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Navigating risks and rewards in percutaneous transcatheter mitral commissurotomy: A multicenter hemodynamic analysis of safety and efficacy in symptomatic mitral stenosis

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Abstract. *Aims:* This study evaluates the safety and efficacy of Percutaneous Transcatheter Mitral Commissurotomy (PTMC) in treating symptomatic rheumatic mitral stenosis (MS), using invasive hemodynamic parameters. PTMC, a less invasive alternative to surgical mitral valvotomy, is widely used for severe MS but involves risks like mitral regurgitation (MR) and procedural complications. We aimed to assess PTMC's safety through changes in left ventricular end-diastolic pressure (LVEDP) and efficacy via reductions in left atrial pressure (LAP) in a multicenter cohort.

Methods: This prospective, two-year study included 328 patients undergoing PTMC at IPGIMER-SSKM, Kolkata, and IMS-BHU, Varanasi, India. Patients were symptomatic, over 18 years old, and had severe MS (MVA ≤1.5 cm^2) with favorable valve morphology. Exclusions included left atrial thrombus, significant MR, and additional valve disease. PTMC was performed with a 24-28 mm Accura balloon catheter. Outcomes were grouped by procedural safety (LVEDP increase <50%) and efficacy (LAP reduction ≥50%).

Results: The mean participant age was 37.92 years, with 72.2% female. Procedures were both safe and efficacious in 26.83% of cases, and safe but inefficacious in 32.32%. Older patients were more likely to have unfavorable outcomes (p=0.0012), with no significant gender-based differences.

Conclusion: PTMC effectively reduces LAP in severe MS but involves risks, particularly for older patients with complex valve morphology. PTMC is beneficial when performed in experienced centers, but careful patient selection and further long-term studies are essential to enhance procedural outcomes. Fig. 1, Tab. 3, Ref. 15, on-line full text (Free, PDF), www.cardiologyletters.sk

Keywords: Efficacy – Hemodynamics – Mitral Stenosis – PTMC – Safety

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PTMC, pioneered in Japan in 1982 by Kanji Inoue, was developed as a minimally invasive alternative to surgical mitral valvotomy for treating rheumatic MS, especially in countries where rheumatic heart disease (RHD) remains prevalent (1). This technique involves the transvenous insertion of a balloon catheter to dilate the stenotic mitral valve, thereby reducing both trans-mitral gradient and left atrial pressure, thus relieving symptoms such as dyspnea and fatigue. The procedure has evolved, with the Inoue technique becoming widely adopted due to its self-positioning capability and lower complication-rate (2).

Historically, the efficacy of PTMC has been measured using changes in mitral valve area (MVA) and mean pressure gradients, often confirmed via echocardiography and hemodynamic assessments through catheterization. Various metrics like the Wilkins score have aided in predicting procedural success, factoring in valve morphology such as leaflet thickness and calcification (3).

Our study aimed to assess the procedure's safety and efficacy through a multicentric, prospective approach with rigorous inclusion criteria. The novelty lies in its focus on invasive hemodynamic parameters (LAP and LVEDP) and multi-center data, which address gaps in previous studies that relied more on echocardiographic rather than direct hemodynamic measurements.

Materials and Methods

Data from three hundred and twenty eight patients undergoing PTMC for rheumatic MS was collected using a standard, validated proforma between 17th January 2022 and 16th January 2024s in the cardiology departments of the Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital (IPGIMER and SSKM Hospital), Kolkata, India and the Institute of Medical Sciences, Banaras Hindu University (IMS-BHU), Varanasi, India.

The primary aim of this study was to assess the safety and efficacy of Percutaneous Transcatheter Mitral Commissurotomy (PTMC) as a treatment for isolated rheumatic MS using invasive hemodynamic catheterization studies by measurement of the left ventricular end diastolic pressure (LVEDP) and left atrial pressure (LAP) as surrogate markers of the safety and efficacy of this procedure respectively.

Major inclusion criteria included:

i. Patients greater than 18 years of age with echocardiographic evidence of isolated rheumatic MS.
ii. Patients with Mitral valve area ≤1.5 cm^2 and symptoms (e.g., dyspnea, fatigue).
iii. Patients with favorable mitral valve morphology (Minimal calcification, subvalvular thickening, or commissural fusion (Wilkins score ≤8)).
iv. Patients with absence of left atrial thrombus

Major exclusion criteria included:

i. Patients less than 18 years of age
ii. Patients who did not give consent
iii. Patients with more than mild (grade > 1) mitral regurgitation (MR), concomitant aortic valve disease, ischemic heart disease, atrial fibrillation, or hypertension.

A pre-designed validated, semi structured questionnaire and proforma was used to collect the data. Basic personal details (age, gender) were followed by a detailed trans-thoracic echocardiographic evaluation and the planimetry area and pressure half-time methods were used to calculate the mitral valve orifice area, before and after the PTMC procedure. Cardiac catheterization was performed to evaluate the LVEDP (Left Ventricular end diastolic pressure) and the LAP (Left atrial pressure), before and after the PTMC procedure. A 5F pigtail catheter was advanced through the femoral artery LV end--diastolic pressure (LVEDP) before and after the PTMC. LVEDP measurement was performed using pressure tracing just after the atrial contraction and during the simultaneous ECG recording; the pressure measurement point corresponded to the top of the R wave. Trans-septal puncture was performed with an 8F Mullins sheath, dilator, and a Brockenbrough needle. Left atrial pressure (LAP) was subsequently recorded. Pressure tracings were stored and analyzed off-line. PTMC was performed using a 24 to 28 mm Accura balloon catheter. The procedure was considered successful if the resultant MVA was >1.5 cm^2 or at least equal to, or more than twice the original MVA size, with less than +1 grade increase in MR. All Echocardiographic evaluations, catheterizations and procedures were done by expert interventional cardiologists with at least 5 years of experience.

Safety of the PTMC procedure:

The procedure was defined as "safe" (4) if the increase in left ventricular end-diastolic pressure was less than fifty percent of its original value.

Efficacy of the PTMC procedure:

The procedure was defined as "efficacious" (5) if the left atrial pressure reduced by at least fifty percent of its original value.

The participants were then categorized into 4 groups: (a) Safe and Efficacious, (b) Unsafe and Efficacious, (c) Safe but inefficacious, (d) Unsafe and inefficacious.

The study was conducted with the approval of the Institutional Ethics Committees of the Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital (IPGIMER and SSKM Hospital), Kolkata, India, and the Institute of Medical Sciences, Banaras Hindu University, Varanasi, India and written informed consent was obtained from all the study participants prior to enrolling them in our study.

Statistical analysis was conducted using IBM SPSS Statistics, Version 25.0. Continuous measurements are presented as Mean ± SD; chi-square test was used to assess associations, and a p-value < 0.05 was considered statistically significant.

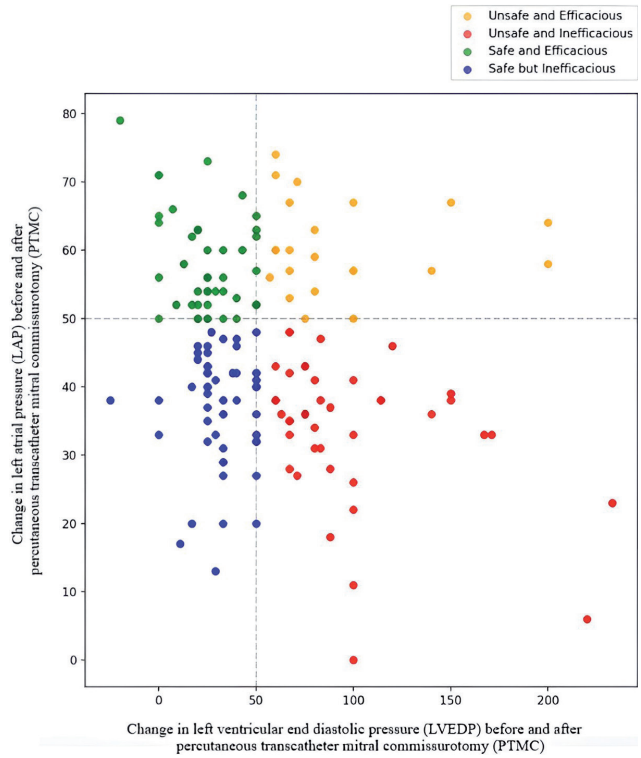

Figure 1 Patient outcomes based on safety and efficacy

Results

Baseline Data

The sample had a mean age of 37.92 years, with a gender skew towards females (72.2%). The histogram indicated a normal distribution with a concentration in middle-age ranges.

Categorization according to safety and efficacy

As shown in **Table 1** and **Figure 1**, the largest proportion of patients (32.32%) experienced a safe but inefficacious PTMC procedure, while a substantial subset (26.83%) had outcomes that were both safe and efficacious. A total of 26.22% of the study population underwent a procedure that was both unsafe and inefficacious, and the smallest proportion (14.63%) had an unsafe but efficacious outcome. Out of the 328 patients who underwent PTMC, 194 (59.14%) had a safe procedure, defined by a less than fifty percent increase in left ventricular end-diastolic pressure (LVEDP) following the procedure. Meanwhile, 136 patients (41.46%) achieved an efficacious procedure, demonstrated by a greater than fifty percent decrease in left atrial pressure (LAP) post-procedure.

The Spearman correlation coefficient between the "change in left atrial pressure (LAP) before and after PTMC" and the "change in LVEDP before and after PTMC" was of -0.21 ($p = 0.0487$), which suggests a weak but statistically significant inverse relationship. The negative coefficient indicates that, as LAP decreases following Percutaneous Transcatheter Mitral Commissurotomy (PTMC), LVEDP shows a slight tendency to increase or, at minimum, decrease less substantially. This relationship is statistically significant at the conventional significance level ($p < 0.05$), indicating that the observed correlation is unlikely due to chance.

Table 1 Subgroup categorization of procedure according to safety and efficacy

Category	n (Frequency)	Percentage
Safe and Efficacious	88	26.83
Safe but Inefficacious	106	32.32
Unsafe but Efficacious	48	14.63
Unsafe and Inefficacious	86	26.22

In the context of our study, this finding implies a nuanced hemodynamic interaction following PTMC. While PTMC is effective in reducing LAP — a primary goal of the procedure to alleviate symptoms in patients with severe mitral stenosis — the observed inverse relationship with LVEDP suggests that this reduction in LAP may, in some patients, be accompanied by a compensatory or reactive increase in LVEDP. This could occur as the left ventricle adjusts to the sudden increase in blood flow enabled by the newly widened mitral valve.

Gender analysis according to each sub-group

Table 2 demonstrates that, consistent with the baseline gender distribution in this study, females comprised a higher proportion in each subgroup. In subgroup analysis, the highest relative proportion of males (41.66% vs. 58.33% for females) was found in the group that had an **efficacious but unsafe** procedure, whereas the largest proportion of females (76.74% vs 23.25% for males) was observed in the group that experienced a procedure that was **neither safe nor efficacious**. However, this association between gender and subgroup distribution was not statistically significant (p=0.1218).

Age group analysis of each sub-group

As shown in **Table 3**, these results reveal several insights regarding the significant relationship (p=0.0012) between age and the safety and efficacy outcomes of the PTMC procedure. The analysis across the four subgroups — safe and efficacious, safe but inefficacious, unsafe but efficacious, and unsafe and inefficacious — indicates potential trends regarding age:

Mean age differences across categories: The mean ages across the categories suggest variations in outcomes that might be age-related. Patients who experienced a Safe and Efficacious procedure had a mean age of 36.89 years, slightly younger than those in the Safe but Inefficacious and Unsafe and Inefficacious groups, with mean ages of 40.02 and 39.33 years, respectively. The youngest mean age (33.04 years) was in the Unsafe but Efficacious group, suggesting that while younger patients in this group achieved efficacy in terms of left atrial pressure reduction, they faced a higher risk in terms of safety (increased LVEDP).

Age Group Distribution (Under 30 vs. Over 31 Years): The safe and efficacious group had a relatively balanced distribution between younger and older patients, with 34 patients under 30 years and 54 patients over 31 years. This indicates that both age groups can achieve optimal outcomes with PTMC when other factors, such as valve morphology, are favorable. In contrast, the Safe but Inefficacious and Unsafe and Inefficacious groups had a significantly higher number of patients over 31 years (82 and 24, respectively). This pattern suggests that older patients may be more prone to procedures that fail to achieve efficacy, potentially due to factors such as valve rigidity and calcification, which are more common with age. The unsafe but efficacious category, with 20 patients under 30 and 64 over 31, indicates that while some older patients benefit in terms of efficacy, they may also be at a higher risk for complications, possibly due to age-related comorbidities or anatomical challenges.

Discussion

This study represents a comprehensive, multi-center analysis of the safety and efficacy of Percutaneous Transcatheter Mitral Commissurotomy (PTMC) for the treatment of rheumatic MS, with outcomes assessed

Table 2 Gender analysis of each sub-group

Category	Males n=frequency (% of total in that group)	Females n=frequency (% of total in that group)
Safe and Efficacious	22 (25%)	66 (75%)
Safe but Inefficacious	30 (28.3%)	76 (71.7%)
Unsafe but Efficacious	20 (41.66%)	28 (58.33%)
Unsafe and Inefficacious	20 (23.25%)	66 (76.74%)

(p-value = 0.1218)

The chi-square test for gender distribution across subgroups showed no significant association.

Table 3 Age group analysis of each sub-group

Category	Mean age (years)	Age <30 years (n=frequency)	Age >31 years (n=frequency)
Safe and Efficacious	36.89	34	54
Safe but Inefficacious	40.02	24	82
Unsafe but Efficacious	33.04	20	64
Unsafe and Inefficacious	39.33	24	24

(p-value = 0.0012)

The chi-square test indicates a significant association between age groups and outcome subgroups (p-value = 0.0012), suggesting that age may influence the distribution of safety and efficacy outcomes.

using invasive hemodynamic measures, specifically left atrial pressure (LAP) and left ventricular end-diastolic pressure (LVEDP). The results demonstrate that PTMC can effectively relieve MS symptoms while presenting certain risks, particularly among older patients.

Our study showed that 26.83% of procedures were both safe and efficacious, 32.32% were safe but inefficacious, 26.22% were both unsafe and inefficacious, and 14.63% were unsafe but efficacious. This distribution of outcomes aligns with studies such as Sulaiman et al.[4], which also reported PTMC as generally safe, achieving significant symptom improvement in over 90% of cases but with a restenosis rate of 23% within one year due to valve anatomy and patient comorbidities. Similarly, Palacios et al. (5). found that PTMC yielded favorable outcomes in 82% of patients, though it emphasized the importance of appropriate valve morphology and patient selection for optimal efficacy. These studies collectively highlight the procedure's variable effectiveness across patient demographics, particularly in those with anatomical complexities.

Age was a significant predictor of safety and efficacy in our study, with older patients more likely to experience adverse outcomes (p=0.0012). This trend has been echoed in other research, such as the work by Gamra H et al., (6) who found that older age correlated with increased complications and less favorable long-term results due to calcified and fibrotic valve morphology. Additionally, Nobuyoshi M et al. (4) reported a higher restenosis rate in older patients undergoing PTMC, reinforcing the notion that age and valve pliability are critical factors in predicting success (7). These findings emphasize the importance of careful patient selection, particularly for older individuals, who may face greater risks of complications and less durable outcomes.

Although our study showed a higher proportion of females in each subgroup, gender differences between the outcomes were not statistically significant (p=0.1218). This is consistent with findings from Cohen DJ et al. (8), who also observed a higher percentage of female participants but found no significant difference in outcomes based on gender. However, Cruz-Gonzalez I et al. noted a slightly higher incidence of procedural success in males post-PTMC (9). This discrepancy across studies underscores the need for further research to ascertain if gender-specific factors influence procedural outcomes.

The development of significant MR is a known complication of PTMC, occurring in 50% of patients in varying degrees depending on the cohort and procedure (10). In our study, 26.22% of patients experienced both unsafe and inefficacious procedures, with MR being a likely contributor to this category. Desabandhu et al. found that moderate pre-existing MR increased the likelihood of severe MR post-procedure, like our findings that pre-existing MR can impact outcomes (11). Zaki A et al. also reported a 6.5% incidence of restenosis and progressive MR over a 5-year period, reinforcing the need for long-term monitoring in patients post-PTMC (12). Our data align with these studies, highlighting MR as a significant post-procedural risk that can affect both the efficacy and safety of PTMC, especially in anatomically complex cases.

Our study required a favorable mitral valve morphology (Wilkins score ≤8), as severe calcification and thickening have been associated with poor outcomes. This aligns with findings by Mughal S et al., who reported that patients with lower Wilkins scores showed significantly better outcomes, as these valves are more amenable to dilation without causing MR (13). Additionally, Babu DS et al. emphasized the importance of assessing valve morphology, showing that lower echocardiographic scores predicted more favorable long-term outcomes, particularly in terms of reducing restenosis and MR (14). These results underscore that PTMC efficacy is closely tied to valve pliability, suggesting that pre-procedural imaging assessments are crucial to predict procedural success.

Our study's use of invasive hemodynamic measurements, in addition to echocardiographic assessments, is a distinctive strength, providing a more precise assessment of PTMC's physiological impact. Few studies, such as that by Sulaiman KJ et al., have employed invasive hemodynamics in evaluating PTMC, and findings align with ours, showing invasive measurements add significant value in assessing procedural outcomes (15). This approach may offer insights for centers with advanced catheterization capabilities, although it may not be feasible in all settings due to resource constraints. Echocardiographic parameters such as transmitral gradient, MVA, and MR severity are indeed critical for assessing

PTMC outcomes. However, the primary focus of our study was to evaluate immediate, short-term procedural impacts using invasive hemodynamic parameters (LAP and LVEDP). This approach provides:

- **Real-Time Data**: Invasive measurements allow real-time, precise assessment of procedural changes.
- **Procedure-Specific Insights**: Hemodynamic measurements directly reflect the physiological effects of PTMC, such as immediate changes in atrial and ventricular pressures.

While our study provides valuable insights, several limitations must be acknowledged: (i) Short Follow-Up Duration: The study's follow-up period was limited to immediate post-procedural outcomes, precluding assessment of long-term complications like restenosis or progressive MR. Longer-term data would better inform durability and late complications. (ii) Absence of a Control Group: Without a control group undergoing alternative therapies, such as surgical mitral valvotomy, direct comparison of PTMC outcomes with other treatment modalities is challenging. (iii) Sample Population Limitations: The cohort was largely composed of middle-aged females, which may limit the generalizability of findings to populations with different demographics, particularly younger or predominantly male groups. (iv) Lack of Advanced Imaging Modalities: Advanced imaging techniques like intracardiac echocardiography (ICE) were not used, which could offer enhanced guidance and possibly reduce procedural risks. (v) "Unsafe and inefficacious" categorizations highlight procedural risks rather than guaranteed long-term adverse outcomes. Follow-up studies are essential to validate these predictions.

Future research should aim to incorporate (a) Extended Follow-Up: To assess the long-term efficacy and durability of PTMC, particularly regarding restenosis and late MR development. (b) Comparative Studies: Randomized studies comparing PTMC with surgical valvotomy or other interventional approaches could provide clearer insights into the optimal treatment approach. (c) Role of Advanced Imaging: Employing real-time imaging modalities such as ICE could refine procedural accuracy, potentially improving safety and efficacy, especially in high-risk populations. (d) Age- and Gender-Specific Protocols: Given the influence of age on outcomes, developing tailored protocols for older patients may improve procedural success rates.

Conclusion

This multicenter study underscores PTMC as a valuable therapeutic option for symptomatic rheumatic MS, especially in areas with high prevalence of rheumatic heart disease. While PTMC is generally effective in reducing left atrial pressure and alleviating symptoms it carries inherent risks, particularly among older patients and those with complex valve anatomy.

A significant contribution of our study is the novel approach to assessing PTMC safety and efficacy using invasive hemodynamic monitoring, specifically through left atrial pressure (LAP) and left ventricular end-diastolic pressure (LVEDP). This method provides a precise, real-time assessment of procedural outcomes, offering a more nuanced understanding beyond traditional echocardiographic measurements. By categorizing outcomes based on hemodynamic response, our study offers a new framework for evaluating PTMC success and guiding clinical decisions, which may help refine patient selection and optimize procedural strategies.

Overall, our findings highlight that PTMC is most beneficial when conducted with careful anatomical evaluation and in experienced centers, and emphasize the value of hemodynamic monitoring in enhancing the safety and efficacy of this intervention. Future research, especially with extended follow-up and comparative studies, will be essential to further establish this hemodynamic assessment as a standard for evaluating long-term outcomes and durability of PTMC in MS treatment.

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