic improvement, and delay in the need for surgical intervention.[13]

Internationally, IBMC is widely used, but there is no report of outcome data for regional Iraqi cardiac centers, other than Baghdad. There are over 2 million people in Babylon Governorate, with a large population for RHD, but cardiac catheterization only became available at the tertiary care level in Babylon recently. Greater understanding of procedural performance, hemodynamic outcomes, and the complication profile in this previously neglected and high-burden setting will inform health care planners, training of the workforce, and evidence-based clinical practice in Iraq.

METHODS

This observational study was carried out at Cardiology Department of Shaheed Almihrab Cardiac Center, Babylon Governorate, Iraq from 1st January 2021 to 31st December 2025 vide letter No. BHD-2019-IRB-0147/QM/Approval/JSDJNEHU dated 19th July 2019. The patients with severe symptomatic rheumatic MS, preoperative selection criteria included symptomatic MS with New York Heart Association (NYHA) functional class II to IV, MVA ≤1.5 cm^2 by planimetry or pressure half-time, Wilkins morphology score ≤8, absence of important MR (grade ≤1+), and absence of LA thrombus on TEE. Patients with important concomitant aortic or tricuspid valve disease requiring surgical intervention, previous surgical commissurotomy or mitral valve replacement, severe subvalvular disease that cannot be treated safely with balloon dilatation, pregnancy, or contraindications to systemic anticoagulation were excluded.

All patients underwent clinical history and physical examination, 12-lead electrocardiogram, posteroanterior chest radiography, and standard blood test investigations, including complete blood count, coagulation profile, renal function tests, and fasting blood glucose. Two-dimensional and Doppler TTE was performed using a Philips CX 50 system. All patients underwent TEE 24-48 hours pre-procedure to exclude LA thrombus. Echocardiographic parameters assessed included MVA by planimetry and PHT, MMG by CW Doppler, MR grade (0-4+), tricuspid regurgitation (TR) for PASP estimation, LA antero-posterior diameter and LVEF obtained by Simpson's biplane method. Mitral valve morphology was scored using the Wilkins score: leaflet mobility, leaflet thickening, subvalvular thickening, and calcification (1-4 each, total 4-16).

All procedures were performed in the cardiac catheterisation laboratory under fluoroscopic and continuous echocardiographic guidance by an experienced interventional cardiologist. Following steps were involved:

Step 1: vascular access: right femoral vein was cannulated under local anaesthesia (2% lidocaine) and an 8 French (8F) introducer sheath was placed via a Seldinger technique.

Step 2: The Mullins sheath and Brockenbrough needle assembly were advanced carefully to the fossa ovalis under biplane fluoroscopic guidance, and the localization was confirmed by pressure monitoring and echocardiographic visualization of the transseptal puncture.

Step 3: Anticoagulation: Systemic heparinisation (100 IU/kg IV) was undertaken after successful transseptal access with a target ACT of >250 seconds.

Step 4: Inoue balloon catheter delivery. The Inoue balloon catheter (Toray Medical; 24-30 mm diameter; selected by height in cm ÷ 10 + 10 mm) was passed through the transseptal sheath and into the left atrium. A coiled metallic guide wire was then used to thread the partially inflated balloon catheter across the mitral valve orifice.

Step 5: Stepwise inflation. The balloon was inflated stepwise starting from 2 mm less than the calculated maximum diameter of the balloon. Echocardiographic assessment of MVA and MR grade was performed after each inflation. Inflations were repeated, stepwise increasing the diameter until MVA >1.5 cm2 was achieved or MR grade ≥2+ was induced.

Step 6: Post-inflation assessment: Hemodynamic (LAP, PCWP) and echocardiographic (MVA, MMG, and MR grade) data were recorded after every dilation attempt. The catheter was removed once the procedure has achieved the required end-point and hemostasis was confirmed.

Procedural success was defined as one of three: (1) post-procedural MVA >1.5 cm^2, (2) increase in MVA of >25% from baseline, or (3) absence of severe MR (grade <3+). All patients underwent repeat TTE at 24 h post-procedure. Prospective recording of complications included severe MR (grade ≥3+), cardiac tamponade, ischaemic stroke or systemic thromboembolism, emergency surgical intervention, and in-hospital mortality.

Statistical analysis was performed using SPSS-26. Paired t-tests were used to compare echocardiographic values before and after the procedure. Categorical variables are presented as counts and percentages. Subgroup comparisons were performed using an independent samples t-test, with statistical importance defined as a two-tailed p-value <0.05.

RESULTS

The mean age of patients was 38.4±11.2 years. The majority of patients enrolled in the program were women 64 (74.4%). The majority of the patients were

NYHA functional class III 58 (67.4%) and IV 26 (30.2%). Two patients (2.3%) were in functional class II. Atrial fibrillation was present in 29 (33.7%) patients (Table 1). The mean Wilkins score was 6.8±1.2, confirming overall favourable valve morphology across the cohort. Severe pulmonary hypertension (PASP >50 mmHg) was present in 34 patients (39.5%) [Table2].

IBMC induced meaningful improvements in all the primary hemodynamic parameters. MVA was increased from 0.91±0.18 cm^2 to 1.79±0.24 cm^2 (+0.88 cm^2; +96.7%; p <0.001), and MMG was reduced from 14.2±4.6 mmHg to 5.1±2.3 mmHg (−64.1%; p <0.001). Post-PCI mean PASP decreased from 48.6±14.2 mmHg to 31.4±10.8 (−35.4%; p<0.001) and there was no meaningful change in LVEF (pre: 62.4±5.8%; post: 62.1±5.9%; p=0.72). Overall procedural success was achieved in 81 of 86 patients (94.2%) [Table 3].

Characteristic	Value	%
Age (years)	38.4±11.2	
Gender		
Female	64	74.4
Male	22	25.6
NYHA Class II	2	2.3
NYHA Class III	58	67.4
NYHA Class IV	26	30.2
Atrial Fibrillation	29	33.7
Sinus Rhythm	57	66.3
Prior history of acute rheumatic fever	71	82.6
Hypertension	18	20.9
Diabetes Mellitus	11	12.8
Previous cardiac intervention (none)	86	100

Table No. 1: Baseline Demographic and Clinical Characteristics (n = 86)

Table No. 2: Baseline echocardiographic parameters (n = 86)

Echocardiographic Parameter	Mean±SD	Range
Wilkins Score	6.8±1.2	5 – 8
Mitral valve area - planimetry (cm^2)	0.91±0.18	0.6 – 1.4
Mitral valve area - pressure half-time (cm^2)	0.93±0.20	0.6 – 1.4
Mean mitral gradient (mmHg)	14.2±4.6	7 – 28
Pulmonary artery systolic pressure (mmHg)	48.6±14.2	28 – 90
Left atrial diameter (mm)	48.2±7.4	34 – 68
Left ventricular ejection fraction (%)	62.4±5.8	50 – 74
Mitral regurgitation grade 0-1+ (n, %)	86 (100%)	-

Table No. 3: Pre- and post-procedural hemodynamic parameters (n = 86)

Parameter	Pre-IBMC	Post-IBMC	Change	p-value
MVA - planimetry (cm^2)	0.91±0.18	1.79±0.24	+96.7%	<0.001
Mean mitral gradient (mmHg)	14.2±4.6	5.1±2.3	-64.1%	<0.001
PASP (mmHg)	48.6±14.2	31.4±10.8	-35.4%	<0.001
Left atrial diameter (mm)	48.2±7.4	44.6±6.9	-7.5%	0.003
LVEF (%)	62.4±5.8	62.1±5.9	Stable	0.72
Procedural success rate	-	94.2% (81/86)	-	-
Maximum balloon diameter used (mm)	26.8±1.4	-	-	-
Number of balloon inflations	3.2±0.9	-	-	-
Procedure duration (minutes)	52.4±18.6	-	-	-
Fluoroscopy time (minutes)	18.2±6.4	-	-	-

Table No. 4: Procedural complications (n = 86)

Complication	No.	%	Management
Severe MR (grade ≥3+)	3	3.5	2 urgent surgery; 1 conservative
Cardiac tamponade	1	1.2	Bedside pericardiocentesis
Ischaemic stroke/embolism	-	-	-
Procedural mortality	-	-	-
Emergency surgery (total)	2	2.3	Mitral valve replacement
Any major complication	4	4.7	-

Improvements in functional class were also dramatic. Before the procedure, 2.3% were class II according to NYHA criteria while 67.4 and 30.2% were class III and IV respectively. After the procedure, 69.8% of patients

improved to NYHA class I, 23.3% to class II and 4.7% to class III, leaving 2.3% (2 patients) with no improvement, corresponding to failure of the procedure. Before the procedure, the mean NYHA class was 3.28±0.52; after the procedure, it was 1.35±0.58 ($p<0.001$).

Major complications occurred in 4 patients (4.7%) [Table 4]. Three patients (3.5%) had severe MR (grade ≥3+) due to tearing of the non-commissural leaflet on echocardiography. Two of these patients were immediately scheduled for surgical mitral valve replacement. The remaining case was managed conservatively with the intention of surgery at a later date. Transseptal puncture-related cardiac tamponade occurred in 1 patient (1.2%) requiring bedside pericardiocentesis, and no deaths, ischaemic strokes (IS), or systemic thromboembolic complications (STE) related to the procedure were reported. In patients with AF (n=29) the procedural success rate was lower than in those in SR (n=57), 89.7% versus 96.5%, p=0.04, and PASP reduced less (p=0.03) possibly because they had more severe disease, with more advanced and irreversible pulmonary vascular remodelling. Since gain in MVA (p=0.21) and reduction in MMG (p=0.18) were not markedly different between both groups, it confirms the meaningful hemodynamic benefit of the IBMC in both rhythm subsets 4.

DISCUSSION

In the present study, safety, efficacy and reproducibility in a high RHD-burden population showed the success rates of 94.2%, MVA increase of 96.7%, MMG reduction of 64.1%, and PASP reduction of 35.4%, with no procedural mortality, seems comparable to high-volume international centres. This study showed that mostly young women with advanced symptomatic MS (mean age 38.4 years; 74.4% female) are similar to what would be expected from the epidemiologic features of rheumatic MS in Middle East and developing world. The bias towards female sex in RHD is established, and thought to result from differential immune responsiveness to Group A Streptococcus infection, and putative hormonal effects on the rheumatic inflammatory cascade.[9] The majority (97.7%) of patients present in NYHA class III/IV, similar to late presentation in systems with poor access to cardiological services, as is well recognizedLMICs.[16]

The success rate of the present study 94.2% compares very favorably with the published international experience because, Zhang et al[3] report a 90.3% rate for their multicentre Chinese experience. Reported rates 90-98% in the general population 11) and 91-97% in selected patients 15, 2021 ESC/EACTS guidelines) closely matched our single-centre experience. Our good results may reflect the favorable morphology of our patient population (mean Wilkins score 6.8): patients with a Wilkins score <8 have pliant, mobile leaflets, which tend to respond to balloon dilatation with commissural splitting rather than leaflet tearing 16; Palacios et al.[13]

In fact, the average gain in MVA in our series (0.91→1.79 cm^2; +96.7%) was at the high end of that previously reported worldwide. The 2020 ACC/AHA guidelines cite a gain of 85-100% in subsets of patients eligible for PBMV 13, exactly in line with our results. Moreover, the post-procedural MVA of 1.79 cm^2 exceeds the threshold of 1.5 cm^2 for haemodynamic success and approaches the post-procedural MVA of 2.0 cm^2 associated with the best long-term durability, published by Palacios et al[13] and Chmielak et al.[5] Thus, the 64.1% reduction in MMG led to near-normalization of the transmitral pressure gradient. The echocardiographic change corresponded with patient improvement, with 93.1% of patients improving by one or more NYHA classes and 69.8% improving to NYHA class I, from severely symptomatic disease to functionally normal.

A 35.4% reduction in the PASP (48.6→31.4 mmHg) confirms the systemic hemodynamic effect of successful IBMC. Relieving the mitral obstruction produces rapid reductions in left atrial pressure that are transmitted in a retrograde fashion to the pulmonary circulation. Residual mild pulmonary hypertension in our cohort is consistent with the fact that after chronic pulmonary artery pressure elevation PASP usually does not normalize completely in the short term and takes weeks to months for remodeling to bring it back to baseline levels and follow-up is likely to show continued PASP reduction.[2,14]

In the non procedural adverse events, no deaths were seen for the tricuspid procedures, and 4.7% of patients experienced a major complication. Severe MR occurred in 3.5% of patients, which was within the 2-9% reported worldwide.[1,14] Calcified and morphologically difficult valves may predispose to this complication. One patient (1.2%) had cardiac tamponade, which occurred at transseptal puncture and was resolved with no other sequelae. Operator experience is important. The lack of ischaemic stroke is consistent with the effectiveness of the heparinisation protocol and TEE screening.

The outcome of IBMC is less favorable in AF (89.7% vs 96.5%). AF has been shown to be an independent predictor of poor outcome with IBMC due to longer duration of disease, subvalvular involvement, and dilated left atrial size.[4,5] The MVA and MMG results from the AF subgroup were similar, confirming the IBMC is appropriate in a higher risk population. This study showed that high-quality IBMC can be delivered at a regional Iraqi cardiac center for a population with meaningful barriers to access to cardiac surgical services. A dedicated IBMC program at Shaheed Almihrab Cardiac Center is an important structural advance for cardiovascular care in the Babylon region

of Iraq. Prior to this, patients had to be referred to Baghdad, about 100 km away or abroad at a cost, a longer time, and more complicated treatment.

CONCLUSION

Inoue balloon mitral commissurotomy by percutaneous transvenous approach for patients with severe rheumatic mitral stenosis in a regional tertiary care hospital in Babylon, Iraq, is a safe, effective, clinically relevant, and practical procedure, with a success rate of 94.2% and a mean increase in MVA of 96.7%, MMG reduction of 64.1%, and PASP reduction of 35.4% in well-selected patients. Acceptable complication rates emerged, with no procedural deaths, low rates of moderate to severe MR and cardiac tamponade, and an important proportion of patients ending up in NYHA functional class I to II.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Shokry Faaz Alsaad
Drafting or Revising Critically:	Shokry Faaz Alsaad
Final Approval of version:	The above author
Agreement to accountable for all aspects of work:	The above author

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