



**IMMEDIATE AND SHORT-TERM OUTCOMES OF PERCUTANEOUS BALLOON
MITRAL COMMISSUROTOMY FOR SEVERE MITRAL STENOSIS AND
ASSOCIATED FACTORS, IN CARDIAC CENTER, SAINT PAUL'S HOSPITAL
MILLENNIUM MEDICAL COLLEGE,, ADDIS ABABA, ETHIOPIA**

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ABBREVIATIONS/ACRONYMS

ACC:	American College of Cardiology
AF:	Atrial Fibrillation
ARF:	Acute Rheumatic Fever
BMC:	Balloon Mitral Commissurotomy
BMV:	Balloon Mitral Valvotomy
Cath Lab:	Catheterization Laboratory
CHF:	Congestive Heart Failure
CI:	Confidence Interval
CV:	Cardiovascular
Echo-	Echocardiography
ESC:	European Society of Cardiology
FC:	Functional Class
GAS:	Group A Streptococcus
HIC:	High Income Country
LA:	Left Atrium
LAP:	Left Atrial Pressure
LMIC:	Low and Medium Income Country
MR:	Mitral Regurgitation
MS:	Mitral Stenosis
MTMPG:	Mean Trans Mitral Pressure Gradient
MV:	Mitral Valve

MVA: Mitral Valve Area

MVG: Mitral Valve Gradient

MVPG: : Mitral Valve Pressure Gradient

MVR: Mitral Valve Replacement

NYHA: New York Heart Association

P: P-Value

PBMC: Percutaneous Balloon Mitral Commissurotomy

PCI: Percutaneous Coronary Intervention

PHT: Pressure Half Time

PMBC: Percutaneous Mitral Balloon Commissurotomy

PMC: Percutaneous Mitral Commissurotomy

PMV: Percutaneous Mitral Valvotomy

PTMC: Percutaneous Mitral Commissurotomy

RHD: Rheumatic Heart Diseases

SC: Surgical Commissurotomy

SPHMMC: Saint Paul's Hospital Millennium Medical College

SR: Sinus Rhythm

TEE: Trans Esophageal Echocardiography

TR: Tricuspid Regurgitation

TTE: Transthoracic Echocardiography

WHO: World Health Organization

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ABSTRACT

BACKGROUND_ *Percutaneous mitral balloon commissurotomy (PMBC) is the treatment of choice for patients with mitral valve stenosis (MS) with favorable anatomy and prevents complications inherent to a surgical intervention.*

AIM_ *The aim of this study was to assess immediate and short term outcome of percutaneous balloon mitral commissurotomy for symptomatic patients with rheumatic severe mitral stenosis at Saint Paul's Hospital Millennium Medical College, Cardiac Center.*

METHODS- *Clinical data of 91 consecutive patients who underwent PMBC at Saint Paul's Hospital Millennium Medical College, Cardiac Center from February 2018-June 30 2021 were analyzed retrospectively. Demographic, clinical, echocardiographic and hemodynamic (pre and post procedure) data of patients were collected and analyzed. Data was collected with check list and patient telephone contact and was entered and cleaned with Epi Info 7.2.1 and analyzed with SPSS version 25. Paired t-test and Fisher's Exact Test were used to see association and p-value ≤ 0.05 was used to show statistically significant association.*

Results: *Of the 91 PMBC done in the center, the majority (91.2%) had successful procedure. The mean age of patients were 28.56 ± 8.039 years and 78% were females. The mean Wilkin's score was 6.62 ± 1.10 . After PMBC the mean mitral valve area was increased from 0.799 ± 0.18 cm² to 1.674 ± 0.37 cm² and Trans mitral mean pressure gradient was reduced from 20 ± 7.635 mmHg to 7.71 ± 4.40 mmHg ($P < 0.001$). Over all eight (8.8%) patients developed complication, from these two (2.2%) patients developed significant mitral regurgitation. The major predictors identified for poor immediate outcome were atrial fibrillation and high Wilkins score, while the predictor for New York Heart Association functional class improvement 3 months after the PMBC were Wilkin's score ≤ 8 and Post PMC mitral valve area > 1.5 cm².*

CONCLUSION- *Percutaneous mitral balloon commissurotomy is a safe procedure with excellent immediate and short-term results.*

Keywords: *Percutaneous Mitral Balloon Commissurotomy, Predictors, saint peter specialized hospital Cardiac Center, Ethiopia*

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1. INTRODUCTION

1.1. BACKGROUND

Rheumatic heart disease (RHD), an inflammatory heart valve condition, is a chronic sequel of acute rheumatic fever (ARF)(1).The incidence of ARF peaks between 5 and 15 years of age and is rare over 30 years of age. ARF incidence is similar in males and females but the risk of RHD is 1.6–2.0 times greater in women likely due to several factors including worsening of existing disease during pregnancy, GAS exposure during child rearing, limited access to services and intrinsic/hormonal factors.(2)

Although the prevalence of RHD has declined sharply in industrialized countries during the last century, RHD remains a major cause of cardiovascular disease in developing nations(3)(4). Unlike other valvular lesions, which might be attributed to multiple etiologies, Mitral stenosis (MS) alone or in combination with other valvular lesions is the only lesion almost exclusively attributed to rheumatic heart disease. MS progresses rapidly and lead to serious disability early in life. Commissural fusion, leaflet thickening and alteration of the sub valvular apparatus are the dominant mechanisms causing clinically important MS of rheumatic origin (5)

MS is a progressive disease, leading to symptoms like palpitations, dyspnea, and fatigue and include fatal complications like pulmonary hypertension, pulmonary edema, and systemic embolism due to arrhythmias. Management comprises of medical therapy to relieve symptoms, and if it does not to relieve the symptoms of valvular obstruction will need to be dilated the valve either surgically or by balloon. The surgical commissurotomy both open and closed were the only methods for many years by which mitral stenosis could be corrected, till the development of percutaneous balloon mitral commissurotomy (PBMV) in 1984 by a pioneering Japanese cardiac surgeon Inoue K(6)

Echocardiography is the main imaging modality used to assess the anatomic severity and the hemodynamic consequences of MS, which enables detailed assessment of Mitral valve (MV) pathology, extent of involvement of the subvalvular mitral apparatus, and concomitant involvement of other valves. Transthoracic echocardiography (TTE) is sufficient to grade MS and MR severity and to characterize the

morphology of the MV. Transesophageal echocardiography (TEE) is needed in addition when the MV cannot be adequately imaged with TTE and prior to a percutaneous or surgical procedure in order to exclude effectively intracardiac thrombi(4). Severe mitral stenosis is defined as a mitral valve area of $\leq 1.5 \text{ cm}^2$ and a diastolic pressure half time of ≥ 150 millisecond (7).

Mitral valve anatomy is the strongest independent predictor of success after PBMC. The Wilkins echocardiographic score is used widely to guide patient selection for BMV. This score is based on an assessment of four of the following 1) leaflet thickness, 2) leaflet mobility, and 3) leaflet calcification and 4) the extent of sub valvular disease, each of them have 1-4 score, so a total score of 4-16 will be calculated. But commissural morphology is not directly examined. A significant subset of patients with high Wilkins scores still attain a good result after PBMC(8)

Since 1984 as an alternative to surgical mitral commissurotomies for treatment of rheumatic MS, PBMC has been used successfully for the last more than 30 years, Recent guidelines recommend PBMC as the first therapeutic option for thermodynamically significant or symptomatic MS when MV morphology favors PBMC.(9)

PBMC is generally performed in the cardiac catheterization laboratory under either conscious sedation or general anesthesia, percutaneously using the double-balloon or the Inoue techniques. Balloon size was selected according to the patient's height. The balloon was inflated stepwise under fluoroscopic guidance until the reduction in trans mitral gradient is satisfactory(4).

1.2. Statement of the problem

In 2015, there were 33.4 million cases of RHD and 10.5 million disability-adjusted life years due to rheumatic heart disease globally. The death due to rheumatic heart disease was 319,400. The global mortality burden of RHD decreased by nearly 50 percent from 1990 to 2015, but the prevalence varied widely among countries and was highest in Oceania, central sub-Saharan Africa, and South Asia. Estimated age-standardized prevalence of RHD was 3.4 cases per 100,000 population in no endemic countries and 444 cases per 100,000 population in endemic countries.(10)

Nearly half the patients with RHD presenting to hospitals in developing countries have mitral stenosis (MS), and about 73% of these have moderate to severe stenosis. MS, when untreated, often leads to atrial fibrillation (AF), congestive heart failure (CHF) and stroke(11)

A multisite echocardiography-based screening done school age children in Ethiopia in 2016 showed that, RHD involved the mitral valve in 42 subjects; and the aortic valve in 6 of the subjects. Fifteen (0.5%) had borderline RHD. Definite RHD is about three fold higher than borderline RHD. MS in 3 of the students, whose mean age was 12.7 years(12)

A cross-sectional study in 2010 at Jimma university medical center, cardiac clinic, among 256 RHD patients, the distribution of valvular lesion included isolated mitral stenosis (MS) in 99 (51.3%), combined MS and mitral regurgitation (MR) 49(25.4%), isolated MR and isolated aortic regurgitation (AR) each 12(6.2%), combined AR and MS 11(5.7%), and others 10(5.2%)(13)

PBMC is associated with significant changes in mitral valve morphology in terms of splitting of the fused mitral commissures, increased mitral valve area, improved leaflet excursion and splitting of the sub-valvular structures(5). PBMC can be performed effectively and safely in selected patients ≥ 50 years old with good immediate result but result is inferior to young patients(14–16).

Possible Complications associated with PBMC include: bleeding at the catheter insertion site, blood clot or damage to the blood vessel at the insertion site, infection at the catheter insertion site, cardiac arrhythmias, embolic event, tamponade, iatrogenic atrial septal defect, mitral regurgitation. The following contraindications need to be ruled out prior to a PBMC: Mitral valve area (MVA) $> 1.5 \text{ cm}^2$, presence of a thrombus in LA cavity and/or LA appendage, MR $>$ mild, severe or bi-commissural calcification, absence of commissural fusion, severe concomitant valve disease, concomitant coronary artery disease requiring surgery(4)

1.3. Significance of the study

RHD is the most common cause of cardiovascular admissions and death in Sub Saharan countries including our country and the most common involvement is mitral valve as MS alone or in combination with other valve lesions.

PBMC is the treatment of choice for patients with severe mitral valve stenosis (MS) with favorable valve morphology. PBMC is being done at Saint Paul's Hospital Millennium Medical College, Cardiac Center since February 15/2018 initially as campaign by abroad cardiologists and by Ethiopian interventional cardiologists since 2019 and being done weekly since 2021 but no study done so far to assess the outcome of PBMC.

This study aims assessing immediate and short-term outcome of PBMC and associated factors in patients who had symptomatic severe rheumatic Mitral stenosis. This was the first study in our Hospital; the result of this study will be used as guide for subsequent management plans for Saint Paul Hospital Millennium Medical College and Ministry of health at large and to be used to improve the quality of health care service.

2. Literature review

2.1. Outcome of PMC

A systematic review and meta- analysis of randomized controlled trials showed that the immediate post procedural MVA was similar between PBMC and surgical commissurotomy (SC). The immediate mean MVG was significantly lower in the patients undergoing PBMC than SC. PBMC is likely to confer less procedural risk than SC, and is associated with a shorter duration of hospitalization, costs and is generally the preferred form of treatment.(17)

There are several randomized studies comparing PBMC with open chest commissurotomy or closed chest commissurotomy for patients with favorable characteristics (i.e., young patients with favorable anatomy). Results showed that balloon commissurotomy is at least comparable to surgical commissurotomy regarding immediate and long-term results. In addition, if restenosis occurs, patients treated by PBMC could undergo repeat balloon or surgery without the difficulties and inherent risks resulting from pericardial adhesion and chest wall scarring.(18)

An Indian Study showed successful PBMC was achieved with significant increase in planimetry and pressure half time (PHT) measured MVA (increased from $0.80 \pm 0.13 \text{ cm}^2$ to $1.65 \pm 0.36 \text{ cm}^2$ as measured by echocardiography) as well as significant drop in mean gradient across the mitral valve and pulmonary artery systolic pressure.(6)

In a study from Pakistan in 2019 done to asses quality of life after PBMC, showed that the NYHA score improved from 2.9 ± 0.38 to 2.1 ± 0.42 and 1.1 ± 0.35 , after one month and three month of percutaneous trans mitral commissurotomy respectively and MVA improved from 0.8 ± 0.67 before PBMC to 1.73 ± 0.89 after one month and 1.91 ± 1.28 after 3 months of follow up and concludes that Successful PBMC improves the quality of life in Mitral Stenosis patients.(19)

A study from CARDIOVASCULAR JOURNAL OF AFRICA(CJA) in 2018,done on A total of 11 patients, all teenagers or young adults, showed Mean mitral valve area increased from $0.69 \pm 0.13 \text{ cm}^2$ (range 0.5–0.9) before dilation to $1.44 \pm 0.25 \text{ cm}^2$ (range 1.1–1.9) after dilation ($p < .001$). At the follow up, up to 20 months later, all the patients were in NYHA functional class I–II. Mean mitral valve area remained stable at $1.43 \pm 0.32 \text{ cm}^2$ (range 1.1–1.9)(5)

In Ethiopian study, the procedural success rate (97.88%) while optimal result was (92.42%) with no hospital mortality rate. Prior to the procedure, the mean mitral valve area was 0.8 ± 0.23 cm², and after PBMC, the mean mitral valve area improved significantly (1.76 ± 0.4 cm²; $p < 0.001$). A reduction in MVG from 18.5 ± 7.29 mmHg to 6.15 ± 2.75 ($p < 0.001$) and the Wilkins Mitral valve score was 7.32 ± 1.35 (15).

2.2. Predictors of outcome

In one Korean retrospective study in 2018 which was done on 1187 patients who had PBMC for Rheumatic Mitral Stenosis. Patients with optimal results were significantly younger and had sinus rhythm, had significantly lower echocardiographic score, larger pre MVA, smaller left atrium diameter, and less frequent significant TR ($\geq$ GII).(20)

Another Indian study, a retrospective, observational study done on 37 patients showed that PBMV is an effective treatment for acquired mitral stenosis, as demonstrated by the immediate hemodynamic results in all 37 procedures. Marked valvular calcification, leaflet immobility, severe subvalvular thickening and the presence of atrial fibrillation were factors that adversely influence the results of PBMV. Echocardiographic analysis showed that patients who have an increase in mitral valve area, immediately after PBMV, and had shown no significant decrease in mitral valve area after 6 months.(21)

In Igor F. Palacios study at Harvard Medical School, Boston, which was done on 879 patients who underwent PM, identified that larger pre-PMV MVA, less degree of pre-PMV MR, younger age, absence of previous surgical commissurotomy, male sex, and Echo-Score ≤ 8 are independent predictors of procedural success(22)

From Iran, cross sectional study done in 2016, Out of 1000 patients who were enrolled in the study which compares PMC outcome in patients with AF versus SR, the AF group was older, was more in dyspnea NYHA functional class (III-IV), had greater MR before PBMV, higher mitral valve echo scores, and higher mTMPG compared to the SR group, post PBMC there were more cases of severe MR ($MR \geq 3+$) and dyspnea NYHA-FC (III-IV), higher LAP, higher mTMPG and smaller MVA in the AF group compared to the SR group(23)

In a single center study at Harvard Medical School, Boston which involves 876 patients, Procedural success was inversely associated with increasing preprocedural MR severity; ..

preprocedural MR ≥ 1 was associated with a lower likelihood of achieving an increase in post procedural MVA $\geq 50\%$ also independently and inversely predicted post- procedural MVA ≥ 1.5 cm².(24)

The immediate outcome was inversely proportional to the MVS (AOR=0.25; 95%CI=0.09-0.70) while the odds of atrial fibrillation was 4.4 times more likely to have an excellent outcome(15).

2.3. In-Hospital Adverse Events

In Harvard Medical School, Boston a single center study which involves 876 patients increasing preprocedural MR severity was associated with increasing procedural and in-hospital mortality but was not an independent predictor of either outcome. Greater preprocedural MR severity was associated with increased procedure-related cardiac tamponade, with preprocedural MR $\geq$ severe post procedural MR was the most common procedural complication and occurred in 80 patients (9.2%).(24)

In another study from Harvard Medical School, Igor F. Palacios study, out of 879 patients who underwent PBMC, there were 18 (1.9%) in-hospital deaths, and 6 (0.6%) of these were procedure-related deaths. Severe post- PBMC MR ≥ 3 Sellers' grade) occurred in 88 (9.4%) patients, Thirty-one patients (3.3%) underwent MVR during their hospitalization, with a higher incidence in patients with Echo-Score > 8 . Emergent MVR was required in 13 of 939 (1.4%) patients. Pericardial tamponade occurred in 9 (1%) patients. A left to right shunt was detected in 50 (5.3%) patients. Thromboembolic events occurred in 17 (1.8%) patients in the overall population. 5 (0.5%) patients developed complete atrioventricular block(22)

From Iran cross sectional study done in 2016 ,out of 1000 patients who were enrolled in the study, adverse events following PMC(including MVR, re-PBMV, stroke, peripheral embolism and death) were seen in 148 (35.7%) patients in the AF group and in 93 (15.9%) patients in the SR group (P < 0.001). Severe MR occurred in 4 (1%) patients in the AF group and in none of the SR group (P = 0.02). Pericardial tamponade occurred in 1 (0.2%) patient in the AF group and in none of the SR group (P = 0.41).(23)

In Ethiopian study twenty-four (7.2%) patients out of 330 patients had complications. Of these, one patient developed large pericardial effusion amounting to cardiac tamponade which was

relieved with tapping and procedure completed before discharge. Mild pericardial effusion was seen in 5 (1.5%) patients and PMBC was deferred in the three of these patients (one of them went for surgery and two repeat procedures were done successfully before discharge). New onset atrial fibrillation was encountered in 2 (0.6%) patients during and immediately after PMBC. One patient (0.3%) developed cerebrovascular accident with significant neurological deficits during procedure, which recovered gradually, and two patients had a transient ischemic attack(15)

3. OBJECTIVE

3.1 General objective:

To assess immediate and short term outcomes of percutaneous balloon mitral commissurotomy for patients with symptomatic severe rheumatic MS

3.2 Specific objective:

To determine immediate outcomes of PBMC for patients with symptomatic severe rheumatic MS

To identify predictors of successful PBMC for patients with symptomatic severe rheumatic MS

To determine NYHA functional class improvement 3 months after PBMC

To identify predictors of NYHA functional class improvement 3 months after PBMC.

4. METHODS AND MATERIALS

4.1. Study area and study period

St Peter Specialized Hospital is located in Addis Ababa, Ethiopia. It was established in 1961 as a TB Specialized Hospital which later became a comprehensive hospital under Federal Ministry of Health. The hospital provides various services especially in tuberculosis diagnosis and treatment with admission capacity of around 250. The Hospitals has inpatient services and outpatient specialty clinics where patients are referred for specific chronic disease for follow-up.

As of September 2017 Saint Paul's Hospital Millennium Medical College had opened a Cardiac Center (Cath Lab) at St Peter Specialized Hospital, which is run by internal medicine department, Cardiology unit, where cardiovascular outpatient clinic, cardiovascular inpatient care, Coronary Intensive Care Unit, coronary angiography and PCI services are being delivered and later start PBMC service in February 15/2018.

The study was conducted from February 01 to August 30/2021 at Saint Peter's specialized hospital cardiac center.

4.2. Study design

Single center retrospective observational study

4.3. Study population and sample size determination

All patients who had PBMC at Cardiac Center from February 15/2018 –June 30/2021 G.C.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria

All patients who had PBMC from February 15/2018-June 30/2021

4.4.2. Exclusion criteria

Incomplete data

Patients who had a repeat PBMC within the study period

4.5. Sample size and sampling procedures

We enrolled all eligible patients who had PBMC at the cardiac center. Totally hundred five PMBC was done from February 15 2018-June 30 2021.

From these four were repeat procedure (done for failed initial procedure), five patients had incomplete data, five patients card was lost. Finally ninety one patients were enrolled in this study.

4.6. Variables

4.6.1. Independent variables

Age

Sex

Residence

Valve morphology based on Echo score (Wilkins score)

Degree of MR

Rhythm

MVA

MVPG

Pre PMC NYHA functional class

4.6.2. Dependent variables

Successfulness of the procedure based on echocardiographic criteria

NYHA functional class 3 months after PBMC

4.7. Data collection tools

Data abstraction tool was prepared in English by reviewing different literatures(5,6,16,22) and used to explore the objectives of the study with four components. Data collectors were Physicians and they were trained on the variables and the collected data was reviewed daily by primary investigator.

Part one: socio demographic factors

Part two: hemodynamic parameters based on Echocardiography pre and post PBMC (this parameters were documented on on patients card the chart by cardiologists before and immediately after procedure, so data is taken from there documentation)

Part thee: in hospital complication of PBMC

Part four: clinical parameters before and 3 months after PMC.

The first three parameters were collected from chart review and NYHA functional class three months after PMC was collected through patient interview with cell phone(the guardian for age <18 years) by translating the English to local language the patient/guardian can speak.

4.8. Data quality

Data was checked for completeness and consistency for each clinical and hemodynamic variables by principal investigator. The quality of data was further ascertained during the data entry and cleaning process.

4.9. Data processing and analysis

The collected data was entered and cleaned and further analysis done using SPSS version 25 Statistical software. Frequencies and cross tabulations were used to summarize descriptive statistics of the data. Tables and figures were used for data presentation. Means and standard deviation were used for continuous variables.

Paired t-test was used to compare the mean differences of hemodynamic variables before and after PBMC. Fisher's Exact Test analysis was done to examine association between categorical variables. Multivariable logistic regression analysis was not conducted because the sample size is small. Statistical analysis was done using the Statistical Package for Social Sciences software (SPSS) version 25 and P-value less than 0.05 was used to show significant association.

4.10. Ethical clearance

Ethical clearance was obtained from research ethics committee of Saint Paul's Hospital Millennium Medical College and Saint Peter Specialized Hospital. During cell phone communication, Study subjects were briefed about the significance of the study and each subject was given the opportunity to

give verbal informed consent, or withdraw from the interview if they didn't agree and advised to continue their follow up.

4.11. Dissemination of results

The finding of this study will be given to department of internal medicine and will be presented to SPHMMC community and then will be published in locally accessible or international journals and will be used as baseline for subsequent studies.

4.12. Operational definition

Successful PMBC: was defined by a 50% reduction in the mean mitral valve gradient and a doubling of the mitral valve area and/or MVA > 1.5 cm² (7)

Failed PMBC: Those who didn't fulfill successfulness criteria(7)

Significant MR: MR worsening by > 2+ from baseline(7)

Procedure-related deaths were defined as those occurring during the PMV procedure and those occurring from complications directly related to the PMV(22).

In-hospital death was defined as any death occurring during the hospitalization independent of its cause(22).

NYHA class;(9)

NYHA class/Dyspnea grade	Description
I	No symptoms and no limitation in ordinary physical activity (E.g Shortness of breath when walking, climbing stairs)
II	Mild symptoms: mild Shortness of breath and/or angina and slight limitation of during ordinary activity.
III	Marked limitation in activity due to symptoms even less than ordinary activity (e.g., dressing/ undressing, going to toilet (< 100m walk).
IV	Severe limitation, experiences symptoms while at rest

5. RESULTS

5.1 Socio-demographic data and Clinical characteristics of MS patients who had PBMC

Ninety one patients who had PBMC were enrolled in this study. As shown in table 1, 71 (78%) patients were females. Forty six (50.5%) patients were from rural area. The mean $\pm$ SD age of patients were 28.56 ± 8.04 years which ranged from 16-54 years with the majority (73.6%) being in the age group (20-40) years. As shown in table 2, 69 (75.9%) of patients had sinus rhythm. Fifty one (56%), thirty six (39.6%) patients were in NYHA class II and III heart failure, respectively and four (4.4%) patients were in NYHA class IV.

Table 1: Sociodemographic characteristics of MS patients who had PMBC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91)

Sociodemographic characteristics		Frequency	Percent (%)
Age	≤ 20	17	18.7
	21-40	67	73.6
	>40	7	7.7
Sex	Female	71	78.0
	Male	20	22.0
Residency	Rural	46	50.5
	Urban	45	49.5

As shown in table 2, 69 (75.9%) of patients had sinus rhythm. Fifty one (56%), 36 (39.6%) patients were in NYHA class II and III heart failure, respectively and 4 (4.4%) patients were in NYHA class IV.

Table 2: Clinical characteristics of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91)

Clinical characteristics		Pre PBMC(n=91)	Post PBMC (n=84)
Pre PMC Rhythm (%)	Sinus	69(75.9)	NA
	Non sinus(AF/atrial flutter)	22(24.1)	NA
Pre PMC NYHA functional class,n(%)*	I	0	74(88.1)
	II	51(56.0)	8(9.5)
	III	36(39.6)	2(2.4)
	IV	4(4.4)	0

NA=not available (Since it is not dependent variable, we didn't assessed post PBMC rhythm)

* Post PMC NYHA class data was available for 84 patients and it was assessed 3 months after PMC.

5.2 Echocardiographic pre and post procedure hemodynamic characteristics of MS patients who had PBMC

As shown in table 3, the mean Wilkin's score was 6.62 ± 1.10 , which ranged 4-11 and Only 4 (4.4%) patients had score >8. Prior to PBMC, the mean mitral valve area was 0.799 ± 0.18 cm², which ranged from 0.4-1.4cm² and after PBMC the mean mitral valve area was increased to 1.674 ± 0.37 cm²($P<0.001$). Trans mitral mean pressure gradient was reduced from 20 ± 7.635 mmHg to 7.71 ± 4.40 mmHg ($P <0.001$). The mean pre and post PBMC LA pressure for 56 (those who had documented value) patients was 24.91 ± 9.25 and 13.11 ± 6.82 , respectively ($P<0.001$).

At baseline none of the patients had severe MR, moderate MR was found in only 5 (5.5%) patients and after the procedure, 19 (20.9%) patients developed moderate MR. None of the patients had developed severe MR. From patients who had no MR preprocedure,39 (43.3%) patients develop some degree of MR($P<0.001$) and in 26 (28.6%) patients the MR was worsened by grade I , while in 10 (11%) patients the MR was worsened by grade II and in 2 patients the MR was worsen by grade III (from no MR to moderate MR).

Table 3: Echocardiographic pre and post PBMC Hemodynamic characteristics of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91)

Hemodynamic parameters		Pre PBMC(n=91)	Post PBMC(n=91)	p-value
Wilkin's score points		6.62 ± 1.10	NA	
Wilkin's score >8 n (%)		4(4.4)	NA	
Mitral valve area assessed by planimetry,cm ²		0.799 ± 0.18	1.674 ± 0.37	<0.001*
Mitral valve pressure gradient,mmHg		20 ± 7.635	7.71 ± 4.40	<0.001*
LA pressure,mmHg**		24.91 ± 9.25	13.11 ± 6.82	<0.001*
Mitral regurgitation(MR)		2.15 ± 0.95	2.77 ± 0.95	<0.001**
Degree of MR,n(%)	No MR	30(33)	13(14.3)	
	Trace	22(24.2)	14(15.4)	
	Mild	34(37.4)	45(49.5)	
	Moderate	5(5.5)	19(20.9)	

NA= not available. N= number of patients

**With Fisher's Exact Test analysis. *with Paired t-test analysis.

** Data is available for 55 and 56 patients for pre procedure and post procedures, respectively

5.3 Outcome characteristics

As shown in table 4, 68 (74.7%) patients had post procedure MVA > 1.5 cm² and MVA was doubled for 78 (85.7%) patients. The procedure was successful in 83(91.2%) of cases with the post PBMC MVA ranged from 1.2-3.1 cm² in successful cases.

There were a total of 8 (8.8%) unsuccessful procedures. From these, 3 were due to failure to cross the mitral valve, 1 was due to difficulty of puncturing the atrial septum and the other 4 didn't fulfill hemodynamic successfulness criteria.

Over all 8 (8.8%) patients had developed some degree of complication. From these 2 (2.2%) patients who had no pre procedure MR developed moderate post procedure MR (significant MR). Three patients (3.3%) developed arrhythmia (1(1.1%) bradycardia requiring atropine during the procedure and 2 (2.2%) patients had developed incessant atrial fibrillation requiring

cardioversion during the procedure and one developed persistent atrial fibrillation at discharge while it was turned to sinus for the other patient. Other 2 patients (2.2%) developed bleeding from catheter insertion site. From these one patient developed hypotension requiring fluid resuscitation while the other didn't require fluid. One patient (1.1%) had developed hospital acquired pneumonia and left leg monoparesis which was improved at discharge. There was no pericardial tamponade or death.

Eighty two (97.6%) of patients were in NYHA functional class I and II at least three months after PBMC. From these 88.1% were in NYHA class I and 9.5% were in NYHA class II. Only 2 (2.4%) patients were in NYHA class III and none of patients were in NYHA class IV.

Table 4: Successfulness, complication and NYHA functional class 3 months after PMBC of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91).

Outcome characteristics		Frequency	Percent (%)
Post PMC MVA, by planimetry >1.5 cm ²		68	74.7
MVA doubled ,post PMC		78	85.7
Successfulness of PMC	Successful	83	91.2
	Failed	8	8.8
Post PMC complication	No complication	85	93.4
	Bleeding	2	2.2
	Arrhythmia	3	3.3
	Others**	1	1.1
	Moderate MR*	2	2.2
NYHA functional class 3 months after PMC**	I & II	82	97.6
	III	2	2.4

** Others include: cardiac tamponade,HAP,death,atrial septal defect

* Moderate MR which developed in patients who had no MR pre-PBMC.

**Data was available for 84 patients

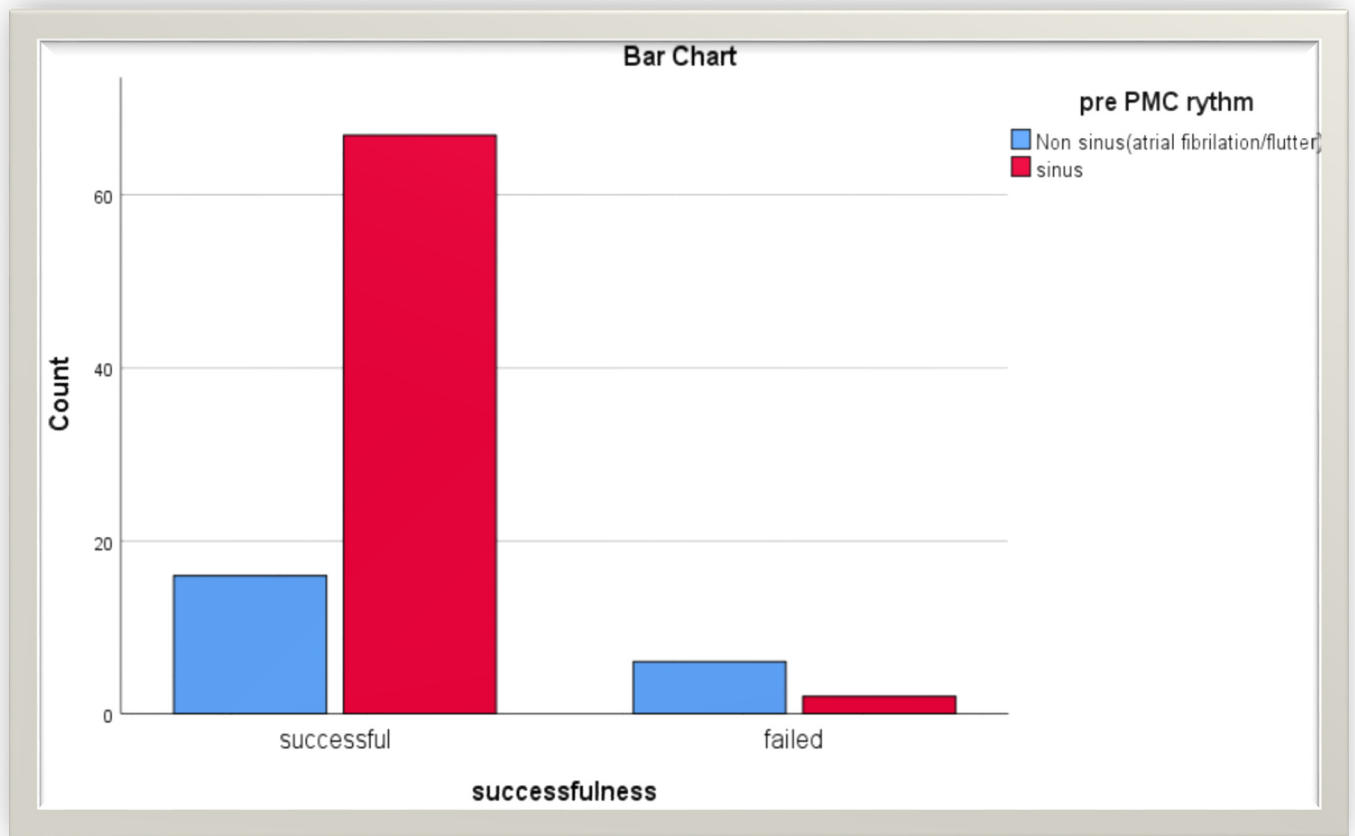


Figure 1: successfulness of PMC based on rhythm of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91).

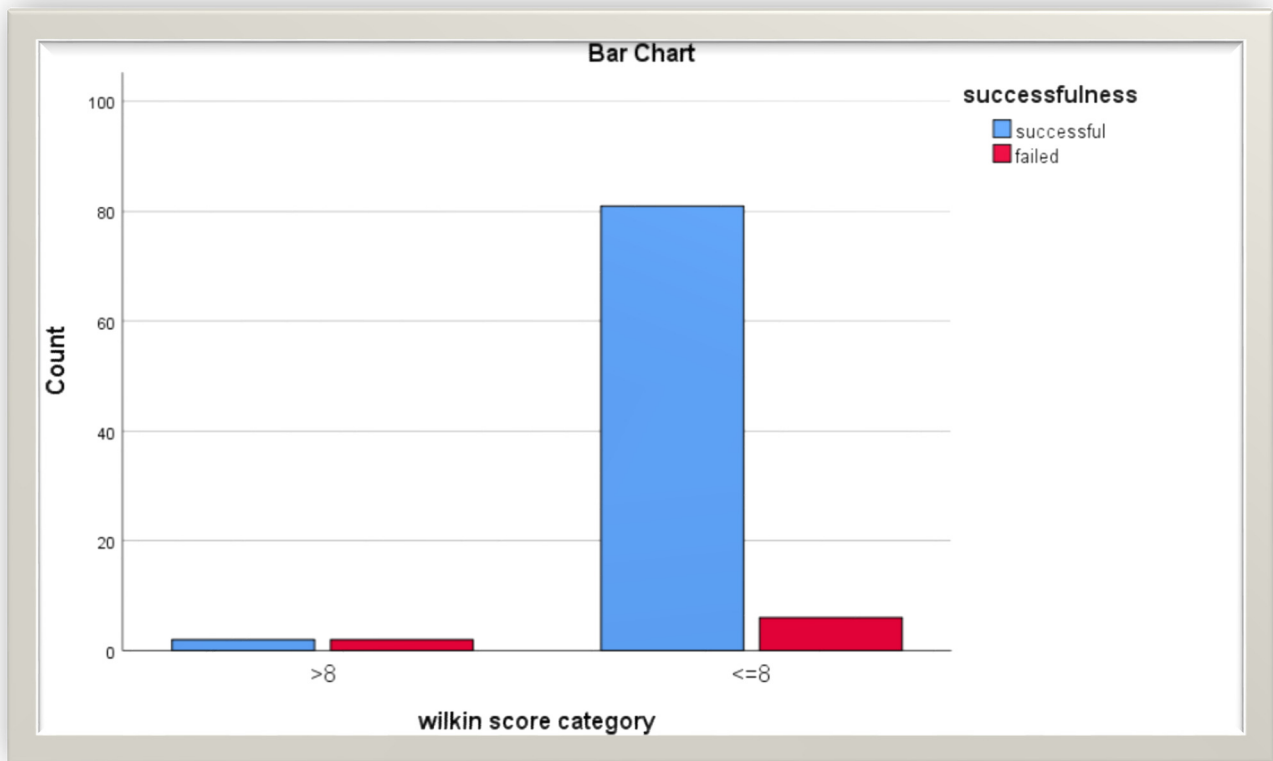


Figure 2: successfulness based on wilkins score of MS patients who had PBMC at Saint Paul’s Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91).

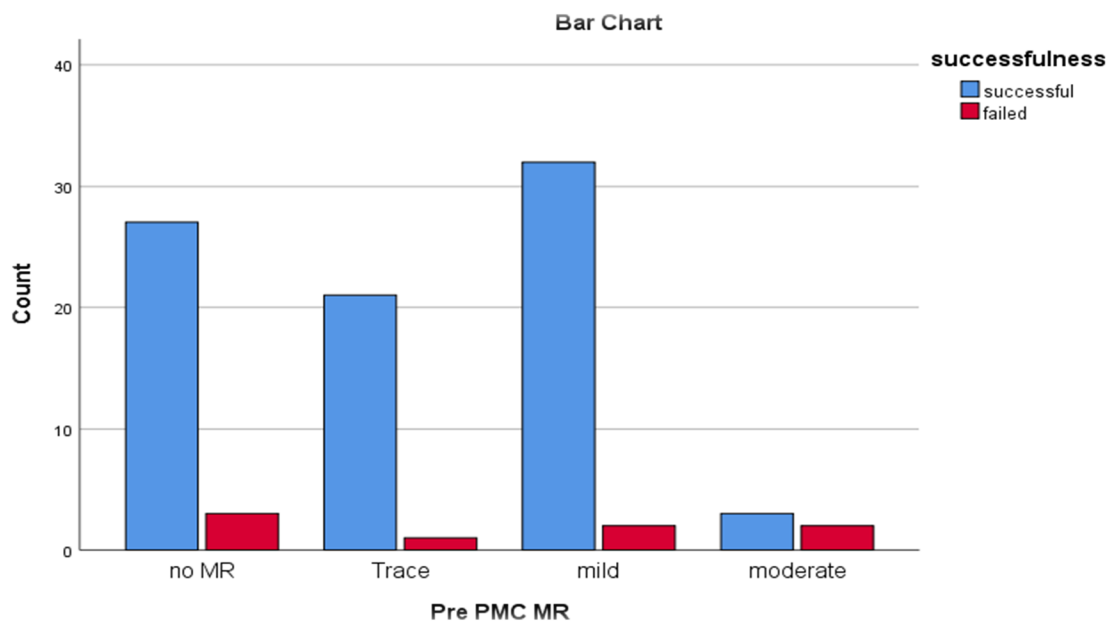


Figure 3: successfulness based on pre PMC degree of MR of MS patients who had PBMC at Saint Paul’s Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91).

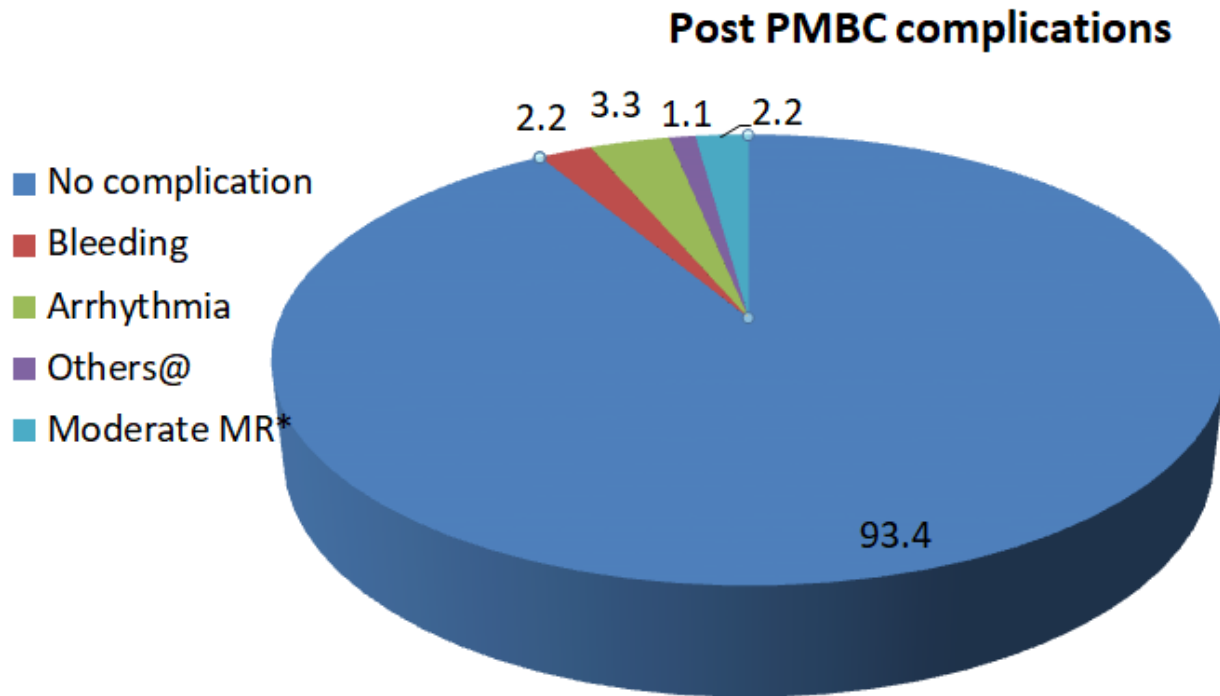


Figure 4: showed types of post PMBC complication of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91).

5.5 Factors that affect the outcome

5.5.1 Factors associated with successfulness of PBMC

As shown in table 5 below, Fisher's Exact Test analysis, showed association between success of the PBMC with Wilkin's score and heart rhythm with ($p \leq 0.05$). There were no association between successfulness of BPBC with age, sex, residency, pre PBMC mitral valve area, pre PBMC degree of MR and NYHA class with ($p > 0.05$). The sample size is too small to do Multivariable logistic regression.

Table 5: Fisher's Exact Test showing predictors of successfulness of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=91).

Variable		Successfulness n(%)		X2	DF	P-value
		Successful	Failed			
Age	≤20	16(88.9)	2(11.1)	1.127	2	0.730
	21-40	57(90.5)	6(9.5)			
	>40	10(100)	0(0)			
Sex	Female	66(93)	5(7)	1.232	1	0.367
	Male	17(85)	3(15)			
Residence	Urban	41(91)	4(9)	0.001	1	1
	Rural	42(91.3)	4(8.7)			
Pre PMC MVA,cm2,	≥ 1.0	11(91.7)	1(8.3)	0.004	1	1
	<1.0	72(91.1)	7(8.9)			
Wilkins score	>8	2(50)	2(50)	8.861	1	0.037
	≤8	81(93.1)	6(6.9)			
Degree of Pre PMC MR	No MR	27(90)	3(10)	7.582	3	0.074
	Trace	21(95.5)	1(4.5)			
	Mild	32(94.1)	2(5.9)			
	Moderate	3(60)	2(40)			
Pre PMC rhythm	Sinus	67(97.1)	2(2.9)	12.36	1	0.002
	Non sinus	16(72.7)	6(27.3)			
Pre PMC NYHA functional class	IV	4(100)	0(0)	1.418	2	0.629
	III	34(94.4)	2(5.6)			
	II	45(73.8)	6(26.2)			

5.5.2 Factors that predicts short term (at 3 months) improvement in NYHA functional class

As shown in table 6 below, Fisher's Exact Test analysis showed associations between improvement in NYHA functional class at 3 months post PBMC with Wilkin's score and post PBMC MVA with ($p \leq 0.05$). There were no association with age, sex, residency, pre PBMC mitral valve area, pre and post PMC degree of MR and pre-PBMC NYHA functional class with ($p > 0.05$). The sample size is too small to do Multivariable logistic regression.

Table 6: Fisher's Exact Test showing predictors of short term (at 3 months) improvement in NYHA functional class among MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=84).

Variable		NYHA functional class at 3 months*n(%)		X2	DF	P-value
		II & III	I			
Pre PMC MVA,cm2,planimetry	≥ 1.0	2(18.2)	9(81.8)	0.476	1	0.613
	<1.0	8(11)	65(89)			
Post PMCMVA,cm2,by planimetry	≤ 1.5	5(26.3)	14(73.7)	4.862	1	0.042
	>1.5	5(7.7)	60(92.3)			
Wilkins score	>8	2((66.7)	1(13.3)	8.896	1	0.036
	≤8	8(9.9)	73(90.1)			
Degree of Pre PMC MR	No MR	3(11.1)	24(88.8)	4.627	3	0.228
	Trace	3(13.6)	19(86.4)			
	Mild	2(6.7)	28(93.3)			
	Moderate	2(40)	3(60)			
Pre PMC rhythm	Sinus	5(8.1)	57(91.9)	3.329	1	0.118
	Non sinus	5(22.7)	17(77.3)			
Pre PMC NYHA functional class	IV	1(25)	3(75)	0.766	2	0.583
	III	4(12.5)	28(87.5)			
	II	5(10.4)	43(89.6)			

* Data was available for 84 pts.

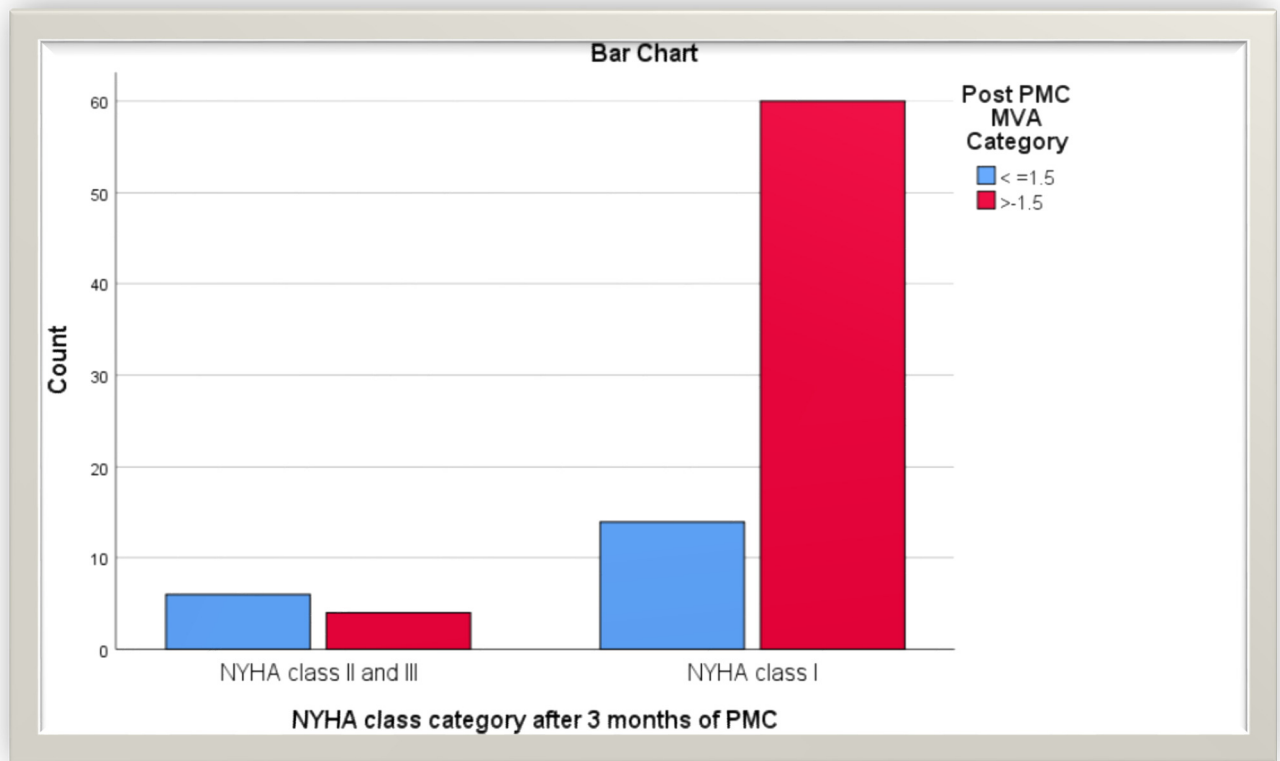


Figure 5: Showing association of NYHA functional class after 3 months of PMC with post PMC MVA of MS patients who had PBMC at Saint Paul's Hospital Millennium Medical College, Cardiac Center, Addis Ababa, 2021(n=84).

6. DISCUSSION

Since its first clinical application by Inoue and his fellows in 1984, Balloon mitral valvotomy was used as the best and safe intervention for morphologically favorable severe mitral stenosis for more than 30 years worldwide replacing surgical intervention. Since the service was started in our setup recently in 2018, this study has addressed an important issue of practical importance in the management of symptomatic severe mitral stenosis in local context.

The majority of patients in our study(78%) were female which is comparable with other studies done in Ethiopia (72.2%)(15), North America multicenter study (84%)(25) and it correlates with the high prevalence of rheumatic mitral stenosis in females. The incidence of AF in our study was 24% which was similar with other Ethiopian study (20.3%)(15), Indian study (15.7%)(26), Boston study (35%)(27).

In this study the mean mitral valve area was increased from 0.799 ± 0.18 cm² to 1.674 ± 0.37 cm²($p < 0.001$) and Trans mitral mean pressure gradient was reduced from 20 ± 7.635 mmHg to 7.71 ± 4.40 mmHg ($p < 0.001$) which was comparable with Ethiopian study(15) which showed the mean mitral valve area increment from 0.8 ± 0.23 cm² to 1.76 ± 0.4 cm² and a reduction in transmitral mean gradient from 18.5 ± 7.29 mmHg to 6.15 ± 2.75 . Also similar with North American study(28), Boston study(27), Indian study(26)). Over all the procedure was successful in eighty three (91.2%) patients which was slightly lower than the study done in Ethiopia(15) which showed (97.88%) successfulness. These may be due to some technical problems since the procedure is started recently and four of the failed procedures were occurred during the initiation of the service. But it was comparable with the study done in India which showed 89.19% successfulness(21) and was higher as compared to Boston study(69%)(27) and North American multicenter study(74%)(28). This may be due to patient characteristics showing the majority of western patients had calcific mitral stenosis which decreases the success rate because of high likely of having high Wilkin's score.

It is known that the outcomes of PBMC in patients with high mitral valve score(wilkins score > 8) is inferior to outcomes of patient whose total wilkin's scores is < 8 . Our study is also showed that mitral valve score > 8 was associated with reduced outcome with ($p=0.037$) which is consistent with the study done in Ethiopia(15), Boston study(29), Indian study(21).

Also in this study none sinus rhythm was associated with reduced procedural successfulness ($p = 0.002$) which is consistent with Ethiopian study(15), Indian study(21), Boston study(23). Other studies(18)(21)(30) showed that high pre PMC MVA and high pre procedural transmitral pressure gradient were associated with successful outcome, in contrast to this our study didn't show association($p > 0.05$) and also the degree of pre PMC MR didn't showed significant association with immediate outcomes($p=0.16$). This may be due to small sample size of the study population. Like Ethiopian study (16) our study didn't showed any association between successful PBMC and patient age, gender, and residency.

In our study the PMC was failed in eight patients(8.8%),of these 3 (3.3%) were due to failure to cross the mitral valve, which is comparable to the Ethiopian study which had (2.12%) unsuccessful PMC due to failure to cross the mitral valve(15), Indian study showed 8.1% failed PMC due to failure to cross the MV(21). One was due to difficulty of puncturing the atrial septum, Other four didn't fulfill successfulness criteria immediately after the procedure, but majority of these patients had improvement in NYHA class after 3 months of PBMC, this may be due to commissural splitting which may bring about the improvement in symptoms and functional class without increase in MVA or may be due to difficulty of measuring the MVA post PMC accurately rather than true unsuccessfulness.

In our study eight patients (8.8%) had developed complications which is comparable with the Ethiopian study which showed 7.2%(15). In contrast to our finding Iran study showed 35.7% patients developed complications(23). These difference may be due to small sample size in our study and majority of patients in Iran study were old (mean age 49.15 ± 12.98 years and had atrial fibrillation) as compared to our study (mean age 28.56 ± 8.03 years). From eight patients two patients developed incessant atrial fibrillation requiring cardioversion and one of the patient had persistent atrial fibrillation then wards, one patient developed bradycardia requiring atropine, two patients developed bleeding from catheter insertion site and one of the patient required fluid resuscitation. But in contrast to other studies none of our patients had pericardial tamponade, atrial septal defect or in hospital mortality. Ethiopian study showed new onset atrial fibrillation(0.6%),cardiac tamponade (0.3%),mild pericardial effusion(1.5%), stroke(0.3%), peripheral arterial embolization (0.3%)(15), and Indian study showed pericardial effusion(2.7%)(21)

In our study nineteen (20.9%) of patients developed moderate MR, from these only two (2.2%) patients had a grade 3+ worsening and none of our patients had developed severe MR. This finding showed the incidence of moderate-severe MR was lower than other studies. Ethiopia study showed Significant MR (greater than moderate MR or Severe MR) in 2.7% of patients, from these mitral valve surgery was required for 0.3% of cases (15), Boston study showed severe MR in 9.2% of patients (24), Harvard medical school study showed 9.4% (29)

In our study 3 months after the PMC seventy four patients (88.1%) were in NYHA functional class I, eight (9.5%) patients were in class II, two (2.4%) patients were in class III and no patient had class IV and being in NYHA class I is positively associated with low Wilkin's score ($p=0.036$) and post PMBC MVA $>1.5\text{cm}^2$ ($p=0.042$). These result was comparable with the findings of study done in a tertiary center in India (21), Pakistan (19).

7. STRENGTH AND LIMITATION OF THE STUDY

This study is the first to report the outcome of PBMC done at Saint Paul's Hospital Millennium Medical College, Cardiac Center and the second report in the Ethiopian settings. The study addressed the outcome of an important procedure being practiced in our Hospital recently which is done for Rheumatic MS. This study showed the results of heterogeneous patients from different geographic area since patients were referred from different corner of Ethiopia for the procedure.

Even though our study showed two important predictors of immediate outcome, obviously the sample size is small to assess all predictors of procedural success. From the 91 patients who were enrolled in this study, seven patients didn't have follow up and we couldn't reached them via phone call to assess their improvement in NYHA functional class at 3months, this may be because it is likely that patients may have not received follow-up due to an adverse event and this may have affected the results of our study. Our study addressed only immediate outcome and incomplete short term outcome, which doesn't addressed long term outcome. Finally it is a retrospective study with its limitation.

8. CONCLUSION AND RECOMENDATION

8.1: CONCLUSION

In this study the success rate of .PBMC was 91.1%. In-hospital complications happened in 8.8% of patients with no mortality. Majority of patients had shown significant improvement in NYHA functional class (88.1% of patients were in NYHA class I 3 months after PBMC).

Success rate was associated with high welkins score and atrial fibrillation. Post PMC NYHA class improvement was associated with post PMBC MVA >1.5cm² and Wilkins score

Therefore PBMC is a safe and effective procedure for management of patients with symptomatic severe mitral stenosis who have favorable valve morphology. These study findings can be used as baseline for subsequent researches in this area including those assessing short term and long term outcomes.

8.2: RECOMMENDATION

Since heart failure due to RHD is the major cause of cardiovascular admission in resource limited countries like us. The following are recommended

For Fellow Researchers

To asses immediate outcomes of PMBC with large sample size including other important predictors of outcome and to asses short term and long term outcomes of PMBC

For Healthcare Administrators and Policy makers

PMBC service should be widely available in the country

Increasing the number of expertise in the field

For SPHMMC Cardiology unit

Focus has to be given to availing consumable resources needed for timely PMBC service

Proper documentation PMBC results

For Saint Peter Specialized Hospital

Proper chart keeping/digitalization of patient file

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ANNEXES

Consent form: (verbal)

Hello, my name is _____**DrMershaMamo**_____. I am a physician working in SPHMMC and I am going to have a research on cardiac patients. The aim of study is **“to asses of immediate and short term outcomes of percutaneous balloon mitral commissurotomy for symptomatic patients with rheumatic severe mitral stenosis and associated factors, in saint peter specialized hospital”**. I will take a few minutes to ask you some questions about your condition after the procedure which was done for you in saint peter hospital. I took your clinical data from your medical recording chart. You have the option to decline to participate in this study if you feel uncomfortable. The information you give us will be kept confidential. We will not be collecting or retaining any information about your identity. You will not be required to pay for anything.

Participant's card number _____

Data collection check list

1. Sociodemographic data

Age (in years)	≤20
	21-40
	>40
Sex	Male
	Female
Residence	Urban
	Rural

2.1 Hemodynamic parameters by echocardiography immediately before and after PMC

Parameter	Pre-PMC	Post-PMC	
MVA(by planimetry)			
MR grade			
MVPG(In mmHg)			
LA pressure (in mmHg)			

2.2 Echo score (Wilkins score)

Echo score ≤8	
Echo score >8	

3. hospital complications(More than one choice possible)

Parameter In		
Bleeding from catheter insertion site		
Hematoma at catheter insertion site		
Infection at insertion site		
Thromboembolic events	Stroke	
	Intracardiac thrombus	
Dysrhythmias	Brady arrhythmia	
	tachyarrhythmia	
Cardiac taponade		
Iatrogenic atrial septal defect		
Procedure related death		
In hospital death		
Others... (please specify)		

4. Clinical parameters

4.1 Rhythm

- 1) Sinus
- 2) AF
- 3) Atrial flutter

4.2 NYHA functional class

4.2.1 NYHA functional class before PMC

- 1) No symptoms and no limitation in ordinary physical activity (E.g Shortness of breath when walking, climbing stairs (NYHHA I)

- 2) Mild symptoms: mild Shortness of breath and/or angina and slight limitation of during ordinary activity(NYHA class II)
- 3) Marked limitation in activity due to symptoms even less than ordinary activity (e.g., dressing/undressing, going to toilet (< 100m walk).(NYHA class III)
- 4) Severe limitation, experiences symptoms while at rest, bedbound most of the time (NYHA class IV)

4.3.2 NYHA functional class after 3 months of PMC but less than 5 years(was translated to local language which patients can speak)

- 1) No symptoms and no limitation in ordinary physical activity (E.g Shortness of breath when walking, climbing stairs (NYHHA class I)
- 2) Mild symptoms: mild Shortness of breath and/or angina and slight limitation of during ordinary activity (NYHA class II)
- 3) Marked limitation in activity due to symptoms even less than ordinary activity (e.g., dressing/undressing, going to toilet (< 100m walk). (NYHA class III)
- 4) Severe limitation, experiences symptoms while at rest, bedbound most of the time (NYHA class IV)

Declaration of investigator

I the undersigned resident declare that this research project is my original work in partial fulfillment of the requirement for certificate of specialty in internal medicine. I also declare that it has never been presented in this or any other higher institution and all the resources and materials used in the research work have been duly acknowledged.

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Name of investigator:_____

Signature:_____

Date: _____

Advisors:

Name of Public Health Advisor:_____

Signature:_____

Date:_____

Name of Clinical Advisor: _____

Signature_____

Date: _____