Percutaneous Mitral Commissurotomy: Procedural Characteristics and Predictors of Failure and Restenosis

Dilatation Mitrale Percutanée : Caractéristiques Procédurales et Facteurs Prédictifs d'Échec et de Resténose

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Summary

Introduction : Percutaneous mitral commissurotomy (PMC) is preferred treatment of rheumatic mitral stenosis (MS). This study analysed the procedure and identified predictors of failure and restenosis.

Methods: This was a Cross-sectional analytical study (2015–2023) including 35 patients who underwent PMC at Menzel Bourguiba Hospital for severe mitral stenosis or restenosis.

Results: The mean age was 54 years with a female predominance. In our study, 20% of patients were hypertensive, 5 % had a history of atrial fibrillation, 17% had acute rheumatic fever, and 25 % had undergone at least one PMC.The mean follow-up period was 10.51 months.

The mitral valve area was estimated at 1.13 cm² and the mean gradient at 10.45 mmHg. The Wilkins score was 5.88 with a score greater than 8 in 25 % of patients. The PMC procedure was performed using the Inoue balloon. The femoral vein was the access site, and balloon sizes used were number 28 (28% of the population) and number 30 (71% of patients). The mean number of inflations was 2.2. The complication rate was 14 %. Factors favouring complications were arterial hypertension (P=0,016) and an age over 55 years (P=0,049). During follow-up, surgical indication for mitral valve replacement was indicated in 31% of cases. The restenosis rate was 25 % after an average follow-up of 6.33 months. Factors favouring mitral restenosis were hypertension (P=0,033) and a history of two or more PMCs (P=0,003 in univariate analysis) and (P=0,014 in multivariate analysis).

Conclusion: Hypertension and prior PMC predict early complications and restenosis.

Keywords

Mitral Stenosis ; Percutaneous Mitral Commissurotomy ;Predictive Factor

Résumé

Introduction: La dilatation mitrale percutanée (DMPC) constitue le traitement de référence du rétrécissement mitral d'origine rhumatismale. Cette étude analyse le déroulement de la procédure et identifie les facteurs prédictifs d'échec et de resténose.

Méthodes : Il s'agit d'une étude analytique transversale (2015-2023) incluant 35 patients ayant bénéficié d'une DMPC à l'hôpital de Menzel Bourguiba pour une sténose ou resténose mitrale serrée

Résultats : L'âge moyen était de 54 ans. Dans notre population, 20 % étaient hypertendus, 5,7 % présentaient des antécédents de fibrillation atriale, 17 % avaient un antécédent de rhumatisme articulaire aigu et 25 % avaient déjà bénéficié d'au moins une DMPC. La surface valvulaire mitrale moyenne était de 1,13 cm² et le gradient moyen de 10,45 mmHg. Le score de Wilkins moyen était de 5,88 et 25 % des patients avaient un score supérieur à 8. La DPMC été réalisée avec le ballon d'Inoue, par voie fémorale, utilisant les tailles 28 et 30. Le nombre moyen d'inflations était de 2,2. Le taux de complications était de 14 %. Les facteurs associés aux complications étaient l'hypertension artérielle (P = 0,016) et l'âge > 55 ans (P = 0,049).

Une indication de remplacement valvulaire chirurgical était posée dans 31 % des cas. Le taux de resténose était de 25 % après un suivi moyen de 6,33 mois. Les facteurs prédictifs de resténose étaient l'hypertension et un antécédent de deux DMPC ou plus

Conclusion : L'hypertension artérielle et les antécédents de DMPC constituent des facteurs prédictifs de complications et de resténose.

Mots-clés

rétrécissement mitral dilatation mitrale percutanée facteurs prédictifs

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INTRODUCTION

Percutaneous mitral Commissurotomy (PMC) was introduced over 30 years ago for the treatment of mitral stenosis, , predominantly of rheumatic aetiology, accounting for 85% of cases, and infrequently observed in Western nations (1).

Described by Inoué in 1984, PMC replicates the surgical intervention through the inflation of a balloon at the level of the mitral valve (2).

In Tunisia, this technique was introduced in 1987. It is a well-mastered and reproducible technique that has been validated through several Tunisian studies (3–5).

At the cardiology department of Menzel Bourguiba Hospital PMC was introduced in 2015.

The aims of this study were:

- To describe the epidemiological, clinical, and echocardiographic characteristics, alongside comprehensive analysis of all PMC procedures conducted within the department.
- To study the predictive factors of failure and restenosis after PMC

METHODS

Study Design

A cross-sectional analytical study conducted from January 2015 to December 2023, involving 35 patients who underwent percutaneous mitral commisurotomy at the cardiac catheterization laboratory of Menzel Bourguiba. It included patients aged over 18 years with severe mitral stenosis or severe mitral restenosis diagnosed by transthoracic echocardiography and defined as a mitral valve area ≤ 1.5 cm^2 by planimetry or by pressure half-time (PHT) according to the 2021 recommendations of the European Society of Cardiology(6) and the American Society of Cardiology (ASE).

Pregnant women and patients with contraindications for undergoing PMC (7)(Presence of Left atrial thrombosis, Mitral regurgitation beyond grade II severity ,Significant aortic valve disease, Coronary artery disease requiring coronary artery bypass grafting, Contraindication to transseptal catheterization) were not included.

Data Collection

The medical history of all patients was documented, encompassing on Acute Rheumatic Fever (ARF), Atrial Fibrillation (AF) and history of previous PMC with the number of procedures performed and the exact date of the last intervention.

A transthoracic echocardiography (TTE) was performed using a General Electric Vivid 9 apparatus The parameters studied included: Left Ventricular End-Diastolic Diameter (LVEDD), Interventricular Septum Thickness, Posterior Wall Thickness, Left Ventricular Ejection Fraction (LVEF) by Simpson's biplane method, Left Atrial (LA) Size, Tricuspid Annular Diameter, Mitral Valve area (by planimetry and pressure half-time (PHT)), Transmitral gradient, Systolic Pulmonary Arterial Pressures.

We also conducted an evaluation of the mitral valve and subvalvular apparatus morphology using the Wilkins echocardiographic score, in addition to assessing for other valvular pathologies.

Systematic transoesophageal echocardiography was performed 48 hours before the procedure to exclude left atrial thrombus and better assess valve anatomy, quantify mitral regurgitation, and verify interatrial septum integrity.

Immediate post-procedural echocardiography was performed in the cardiac catheterization laboratory to: Evaluate mitral valve area, mean transmitral gradient, quantify mitral regurgitation, assess valve and commissure status for possible surgical intervention, evaluate interatrial septum and the presence of left-to-right shunts, and detect pericardial effusion.

Immediate procedural success was defined as achieving a mitral valve area ≥ 1.5 cm^2 with echocardiographic grade ≤ 2 mitral regurgitation.

Immediate post-procedural complications were defined as death, tamponade, thromboembolic events, and/or severe mitral regurgitation (≥ grade 3).

Dates of follow-up TTEs were recorded, and follow-up duration was calculated from the exact date of PMC to the follow-up TTE date. In cases of mitral restenosis, restenosis rate and subsequent treatment decisions were documented.

Statistical Data Analysis

Data were entered and analysed using SPSS version 25 software.

For comparisons between percentages and means a Statistical significant was considered if $P < 0,05$.

Our study is cross-sectional, focusing on the events "post-PMC complications" and "mitral restenosis" defined here

as primary outcome measures. we calculated crude Odds Ratios (OR) presented with their 95% confidence interval.

Ethical Considerations Patient Consent

The data were processed and analysed completely anonymously The authors confirm that patient consent forms have been obtained for this article.

We have no conflicts of interest to declare.

RESULTS

The mean age of the patients was 54±11.07 years, ranging from 31 to 73 years. The majority of the study population was over 40 years old, with a rate of 82 %.

Our population was predominantly female (77 % women and 22 % men), resulting in a sex ratio of 0,29.

In our study, 20% of patients were hypertensive, 8 % were diabetic, and 5 % had dyslipidemia. A history of atrial fibrillation (AF) was present in 22 cases (62 % of the population), while acute rheumatic fever (ARF) was noted in 17 % of the population and 25 % of the sample had a history of at least one PMC.

The echocardiographic Data before PMC had shown that:

The average mitral valve area was estimated at 1.1cm^2 by planimetry and 1.1 cm^2 by pressure half-time (PHT). A mitral valve area less than 1 cm^2 was found in 31 % of the population.

An anatomical study of the mitral valve revealed bicommisural fusion in 77 % of cases, calcifications in 34 %, and subvalvular apparatus remodelling in 40% of cases. The mean Wilkins score was 5.88, with a score higher than 8 in 25 % of patients.

The mean left ventricular gradient was 10.4 mmHg, with values greater than 5 mmHg found in 74 % of the sample. The mean left atrial surface was 45.5 cm^2, with a surface greater than 20 cm^2 found in 97 % of patients.

The mean left ventricular ejection fraction (LVEF) was 60%. Left ventricular dysfunction was noted in only 2 % of cases.

The mean pulmonary artery systolic pressure (PAPS) was estimated at 45.5 mmHg. PAPS greater than 50 mmHg were found in 71 % of the population.

(Refer to Table 1 for a comprehensive summary of all the echocardiographic parameters studied before PMC)

Table 1. Echocardiographie data before PMC

	Minimum	Maximum	Mean	Standard Deviation
Mitral valve area by planimetry (cm²)	0,8	1,5	1,1	0,1
Mitral valve area by PHT (cm²)	0,8	1,5	1,1	0,1
Gradient (mm Hg)	3	28	10,4	6
Left Ventricular End-Diastolic Diameter (mm)	39	57	50,8	4,2
Interventricular Septum Thickness (mm)	6	14	9,4	1,6
Posterior Wall Thickness (mm)	6	13	9	1,5
Left ventricular ejection fraction (LVEF) (%)	43	80	60,6	7,1
Pulmonary artery systolic pressure (mmHg)	20	99	45,5	15,6
Left atrial area (cm²)	23	80	35,6	10,6
Wilkins score	4	9	5,8	1,2
Tricuspid annular diameter (mm)	16	43	32,5	6,9

PHT=pressure half-time

In 68.6% of cases, mitral regurgitation was not observed, while tricuspid regurgitation was present in 48 % of cases. No cases of right ventricular systolic dysfunction were detected.

Procedure of PMC

In all patients, venous access was obtained via the right femoral vein using a 7F femoral sheath after local anaesthesia with lidocaine. The PMC procedure was performed by only 2 operators, with the first performing 65 % and the second 34 % of the series.

The use of a Pigtail catheter in the aorta was noted in 57 % of cases. Materials used in all procedures were: Arterial introducer, Brockenbrough needle, Mullins sheath with dilator, Inoué wire, Inoué balloon. Localization to identify the optimal site for transseptal puncture was based on fluoroscopic landmarks. In only one case, atrioseptotomy was challenging, requiring guidance by TEE. For the size of the Inoué balloon used, the two main balloon sizes were Balloon number 28 in 28 % of the population and Balloon number 30 in 71 % of patients.

The average number of inflations was 2.2, with a minimum of one inflation and a maximum of four inflations. The average left atrial pressure before PMC was 28.3 mmHg, which decreased to 16.5 mmHg after PMC.

The complication rate in our series was 14%, with chordae rupture in 5 % of cases and an indication for mitral valve replacement. We did not note any cases

of death, pericardial effusion, or tamponade. Failure to cross the mitral orifice was observed in 8 % of cases.

Table 2 summarizes the immediate echocardiographic results following PMC in the cardiac catheterization laboratory.

Table 2. Immediate Results after PMC

	Minimum	Maximum	Mean	Standard Deviation
Mitral valve area by planimetry (cm²)	0,9	3,3	2	0,5
Mitral valve area by PHT (cm²)	1,1	2,2	1,8	0,6
Gradient (mm Hg)	2	22	6,1	3,5
LVEDD (mm)	48	59	52,5	3,9
LVEF %	40	70	57	8,7
PASP (mmHg)	19	90	45	22,2

PASP= Pulmonary Arterial Systolic Pressures; LVEDD= Left ventricular end-diastolic diameter; LVEF= Left ventricular ejection fraction

The diagnosis of essential hypertension was retained in 67 patients (64.4% of the population). The cause of hypertension was found in 37 (35.6%) of the cases 5 of which were iatrogenic, due to oestroprogestative pills and anti-inflammatory drugs and 32 (86.4%) were due to organic causes. Among organic ones, 2 cases of primary aldosteronism, 1 case of Cushing syndrome , 4 renal artery stenosis (1 of which because of fibromuscular dysplasia ,another because of Takayashu disease and 2 cases because of atherosclerosis), 7 cases of kidney disease (3 auto-immune kidney disorders, 1 case of polycystic kidney disease and 4 chronic nephropathies), 9 Obstructive sleep apnea syndrome and 5 cases of aortic coarctation. Figure 1 summarizes the different causes of hypertension in the studied population. According to gender, hypertensive young women had more secondary hypertension than men (43.8% against 25.5%) with a statistically significant difference (p = 0.04).

Table 3 summarizes the improvement in echocardiographic and hemodynamic parameters after PMC.

Table 3. Echocardiographic and hemodynamic improvement parameters before PMC and after PMC

Parameters	Before PMC	After PMC
Transmitral Gradient (mm Hg)	10,4	6,1
PASP (mm Hg)	45,5	45
Mitral Valve Area (cm²)	1,1	2
Left Atrial Pressure (mm Hg)	28,3	16,5

PASP= Pulmonary Arterial Systolic Pressures

In immediate post-procedure; A grade IV mitral regurgitation (MR) was reported in 2 % of cases, Grade II MR was noted in 11 % of cases, Grade I MR was found in 8 % of the population and No MR was noted in 11% of cases.

Regarding immediate post-procedure tricuspid regurgitation (TR) assessment, No TR was observed in 11% of cases, Grade I TR was present in 14 % of the population, Grade III TR was observed in 8% of cases.

Evaluation of the interatrial septum showed persistent atrial septal defect (ASD) in 8 % (3 cases) with a left-to-right shunt.

The average follow-up period was 10.5 months, with a minimum value of 1 month and a maximum of 72 months.

Table 4 summarizes the echocardiographic data for remote monitoring of the PMC procedure.

Table 4. Echocardiographic data during follow-up

	Minimum	Maximum	Mean	Standard Deviation
Mitral valve area by planimetry (cm²)	0,9	2,7	1,7	0,4
Gradient (mm Hg)	2	15	6,9	3,6
LVEDD (mm)	41	56	46,71	5,3
LVEF %	48	70	57,2	6,9
PASP (mmHg)	23	75	36,5	12,8

PASP= Pulmonary Arterial Systolic Pressures; LVEDD= Left ventricular end-diastolic diameter; LVEF= Left ventricular ejection fraction

During follow-up, surgical indication for mitral valve replacement (MVR) was recommended in 31% of cases, with 14 % of patients undergoing MVR during their follow-up period. Among these patients, surgical indication was due to mitral regurgitation (MR) in 2 % of cases, often associated with tricuspid annuloplasty in 8.6% of cases with grade III tricuspid regurgitation (TR). Repeat PMC was attempted in only 5% of cases.

The incidence of mitral restenosis in our study cohort stood at 25 %, after an average follow-up of 6.33 months (minimum at 1 month, maximum after 24 months. The second part of our study aimed to identify predictive factors for post-PMC complications and mitral restenosis.

We investigated factors predisposing to complications, and the results showed that hypertension (HTN) was associated with a higher rate of post-PMC complications with a significance of P= 0.016 and OR = 9.750, 95% CI [1.223-77.724].

Similarly, an age over 55 years was significantly associated with complications. Indeed, no complications were encountered in patients under 55 years old, whereas 5 cases were observed in older patients, with a significance of P=0.049, OR = 1.313, 95% CI [1.033-1.667].

No association was found between other comorbidities and complications related to PMC. The P-values for these comorbidities were as follows: History of two or more prior PMC procedures (P=0.693), diabetes mellitus (P=0.460), acute rheumatic fever (P=0.272), and atrial fibrillation (P=0.886).

No echocardiographic parameter tested was found to be correlated with the risk of developing a complication during PMC. The parameters tested included the presence of calcification, subvalvular remodelling, a Wilkins score greater than 8, and pulmonary artery pressures (PAPs) greater than 50 mmHg. (refer to Table 5 summarizing the P-values for each parameter)

Table 5. Echocardiographic predictive factors of failure

Parameters	General Population (n=35)	Population with Success (n=30)	Population with Failure (n=5)	P
Wilkins Score > 8	1	8	2	0,541
Calcifications	12	9	3	0,191
Subvalvular Remodeling	14	12	2	NS
PASP > 50mmHg	10	10	0	0,127

PASP= Pulmonary Arterial Systolic Pressures

We tested procedural parameters of PMC; however, no correlation was found between PMC complications and the tested factors with the following P-values: challenging atrial septostomy (p=0.679), Operator expertise (P=0.191), Balloon size (p=0.541),Number of inflations (P=0.487),Use of a pigtail catheter in the aorta (P=0.07).

Hypertension emerged as a factor favoring restenosis with a significance of P = 0.033, OR = 6.133, 95% CI [1.032 – 36.449]. In our study, 14% of the population had a history of two or more prior PMC procedures. We observed a correlation between this parameter and mitral restenosis after PMC.In univariate analysis, a history of two or more prior PMC procedures showed a significance of P= 0.003, OR=20,000,95% CI [1,828-218,903] . This result was confirmed in multivariate analysis with a significance of P=0.014, OR=20,000,95% CI [1,828-218,903]. Other medical histories did not show a correlation with mitral restenosis (refer to Table 6 summarizing the P-values for each parameter).

Table 6. Mitral restenosis and comorbidities

Comorbidites	P	OR	IC à [95%]
Sex	0,33	0.33	0.36-3.22
Prioir PMC	0,136	3.3	0.65-17.27
Diabetes	0,287	0.88	0.77-1.01
Dyslipidemia	0,392	0.92	0.82-1.03
Acute rheumatic fever	0,577	0.52	0.53-5.21
Atrial fibrillation	0,599	1.51	0.32-7.07
Age younger than 40 years	0,113	1.4	1.13-1.85
Age older than 55 years	0,207	3	0.52-7.55

We examined echocardiographic parameters potentially associated with mitral restenosis post-PMC. However, no correlation was identified between mitral restenosis and the following parameters: LVEDD greater than 50 mm (P=0.544), gradient greater than 5 mm Hg (P=0.245), valve area less than 1 cm^2 (P=0.490), presence of calcifications (P=0.456), subvalvular apparatus remodelling (P=0.207), Wilkins score greater than 8 (P=0.625), pulmonary artery systolic pressure (PAPS) greater than 50 mm Hg (P=0.625), left atrial dilation (P=0.085), persistence of an interatrial communication (P=0.287), and presence of mitral regurgitation (P=0.639).

We also tested procedural parameters of PMC that could predict restenosis; however, no correlation was found between mitral restenosis and: Challenging atrial septostomy (P=0.551), Operator expertise (P=0.376), Balloon size (P=0.179), Number of inflations (P=0.490), Use of a pigtail catheter in the aorta (P=0.503).

DISCUSSION

Mitral valve stenosis, despite its significant decline in industrialized countries, remains a major health issue in developing countries (8). Percutaneous mitral commisurotomy represents the gold standard treatment with appropriate indications.

In Tunisia, Dr. Mechmèche at Rabta Hospital in Tunis introduced this technique in 1986. The first PMC performed at Menzel Bourguiba Hospital took place in January,2015.

Over the past two decades, indications for the procedure have expanded to include patients with unfavourable valve anatomy and associated comorbidities. The procedure is increasingly performed in older patients with comorbidities and more deformed valves(9-11) .Hypertension (HTN) was common in our population (20%), comparable to other literature series where it varies between 18 and 40%(12).

A cross-sectional study (13) from 1998 to 2010 reported trends

of increasing procedural complication rates associated with older age and associated comorbidities. Our study revealed that HTN was associated with a higher rate of complications (P=0.016, OR=9.750, 95% CI [1.223-77.724]), as well as age over 55 years (P=0.049, OR=1.313, 95% CI [1.033-1.667]).

For patient selection, the most widely used method is proposed by Wilkins et al(14).The Wilkins score. However, this score fails to predict outcomes in those with scores of 9 to 11, representing an intermediate population that has gradually been selected for the procedure. In our study, a Wilkins score greater than 8 was not associated with a higher rate of complications (P=0.541) or a higher restenosis rate (P=0.625).

PMC is also indicated if there is a contraindication or high risk for surgery: severe pulmonary arterial hypertension (15), and especially in elderly subjects. In our series, 28.6% of participants had PAPS greater than 50 mm Hg without it being a factor favoring PMC-related complications (P=0.127) or long-term mitral restenosis (P=0.625).

The Inoué balloon technique (16)is the most commonly used worldwide as it is faster, less labour-intensive, and requires less fluoroscopy time than the double-balloon technique. In our series, all patients underwent PMC using the Inoué balloon.

One of the simplest and most widely used methods to locate the optimal site for transseptal puncture is the use of fluoroscopic landmarks. Alternatively, transoesophageal echocardiography can help identify the location of transseptal puncture, hence the current trend of almost constant coupling with TEE. In our series, only one case had laborious atrial septostomy requiring guidance by TEE.

Procedure success rates varied widely between studies. In general, these rates ranged between 65% and 80%, with some authors reporting rates exceeding 90% in considerable-sized cohorts (17). For our study, the success rate was 85 %.

The most commonly described independent predictors of complications in studies were gender (worse outcomes observed in women (18)), age, and New York Heart Association (NYHA) functional class. Our study proved that age over 55 years was predictive of complications (P= 0.049 OR = 1.313 95% CI [1.033-1.667]), but not female gender.

The complication rate in our series was 14 %, with leaflet tear in 5 % of cases and an indication for mitral valve replacement. We noted no cases of death, pericardial effusion, or tamponade syndrome.

A recent study (19) showed that, out of 912 consecutive patients undergoing PMC and followed for up to 20 years, 30% still had good functional outcomes. However, Mitral restenosis remains the main cause of late functional deterioration after successful PMC, occurring approximately in 7 to 21% of cases (20,21).The restenosis rate in our study was 25 %.

Song et al (22) have clearly shown that the immediate post-PMC mitral valve area is the most important predictor of both restenosis and major clinical events. It has also been demonstrated that severe post-procedural mitral regurgitation (MR) is associated with a less favourable long-term event-free survival. the grades of pre and post-procedural MR independently predicted long-term clinical outcomes after PMC (23). Data that our study did not prove due to the small number of participants compared to other studies. Sagie A et al (24)identified (Patient age, NYHA Class IV, Mitral valve area, Previous surgical commissurotomy, Presence of MR, Wilkins Echocardiographic Score >= 8, and Presence of tricuspid regurgitation)as predictive factors for mitral restenosis after PMC:. Other studies (25,26) have described the following factors as predictive of mitral restenosis :Mitral valve area post-PMC< 1.8 cm^2,Presence of post-procedural mitral regurgitation, Average mitral gradient after PMC ,Pulmonary artery pressures, Development of significant late tricuspid regurgitation even in the absence of pulmonary hypertension, Progressive increase in left atrium volume even after successful PMC and Presence of atrial fibrillation.

In our study, hypertension appeared as a favoring factor for mitral restenosis with P = 0.033 OR = 6.133 95% CI [1.032 – 36.449], as well as a history of two or more PMC procedures with a P-value of 0.003 (in univariate analysis) and P-value of 0.014 (in multivariate analysis).

LIMITATIONS

Limitations of this study include the small sample size, which may affect statistical power, and the exclusive use of conventional 2-dimensional echocardiography. Strengths of the study include the detailed examination of each patient who underwent PMC, with regular echocardiographic and clinical follow-up (average follow-up time of 10.51 months). No patients were lost to follow-up, and when surgical intervention was indicated, it was performed. This study is the first to describe the experience of a regional hospital in Tunisia

regarding PMC, with an average of 4 to 5 PMC procedures performed annually and results consistent with global standards and recommendations, while confirming certain predictors of procedural complications and mitral restenosis.

CONCLUSION

Percutaneous mitral commissurotomy is the treatment for rheumatic mitral stenosis . The PMC procedure was performed using the Inoue balloon technique according to the steps and recommendations. Factors favoring complications were arterial hypertension and age over 55 years .Factors favoring mitral restenosis were hypertension and a history of two or more PMCs

Our results are consistent with literature data, confirming that PMC is the treatment of choice for MS, provided there is appropriate indication and careful surveillance.

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