Original Article

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Percutaneous Transvenous Mitral Commissurotomy in Middle Aged Indian Population- A Cross-sectional Study

Others Section

JAYANTY VENKATA BALASUBRAMANIYAN[1], RH LAKSHMI[2], PHALGUN BADIMELA[3], JAYANTY SRI SATYANARAYANA MURTHY[4]

ABSTRACT

Introduction: Mitral Stenosis (MS) is a chronic complication seen among patients with Rheumatic Heart Disease (RHD). Percutaneous Transvenous Mitral Commissurotomy (PTMC) is a non surgical intervention indicated exclusively for MS with favourable valve morphology.

Aim: To determine the outcomes of PTMC in middle aged Indian population in relation to clinical and haemodynamic parameters.

Materials and Methods: This retrospective cross-sectional study conducted at a tertiary care hospital in Chennai, Tamil Nadu, between 1994 and 2019. Study was based on analysis of data from 82 patients diagnosed with MS, that underwent successful PTMC. Patients in the age group of 40 to 60 years with symptomatic MS {Mitral Valve Area (MVA) <1.5 cm^2 on echocardiogram} were included in this study. Successful PTMC was defined in terms of MVA >1.5 cm^2. Participants were divided into two groups based on Wilkins score of 8 as a cut-off. The continuous variables of the study subjects were described and interpreted by averages and compared between the groups by independent t-test. The pre, post and follow-up characteristics were analysed by averages and interpreted by paired t-test and confirmed by repeated measures of ANOVA.

Results: Group A with Wilkin's score ≤8 showed better results in terms of functional status improvement [New York Heart Association (NYHA) classification], MVA, mean gradient across mitral valve and Pulmonary Arterial Pressure (PAP) with p-values <0.05 after a mean follow-up period of one year.

Conclusion: Long-term outcomes of PTMC is better in patients with lower Wilkin's score than those with higher scores in terms of functional status improvement, maintenance of MVA and mitral valve mean gradient pressure. These factors favour the optimal utilisation of PTMC as an alternative to surgery especially among middle aged population.

Keywords: Mitral stenosis, Mitral valve area, Rheumatic heart disease, Wilkin's score

INTRODUCTION

Acute Rheumatic Fever (RF), a disease of poverty associated with other poor health social determinants is commonly seen in low income countries [1]. It is not uncommon to see many young adults in these low-income settings with Rheumatic Heart Disease (RHD), which is a sequela of acute RF [2]. The delayed immune response of Group A streptococcal pharyngitis results in several non-suppurative complications, of which RF and RHD are the most common especially in developing countries, particularly amidst children and young adults [3,4]. An estimated 4.71 lac cases of acute RF have been reported by WHO throughout the world annually with about 33,6000 of them in the age group of 5-14 years of age [5]. It has been projected that 6·1 million years of potential life lost before age 70 years in 1990 was caused by acute RF/RHD of which 5.5 million occurred in less developed countries [6]. The World Health Report in 2004 estimated that 5.9 million disability-adjusted life years lost during 2002 was attributed to RHD alone [7]. Though the incidence of RHD in recent times has seen a decline especially in Developed countries yet it ceases to be a common problem in developing countries especially like India which contributes to about 25-50% of newly diagnosed cases of RHD all over the world. RF is still the cause of mitral valve disease worldwide with the majority of them living in the developing world (79%) [8].

Mitral Stenosis is one of the most common complication of RS. MS is a progressive condition whose symptoms worsen due to increased heart rate and increased cardiac output resulting from increase of trans-mitral gradients [9]. In developed countries an average time of more than nine years was noted for progression from mild to severe with a latency of 20-40 years after an episode of RF [10,11]. Longitudinal studies based on echo-cardiography showed the average decrease in MVA to be around 0.09 cm^2/year with higher trans mitral gradients and Wilkin's echocardiographic scores (>8) which point towards a more rapid and progressive course [12,13]. In a combined analysis of 759 unoperated patients with MS series with ten year follow-up an overall survival rate of only around 50% but with survival rates of more than 80% was seen among mildly symptomatic patients [14]. This ten-year survival becomes less than 15% in the event of untreated MS [15]. In developing countries, recurrence of RF is a crucial issue, because of persistence of predisposing factors and poor access to diagnostic and prophylactic measures [16].

Treatment options can be decided between medical management or PTMC or surgery based on the nature and severity of the disease. Since 1984, PTMC has become an important alternative for surgery [17]. PTMC is one of the nonsurgical commissurotomy in the patients with haemodynamically significant MS [18]. Its clinical applications are widely accepted and reported in a large series [19-22]. In patients with suitable anatomy of the valve, the results of PTMC were equal to open and closed surgical mitral valvotomy [23,24]. PTMC has been widened its application to situations where other alternatives such as surgical commissurotomy is not advisable, like in elderly with calcific MS [25].

This study was intended to throw light upon PTMC as a procedure which has lost its importance especially following introduction of advanced surgical procedures for management of MS. Studies that assess the utility of PTMC as the procedure of choice in developing countries especially among middle aged population with MS are limited. This study highlights the outcome of PTMC in individuals with symptomatic MS in terms of clinical and haemodynamic outcomes.

MATERIALS AND METHODS

This was a retrospective cross-sectional study done in the Department of Cardiology at a tertiary care centre in Chennai, Tamil Nadu, India for 25 years time duration from 1994-2019. Ethics committee approval was obtained (Ref No: CSP-MED/2019/Mar/35/21) and written informed consent from all the participants for the procedure was obtained stating that the results will be used for research in future. Eighty-two patients with MS who underwent successful PTMC between 1994 and 2019 were selected.

Inclusion criteria: Patients of both sex with symptomatic MS (MVA <1.5 cm^2) who underwent successful PTMC within the study period were included in the study.

Exclusion criteria: Patients with mild MS (MVA >1.5 cm^2), Grade II Mitral Regurgitation (MR) or more, Left Atrium (LA) or Left Atrial Appendage (LAA) thrombus, Congestive cardiac failure, Wilkin's score >12, and patients who needed surgery were excluded.

Procedure

Evaluation of all patients for functional disability was done using NYHA classification [26]. ECG, transthoracic echocardiography, transesophageal echocardiography was done as a part of preprocedural evaluation was done using the self-positioning single balloon (Inoue-Balloon Catheter) under strict aseptic precautions through femoral venous approach under local anesthesia. Balloon size was decided based on the following formula.

Balloon size (mm)={Height in Cm/10}+10

Inflation was started at 1-2 mm less than maximum diameter and stopped if optimal results were not achieved with the maximum balloon diameter. The interatrial septum was traversed using balloon catheter tip and the stiffening cannula was used for passing the balloon portion into the LA which was then maneuvered into the left ventricle. The balloon was inflated using diluted contrast material to the point of disappearance of waist. As per the hospital protocol, Haemodynamic parameters post PTMC such as MVA, PPA were considered for analysis. Post procedure MR severity was graded based on Seller's classification from Grade 0 to Grade 4 which was assessed using Cine left ventriculography in Right Anterior Oblique (RAC) view [27]. Valve morphology was reassessed using Wilkin's score with data from complete echo doppler study repeated after 24 hours using Trans Thoracic Echocadiogram (TTE) and Trans Esophageal Echocardiogram (TEE) [28]. MVA was reassessed using pressure half time based on the average of three cardiac cycle recordings. Other parameters included for the study were peak and mean trans mitral pressures and pulmonary artery pressures Successful PTMC was defined in terms of MVA >1.5 cm^2 and MR of less than Grade II. The data was analysed in two groups based on the valve morphology using Wilkin's score. Group A comprised data from patients with Wilkin's score of ≤8 and Group B comprised of data from patients with Wilkin's score of >8. Follow-up assessment data at the end of one year included echocardiographic hematological parameters like MVA, mean and peak gradients, PA pressures.

STATISTICAL ANALYSIS

The continuous variables of the study subjects were described and interpreted by averages and compared between the groups by independent t-test. The pre, post and follow-up characteristics were analysed by averages and interpreted by paired t-test and confirmed by Repeated measures of ANOVA. The above statistical procedures were under taken with the help of the statistical package namely IBM SPSS statistics-20. The p-values less than or equal to 0.05 (p≤0.05) were considered as statistically significant.

RESULTS

A total of 82 patients aged more than 40 years, who underwent PTMC were included in the study. Group A included 56 patients with Wilkin's score of ≤8 and Group B included 26 patients with Wilkin's score of >8. Mean age in group A was 46.6±5.8 and in group B was 44.9±5.0. The difference in age was not statistically significant (p=0.206) The mean age of the participants was 46.1±5.6 years with range of 40-61 years [Table/Fig-1].

Age group (years)	Group-A	Group-B	Total
	Frequency (%)	Frequency (%)	Frequency (%)
40-44	21 (25.6)	14 (17.1)	35 (42.7)
45-49	22 (26.8)	6 (7.3)	28 (34.1)
50-54	8 (9.8)	5 (6.1)	13 (15.9)
55-59	3 (3.7)	1 (1.2)	4 (4.9)
60+	2 (2.4)	0 (0)	2 (2.4)
Total	56 (68.3)	26 (31.7)	82 (100)
Mean±SD	46.6±5.8	44.9±5.0	46.1±5.6
Significance	t*=1.275, df=80, p=0.206 * Student t-test		Range=40 to 61

[Table/Fig-1]: Comparison of group-A and B according to their age.

This study revealed that there was a significant improvement in functional status (NYHA classification) of the patient post PTMC in both the groups, but in group B the functional status in follow-up did not sustain, though it was not statistically significant (p=0.228). The mean MVA pre procedure in group A was 0.9 cm^2, post PTMC the mean MVA in group A was 2.1 cm^2 and on follow-up the mean MVA in group A was 1.8 cm^2 (p<0.001). The mean difference in MVA in group B during, pre, post and follow-up visits was statistically significant (p<0.001) implying that restenosis rate in group B (with area loss of 0.3 cm^2) was more significant than in group A (with area loss of 0.5 cm^2). The difference in mean gradients in group A during pre, post and follow-up visits and in group B during was also statistically significant (p<0.05). Difference in PAP in group A and group B during pre, post and follow-up visits respectively was also statistically significant (p<0.05). These data indicate that improvement in MVA, mean gradients and PAPs was sustainable better in group A than in group B [Table/Fig-2]. Sustainability is shown by the significant persisting difference in haemodynamic values between the groups during follow-up [Table/Fig-3].

Variables	Groups (n)	Levels		Level-1	Level-2	Improved	Significance*
		1	2	Mean (SD)	Mean (SD)	Mean (SD)	p-value
NYHA	A (56)	Pre	Post	2.6 (0.6)	1.1 (0.6)	1.5 (0.7)	<0.001
		Post	FU	1.1 (0.6)	1.3 (0.7)	0.2 (0.7)	0.011
		Pre	FU	2.6 (0.6)	1.3 (0.7)	1.3 (0.7)	<0.001
	B (26)	Pre	Post	2.7 (0.5)	1.7 (0.7)	1.0 (0.8)	<0.001
		Post	FU	1.7 (0.7)	2.5 (0.9)	0.8 (0.7)	<0.001
		Pre	FU	2.7 (0.5)	2.5 (0.9)	0.2 (0.9)	0.228
MVA	A (56)	Pre	Post	0.9 (0.2)	2.1 (0.3)	1.2 (0.4)	<0.001
		Post	FU	2.1 (0.3)	1.8 (0.4)	0.3 (0.3)	<0.001
		Pre	FU	0.9 (0.2)	1.8 (0.4)	0.9 (0.3)	<0.001
	B (26)	Pre	Post	0.9 (0.1)	1.9 (0.2)	1 (0.3)	<0.001
		Post	FU	1.9 (0.2)	1.4 (0.5)	0.5 (0.5)	<0.001
		Pre	FU	0.9 (0.1)	1.4 (0.5)	0.5 (0.6)	<0.001
MG	A (56)	Pre	Post	13.6 (3.7)	6.4 (2.8)	7.2 (3.6)	<0.001
		Post	FU	6.4 (2.8)	8.4 (3.8)	2 (2.9)	<0.001
		Pre	FU	13.6 (3.7)	8.4 (3.8)	5.2 (4.1)	<0.001
	B (26)	Pre	Post	15 (4.2)	9.4 (3)	5.5 (3.4)	<0.001
		Post	FU	9.4 (3)	11.7 (4.4)	2.3 (3.5)	0.003
		Pre	FU	15 (4.2)	11.7 (4.4)	3.3 (4.8)	0.002

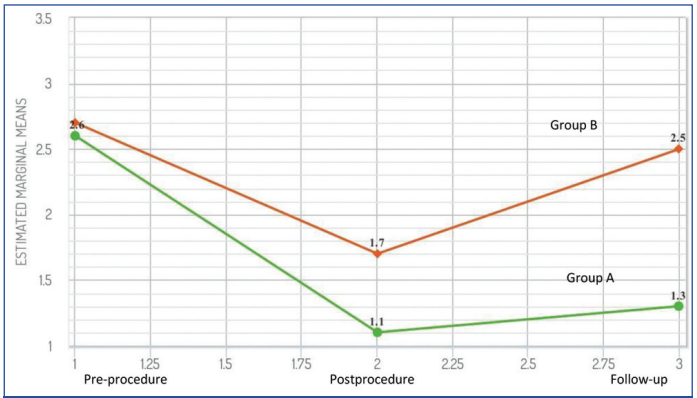
PAP	A (56)	Pre	Post	54.6 (15.4)	33.5 (11.7)	21.1 (14.1)	<0.001
		Post	FU	33.5 (11.7)	36.9 (15.9)	3.4 (7.4)	0.001
		Pre	FU	54.6 (15.4)	36.9 (15.9)	17.7 (16.7)	<0.001
	B (26)	Pre	Post	64.3 (18)	45.7 (16.7)	18.6 (11.2)	<0.001
		Post	FU	45.7 (16.7)	54.3 (22.4)	8.6 (10)	<0.001
		Pre	FU	64.3 (18)	54.3 (22.4)	10 (16.1)	0.004

[Table/Fig-2]: Comparison of outcome parameters within groups A and B at baseline and at end of 1 year.
NYHA: New York heart association; MVA: Mitral valve area; MG: Mitral valve gradient; PAP: Pulmonary artery pressure: Pre: Pre procedure (PTMC), Postpost procedure (PTMC), FU: Follow-up at 1 year * using ANOVA

Variables	Time	Group-A (56) Mean (SD)	Group-B (26) Mean (SD)	p-value*
NYHA	Pre	2.6 (0.6)	2.7 (0.4)	0.212
	Post	1.1 (0.6)	1.7 (0.7)	<0.001
	FU	1.3 (0.7)	2.5 (0.9)	<0.001
MVA	Pre	0.90 (0.2)	0.88 (0.1)	0.501
	Post	2.1 (0.3)	1.8 (0.2)	0.002
	FU	1.8 (0.4)	1.4 (0.5)	<0.001
MG	Pre	13.6 (3.7)	15.0 (4.2)	0.143
	Post	6.4 (2.8)	9.4 (3.0)	<0.001
	FU	8.4 (3.8)	11.7 (4.4)	0.001
PAP	Pre	54.6 (15.4)	64.4 (18.0)	0.014
	Post	33.5 (11.8)	45.7 (16.7)	<0.001
	FU	36.9 (15.9)	54.3 (22.4)	<0.001

[Table/Fig-3]: Comparison of outcome parameters between the group A and B at baseline and at 1 year.
*using Analysis of variance

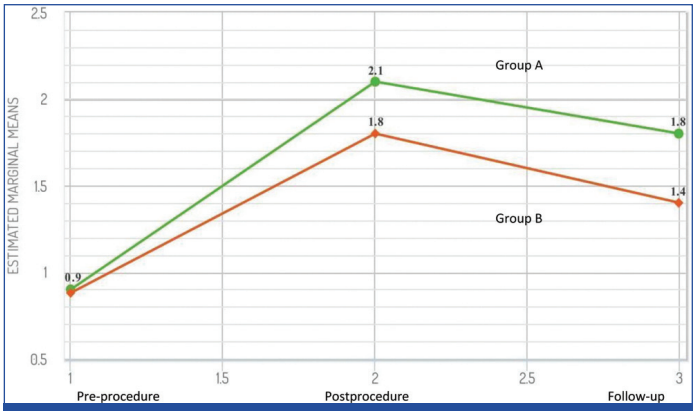
All haemodynamic parameters (NYHA, MVA, MG PAP) following PTMC have better outcome in those with Wilkins score ≤8 compared to those with scores >8 as evident from the trends and these are reflected in the follow-up period also [Table/Fig-4-7]. These findings favour PTMC as a procedure of choice especially in individuals with lesser Wilkin's score compared to those with scores above 8.



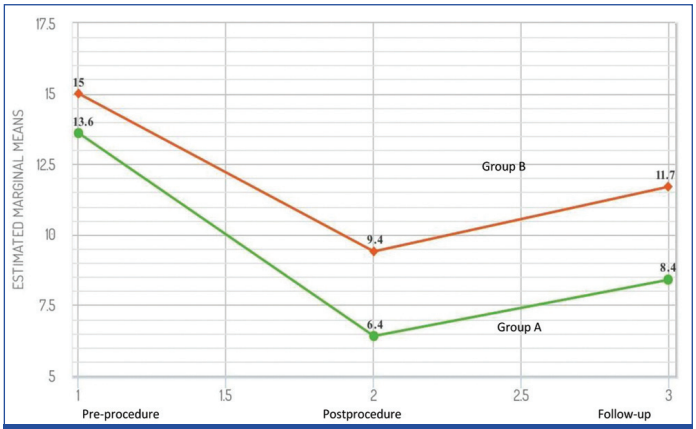
[Table/Fig-4]: Trends of NYHA of two groups at baseline and at 1 year

DISCUSSION

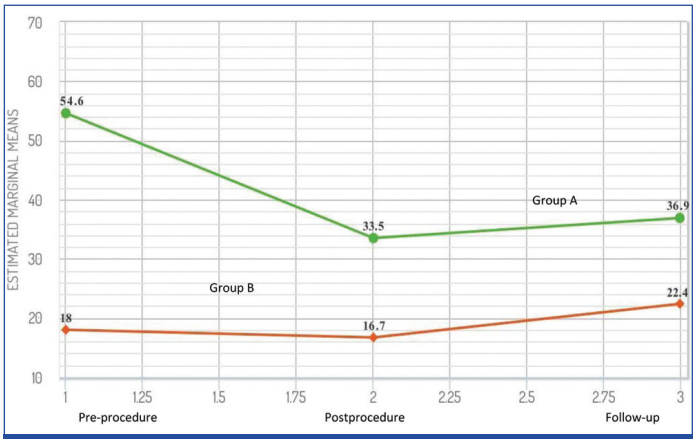
The present study brings out the clinical and haemodynamic outcomes of middle-aged Indian population who have undergone PTMC for MS. In this study a lower Wilkins score was a better predictor of long-term outcome especially in terms of functional status improvement, maintenance of MVA and mitral valve mean gradient pressure for those undergoing PTMC. A study by Palacios IF et al., revealed that lower Wilkin's scores (<8) had significant impact on the immediate outcome, post PTMC, similar to the present study [29]. There are other



[Table/Fig-5]: Comparison and trends of MVA within and between the two groups at baseline and at end of 1 year.



[Table/Fig-6]: Comparison and trends of MG within and between the two groups at baseline and at 1 year.



[Table/Fig-7]: Comparison and trends of PAP within and between the two groups at baseline and at 1 year.

studies, which revealed that mitral anatomy as the best predictor of outcome of PTMC, though a good result could also be obtained in higher Wilkin's score [18-21]. Ongoing rheumatic process along with abnormal turbulences will cause further fusion of commissures, valve thickening and calcification in post PTMC. This study revealed there is a significant decrease in mean MVA on follow-up in both the groups but more in group A, than group B. Restenosis is defined as 50% loss of area gain, but in the patients with poor initial outcome, restenosis can be defined with only a mild area loss. The percentage of restenosis were variable in different studies. A study by Devi YP et al., in India has shown that the influence of several factors like pre PTMC left atrial size, MVA, subvalvular fusion was more important for occurrence of restenosis 10 years after successful PTMC than by immediate post PTMC parameters [30]. This study also highlights the importance of pre-PTMC Wilkin's score and Atrial Fibrillation (AF) as reliable predictors of restenosis. In RHD with mitral valve involvement, disease progression is the result of abnormal turbulences generated by the deformed valve and/or low-grade progressive subclinical rheumatic process.

In a study by Hernandez R et al., the event free survival rate at seven years post PTMC was 69% which confirms the beneficial effect of the procedure on a long-term basis. Also, patients with lower Wilkins scores and good results had about 88% probability of being disease free for seven years. The study also revealed that the restenosis rate in Spanish patients was 10%, 18% and 39%, at four, five and seven years, respectively [13]. A study on the rate of restenosis by Claire B et al., in American patients has shown the incidence to the value of 40% by six years. This study points towards MVA as a strong predictive factor of late functional results of PTMC namely restenosis and is dependent on age with prognostic impact being higher with young patients and decreasing as age advances with no significance after 70 years of age. MVA , especially after PTMC has been shown to vary according to cardiac output. which makes other valve stenosis indexes add to the prognostic value of MVA after PMC. Late functional results in particular restenosis, is highly dependent on follow-up mitral valve function determined by valve function immediately after PMC and is assessed by final MVA and gradient followed by progressive restenosis. One important factor that influences restenosis is age, because it indirectly reflects the heart valve disease duration which in turn is responsible for the structural changes of the mitral valve [31]. Restenosis was encountered in a study by Fawzy ME et al., among 17.4% of patients who had underwent successful PMC and post-PTMC Cox regression analysis identified that Wilkin's score of > 8 as a predictor of restenosis. The study also demonstrated the restenosis-free probability at seven years as 81%, at 10 years as 68%, and at 13 years as 51% and a low Wilkin's score of <8 as a predictor of being free from restenosis comparable to the present study [13,32]. A 10-year period follow-up study on restenosis following successful PTMC by Devi YP et al., showed that restenosis was influenced more by pre PTMC left atrial size, MVA, subvalvular fusion than on immediate post PTMC parameters [30].

The changes in Mean trans mitral gradients and pulmonary artery pressures immediately post PTMC in this study were significant. A study by Chen C-R et al., revealed PA pressures reduced from 51.2±14.8 to 33.9±8.8 mm Hg [33]. The importance of PA pressures comparing with Wilkin's valve morphology scores needs to be defined in future. Multivariate analysis of previous studies showed that pre-PMV MVA, less degree of pre-PMV MR, younger age, and Wilkin's score <8 as independent predictors of procedural success. This was comparable to the present study results, with MVA, PAP and Wilkin's score <8 having a better outcome among those with successful PMC. Higher NYHA functional class is an independent predictor of poor functional results during long-term follow-up. However, in the present study no classification of NYHA was done and comparison made between different classes of NYHA and outcome post procedure and follow-up [34,35].

Limitation(s)

The data was collected from only one clinical setting; hence the findings cannot be generalised to the whole population. The convenient sampling method used in this study could be a potential source of bias especially in the allocation of groups, but the groups were similar in terms of age distribution and other haemodynamic parameters. The limitations of the sampling method employed could be overcome in view of the low resource settings and the low volume turn out of patients especially in a developing country.

CONCLUSION(S)

The PTMC a time-tested procedure for management of MS especially following RF has been neglected in the recent years with advent of modern surgical techniques. The current study highlights this procedure especially among symptomatic individuals with MS especially for Wilkins grade ≤8 for whom surgery is not indicated. This procedure is especially of vital importance in developing countries where the incidence of Rheumatic MS is higher and chances of restenosis is high among middle aged population who are the most productive group in the population of a country.

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Cardiology, Sri Ramachandra Institute of Higher Education and Research, Chennai, Tamil Nadu, India.
2. Consultant, Department of Cardiology, Sri Ramachandra Institute of Higher Education and Research, Chennai, Tamil Nadu, India.
3. Senior Resident, Department of Cardiology, Sri Ramachandra Institute of Higher Education and Research, Chennai, Tamil Nadu, India.
4. Professor, Department of Cardiology, Sri Ramachandra Institute of Higher Education and Research, Chennai, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Jayanty Venkata Balasubramaniyan,
22/12, G S T Road, Guindy, Chennai, Tamil Nadu, India.
E-mail: drjvbala@gmail.com

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