ORIGINAL ARTICLE

PERCUTANEOUS TRANSMITRAL COMMISSUROTOMY - CLINICAL AND ECHOCARDIOGRAPHIC FOLLOW-UP IN SEVERE MITRAL STENOSIS

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Objectives: To study the long term clinical and echocardiographic outcomes of percutaneous Trans mitral balloon commissurotomy (PTMC) performed in patients with severe mitral stenosis.

Methodology: Total 103 patients were enrolled in this study. Their PTMC procedure was performed between the years 2015 to 2019. Those patients who returned for follow-up in the year 2021 were enrolled. At the time of follow-up their clinical and echocardiographic parameters were recorded.

Results: The mean age was 27.44±6.26 years and 97 (94.2%) of them were female. Mitral valve area was improved significantly, planimetry; 0.813±1.39 vs. 1.288±0.21cm^2 and PHT; 0.871±0.13 vs. 1.336±0.19 cm^2 between baseline and follow-up, respectively. Pressure gradient across mitral valve also improved 7.233±2.81 vs. 14.407±0.92 mmHg between baseline and follow-up, respectively. Pulmonary artery pressures were also reduced significantly 24±0.27 vs. 55±2.41 mmHg as well as the right ventricular systolic pressures 24.4±2.94 vs. 62.34±10.98 mmHg between baseline and follow-up, respectively. At follow-up, 70.9% had NYHA I class, 16.5% had NYHA II class, 11.7% had NYHA III class, and 1% had NYHA IV class compared to 6.8%, 5.8%, 33.9%, and 53.4% pre-procedure, respectively.

Conclusion: Long term follow-up of patients after PTMC showed satisfactory outcomes both clinically, as evident from improvement in NYHA functional class, and from echocardiographic stand point with sustained increase in mitral valve area over the period of years. Overall the results of PTMC performed in patients with severe mitral stenosis are satisfactory.

Keywords: mitral stenosis, rheumatic heart disease, PTMC, long term follow-up, echocardiography

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INTRODUCTION

Rheumatic heart disease (RHD) remains a challenge for low to middle socio economic class of developing nations.[1-3] It is the leading cause of cardiovascular morbidity and mortality in younger population.[3] Damage to the valves may occur due to immune response against group-A streptococcus (GAS) bacterial infection.[1] Factors that may contribute to the increased incidence of RHD are lack of awareness and limited access to healthcare facilities, poverty, overcrowding, poor living conditions and malnutrition.[3]

Mitral stenosis is the commonest manifestation of RHD. It results in narrowing of mitral valve area and thus effects its function.[2] The process is gradual and may take years until the narrowing reaches the critical limit and patient develops signs and symptoms. Yearly rate of reduction in mitral valve area varies from 0.1 to 0.3 cm^2.[2] Since the introduction of the Inoue balloon in 1980s, the treatment of severe mitral stenosis has revolutionalised and percutaneous trans mitral commissurotomy (TPMC) has become the mainstay of treatment for symptomatic patients with favorable valve morphology.[4,5]

A successful PTMC increases the optimal mitral valve area and should not cause significant mitral regurgitation.[6,7] The candidates are selected for PTMC by echocardiographic assessment of mitral valve and its dimensions. Wilkin's score calculated through echo is an important tool for patient's selection.[8,9]

Our study is based on the long-term follow-up results of PTMC evaluated in a series of patients. Limited data is available on this subject. To the best of our

knowledge, not many studies are available in our country on intermediate to long term follow-up after successful PTMC. This study was designed to determine the outcome of PTMC at various follow-up intervals at a local tertiary center in selected group of patients in a defined period of time.

METHODOLOGY

It was a descriptive study conducted at the National Institute of Cardiovascular Diseases which is a tertiary care hospital in Karachi. Study was conducted after approval from ethical review board (ERB) of the hospital. Total 103 patients were included who underwent PTMC procedure between 2015 to 2019. During the 5 year period almost 230 PTMC procedures were performed by two experienced operators. Those patients who were lost to follow-up or who refused to come for follow-up visit due to long travel distances were excluded. In the year 2021 all the patients were contacted over telephone on their provided phone numbers through hospital's records. Those who were not reachable due to change in contact numbers or switched off status were contacted thrice at different time intervals and if with same status were excluded from the study. Telephonic interviews of all the study population were performed to collect data according to the proforma. During the year 2021 all the patients were scheduled for follow-up echocardiographic study after obtaining their informed consent at the hospital's ECHO department. The echocardiographic parameters such as mitral valve area (MVA), pulmonary artery pressure (PAP), mean pressure gradient (MPG) across mitral valve, right ventricular systolic pressure (RVSP), left atrial diameter (LA dia), right ventricular diastolic diameter (RVDD), mitral regurgitation (MR) and ejection fraction (EF) were recorded on the pre designed Performa. At follow-up visit, ECG was recorded to evaluate the rhythm. Pre procedure Echo reports were collected from all the study patients at the time of follow-up and variables were recorded. The record of any adverse cardiac event was also noted. Adverse cardiac events included cardiac-related death, repeat PTMC or surgical mitral valve replacement (MVR).

All patients with mitral valve area (MVA) < 1.5 cm^2 and who were candidates for PTMC were included. Only Successful PTMC interventions were included. All participants gave their informed consent. Institutional Ethical review Committee approval was obtained for conducting the study. Those who underwent trans esophageal echo before PTMC, their reports were collected and variables recorded. All the patients were advised to bring discharge summaries at the time of follow-up and the record of immediate echo that was performed post PTMC procedure during hospital stay and acute in-hospital complications (if any) were recorded through the summary.

Patients with moderate to severe mitral or aortic regurgitation and/or Aortic stenosis, pulmonary and tricuspid valve disease**,** Diabetes, hypertension**,** lung disease, coronary artery disease, Reduced LVEF and Suboptimal results of PTMC were excluded. Patients who were lost to follow-up were also excluded.

All the study patients underwent a baseline transthoracic echocardiography (TTE) before PTMC. MVA was measured by planimetry and pressure half-time. The peak and mean trans-mitral pressure gradients were measured using continuous wave Doppler. The degree of MR was recorded as mild, moderate or severe based on Doppler color flow mapping. Mitral valve morphology was evaluated using Wilkin's scoring system which include mitral leaflet mobility, valvular and subvalvular thickening and calcification. Systolic pulmonary arterial pressure (sPAP) was measured in mmHg through the tricuspid regurgitation jet. Left atrial diameter was calculated in millimeters and mean trans-mitral pressure gradient (MPG) in mmHg. Trans esophageal echocardiography was also performed before the procedure in order to rule out thrombi in the left atrium or the left atrial appendage. Immediately after the procedure, TTE was performed to rule out complications like severe MR and cardiac tamponade. MVA was also calculated to confirm the immediate success of PTMC. Follow-up echo was performed after 24 hours of PTMC procedure in-hospital and then at outpatient follow-up visit.

All PTMC procedures were performed by experienced operators with either an Inoue balloon catheter or multi track double balloon system depending on operator's choice. Procedures were performed via anterograde trans-septal approach in all patients. Optimal balloon size (mm) was estimated with the formula height (cm)/10+10. Sequential balloon inflation technique was used.

Data analysis was done by using IBM SPSS version 26. Mean ± standard deviation (SD) were calculated for continuous variables while frequency and percentage were calculated from categorical and ordinal variables. Two-sided probability value < 0.05, considered as statistical criteria of significance for study variables. For the association between the Pre and Post PTMC study variables McNemar Test- Cross Tab, NPar Test- Marginal Homogeneity Test, Paired Sample t-Test were applied. A Chi-square test and one way ANOVA were used to observe the effect of time duration between the follow-up and PTMC procedure

date with other study variables. For the graphical presentation of data, histogram with normal data curve was used.

RESULTS

Our study included 103 patients who returned for follow-up at different intervals after successful PTMC. Mean age was 27.44±6.26 years, mean height was 156.7±12.46 cm, mean weight was 48.4± 07.36 kg, and 97 (94.2%) of these patients were female and none were pregnant.

The follow-up duration was divided into 5 intervals which corresponds to the time when patients returned for follow-up since the time their successful procedure was performed as shown in Figure 1. Out of the total, around 44% came for follow-up visit after 2 years' time, around 31% came after 3 years, 23% after 4 years, 4% came after 5 years, and 1% patients visited after 6 years for follow-up respectively.

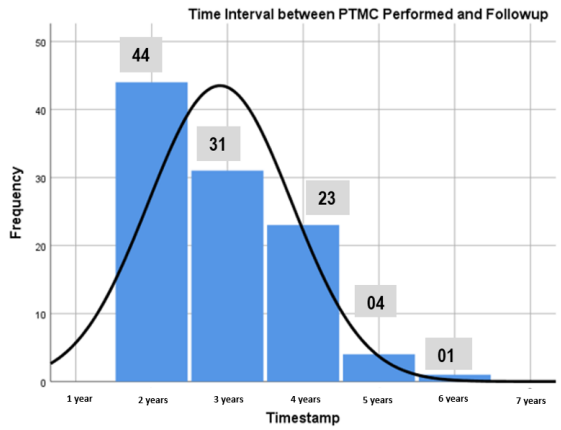

Figure 1: Time interval between PTMC intervention and follow-up

Clinical Status: Comparison of clinical status of all study patients pre PTMC and post PTMC is shown in Table 1. Out of the total patients before PTMC procedure, 6.8% had NYHA I class, 5.8% had NYHA II class, 33.9% had NYHA III class and 53.4% had NYHA IV class symptoms which was improved significantly after PTMC. Majority of the patients had normal sinus rhythm before and after the PTMC procedure. Out of the 3.9% of the patients who had atrial fibrillation prior to PTMC, only 2.9% had a history of CVA/stroke before the procedure with no residual neurologic deficit.

2D echo parameters before and after PTMC: All patients who underwent PTMC had a Wilkins score of < 8. MVA calculated through planimetry was 0.8 ± 0.08 and through PHT was 0.87±0.06 cm2. Mean trans mitral pressure gradient calculated as 14.41 ± 0.92 mmHg. LA diameter was 37.1 ± 2.94 mm. LVEF was 57.86 ± 3.81%. Pulmonary artery systolic pressure was 55 ± 2.41 mmHg. Around 91.3% patients had mild MR, 8.7% had moderate MR and none had severe MR prior to PTMC procedure. Table 1 describes the comparative analysis of echo parameters both before and after the PTMC procedure.

Table 1: Comparison of clinical status and echocardiographic characteristics before and after PTMC in study population

	Pre PTMC	Post PTMC	P-value
Clinical Status			
Cerebrovascular accident /stroke	3 (2.9%)	0 (0.0%)	0.250a
Associated valvular heart disease	0 (0.0%)	0 (0.0%)	-
New York Heart Association Class			
Class I	7 (6.8%)	73 (70.9%)	0.010b
Class II	6 (5.8%)	17 (16.5%)	
Class III	35(33.9%)	12 (11.7%)	
Class IV	55(53.4%)	01 (1%)	
ECG			
Normal Sinus Rhythm	99 (96.1%)	97 (94.2%)	0.750a
Atrial Fibrillation	4 (3.9%)	6 (5.8%)	
Echocardiographic Parameters			
Mitral Regurgitation			
Mild	94 (91.3%)	86 (83.5%)	<0.001b
Moderate	9 (8.7%)	16 (15.55%)	
Severe	0	01 (01%)	
MVA (Planimetry)	0.813 ± 1.39	1.288 ± 0.21	<0.001c
MVA (Pressure Half Time)	0.871 ± 0.13	1.336 ± 0.19	<0.001c
LA Diameter (mm)	37.097 ± 2.94	35.116 ± 2.84	<0.001c
Willkin's Score	7.50 ± 0.00	NA	x
MPG (mmHg)	14.407 ± 0.92	7.233 ± 2.81	<0.001c
EF (%)	57.864 ± 3.81	63.301 ± 2.37	<0.001c
RVDD (mm)	22.59± 4.09	20.1± 1.7	0.050c
RVSP (mmHg)	62.34±10.98	24.4 ± 2.94	0.050c
PAP (mmHg)	55 ± 2.41	24 ± 0.27	0.050c

aMcNemar Test, bNPar Test- Marginal Homogeneity Test, Paired Sample t-Test
MVA: mitral valve area, LA: left atrium, MPG: mean pressure gradient, RVDD: right ventricular diastolic diameter, RVSP: right ventricular systolic pressure, PAP: pulmonary artery pressure

At the time of follow-up, majority of the patients developed mild MR after PTMC. The calculated mitral valve area by planimetery and PHT was >1.2 cm2 in majority of the patients. There was no significant pressure gradient recorded across mitral

valve. Pulmonary artery pressure was also reduced significantly in majority of the patients. No significant difference was noted in ejection fraction before and after the after the PTMC procedure at the time of follow-up. Table 2 represents the follow-up data of all study patients.

Table 2: Descriptive statistics of study population at different follow-up intervals

	2 years	3 years	4 years	5 years	6 years	P-value
Total (N)	**44**	**31**	**23**	**4**	**1**	**-**
Mitral Regurgitation						
Pre PTMC						
Mild	39 (37.86%)	30 (29.12%)	20 (19.41%)	4 (3.83%)	1(0.97%)	0.631a
Moderate	5(4.85%)	1 (0.97%)	3(2.91%)	0 (0.0%)	0 (0.0%)	
Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Post PTMC						
Mild	35(33.98%)	27(26.21%)	19(18.44)	4(3.83%)	1(0.97%)	0.946a
Moderate	8(7.76%)	4(3.83%)	4(3.83%)	0 (0.0%)	0 (0.0%)	
Severe	1(0.97%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Mitral Valve Area cm^2 (Planimetry)						
Pre PTMC	0.81 ± 0.15	0.80 ± 0.17	0.84 ± 0.07	0.82 ± 0.09	0.9	0.801b
Post PTMC	1.32 ± 0.24	1.29 ± 0.17	1.2 ± 0.17	1.08 ± 0.08	1.5	0.149b
Mitral Valve Area cm^2 (Pressure Half Time)						
Pre PTMC	0.87 ± 0.06	0.87 ± 0.05	0.86 ± 0.06	0.87 ± 0.09	0.9	0.967b
Post PTMC	1.36 ± 0.19	1.34 ± 0.19	1.31 ± 0.19	1.11 ± 0.07	1.5	0.114b
Left Atrial Diameter (mm)						
Pre PTMC	37.11 ± 2.63	36.93 ± 3.01	37.35 ± 3.47	37.5 ± 3.41	34	0.842b
Post PTMC	34.86 ± 3.00	34.84 ± 2.72	35.35 ± 2.42	39.0 ± 2.58	34	0.075b
Mean Pressure Gradient (mmHg)						
Pre PTMC	14.36 ± 0.89	14.39 ± 0.95	14.35 ± 0.83	15.5 ± 1.29	14	0.198b
Post PTMC	7.09 ± 2.04	6.81 ± 0.65	8.17 ± 5.16	6.75 ± 0.96	7	0.482b
Ejection Fraction (%)						
Pre PTMC	57.61 ± 3.81	57.58 ± 3.84	58.69 ± 3.76	56.25 ± 2.50	65	0.225b
Post PTMC	63.64 ± 2.25	62.90 ± 2.51	62.83 ± 2.53	65.0 ± 0.001	65	0.269b
Pulmonary Artery Pressure (mmHg)						
Pre PTMC	40.46 ± 13.68	45.53 ± 14.24	50.04 ± 23.26	48.24 ± 21.23	43	0.005b
Post PTMC	25. 32 ± 3.53	32.51 ± 7.23	38.01 ± 0.72	41. 45 ± 9.82	42	0.005b

a Chi-Square, b One Way ANOVA

DISCUSSION

The essence of this study is the procedural success of PTMC in terms of clinical and echocardiographic improvement both immediately and at intermediate to long term follow-up, performed in symptomatic patients with severe MS. Both younger age group and favorable valve morphology are predictors of successful outcomes in this study.

Our study showed statistically significant results of decrease in MVA, MPG and PAP after the procedure. Long term follow-up echo showed patent mitral valve with less severe gradients across the valve. Significant symptomatic improvement was shown in study population because of improvement in NYHA functional class. Comparative analysis of all study patients over a period of 2-6 years follow-up time has shown sustained improvements in mitral valve area and pulmonary arterial pressures with less severe mitral regurgitations, leaving the patients almost symptoms free for a longer period of time.

Majority of the Follow-up studies after PTMC have shown functional improvement in patients.[10-14] In our present study, almost 90% of the patients were in NYHA functional class I/II. This is relatable to a fall in pulmonary arterial pressure and improvement in right ventricular systolic pressure after PTMC. As the time elapsed, some of the patients have reported worsening shortness of breath which can be attributed to MVA loss and rising pulmonary arterial pressures over time.

Various studies have observed suboptimal results of PTMC in higher age groups.[8] Unfavorable valve anatomy, calcification, higher Wilkin's score and probably higher frequency of atrial fibrillation in elderly population can explain the suboptimal results in such individuals.[9]

PTMC proves to be an effective and comparatively safer procedure with good clinical results in majority of patients. The benefits are mostly persistent on long-term follow-up. PTMC should be considered the treatment of choice in patients with severe mitral stenosis and favorable valve anatomy in all age groups.[15-19] It is a valuable treatment in developing countries where the majority of the patients have severe disease at a young age and may require repeat intervention. The surgical risk can be minimized significantly if PTMC is opted for the treatment.[15-19]

This study does not include patients with suboptimal PTMC results. Frequency of Re-do PTMC procedures after successful first attempt were also not studied. Sample size was smaller due to patients' drop out and loss to follow-up. Future studies are needed to address current study limitations.

CONCLUSION

Long term follow-up results of PTMC performed in carefully selected patients are satisfactory. PTMC is indeed a treatment of choice for severe mitral stenosis in selected group of patients in developing countries like ours.

AUTHORS' CONTRIBUTION:BK and TS: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. RA, SS, and YP: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

Conflict of interest: Authors declared no conflict of interest.

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