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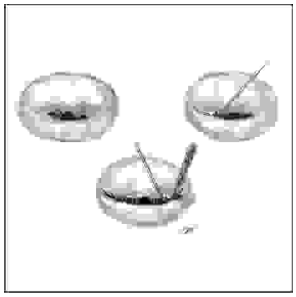
PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY;

OUTCOME OF IN PATIENTS OF MITRAL STENOSIS.



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ABSTRACT... drarehman@gmail.com. **Objective:** To compare the clinical, echocardiographic and angiographic variables after PTMC in patients of mitral stenosis having echo score < 8 and ≥ 8. **Place of study:** Cardiology ward and echocardiography department of the Punjab Institute of Cardiology, Lahore. **Duration of study:** The study was conducted from 15th of January 2006 till 30th of July 2006.**Study Design:** It was a comparative study. **Materials & Methods** Two hundred consecutive patients of mitral stenosis undergoing PTMC were studied. Patients were divided in to two groups. Group I consisted of patient having echo score <8, while Group II contained patients having echo score ≥8. **Results**:The immediate clinical follow-up of 200 patients who underwent PTMC procedure was studied. Patients were divided into 2 groups, Echo-Sc <8 (n=136) and Echo-Sc≥8 (n=64). PTMC resulted in an increase in mitral valve area from 1.0±0.3 to 2.0±0.6 cm^2 in patients with Echo-Sc<8 and from 0.8±0.3 to 1.6±0.6 cm^2 in patients with Echo-Sc≥8 (*P*<0.0001). Procedural success was 83.5% for the overall group, with patients with Echo-Sc <8 having a higher procedural success (93.4% versus 62.5%; *P*<0.0001). Thirty three (16.5%) patients had unsuccessful procedures. There was 1(0.5%) in-hospital death. Severe post- PTMC MR (≥3 grade) occurred in 19(9.4%) patients, with grade III in 12 (6%) and grade IV in 7(3.5%). Emergent MVR was required in 3(1.5%) of 200 patients. Pericardial tamponade occurred in 2(1%) patients. Thromboembolic events (stroke) occurred in 2(1%) patients in the overall population. Finally 1(0.5%) patient developed complete atrioventricular block. **Conclusions:** Patients with echo score less than 8 have a favourable outcome in terms of procedural success and post procedure complications as compared to patients with echo score ≥8.

Key words: Percutaneous transvenous mitral conmmissurotomy, echocardiography, mitral valve, echo score.

INTRODUCTION

Mitral stenosis is one of the commonest long term complications of Rheumatic fever[1] and approximately 25% of all patients with Rheumatic Heart Disease have

pure mitral stenosis[2]. Two thirds of all patients with Rheumatic mitral stenosis are females. Mitral stenosis is defined as mild, moderate and severe according to mitral valve area. If mitral valve area is >1.5 cm^2 it is mild, 1-1.5 cm^2 it is moderate and <1 cm^2 it is considered to be severe mitral stenosis[3]. Medical treatment is indicated in mild to moderate stenosis[4] surgical treatment and percutaneous Transvenous Mitral commissurotomy (PTMC) are indicated in severe mitral stenosis[5,6] .

The role of PTMC in the management of patients with Rheumatic mitral stenosis has continued to evolve during the last 19 years. Patients selection is fundamental in predicting the immediate results of PTMC[7]. The evaluation and selection of candidates for PTMC require a precise assessment of mitral valve morphology[7,8]. The Echocardiographic score is presently the most widely used technique for the evaluation of the morphological characteristics of the mitral valve[9]. Immediate, short and intermediate follow-up studies have shown that patients with echo score ≤ 8 have superior immediate results and significantly greater survival and freedom from combined events than patients with echo score >8[10].

In Pakistan, few studies have been carried out in different centers on PTMC in patients with severe mitral stenosis[11-13]. We designed this study to describe the in hospital clinical and echocardiographic and angiographic outcome of PTMC in patients of moderate to severe mitral stenosis at Punjab Institute of Cardiology, Lahore.

MATERIALS AND METHODS

After fulfilling the inclusion criteria 200 consecutive patients of mitral stenosis undergoing PTMC were studied from 15th of January 2006 till 30th of July 2006. The study was conducted at Cardiology ward and echocardiography department of Punjab Institute of Cardiology, Lahore. It was a comparative study. Patients were divided in to two groups. Group I consisted of patient having echo score <8, while Group II contained patients having echo score ≥ 8.

Patients were included in the study on the base of having moderate to severe mitral stenosis, mitral valve morphology suitable for PTMC, with out Left Atrial thrombus, with no more than mild Mitral regurgitation and no other valve diseased especially Aortic valve.

Patients of moderate to severe mitral stenosis with Mitral regurgitation grade 2+, 3+ or 4+ were excluded from the study.

DATA COLLECTION PROCEDURE

A full history was taken particularly age, sex, occupation and address. Symptoms of shortness of breath, palpitations, chest pain and hemoptysis were inquired and filled on a proforma for every case. Clinical status was determined by New York Heart Association classification. Complete physical examination was done with emphasis on pulse, blood pressure, precordial examination and signs of congestive cardiac failure. ECG and X-ray chest and echocardiography were done in all patients. All patients had Echocardiography before PTMC for evaluation of Wilkins Echo Scoring and echo variables i.e. mitral valve area (MVA), Mean Mitral Valve Pressure Gradient (MMVPG), Mitral Regurgitation (MR) grade (0-4) by colour flow Doppler semi quantitative method and Mean Pulmonary Artery Pressure (MPAP) were measured with Doppler with a purpose to describe patients having echo score <8 and ≥ 8. Patients of mitral stenosis found suitable for PTMC on echocardiography were studied. PTMC was performed using Inoue Balloon technique, pre PTMC and post PTMC right and left heart pressure measurements were noted. All patients had a repeat echocardiogram after 24 hours of PTMC in which mitral valve area (MVA), MMVPG, MR grade (0-4) and MPAP were noted. Post-PTMC MVA >1.5 Cm^2 and a post-PTMC MR <2+ was used as a definition of success.

Procedure related complications like in-hospital mortality, emergency mitral valve replacement, pericardial tamponade, thromboembolism, complete heart block, arrhythmias and heart failure secondary to acute mitral regurgitation were studied in each case. All these findings were recorded on preformed proforma. Patients were followed up daily and pulse blood pressure ECG changes and above mentioned complications were monitored till death or discharge of patients. Hospital stay in individual patients was also noted.

STATISTICAL ANALYSIS

All the data will be analyzed by SPSS (Statistical Package for Social Sciences) Version 10.0 for Windows. Continuous variables were expressed as mean±SD and categorical variables as percentage. The continuous variables were analyzed by using student-t test and categorical data analyzed by Chi square test. P value ≤ 0.05 was considered significant. Demographic, clinical, echocardiographic, procedural and angiographic variables were compared in the two groups by applying Chi Square test.

RESULTS

The sample included 200 consecutive patients who underwent PTMC procedures. There were 37(18.5%) male and 163(81.5%) female patients with a mean age of 26±15 years. There were 136(68%) patients with Echo-Sc <8 who underwent PTMC procedures and 64(32%) patients with Echo-Sc $\geq$ 8 who underwent PTMC procedures. Patients with echocardiographic scores $\geq$ 8 were older and presented more frequently in atrial fibrillation. They had more calcified valves under fluoroscopy, and more were NYHA class III and IV. (Table I).

Table-I. Baseline characteristics.

Characteristics	Total (n=200)	Echo Score <8 (n=136)	Echo Score ≥8 (n=64)	P value
Female sex	163(81.5%)	116(85.2%)	47(73.4%)	<0.001*
Age	26±15	25±14	27±15	<0.001**
Atrial fibrillation	78(39%)	44(26.9%)	34(53.1%)	<0.001*
NYHA class				<0.302*
I	3(1.5%)	2(1.5%)	1(1.6%)	
II	48(24%)	38(28%)	10(15.6%)	
III	122(61%)	85(62.5%)	37(57.8%)	
IV	27(13.5%)	11(8%)	16(25%)	
Echo Score	7.7± 2.2	6.4±1.2	9.2±1.4	<0.001**
Subcomponents				
Thickness	2.0±0.7	1.8±0.5	2.6±0.6	<0.001**
Calcium	1.8±0.8	1.4±0.6	2.3±07	<0.001**
Mobility	1.8±0.7	1.5±0.5	2.4±0.6	<0.001**
Subvalvular	2.0±0.8	1.8±0.7	2.3±0.7	<0.001**

** Chi-square test ** Independent sample t-test*
Keys: NYHA Class = *New York Heart Association class*
Pre-PTMC MR = *Pre Percutaneous Transvenous Mitral Commissurotomy Mitral Regurgitation.*

Two hundred PTMC procedures were performed using the Inoue technique. The hemodynamic findings before and after PTMC of the overall patients studied and of patients with Echo-Score <8 and $\geq$8 are shown in Table II. An increase in MVA from 0.9±0.3 to 1.9±0.7 cm^2 (P<0.0001) was noted after PTMC. There was an inverse relationship between Echo-Score and both post-PTMC MVA and PTMC success. Patients with Echo-Sc <8 had

larger increase in post-PTMC MVA (2.0±0.6 versus 1.6±0.6); P<0.0001). Procedural success was 83.5% for the overall group, with patients with Echo-Sc <8 having a higher procedural success (93.4% versus 62.5%; P<0.0001) Table III. Thirty three (16.5%) patients had unsuccessful procedures because of a post-PTMC MVA <1.5 cm^2 and post-PTMC MR ≥3.

Table-II. Pre and post PTMC Hemodynamic results.

Characteristics	Total (n=200)	Echo Score <8 (n=136)	Echo Score ≥8 (n=64)	P Value
MVA mean cm_2				
Pre PTMC	0.9±0.3	1.0±0.3	0.8±0.3	<0.001**
Post PTMC	1.9 ±0.7	2.0±0.6	1.6±0.6	<0.001**
MVPG mean mm Hg				
Pre PTMC	14±6	14±6	15±6	<0.04**
Post PTMC	6±3	5±3	6±3	<0.001**
LA mean mm Hg				
Pre PTMC	25±7	24±7	26±7	<0.001**
Post PTMC	17±7	16±6	18±7	<0.001**
PA mean mm Hg				
Pre PTMC	36±13	34±12	40±14	<0.001**
Post PTMC	29±11	26±10	33±12	<0.001**

*** Independent sample t-test*
***Keys: MVA=** Mitral Valve Area , **MVPG=** Mitral valve pressure gradient*
***LA=** Left Atrial pressure., **PA=** Pulmonary Artery pressure*

Table-III. Procedural outcome

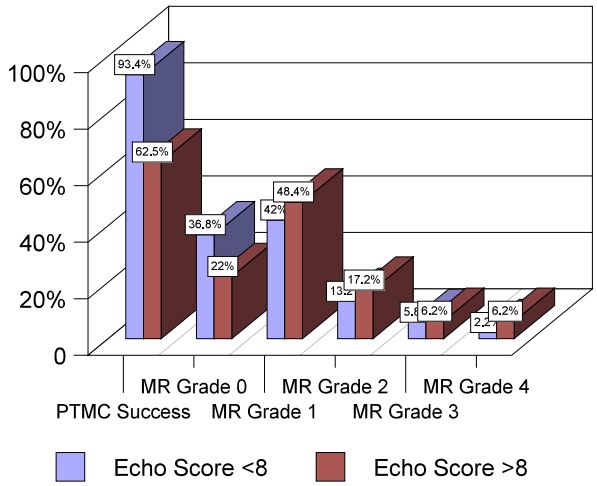
Characteristics	Total (n=200)	Echo Score <8 (n=136)	Echo Score ≥8 (n=64)	P value
PTMC Success	167(83.5%)	127(93.4%)	40(62.5%)	<0.001*
In-hospital death	1(0.5%)	0(0.0%)	1(1.5%)	<0.0006*
Tamponade	2(1%)	1(0.7%)	1(1.5%)	<0.301*
Emergent MVR	3(1.5%)	1(0.7%)	2(3.1%)	<0.121*
Stroke	2(1%)	0(0.0%)	2(3.1%)	<0.308*
Heart block	1(0.5%)	0(0.0%)	1(1.5%)	<0.432*

*** Chi-square test*
***Keys: PTMC=** Percutaneous Transvenous Mitral Commissurotomy*
***Post-PTMC MR=** Post Percutaneous Transvenous Mitral Commissurotomy Mitral Regurgitation.*

The incidence of major adverse in-hospital events occurred more in patients with Echo score ≥8. There was 1(0.5%) in-hospital death. Severe post- PTMC MR (≥3 grade) occurred in 19(9.4%) patients, with grade III in 12 (6%) and grade IV in 7(3.5%) Figure 1. Emergent MVR was required in 3(1.5%) of 200 patients. Pericardial tamponade occurred in 2(1%) patients. Thromboembolic events (stroke) occurred in 2(1%) patients in the overall

population. Finally 1(0.5%) patient developed complete atrioventricular block.

Fig-1. Post PTMC comparison between the two groups.



DISCUSSION

Mitral stenosis is one of the commonest long term complications of Rheumatic fever[1] and approximately 25% of all patients with Rheumatic Heart Disease have pure mitral stenosis[2]. The role of PTMC in the management of patients with Rheumatic mitral stenosis has continued to evolve. Patients selection is fundamental in predicting the immediate results of PTMC[7]. Immediate, short and intermediate follow-up studies have shown that patients with echo score ≤ 8 have superior immediate results and significantly greater survival and freedom from combined events than patients with echo score >8.[10]

Our results are consistent with previous studies demonstrating that PTMC produces good immediate and long-term follow-up results in a selected group of patients with mitral stenosis[14-17]. Hemodynamic and clinical improvement is achieved in the majority of patients with rheumatic mitral stenosis. PTMC resulted in a significant decrease in mitral gradient and an increase in mitral valve area with minimal morbidity and mortality. The majority of patients have a marked clinical improvement, and the hemodynamic and clinical improvement produced by PTMC persists at long-term follow-up[15-17]. In the other series from the Massachusetts General Hospital[18] of 734 patients undergoing PTMC, there was a 0.6% mortality and a 1.3% incidence of thromboembolic episodes and stroke. Pericardial tamponade occurred in 0.8% of cases in this series. Tamponade occurs more frequently from transseptal catheterization and rarely from ventricular perforation. Severe mitral regurgitation occurred in 3% of the patients, with some of them requiring in-hospital mitral valve replacement. An increase in mitral regurgitation >2 grades occurred in 12.5% of patients. It is well tolerated in most patients, and more than half of them have less mitral regurgitation at follow-up cardiac catheterization[18].

We noticed a younger age in patients of Echo score >8 as compared to more ≥ 8, it is consistent with previous studies a study from the Massachusetts General Hospital reported that differences in age and valve morphology may account for the lower survival and event-free survival of PTMC series from United States and Europe. For example, in the series from the Massachusetts General Hospital, 497 patients with echocardiographic scores <8 and a mean age of 51±14 years had an 85% survival and a 45% event-free survival at 8-year follow-up. In contrast, 237 patients with echocardiographic scores ≥ 8 and a mean age of 63±14 years had a 55% 8-year survival, and only 20% of them were free of combined events at 8-year follow-up. A larger number of patients with higher echo-cardiographic scores and mitral valve calcification may account for the 5-year 76% survival and a 51% combined event-free survival reported by Cohen et al[19] in a group of 146 patients undergoing PTMC. On the contrary, survival and event-free survival after PTMC in optimal patients for this technique appear to be similar to those reported after surgical mitral commissurotomy. In the series from the Massachusetts General Hospital, 202 optimal candidates defined as patients 65 years old, in normal sinus rhythm, with echocardiographic scores <8, without mitral valve calcification, and with pre-PTMC mitral regurgitation 1 grade had an excellent immediate and long-term outcome as reflected in a 97% survival and 76% event-free survival at a median follow-up of 61 months. In

patients with optimal mitral valve morphology, surgical mitral commissurotomy has favorable long-term hemodynamic and symptomatic improvement. Similarly to PTMC, patients with advanced age, calcified mitral valves, and those with atrial fibrillation had poorer survival and event-free survival after surgical commissurotomy. Several studies have compared the immediate and early follow-up results of PTMC versus closed surgical commissurotomy in optimal patients for these techniques. The results of these studies have been controversial, showing either superior outcome from PTMC[20,21] or no significant differences between both techniques[22-24] Patel et al[20] randomized 45 patients with mitral stenosis and optimal mitral valve morphology to closed surgical commissurotomy and to PTMC. He demonstrated a larger increase in mitral valve area with PTMC (2.1±0.7 versus 1.3±0.3 cm^2). Shrivastava et al[21] compared the results of single-balloon PTMC, double-balloon PTMC, and closed surgical commissurotomy in three groups of 20 patients each. The mitral valve area after intervention was larger for the double-balloon technique of PTMC. Postintervention valve areas were 1.9±0.8, 1.5±0.4, and 1.5±0.5 cm^2 for the double-balloon, the single-balloon, and the closed surgical commissurotomy techniques, respectively. On the other hand, Arora et al[105] randomized 200 patients with a mean age of 19±7 years and mitral stenosis with optimal mitral valve morphology to PTMC and to closed mitral commissurotomy. Both procedures resulted in similar postintervention mitral valve areas (2.39±0.9 versus 2.2±0.9 cm^2 for the PTMC and the mitral commissurotomy groups, respectively) and no significant differences in event free survival at a mean follow-up period of 26 months. Restenosis documented by echocardiography was low in both groups, 5% in the PTMC group and 4% in the closed commissurotomy group.

Although these initial randomized trials results of PTMC versus surgical commissurotomy are encouraging and favor PTMC for the treatment of patients with rheumatic mitral stenosis with suitable mitral valve anatomy, there is a need for long-term follow-up studies to define more precisely the role of PTMC in patients with echo score >8. The report of Farhat et al[18] provides this long-term follow-up in a cohort of optimal candidates for PTMC and clearly establishes the role of PTMC in the treatment of these patients. The immediate and long-term results of PTMC in these patients are similar to those obtained with open surgical commissurotomy and significantly superior to those obtained with closed surgical commissurotomy. The postintervention mitral valve areas achieved with PTMC were similar to the one obtained after open surgical commissurotomy (2.5±0.5 versus 2.2±0.4 cm^2) but larger than those obtained after closed commissurotomy. These initial changes resulted in an excellent long-term follow-up in the group of patients treated with PTMC, which was comparable with the open commissurotomy group and superior to the closed commissurotomy group.

Thus it seems reasonable to recommend PTMC for patients with Echo-Sc <8, especially if they have other favorable characteristics (age <25 years, <2+ MR, and no previous mitral surgery). The question remains as to which procedure, MVR or PTMC, is more suitable for patients with Echo-Sc $\geq$8. A successful PTMC result is obtained in 54% of these patients, and only 33% of them were free of combined events at follow-up. Because a good immediate outcome was achieved in 61% of patients with Echo-Sc between 9 and 11 and 39% were free of combined events at 5-year follow-up, PTMC might be considered the first choice in these patients if they are free of other risk variables. Conversely, patients with Echo-Sc $\geq$12 should be referred for MVR, because only 36% had successful PTMC and 10% were free of events at followup. Neverthless, PTMC could be considered as a palliative procedure if the patients are nonsurgical candidates.

CONCLUSION

In view of results of the study and review of the literature it can be concluded that PTMC is safe procedure in experienced hands in symptomatic, carefully selected patients with low echocardiographic mitral valve score. Our study shows that PTMC should be the procedure of choice for the treatment of patients with rheumatic mitral stenosis who are, from the clinical and morphological points of view, optimal candidates for PTMC. Pre- PTMC variables especially echo score identify the patients who

will benefit more. Post-PTMC variables like MVA, degree of MR and post-PTMC pulmonary artery pressure in conjunction with pre-PTMC clinical and mitral morphology variables identify the patients most likely to benefit immediate and long-term.

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