

Long-term follow-up of patients with percutaneous mitral commissurotomy

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Abstract

Background: Percutaneous mitral commissurotomy (PMC) has become the procedure of choice for patients with isolated mitral stenosis.

Aim: To assess immediate and long-term results of PMC and identify predictors of event-free survival.

Methods: Percutaneous mitral commissurotomy was attempted in 1380 patients (mean age 49.36±10.0 years) with severe mitral stenosis.

Results: Good immediate results defined as valve area ≥1.5 cm² without regurgitation >2+ were obtained in 1149 (83.3%) patients. The mean follow-up period was 8.2±6.4 (1-17) years. The event-free survival rate (alive, no mitral surgery, no repeat PMC) was 87.7, 75.6 and 69.7% at 5, 10 and 15 years respectively. Cox regression analysis identified old age (p=0.04), high echocardiographic score (p <0.0001), advanced NYHA class after PMC (p=0.005), low mitral valve area after PMC (p <0.0001), high gradient after PMC (p <0.0001), high pulmonary artery systolic pressure after PMC (p <0.0001), and >2+ mitral regurgitation after PMC (p <0.0001) as independent predictors of adverse outcome.

Conclusions: Percutaneous mitral commissurotomy has excellent immediate and long-term results for selected patients with mitral stenosis. Eight years after PMC most of the patients were in good clinical condition and free of any major event. The procedural result was the main determinant of long-term outcome. Prediction of late events is multifactorial. Knowledge of these predictors can improve patient selection and follow-up results.

Key words: mitral stenosis, percutaneous mitral balloon commissurotomy

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Introduction

First described in 1984 by Inoue, percutaneous mitral commissurotomy (PMC) has become a recognised and common therapeutic approach [1]. On the basis of studies conducted so far, the effectiveness of PMC was shown to be high and comparable with open mitral commissurotomy in selected patients [2, 3]. According to current guidelines of the European and American Cardiac Societies, balloon valvuloplasty remains the first-line therapy in patients with isolated stenosis and feasible morphology of the mitral valve [4, 5].

Most studies published so far have presented early and mid-term results of PMC. Reports with long-term follow-up are, however, scarce [6-17]. The first balloon mitral valvuloplasty at the Institute of Cardiology in Warsaw was performed in 1988. The aim of this study was to present and discuss the results of long-term follow-up of patients undergoing PMC in our site.

Methods

Percutaneous mitral commissurotomy was performed at the Institute of Cardiology from September 1988 to December 2005 in 1380 patients (mean age of 49.36±10.0). Patients were referred for the procedure if they had significant stenosis of the mitral valve (orifice area <1.5 cm²) and signs of heart failure (NYHA class ≥II). The decision regarding qualification for PMC was based on clinical assessment and echocardiography, which was used to measure mitral valve area, valvular and subvalvular apparatus lesions, severity of calcifications and mitral regurgitation. Mitral valve area was calculated using Hatle's formula – the constant 220 was divided by pressure half time [18]. Wilkins classification was used to determine severity of lesions of the valve and subvalvular apparatus [19]. To exclude presence of thrombus in the left atrium (LA) all patients, beginning from August 1989 and regardless of heart rhythm, underwent trans-

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-oesophageal echocardiography. The procedure was contraindicated in patients with major lesions, particularly calcifications, in the mitral valve leaflets and/or subvalvular apparatus (>11 Wilkins score). Another contraindication was haemodynamically significant mitral regurgitation (>2+). Moreover, patients were not qualified for PMC if no signs of heart failure were observed.

All patients gave their informed consent for the procedure. The valve was dilated using Inoue technique, as described previously [8]. Blood pressure was measured directly in the left and right atria, pulmonary artery and left ventricle (LV) before and after PMC. Mitral pressure gradient was calculated using blood pressures recorded simultaneously in the LA and LV. Left ventriculography was performed before the procedure to evaluate LV contractility and mitral annulus size and to check for significant mitral regurgitation.

Long-term follow-up

Follow-up outpatient visits were carried out after 6 months and then once a year. At the visit exercise capacity was evaluated according to NYHA functional classification and echocardiography, including the assessment of mitral valve area and pressure gradient, was performed. Patients who failed to attend the follow-up visits were contacted either by phone or mail. In the case of patients lost to follow-up we checked with the Department of National Registers of the Ministry of Internal Affairs whether the patient was alive.

Clinical endpoint was a composite of death, surgical valvular repair or repeat balloon valvuloplasty.

Table I. Baseline characteristics of the study group (N=1380)

Parameter	Value
Mean age [years]	49.36±10.0
Females	1188 (86.1%)
Previous surgical commissurotomy	198 (14.3%)
Chronic atrial fibrillation	531 (38.5%)
Echo score	6.35±1.54

Table II. Immediate echocardiographic, haemodynamic and clinical variables before and after percutaneous mitral commissurotomy (PMC)

	Before PMC	After PMC	p
Mitral valve area (Doppler) [cm ²]	1.15±0.2	1.94±0.4	<0.001
Mean gradient (Doppler) [mmHg]	14.0±5.87	5.4±3.4	<0.001
Mean left atrial pressure [mmHg]	23.0±7.0	15.1±6.3	<0.001
Systolic pulmonary pressure [mmHg]	45.6±15.02	36.7±11.4	<0.001
Cardiac index [l/min/m ²]	2.7-0.6	3.0-0.7	<0.001

Statistical analysis

Statistical analysis was performed using SPSS software. Continuous variables are presented as means ± standard deviations, and qualitative parameters as numbers and percentages. Student's t-test for paired variables was used to compare selected clinical, haemodynamic and echocardiographic parameters at baseline and after the procedure. Differences were considered significant for the p value <0.05.

Probability of adverse event free survival (death, surgical valvular repair or repeat balloon valvuloplasty) was evaluated with Kaplan-Meier survival curves. Cox proportional hazards single- and multifactor regression model was applied for evaluation of determinants of composite clinical endpoint in the long-term follow-up including: a. death, b. need for surgical replacement of the mitral valve, c. repeat balloon valvuloplasty. Contribution of the following factors was analysed: age, sex, history of cardiac surgery prior to PMC, presence of atrial fibrillation, severity of valvular and subvalvular apparatus damage according to Wilkins scoring system, heart failure according to NYHA after PMC, mitral orifice area before and after the procedure assessed with echocardiography, mitral mean pressure gradient before and after the procedure, mean pulmonary artery pressure on catheterisation before and after the procedure, mean LA pressure on catheterisation before and after the procedure, LV end-diastolic pressure, mitral regurgitation before and after the procedure, as well as cardiac index before and after the procedure.

Results

Early outcomes

Clinical and echocardiographic characteristics of the study group are described in Table I. The procedure caused a significant increase of mitral valve area, decrease in valvular pressure gradient, decrease in pulmonary artery pressure and improvement of exercise performance (Tables II and III).

'Good early procedure outcome' defined as mitral valve area after PMC of ≥1.5 cm² with mitral regurgitation ≤2+ and

Table III. Number of patients with mitral insufficiency and NYHA class before and after percutaneous mitral commissurotomy (PMC)

	Before PMC	After PMC
Mitral regurgitation grade		
0	1017	810
1	303	288
2	60	165
3	0	93
4	0	20
NYHA class		
I	0	510
II	313	749
III	1057	73
IV	18	0

without complications was observed in 1149 (83.3%) subjects. Valvular area $<1.5 \text{ cm}^2$ or mitral regurgitation $>2+$ were present in 226 (16.3%) patients. Adverse events such as death or pericardial tamponade occurred in 6 (0.4%) individuals.

Mitral regurgitation $>2+$ was found in 113 (8.2%) patients, including 4+ mitral regurgitation in 20 patients. In patients with $>2+$ regurgitation, 38 (2.8%) required mitral valve replacement within one month after the procedure due to worsening heart failure. Other patients with mitral regurgitation in whom progression of heart failure was not observed were qualified for further follow-up.

No deaths were noted during PMC. Two females died in the perioperative period. One patient after valvular dilation experienced perforation of the inferior vena cava while removing the Inoue catheter. She underwent urgent vascular surgery followed by disseminated intravascular coagulation and death. The other patient died due to sepsis which occurred a few days after the procedure. Pericardial tamponade was observed in four patients. All cases had pericardiocentesis performed resulting in haemodynamic stabilisation in one patient, and surgical intervention was required in the remaining three.

Long-term results

Clinical follow-up involved 1336 patients who required no surgical repair of the mitral valve within 30 days after the percutaneous procedure and were free of complications. Long-term data were collected from 1273 (95.3%) patients including 1104 ones with good early results and 169 with postprocedural mitral valve area $<1.5 \text{ cm}^2$ or mitral regurgitation of $>2+$. The remaining patients did not attend the follow-up visits and did not answer the questionnaires sent. To determine whether patients were still alive the Department of National Registers of the Ministry of Internal Affairs was called.

Mean follow-up duration was 8.2 ± 6.4 (1-17) years for the entire study group. Death as a primary endpoint was observed in 52 (3.9%) of 1336 patients.

From 30 days after the procedure until the end of follow-up, 156 (12.3%) of 1273 subjects required mitral valve replacement and repeat valvuloplasty was performed in 43 (3.4%).

Of 1104 patients with good early outcome, mitral valve replacement was required in 66 (6.0%), whereas in 169 patients with mitral valve area $<1.5 \text{ cm}^2$ or mitral regurgitation $>2+$ after PMC, the valve was replaced in 91 (53.8%) cases ($p < 0.001$). The PMC early outcome did not influence the incidence of re-PMC or mortality rate. In patients with good early procedure outcome 42 (3.7%) patients died and re-PMC was performed in 41 (3.7%) subjects, while in the remaining group 10 (5.3%) patients died and another balloon valvuloplasty was carried out in 8 (4.7%) patients (NS).

Survival in the entire study group free from surgery or re-PMC was 87.7% after 5 years, 75.6% after 10 years and 69.7% after 15 years.

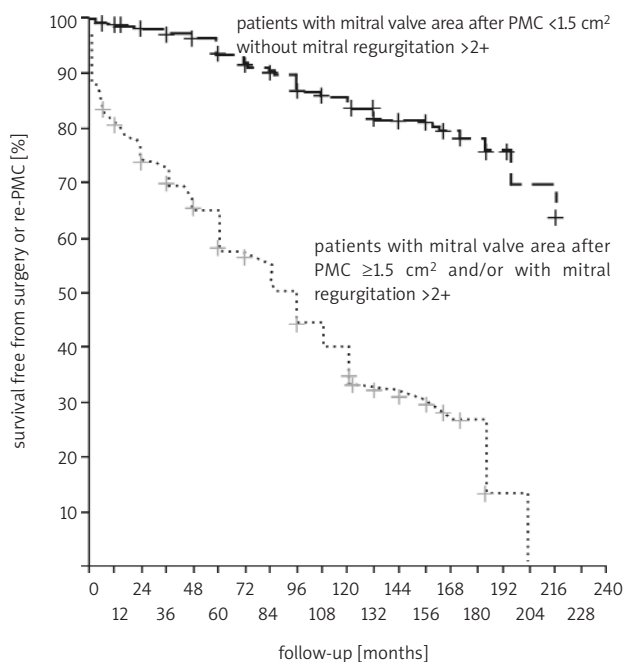


Figure. Adverse event free survival (surgery, surgical mitral valve replacement, re-PMC)

Adverse event free survival was related to the early outcome of PMC. Event-free survival in patients with good early outcome after 5, 10 and 15 years was 93.7%, 83.6% and 78.2%, respectively, and was 58.3%, 34.8% and 26.6% for other patients (Figure).

Multivariate analysis showed that the following factors are associated with the incidence of death, necessity of surgical mitral valve replacement or re-PMC: older age ($p=0.04$), advanced lesions of the mitral valve on echocardiography ($p < 0.0001$), impaired exercise capacity (NYHA class) after PMC ($p=0.005$), small mitral valve area after PMC ($p < 0.0001$), high mitral valvular gradient after PMC ($p < 0.0001$), high systolic pulmonary artery pressure after PMC ($p < 0.0001$), and mitral regurgitation $>2+$ after PMC ($p < 0.0001$).

Discussion

The cohort presented here is one of the largest groups of patients with percutaneous mitral balloon valvuloplasty performed in one site and the mean follow-up period of 8 years is one of the longest.

Age of patients qualified for PMC at the Institute of Cardiology is similar to that reported by other investigators [6, 7, 12, 16]. Most patients in our group were in the age range 46-65 years (56.7%), while patients above 65 years comprised 5.8%. PMC is often the only acceptable method of treatment of the latter due to high prevalence of comorbidities increasing the risk of surgery. The presented material comprised 14.3% of patients in whom the procedure was performed due to restenosis after previous

surgery. The number of such patients will certainly grow in the future as the risk of recurrence of stenosis after surgical repair is reported to be as high as 21% [6, 20, 21].

Direct outcomes

The early results of PMC are very good – increase of valvular area to at least 1.5 cm² without the presence of mitral regurgitation >2+ was achieved in 83.3% of patients. Our results show that balloon valvuloplasty performed by experienced operators is safe and is associated with low risk of complications and periprocedural mortality of 0.2%. Mitral regurgitation >2+ was observed in 8.2% of patients, of whom the majority were qualified for conservative treatment. The most serious cause of significant mitral regurgitation after PMC is rupture of the mitral leaflet or tendinous chord [22, 23]. However, following PMC mitral regurgitation often does not produce significant clinical symptoms [22]. Moreover, we have shown that in more than half of patients regurgitation decreased or resolved completely within several months after the procedure [23, 24]. The possible causes of reversible mitral regurgitation include stretching of mitral annulus during the procedure, worsening of leaflet coaptation after PMC, or ischaemia of papillary muscles [24]. In these cases gradual reduction of mitral regurgitation is observed. Therefore, in patients with mitral regurgitation >2+ after the procedure but without worsening heart failure, a decision regarding surgery should be postponed and made only after the outpatient follow-up period as some of the patients may be safely treated conservatively.

Long-term results

Long-term results of PMC are determined by the early results. As with surgical commissurotomy, in patients after percutaneous procedure with good early outcome the risk of adverse events is considerably lower than in patients with post-procedural mitral valve area <1.5 cm² or mitral regurgitation of >2+. It is worth noting that failure to achieve good early outcome does not preclude benefits to the patient. In some such patients even moderate dilation of the valve significantly improves exercise capacity, allowing routine daily activities. They may maintain good exercise capacity for many years without mitral valve replacement.

The most common adverse event during long-term follow-up is the need for surgery due to restenosis or severe mitral regurgitation. In some patients with restenosis and minor valvular and subvalvular pathology balloon commissurotomy may be repeated; however, for most of them mitral valve replacement is the treatment of choice due to advanced valvular and subvalvular pathology or severe mitral regurgitation.

Post-PMC mitral valve area ≥ 1.5 cm² with mitral regurgitation $\leq 2+$ is associated with long-term improvement of exercise capacity without the need for reintervention. The

importance of early outcome was confirmed by lung et al. They followed 1024 patients after PMC and showed that in the group with good early results 10-year survival free of mitral valve replacement or re-PMC was 56%. For patients with post-procedural mitral valve area of <1.5 cm² or mitral regurgitation >2+ the prognosis was significantly worse [16]. Better results were reported by Fawzy et al., who followed 493 subjects and found the adverse event-free survival rate (surgery, re-PMC, NYHA class III or IV) after 13 years to be 74% [15]. However, the results of this study were heavily influenced by the young age of the patients (mean 31 years).

Severity of valvular and subvalvular pathology is equally important. Palacios et al. based on echocardiography divided patients into two groups. The first included patients with ≥ 8 points according to Wilkins score of severity of valvular and subvalvular lesions, and the second one – patients with >8 points. They found that predicted 12-year survival free from adverse events (death, surgery, re-PMC) in patients with minor lesions was 38% and 22% in the group with score >8 [25].

Independent predictors of long-term outcome of PMC

Multivariate analysis has shown that the long-term results of PMC depend on the appropriate qualification of patients and early outcomes of the procedure. Two independent determinants of long-term results are known prior to the procedure, and the remaining five are associated with the procedure outcome.

The importance of patients' age and severity of valvular and subvalvular pathology as independent determinants of long-term results was shown for patients after both surgical and transluminal balloon commissurotomy [16, 17, 21, 25, 26].

The other factors having an impact on the long-term results are associated with the early results of the procedure. The role of mitral valve area after PMC is highlighted by all investigators [10, 17, 27]. The borderline value of mitral valve area required to achieve good early results is assumed to be ≥ 1.5 cm². Valvular pressure gradient is similarly relevant and regardless of valve area allows the evaluation of PMC outcome. Patient's exercise capacity following PMC is another independent parameter. Two remaining factors are systolic pulmonary artery pressure and severity of mitral regurgitation. Systolic pulmonary artery pressure may remain elevated after valvuloplasty despite good direct outcome and was shown to be an unfavourable predictor of long-term prognosis [27]. Additionally, post-procedural mitral regurgitation >2+ is another negative prognostic factor [15, 21, 25, 26].

Our experience based on a large cohort of patients shows that percutaneous mitral commissurotomy is safe and a good early outcome can be expected in over 80% of patients. Long-term follow-up findings show that

patients with less severe pathology and good early outcome may be expected to have satisfactory long-term survival free from reintervention. On the other hand, results are worse in patients with unsatisfactory procedure outcome. Therefore it is important to correctly qualify patients for PMC and to try to achieve the best possible procedural outcome.

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Odległa obserwacja osób po przezskórnej komisurotomii mitralnej

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Streszczenie

Wstęp: Przezskórna komisurotomia mitralna (ang. *percutaneous mitral commissurotomy*, PMC) jest metodą z wyboru w leczeniu wybranych chorych z izolowanym zwężeniem zastawki dwudzielnej. Przeprowadzone badania wykazały, że skuteczność bezpośrednia PMC jest porównywalna z leczeniem chirurgicznym. Dotychczas opublikowano niewiele doniesień na temat obserwacji wieloletnich po PMC.

Cel: Ocena wyników odległych walwuloplastyki balonowej oraz określenie czynników, które mają wpływ na wystąpienie zdarzeń niepożądanych w trakcie obserwacji.

Metodyka: Od września 1988 do końca grudnia 2005 r. PMC wykonano u 1380 kolejnych chorych (średni wiek 49,36±10,0 lat). Wskazaniem do wykonania zabiegu było istotne zwężenie zastawki dwudzielnej (pole powierzchni <1,5 cm²) i obecność cech niewydolności serca (≥II klasa wg NYHA).

Wyniki: Dobry wynik bezpośredni, zdefiniowany jako uzyskanie pola powierzchni zastawki ≥1,5 cm², niedomykalność mitralna <3+, stwierdzono u 1149 (83,3%) chorych. Na podstawie obserwacji trwającej 8,2±6,4 (1–17) roku wykazano, że prawdopodobieństwo przeżycia bez wymiany zastawki dwudzielnej i/lub bez ponownego PMC wynosi 87,7, 75,6 i 69,7% odpowiednio po 5, 10 i 15 latach. Stwierdzono, że odległe losy chorych zależą w dużym stopniu od wyników bezpośrednich PMC. Przeprowadzona analiza wieloczynnikowa wykazała, że następujące niezależne czynniki mają wpływ na przeżycie bez wystąpienia zdarzenia niepożądanego: starszy wiek (p=0,04), zaawansowane zmiany w zastawce i aparacie podzastawkowym w ocenie echokardiograficznej (p <0,0001), wydolność fizyczna (klasa NYHA) po PMC (p=0,005), wielkość pola powierzchni zastawki po PMC (p <0,0001), wysoki gradient ciśnienia przez zastawkę po PMC (p <0,0001), wysokie ciśnienie skurczowe w tętnicy płucnej po PMC (p <0,0001), niedomykalność mitralna >2+ po PMC (p <0,0001).

Wnioski: Nasze doświadczenia oparte na dużym materiale pokazują, że przezskórna walwuloplastyka balonowa zastawki dwudzielnej jest zabiegiem bezpiecznym, a dobry wynik bezpośredni uzyskuje się u ponad 80% chorych. Długoletnia obserwacja wykazała, że u chorych bez zaawansowanych zmian patologicznych i z dobrym wynikiem bezpośrednim możemy się spodziewać długoletniego przeżycia bez konieczności ponownej interwencji. Natomiast wyniki pozostałych chorych są mniej zadowalające. Wyniki odległe PMC zależą od wielu czynników, których znajomość ułatwia kwalifikację chorych do zabiegu.

Słowa kluczowe: stenoza mitralna, przezskórna komisurotomia mitralna

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