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Original Article

Mid-term results of percutaneous transmitral commissurotomy (PTMC) in central iran

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Abstract

Objectives: Percutaneous Trans-Mitral Commissurotomy (PTMC) is an effective non-surgical treatment in patients with severe rheumatic mitral valve stenosis. This study aimed to evaluate the mid-term results of this procedure in central Iran.

Methods: This retrospective study was performed on 101 patients with severe mitral valve stenosis who underwent successful PTMC from March 2011 to September 2018 in Afshar Hospital in Yazd. At follow-up, all patients underwent clinical examination, two-dimensional and color Doppler echocardiography, and events were recorded. Data were analyzed using SPSS software version 19.

Results: The mean age of the patients was 44.79± 11.72 years, and 83.3% were female. The mean follow-up time was 38.98 23.33 months (6-94 months).25.8% had AF rhythm, and 12% had previous PTMC or OMVC or CMVC. After percutaneous Trans-Mitral Commissurotomy, 97% of patients were in NYHA functional class I, II and the mitral valve area (MVA) increased from 0.92 ± 0.18 to 1.66± 0.29 cm2 ($p<0.0001$). Pulmonary artery systolic pressure decreased from 46.96± 18.56 mmHg to 38.43±14.02 mmHg ($p<0.0001$). The Mean mitral valve gradient decreased from 12.37± 3.99 mmHg to 4.79± 2.38 mmHg ($p<0.0001$). Restenosis rate and severe mitral regurgitation resulting in mitral valve replacement (MVR) were 10.9% and 2%, respectively. Two patients died because of intracranial hemorrhage (ICH). During the follow-up event, free survival was 82.2%. Multivariable analysis revealed that the predictors of shorter event-free survival were AF rhythm (HR; 4.5, 95%CI;1.59-12.9, P=0.005) and post PTMC higher NYHA functional class (HR;2.2, CI;1-4.8,p=0.049).

Conclusions: Mid-term results of percutaneous transmitral commissurotomy (PTMC) in central Iran are the same as in other parts of the world. This procedure is an effective and low-risk treatment for severe mitral valve stenosis.

Keywords: Survival, Rheumatic fever, mitral valve stenosis, percutaneous trans-mitral commissurotomy

Introduction

Rheumatic Heart Disease (RHD) is a common complication of rheumatic fever. (1, 21) While economically developed countries are getting rid of the disease, people in low- and middle-income countries still fall victim. In 2015, approximately 319,900 people in endemic areas and

221,905 people in non-endemic areas died of the disease worldwide. (2) The overall prevalence of RHD in Iran is estimated at 20 per 100,000 population. (3)Mitral stenosis is one of the most common valvular heart diseases in which the patient becomes symptomatic earlier than other valvular diseases. (4)

Percutaneous transmitral commissurotomy (PTMC) is currently the treatment of choice for severe mitral valve stenosis (5). Clinical trials have shown that PTMC is equivalent to Open Mitral Valve Commissurotomy (OMVC) and superior to Closed Mitral Valve Commissurotomy (CMVC) in mid- and long-term outcomes (6, 7, 8). This study aimed to evaluate the mid-term outcomes and survival of patients with this treatment in Yazd in central Iran.

Materials and Methods

This single center retrospective study was performed on patients with severe mitral stenosis who underwent PTMC procedure in Afshar Hospital in Yazd from March 2011 to September 2018. We retrospectively reviewed the hospital records of all patients who underwent PTMC. Among 113 patients who had successful PTMC, 101 patients followed up (89.4%). All patients underwent transthoracic and transesophageal two-dimensional and color Doppler echocardiography before PTMC for suitability of this procedure by a cardiologist with an echocardiographic certificate. They were evaluated for MR severity and the presence of left atrial thrombus. The mitral valve area (MVA) was measured by planimetry. The peak and mean gradients of the mitral valve and pulmonary artery systolic pressure were measured using the Velocity of the TR jet, and the valve score was calculated based on the Wilkins score (9). Additionally, any significant involvement of other heart valves was ruled out. Before the PTMC procedure, all patients underwent left heart catheterization through right femoral artery access. Ascending aortography, left ventriculography, and, if necessary, coronary angiography was performed. Patients underwent PTMC through right femoral vein access under sterile conditions and local anesthesia. Following interatrial septostomy with a Brockenbrough needle, mitral valvotomy proceeded by passing an Inoue balloon (Toray, Inc.) and positioning it in the mitral valve orifice. The maximum size of the balloon was calculated in millimeters by equation: [Height (cm) / 10]+10. The balloon was inflated stepwise and started two millimeters lower than the actual size of the balloon, in case the gradient did not decrease, the balloon would inflate again by increasing by one millimeter to lead to the desired result. After the procedure, patients were transferred to the cardiac care unit to control vital signs and prevent possible bleeding at the access site. The day after PTMC, the patient underwent transthoracic 2D and color Doppler echocardiography, and the mitral valve area (MVA) was measured by planimetry. PTMC was successful if the MVA resulted in$\geq$ 1.5 cm2 or $\geq$ 50% of pre-procedural MVA or the mean transmitral gradient was reduced to $\leq$5 mm Hg and no more than moderate mitral regurgitation. Patients were evaluated for significant complications such as MR, acquired interatrial septal defect (ASD) with left- to right shunt, pericardial effusion or tamponade, and pulmonary artery systolic pressure (PASP) was estimated. If the patient was stable and uncomplicated, he was discharged with a beta-blocker and, if necessary, a diuretic and warfarin. Additionally, it is recommended to inject 1,200,000 units of penicillin benzathine intramuscularly each month to prevent the recurrence of rheumatic fever. The patients are also advised to follow up with their cardiologist for periodic visits. All patients included in this study were called for evaluation. Data from interviews of patients and their relatives were obtained. A questionnaire including demographic information, symptoms, past medical histories, and echocardiographic and electrocardiogram data was completed for each patient. All patients underwent a comprehensive transthoracic two-dimensional and color Doppler echocardiographic examination by a cardiologist with an echocardiographic certificate. The following indices including mitral valve area, transmitral valve gradient, mitral regurgitation, systolic pulmonary artery pressure, and function of other valves and left ventricular ejection fraction (LVEF) were evaluated. The mitral valve area (MVA) of less than 1.5 cm2 was considered mitral valve restenosis. Data were analyzed using SPSS software version 19 (SPSS Inc, Inc, USA). Continuous variables are expressed as mean and standard deviation and categorical variables are expressed as percentage and number. ANOVA test for continuous variables and chi-square, Mann-Whitney, and Wilcoxon signed rank tests for categorical variables were used. Survival analysis was performed using Kaplan-Meier and log-rank test. A forward stepwise multivariable Cox regression analysis was used to identify predictors of events. A p-value of less than 0.05 was considered statistically significant.

Ethical considerations

Informed consent was obtained from all participants in this study. The study protocol and consent forms were approved by the ethics committee of Shahid Sadoughi Medical School in Yazd (IR.SSU.Medicine.Rec.1397.243). All participants were informed of the risks and benefits of participation in the study and were allowed to ask questions. Additionally, they were assured that they could withdraw from the study when they wanted.

Results

Table 1 shows the baseline characteristics of our patients. The mean age of patients was 44.79± 11.72 years. 16.7% were male, and 83.3% were female, with a female-to-male ratio of 4.98. The most common symptoms in patients were shortness of breath and palpitations (57.4% and 21.8%, respectively). There was a definite history of rheumatic fever at 21.8%. Three patients were pregnant, three patients had previous surgical commissurotomy, and nine patients had previous percutaneous transmitral commissurotomy (PTMC).

The following information was obtained:

- 5.9% of individuals had a history of rheumatoid arthritis (RA), while 1% had systemic lupus erythematosus (SLE).
- The prophylaxis rate for rheumatic fever was 17.8%.
- 5% had a history of cerebrovascular accident (CVA).
- Normal sinus rhythm was observed in 74.2% of cases, while atrial fibrillation or atrial flutter was present in 25.8%.
- The mitral valve echo score was ≥ 8 in 81.2% of cases.
- 57.4% of patients had isolated mitral valve disease, and 38.6% had involvement of both the mitral and aortic valves.
- The mean follow-up time was 38.98 ± 23.33 months (ranging from 6 to 94 months).

Table 1. Baseline characteristics of patients

Variable	Value*
Age(year)	44.79 ± 11.72
Sex	
-Female	(84)83.2%
-Male	(17)16.8%
Symptoms	
-Dyspnea	
-Palpitation	(58)57.4%
-Chest pain	(30)29.7%
-chest pain+ palpitation	(3)2.97% (5)4.95%
-Focal neurologic deficit	(5)4.95%
NYHA class	
I	(20)19.7%
II	(23)22.8%
III	(53)52.5%
IV	(5)5%
Past Medical History	
-Acute RF	
-CVA	
-RA	(22)21.8%
-SLE	(5) 4.95%
Abortion	(6) 5.9%
-Spontaneous	(1)1%
-Medical	(19.65)29.2%
Infertility	(4.65)6.2%
Special cases	(4.65)6.2%

Variable	Value*
-During Pregnancy	(3.84)3.6%
-Prior PTMC	(9)8.9%
-Prior OMVC	(2)1.98%
-Prior CMVC	(1)1%
Heart Rhythem	
Normal sinus	(75)74.3%
AF	(26)25.8%
Preprocedural Echocardiography	0.92 ± 0.18
MVA(cm^2)	12.37 ± 3.99
Mean MVG(mmHg)	46.96 ±18.56
SPAP(mmHg)	(4)4.8%
LA size	(30)29.7% (42)41.6% (25)24.8%
-Normal	(41)40.6%
-Mild enlargement	(59)58.4% (1)1%
-Moderate enlargement -Severe enlargement	(16)15.8%
Mitral Regurgitation	(67)66.3%
-No	(10)9.9%
-Mild	(8)8%
-Moderate	(58)57.4%
Tricuspid Regurgitation	(39)38.6%
-No	(1)1%
-Mild	(3)3%
-Moderate	52.7 ± 4.73
-Severe	(5)5%
Valve involvement	82)81.2%
-Isolated Mitral	(19)18.8%
-Mitral+Aortic	
-Mitral+Tricuspid	
-Mitral+Aortic+Tricuspid	
LVEF(%)	
LAA clot Valve score	
≤8	
8<	
Balloon size(mm)	(42)41.6%
-26	(58)57.4%
-28 -30	(1)1%

* The values are displayed as the number of cases, percent, and the mean ± standard deviation. AF: atrial fibrillation, CMVC: closed mitral valve Commissurotomy, CVA: cerebrovascular accident, LA: left atrium, LAA: left atrial appendage, LVEF: left ventricular ejection fraction, MVA: mitral valve area, Mean MVG: mean mitral valve gradient, NYHA: Class New York heart association functional class, OMVC: open mitral valve Commissurotomy, RA: rheumatoid arthritis, RF: rheumatic fever, SLE: systemic lupus erythematous, PASP: pulmonary artery systolic pressure.

Table 2 is a comparison of patients before and after the procedure. At follow-up, 97% of patients were in NYHA class II and I, while before PTMC 57.5% were in classes III and IV (P<0.00001). Comparison of echocardiographic indices before PTMC and after this procedure at follow-up time showed that mitral valve area (MVA) increased from 0.92± 0.18 to 1.66± 0.29 cm2 (P<0.0001) and mean mitral valve gradient (MVG) decreased from 12.37± 3.98 to 4.79± 2.38 mmHg (P<0.0001). On the other hand, the pulmonary artery systolic pressure (PASP) has been reduced from 46± 68 to 38.43± 14.02 mmHg (P<0.0001). There was also a significant increase in the severity of mitral regurgitation and

tricuspid regurgitation (P<0.0001). After PTMC, ASD was developed in five patients without a significant left-to-right shunt. There was also mild pericardial effusion in six cases.

Table2. Comparison of functional class and echocardiographic indices of patientsbefore PTMC and at follow-up

Variable	Pre PTMC	Follow up	P value
NYHA class	(20)19.7% (23)22.8%	(75)74.2%	<0.0001
I	(53)52.5%	(23)22.8%	
II	(5)5%	(3)3%	
III		(0)0%	
IV			
MVA(cm2)	0.92 ± 0.18	1.66 ± 0.29	<0.0001
Mean MVG(mmHg)	12.37 ± 3.99	4.79 ± 2.38	<0.0001
MR	(41)40.6%	(23) 22.8%	<0.0001
-No	(59)58.4%	(56)55.4%	
-Mild	(1)1%	(17)16.8%	
-Moderate	(0)0%	(5)5%	
-Severe			
TR -No	(16)15.8%	(14)13.9%	<0.01
-Mild	(67)66.3%	(65)64.4%	
-Moderate	(10)9.9%	(12)11.9%	
-Severe	(8)8%	(10)9.9%	
PASP (mmHg)	46.96 ± 18.56	38.43 ± 14.02	<0.0001

* The values are displayed as the number of cases, and percent and mean ± standard deviation Mean MVG: mean mitral valve gradient, MR: mitral regurgitation, MVA: mitral valve area, NYHA: Class New York heart association functional classification, TR: tricuspid regurgitation, PASP: pulmonary artery systolic pressure.

Table 3 shows the patients who underwent MVR and who did not. Atrial fibrillation, pre-PTMC TR, post-PTMC TR, pre-PTMC MR, involvement of other valves, and higher NYHA functional class were significantly more common in surgical patients. However, multiple variable analysis using the Cox model by forward stepwise method showed that only heart rhythm (HR; 4.5, 95%CI; 1.59-12.9, P=0.005) and NYHA functional class (HR; 2.2, CI;1-4.8,p=0.049) predict events after PTMC. Event-free survival during three years was 82.2%.

Table3. Comparison of patients who underwent mitral valve replacement surgery after PTMC with those who did not

Variable	Surgical group N=13	NonSurgical group N=88	P-value
Age(yr)	47.6 ± 8.5	44.3 ± 12	0.355
Sex		(71)80.7%	0.082
-Female	(13)100%	(17)19.3%	
-Male	(0) 0%		
Pre PTMC FC			
I	(1)7.7%	(19)21.6%	
II	(3)23.1%	(20)22.7%	0.206
III	(7)53.8%	(46)52.3%	
IV	(2)15.4%	(3)3.4%	
Post PTMCfunctional class			
I	(5)38.3%	(70)79.5%	
II	(5)38.5%	(18)20.5%	<0.0001
II	(3)23.1%	(0)0%	
IV	(0)0%	(0)0%	
Valve Score	(11)84.6%	(71)80.7%	0.701
≤8	(2)15.4%	(17)19.3%	
8<			
pre PTMC MVA(cm2)	0.88 ± 0.16	0.92 ± 0.18	0.30

Variable	Surgical group N=13	NonSurgical group N=88	P-value
post PTMC MVA(cm2)	1.5 ± 0.25	1.67 ± 0.28	0.121
pre PTMC mean MVG(mmHg)	12.6±2	12.3 ± 4.2	0.762
post PTMC mean MVG(mmHg)	5.46 ± 1.8	4.6 ± 2.4	0.281
Valve involvement	(6)46.2%	(52)59.1%	0.041
-IsolatedMitral	(5)38.5%	(34)38.6%	
-Mitral+Aortic -Mitral+Tricuspid	(1)7.7%	(0)0%	
-Mitral+Aortic+Tricuspid	(1)7.7%	(2)2.3%	
Heart Rhythem			
-Normal	(6)46.2%	(69)78.4%	0.033
-AF	(7)53.8%	(19)21.6%	
Pre PTMC MR			
-No	(4)30.8%	(3)42%	
-Mild	(8)61.5%	(51)58%	0.026
-Moderate	(1)7.7%	(0)0%	
Post PTMC MR			
-No	(2)15.4%	(21)23.9%	
-Mild	(7)53.8%	(49)55.7%	0.806
-Moderate	(3)23.1%	(14)15.9%	
-Severe	(1)7.7%	(4)4.5%	
Pre PTMC TR			
-No	(2)15.4%	(14)15.9%	
-Mild	(4)30.8%	(63)71.6%	0.002
-Moderate	(3) 23.1%	(7)8%	
-Severe	(4) 30.8%	(4)4.5%	
Post PTMC TR			
-No	(2)15.4%	(12)13.6%	
-Mild	(4)30.8%	(61)69.3%	0.009
-Moderate	(3) 23.1%	(9)10.2%	
-Severe	(4) 30.8%	(6)6.8%	
LVEF(%)	51.9 ± 5.6	52.8 ± 4.6	0.522
Pre PTMC PASP(mmHg)	53 ± 24	45.7 ± 17	0.18
Post PTMC PASP(mmHg)	44.7 ± 15	37.4 ± 13	0

*The values are displayed as the number of cases and percent LVEF: left ventricular ejection fraction, Mean MVG: mean mitral valve gradient, MR: mitral regurgitation, MVA: mitral valve area, PTMC: percutaneous transmitral commissurotomy, PASP: pulmonary artery systolic pressure, TR: tricuspid regurgitation.

During the follow-up, 13 patients eventually underwent mitral valve replacement (MVR) surgery, with two cases of severe mitral regurgitation (2%) and 11 cases (10.9%) of restenosis. The mean time from PTMC to mitral valve replacement surgery was 2.7±1.9 years.Two deaths occurred during follow-up due to intracranial hemorrhage secondary to warfarin overdose 3 cases of ischemic stroke occurred following thromboembolism. Figure 1 shows the overall and sex-stratified survival curves without events for the study patients, demonstrating a significant relationship between rhythm and functional capacity with survival ($p<0.0001$ and $P<0.0001$, respectively).

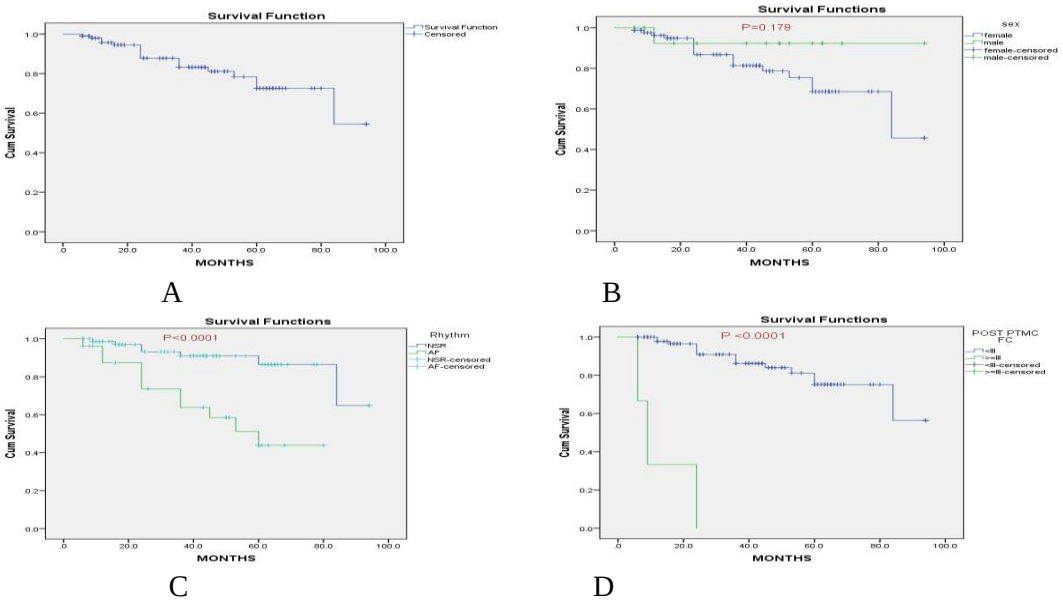

Figure1. A) Kaplan-Meier curves display total event-free survival after percutaneous transmitral commissurotomy for 101 patients based on B) Sex C) Heart rhythm, and D) NYHA functional class. Events include death, mitral valve replacement, and ischemic stroke. Patients with lower NYHA functional class (I, II) and those with sinus rhythm have higher survival rates.

Discussion

Undoubtedly, PTMC is a significant progress in treating patients with severe symptomatic mitral stenosis. It has saved millions of lives effectively and safely since 1984 (5, 25). Large studies have demonstrated the favorable long-term results of this procedure (10, 11). Nevertheless, a comparison of PTMC results with surgical valvotomy has shown that it is equivalent to OMVC and superior to CMVC (6, 7, 8). Ben Farhat and colleagues compared the outcomes of PTMC, OMVC, and CMVC and found no need for reintervention in 90%, 93%, and 57%, respectively (6). Our study showed that in an average of three years, 18% of patients had complications of death and restenosis, severe mitral regurgitation, and ischemic stroke. Event-free survival was 82% at three years. Cohen and colleagues found that predictors of longer event-free survival were one of these pre-procedural findings: lower echocardiographic score, LV end-diastolic pressure, and NYHA functional class (12). In Palacios et al.'s study, the echo score variable, along with clinical characteristics, was found to be the main factor influencing long-term outcomes (13). However, in the present study, the predictors of shorter event-free survival were AF rhythm and higher post-procedure NYHA functional class. These findings are partly indicative of advanced rheumatic disease resulting in larger left atrium size multi-valvular involvement and higher rate of surgery. Song showed that the event-free survival in patients with severe mitral valve stenosis who had an AF rhythm or high echocardiographic score was longer with surgery than percutaneous mitral valvotomy (14). There are different reports on the prevalence of mitral regurgitation after PTMC. Arora and colleagues reported that in 42% of their patients, MR got worse and was severe in 1.1% of cases (19). In our follow-up, the incidence of severe MR was 5% and 2% of patients underwent mitral valve replacement (MVR). Notably, in the study by Kaul, severe mitral regurgitation occurred in 3.3% of 3650 patients after PTMC, of which 1.8% resulted in MVR (20). A 30-year follow-up of PTMC patients reported that post-procedural MR $\geq$ 2 had a hazard rate of 4 for MVR (21). Following PTMC, we had an increase in the mitral valve area and a decrease in systolic pressure of the mitral and pulmonary artery, which improved clinical symptoms and decreased the NYHA function class so that 97% of patients were in functional, classes I, and II.This clinical improvement is due to reduced severity of stenosis and pulmonary artery pressure and improved left and right ventricular function (22, 23). Seven patients developed cerebrovascular accidents that resulted in the death of two people, possibly due to an inappropriate dose of warfarin and fluctuations in anticoagulant levels. This finding warns that a patient on warfarin treatment needs special care. It is noteworthy that patients with mitral stenosis and AF

rhythm are a high-risk group because they take warfarin with a narrow therapeutic index. Additionally, they have an AF rhythm that causes thromboembolic events. Miura found that patients with AF rhythm who underwent PTMC had significantly reduced survival and AF rhythm was an independent predictor of clinical events compared to those with sinus rhythm (24).

Study limitations

This study has a few limitations. Firstly, it is retrospective and was conducted at a single center. Secondly, the number of patients is low due to the decrease in rheumatic fever cases and resulting decrease in valvular heart disease cases in Iran.

Conclusion

In the recent three-year follow-up study, we discovered that percutaneous transluminal mitral commissurotomy (PTMC) yields results similar to those observed in other regions. We concluded that PTMC is a highly effective and safe treatment for patients suffering from severe mitral stenosis.Our findings indicate that atrial fibrillation (AF) rhythm and higher post-procedural NYHA functional class are predictors of shorter event-free survival, likely due to the disease reaching more advanced stages.It underscores the importance of early detection and treatment of rheumatic heart disease and suggests that screening in areas with high prevalence rates could be beneficial. The most effective approach is primary prevention.

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Author contributions

1. Abbas Andishmand: Conceptualization, Methodology, Writing – Original draft, Writing – Review & Editing
2. Hossein Montazer Ghaem: Writing – Original draft, Writing – Review & Editing
3. Somayeh Fallahzadeh: Data collection, Methodology, Investigation, Writing – Original draft, Writing – Review & Editing
4. Mojtaba Andishmand: Writing – Review & Editing
5. Seyedeh Mahdieh Namayandeh: Data analysis, Writing – Review & Editing

Conflicts of Interest

There is no conflict of interest for people involved in this study.

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