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Original Article

Immediate and long-term results of percutaneous mitral commissurotomy: up to 15 years

Nabil Braiteh[1], Ali Zgheib[2], Anthony H Kashou[3], Hani Dimassi[4], Georges Ghanem[5]

[1]United Health Services Hospitals, Wilson Regional Medical Center, Department of Cardiology, 33-57 Harrison St, Johnson City, NY 13790, USA; [2]American University of Beirut, Department of Cardiology, P.O. Box:11-0236, Riad-El-Sold Beirut 1107 2020, Beirut, Lebanon; [3]Mayo Clinic, Department of Internal Medicine, 200 First St. SW, Rochester, MN 55905, USA; [4]Lebanese American University, School of Pharmacy, P.O. Box 36 Byblos, Lebanon; [5]Lebanese American University Medical Center-Rizk Hospital, Gilbert and Rose Marie Chagoury School of Medicine, Zahar Street, Achrafieh P.O. Box 11-3288, Beirut, Lebanon

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Abstract: Purpose: To evaluate immediate and long-term clinical results of percutaneous mitral commissurotomy (PMC) in patients with severe mitral stenosis. Methods: In a retrospective study, data were included from 317 patients over 18 years of age (mean age 45) who had been treated for mitral stenosis between January 1993 and March 2015 with PMC using the Inoue balloon technique. Immediate results: Valvular function improved as evidenced by an increase in mitral valve area from 1.01 ± 0.24 cm^2 to 2 ± 0.31 cm^2 ($P < 0.001$) and a decrease in mean mitral gradient from 13.64 ± 6.03 mm Hg to 5.40 ± 2.49 mm Hg. Long-term follow-up: At 5-15 years (mean 10.2 years, Inter-quartile range 8.25), 105 (33.1%) of the 317 patients were available for follow-up, 95 living patients and 10 deceased. Of the deceased, average time from PMC to death was 8 years. Results were strongly significant showing that age at the time of PMC and surface area before the procedure were the best predictors of survival at 15 years follow-up, showing significance values of $P = 0.022$ and $P = 0.001$, respectively. Conclusions: PMC using the Inoue balloon technique improves morbidity and long-term mortality rates in patients with severe mitral stenosis. Lower Wilkins score and NYHA class at baseline were not found to be significant predictors of mortality in older patients (age > 45). Overall, 65 (61.9%) had survived at 5-15 years follow-up without further cardiac intervention.

Keywords: Percutaneous mitral commissurotomy, long term follow-up, severe mitral stenosis

Introduction

Percutaneous mitral commissurotomy (PMC) was first introduced and described in 1984 as a non-surgical means to treat mitral stenosis [1]. Since that time, many studies have found PMC and surgical intervention to yield comparable immediate, short-term, and long-term results [2-6].

PMC has become the mainstay treatment for symptomatic rheumatic mitral stenosis in patients with favorable valve anatomy [7]. As the indications for PMC continue to expand to include more difficult valve anatomy, increased age, and additional associated comorbidities, the ability to predict patient outcome has become critical in clinical practice. However, there remain few longitudinal studies that assess the outcomes after PMC over time.

This is a retrospective, single-centered study with the aim to analyze both immediate and long-term clinical results of percutaneous mitral commissurotomy (PMC) in patients with severe mitral stenosis.

Methods

Study population

Between January 1993 and March 2015, 317 patients (248 females and 69 males) with mitral stenosis had undergone PMC at the Lebanese American University Medical Center, Beirut, Lebanon. Their ages ranged from 18 to 83 years with a mean age of 45. Of the total, 63.4% were below age 50. The presence of left atrial thrombus was excluded in all patients by echocardiography before PMC. Fifteen patients (4.7%) were in NYHA class II, 272 (85.8%) in class III, and 20 in class IV (9.1%). All patients

Table 1. Background characteristics of all patients that underwent mitral valve commissurotomy

	Number (N)	Percent (%)
Gender		
Female	248	78.2
Male	69	21.8
Total	317	100
Age		
< 40	131	41.3
40-49	70	22.1
50-59	63	19.9
60+	53	16.7
NYHA before PMC		
II	15	4.7
III	273	86.1
IV	29	9.1
Wilkins score before PMC		
6	13	4.1
7	69	21.8
8	90	28.4
9	65	20.5
10	35	11
11	16	5
12	17	5.4
13	4	1.3
14	5	1.5
16	3	0.9

had mitral regurgitation less than 2/4 or severe mitral valve stenosis with valve area < 1.5 cm^2.

Echocardiographic and intra-catheterization

Evaluation 24 hours before and 24-72 hours after PMC, Doppler, and 2-dimensional echocardiography were performed on 317 patients. We excluded the presence of left atrial thrombus by performing transesophageal echocardiography on all patients. The degree of mitral regurgitation was determined by color-flow Doppler echocardiography, pulsed Doppler echocardiography, transesophageal echocardiography and during cardiac catheterization. The scaling score used in our results was obtained during angiography to estimate mitral regurgitation (MR) qualitatively on a scale of 0 to 4, where 1/4 was considered very mild MR and 4/4 was deemed severe MR. Mitral valve area (MVA) and mean trans mitral gradient were assessed by 2-dimensional echocardiography, and Doppler. MVA was calculated from the trans mitral pressure half-time index using Doppler. Morphologic features were categorized according to Wilkins Score, as described by Wilkins et al. [8].

A blinded cardiologist evaluated each echocardiogram for valvular thickening, calcification, mobility, and sub-valvular thickening. The score for each scale was from 0 (normal) to 4 (severely deformed). All scores were added to obtain the overall Wilkins score, ranging from 0 to 16 (**Table 1**).

Study protocol

Hemodynamics and percutaneous mitral commissurotomy: Left and right heart catheterizations were performed using the standard approach, including coronary arteriography and left ventricular and right atrial angiography. Cardiac output was measured by the thermodilution method before and after PMC. In all cases of inter-atrial septal defect, the Fick principle was used to calculate cardiac output after PMC. Mitral valve gradient was calculated after recording left atrial and ventricular pressures. The Gorlin formula was used to calculate valve area, except where severe MR was present. Left ventriculography and oximetry series were also done.

For PMC, the antegrade technique was used in all cases. A Brockenborough catheter and needle were introduced through the femoral vein and passed up into the right atrium. The Brockenborough catheter was pushed over the needle into the left atrium, creating access from the right to the left side of the heart (trans septal). Through the Brockenborough catheter, a special guidewire was passed and looped into the left atrium, and then a 14FG dilating catheter was passed over the wire. The femoral vein puncture site was then dilated with subsequent dilation of the atrial septal wall to allow easy passage of the Inoue balloon into the left atrium. Using special torque wire carbon dioxide, the Inoue balloon catheter was flow-directed and floated across the mitral valve. The Inoue balloon was then inflated with diluted contrast medium across the mitral valve, thereby splitting the balloon commissures to lock the balloon in place. The final step of inflating the middle section of the balloon causes the commissures of the valve to split.

Follow-up

Long-term (5-15 years post-PMC) clinical follow-up was based on a questionnaire conducted by

Table 2. Immediate outcome post PMC

	N	Before		After		Difference		*p*-value
		Mean	SD	Mean	SD	Mean	95% CI	
Mitral regurgitation on echo	317	0.5/4	0.5	1/4	0.67	-0.5	(-0.5, -0.5)	< .001
Mitral Valve area (cm^2)	317	1.01	0.24	2.00	0.31	-0.99	(-1.02, -0.96)	< .001
Mean Mitral Gradient (mm hg)	317	13.64	6.03	5.40	2.49	8.24	(7.66, 8.81)	< .001

Increase in mitral valve area from (1.01 ± 0.24 to 2 ± 0.31 cm^2) (P < 0.001). Mean mitral gradient also was significantly decreased from (13.64 ± 6.03 to 5.40 ± 2.49 mm Hg). The degree of mitral regurgitation on echocardiography was slightly increased from 0.5/4 ± 0.5 to 1/4 ± 0.5. SD (Standard deviation).

telephone interviews to assess NYHA functional class, death vs survival, and need for repeat PMC or surgery. Mitral valve area, ejection fraction, and mitral valve gradient were obtained based on the last echocardiography that was done within the previous 6-12 month of the phone interview. All echocardiograms were done at the same center. Long-term follow-up was limited to 105 patients of the 317. Of those, 95 patients were living and 10 were deceased. Lack of follow-up was mostly due to lack of contact information or patient's failure to return for clinical follow-up with the cardiologist.

Statistical analysis

Abstracted medical records were entered into a computer and analyzed using SPSS V24. Categorical data were summarized using frequency and percentage, while numerical data were summarized using means and standard deviations. Differences in means were tested using the independent t-test for the between-subject effect and the paired t-test for the within-subject effect with 95% confidence intervals. Differences in proportions were tested using Pearson's chi-square (independent groups) or Cochran's Q-test (dependent groups). Statistical significance was assessed at the 0.05 level.

Results

Immediate hemodynamic and echocardiography results

PMC was applied in 317 patients and successful in all. It brought immediate hemodynamic improvement, as seen in **Table 2**, resulting in a significant increase in mitral valve area from 1.01 ± 0.24 to 2 ± 0.31 cm^2 (P < 0.001). Mean mitral gradient significantly decreased from 13.64 ± 6.03 to 5.40 ± 2.49 mm Hg. The degree of mitral regurgitation on echocardiography had increased slightly from 0.5/4 ± 0.5 to 1/4 ± 0.5. Valvular function had improved, as evidenced by a decrease in mean mitral gradient and an increase in valve area (**Table 2**).

Immediate complications after PMC

A total of 9 (2.8%) complications occurred post-PMC. All 9 patients survived following their complications. The other 308 patients (97.2%) did not suffer complications post-PMC. Two (0.6%) patients had a myocardial infarction, 1 (0.3%) had a pericardial effusion, and 6 (1.9%) had cardiac tamponade that required emergency pericardiocentesis. Outcomes of all 9 patients were favorable, surviving the acute complication with no long-term sequelae.

Follow-up and long-term results

Follow-up data for a period of 5-15 years (mean 10.2, IQR 8.25) were available for 105 (33.1%) patients with a mean age of 42.74 years. Two hundred twelve (66.9%) patients were not available for follow-up due to loss of contact information or the lack of clinical follow-up with their cardiologist. There were 10 deaths (9.5%), 4 (3.8%) of which were related to a cardiac event-3 cases of myocardial infarction, and 1 of ventricular fibrillation arrest-whose mean age was 54, and 6 (5.7%) that were not cardiac events (3 cases of stroke, 1 of liver failure, and 2 of sepsis). Ninety-five (90.5%) were living at the time of follow-up. The mean interval from PMC to death was 8 years. Of the 10 deaths, 8 were female and 2 were male.

Of the 105 patients, in the period of 5 to 15 years following the first PMC, 10 (9.5%) required repeat PMC, 20 (19%) required cardiac surgery (13 for mitral valve replacement and 7 for triple vessel bypass), 18 (17.1%) had atrial fibrillation, 5 (4.7%) had an arrhythmia (2 had < 30 s of non-sustained ventricular tachycardia, 2 had episodes of supraventricular tachycardia, and 1 had an episode of atrial flutter), 2 (1.9%) had

Table 3. Change in the NYHA class distribution from before PMC to long term follow up (5-15 years)

NYHA score	Before PMC		Long term follow up of all alive patients		Long term follow up of alive patients that did not require surgery or repeat PMC	
	N	%	N	%	N	%
I	0	-	20	21.05	20	30.7
II	15	4.7	43	45.2	25	38.4
III	273	86.11	28	29.4	16	24.6
IV	29	9.1	4	4.2	4	6.15
Total	317		95		65	
P-value	< .001					

The table above shows that the majority of patients had NYHA scores of III before PMC (86.11%), and in the long-term follow-up, the majority had NYHA scores of II and below (62.5% = 21.05% + 45.2% in all living patients, and 69.1% in living patients who had not required further intervention) (P < 0.001).

Table 4. Predictors of mortality

	Alive			Dead			*p*-value
	N	Mean	SD	N	Mean	SD	
Age at procedure	95	45.08	12.35	10	54.60	11.85	0.022
Pre surface area	95	1.03	0.23	10	0.85	0.12	0.001
Below are Non-significant							
Post surface area	95	2.03	0.27	10	1.88	0.25	0.096
Pre hemodynamic gradient in Cath	86	14.28	5.83	10	14.60	6.80	0.872
Mitral regurg in cath	84	0.51	0.70	10	0.60	0.74	0.691
Balloon size	81	27.26	1.41	9	27.67	1.73	0.424
Pre Mitral regurg on echo	95	0.51	0.67	10	0.85	0.78	0.138
Post Mitral regurg	95	0.95	0.68	10	1.25	0.86	0.194
Pre Gradient	95	13.22	5.51	10	12.80	5.61	0.820
Post Gradient	95	5.26	2.24	10	5.55	1.96	0.690

Results indicating that age at time of PMC and surface area before the procedure were the best predictors of mortality at up to 15 years follow-up were strongly significant: P = 0.022 and P = 0.001, respectively.

a myocardial infarction, and 1 (0.9%) had a 3rd-degree atrioventricular block requiring permanent pacemaker placement.

Overall, 65 (61.9%) of the survivors had no further cardiac intervention after an extended (5-15 years) follow-up. The majority had NYHA scores of III before PMC (86.11%), while during long-term follow-up, the majority had NYHA scores of II and below (62.5% = 21.05% + 45.2% in all surviving patients, and 69.1% in surviving patients who did not require further intervention) (P < 0.001) (**Table 3**).

It should be noted that mitral valve area for these 65 patients decreased from a mean of 1.96 (SD 0.33) to 1.63 (SD 0.58), that is, a mean difference of 0.33, with a 95% CI of 0.18-0.49, which is statistically significant (P < 0.001).

Predictors of mortality

Numerous factors were considered to determine the predictors of mortality by multivariable analysis. These were: age at the time of PMC, surface area before and after commissurotomy, hemodynamic gradient during cardiac catheterization before the procedure, level of mitral regurgitation during cardiac catheterization, balloon size used, mitral regurgitation on echocardiography before and after the procedure, and mean mitral gradient before and after the procedure. These factors were examined for the 95 living patients and the 10 deceased. Results were strongly significant showing that age at the time of PMC and surface area before the procedure were the best predictors of mortality during up to 15 years follow-up, returning significance values of *P* = 0.022 and *P* = 0.001, respectively (**Table 4**). Wilkins

Table 5. Gender, Wilkins, NYHA and survival status

	Status				*p*-value
	Dead		Alive		
	N	%	N	%	
Gender					
Female	8	80.0%	72	75.8%	
Male	2	20.0%	23	24.2%	
Total	10	100.0%	95	100.0%	0.766
Wilkins Score					
6	0	0.0%	3	3.2%	
7	0	0.0%	17	17.9%	
8	4	40.0%	27	28.4%	
9	4	40.0%	24	25.3%	
10	1	10.0%	10	10.5%	
12	0	0.0%	4	4.2%	
13	1	10.0%	5	5.3%	
14	0	0.0%	2	2.1%	0.804
Mean (SD)	9 (1.25)		8.85 (1.78)		0.799
NYHA score					
II	0	0.0%	6	6.3%	
III	10	100.0%	83	87.4%	
IV	0	0.0%	6	6.3%	
Total	10	100.0%	95	100.0%	0.490
Post Mitral Regur					
≤ 1.5	7	70%	81	85.3%	
≥ 2	3	30%	14	14.7%	0.213

scores pre-procedure, NYHA, and gender were assessed using the survival technique. These did not show significance in overall mortality changes (**Table 5**).

Discussion

Very few reports in the literature [9-11] have studied the results at a long-term follow-up of 15 years in patients treated with PMC using the Inoue balloon technique. To our knowledge, this study is the first to do so. PMC using the Inoue balloon technique was performed successfully in 317 patients, in a relatively older population (mean age 45 years) with mitral stenosis. All patients had class 1A recommendations for percutaneous mitral valve commissurotomy as per the American College of Cardiology (ACC) and the American Heart Association (AHA) [7]. Most patients (85.8%) were in NYHA class III. All had mitral regurgitation less than 2/4 or severe mitral valve stenosis with valve area < 1.5 cm^2.

Various techniques are used in different centers, including the double-balloon technique, multitrack technique, and the metallic commissurotomy technique. The multitrack system was described by Bonhoeffer et al. [12], which is similar to the double-balloon technique that employs a monorail system in which one guide wire is required. This allows easier dilation but requires more clinical experience. Metallic commissurotomy was introduced by Cribier et al. in the 1990s [13]. It is effective but has a higher risk of hemopericardium due to placement of a stiff guidewire in the left ventricle.

The Inoue balloon technique is the most commonly used with the highest success rate. It has been compared to the double balloon technique in several studies, and results showed no significant difference in outcomes in some studies [14, 15], while Inoue had a lower risk of complications than others [16].

Our short-term results were similar to certain studies published in the literature [1, 3, 17-20], in which PMC was shown to provide immediate hemodynamic and functional improvement represented by a significant increase in mitral valve area, from 1.01 ± 0.24 to 2 ± 0.31 cm^2 ($P < 0.001$). Mean mitral gradient also was significantly decreased, from 13.64 ± 6.03 to 5.40 ± 2.49 mm Hg, and mitral regurgitation on echocardiography increased slightly from 0.5/4 ± 0.5 to 1/4 ± 0.5.

It should be noted that, in most cases, mitral regurgitation remains unchanged or slightly increases without clinical implications. Severe mitral regurgitation can occur with an incidence of 2-13% [3, 21], which is similar to the incidence in the surgical procedure. In such cases, surgery will be required, and valve repair is done with reasonably good results [22]. In our study, valvular function was improved as evidenced by a decrease in mean mitral gradient and an increase in the valve area.

While the incidence of immediate complications was only 2.8% with 0% periprocedural mortality in our study, most studies report that periprocedural morbidity and mortality are low [2, 23-25], but this will always vary slightly based on the expertise of the center and the physician.

With regard to our long-term (up to 15 years with a mean of 10.2 years and interquartile range of 8.25) follow-up data, we were able to follow only 105 patients (33.1%) for NYHA functional class, death vs survival, and need for repeat PMC or surgery. Two hundred twelve (66.9%) patients were unavailable for follow-up due to lack of contact information or failure to return for clinical follow-up. There was a total of 10 deaths (9.5%), 4 (3.8%) of which were related to a cardiac event (3 cases of myocardial infarction, 1 ventricular fibrillation arrest), with a mean age of 54, and 6 (5.7%) were not cardiac events (3 cases of stroke, 1 of liver failure, and 2 of sepsis). Ninety-five (90.5%) were living at the time of follow-up.

Moreover, of the patients available for follow-up, 30 (28.5%) had required repeat PMC or cardiac surgery for either mitral valve replacement or triple vessel disease. Overall survival rate was 61.9% (65 patients) who did not require further cardiac intervention during an extended period (up to 15 years) of follow-up, meaning that mortality was 38.1% for that follow-up period. These were impressive results compared to other studies in which total survival was reported as 76% at 5 years follow-up [2], 83% at 7 years follow-up, and 61% at ten years follow-up [26].

We found strongly significant results indicating that lower age at the time of PMC and a Larger mitral valve surface area before the procedure were the best predictors of lower overall mortality at up to 15 years follow-up with values of $P = 0.022$ and $P = 0.001$, respectively (**Table 4**).

Most studies reported that Wilkins score representing valve morphology and NYHA class were also good predictors of event-free survival at long-term follow-up [2, 17, 23, 25, 27, 28], but these factors did not return significant results for overall mortality in our study.

We believe our findings are noteworthy. The parameter for long term follow-up in the above-cited studies [2, 17, 23, 25, 27, 28] was less than 15 years, and those studies with a longer follow-up, that is, up to 15 years or more [10, 11] had a much lower mean age at the time of PMC (around 32 years). None of the cited studies had a similar combination of a mean age of 45 and a follow-up duration of 15 years, as in our study.

Based on our results, lower Wilkins score and NYHA class likely do not play a significant role in predicting mortality at this extended period of follow-up, especially in a relatively older population. They may be significant predictors for a certain period but may lose validity for more extended follow-up periods. The most powerful predictors in our study were lower age at the time of PMC and a large mitral valve surface area before the procedure. We believe that these are new findings to be added to the literature and should be considered in future trials, especially when considering older patients undergoing the procedure.

Study limitations

Loss of follow-up on 212 (66.9%) patients, due to lack of contact information or failure to appear for office visits with their cardiologists, represents an important limitation in our study. The probable reason is that most patients are referred from remote areas and have logistical challenges for attending regular follow-up. Moreover, our data were not randomized; test results were gathered at a single center with a single operator performing all procedures. This may affect the complications rate, as the provider's skills may play a role, in addition to other factors. Performing all procedures in a highly experienced center by one provider will help summarize the national data and give a relatively broad overview of the pathology and follow-up results for this disease, especially in view of the fact that our patients originated from most areas of Lebanon.

Comparison with surgery

Immediate and short-term results were similar in both approaches to those reported by Arora et al. [29] in a prospective randomized study of young patients (mean age 19 years) and a study by Raghaba et al. [30] in older patients. A prospective study was done by Turi et al. [4] that included 40 patients with severe mitral stenosis blindly randomized to either closed surgical

mitral commissurotomy or PMC. Results did not reveal differences between the groups in complications, immediate outcomes, or at 3.5-year clinical follow-up.

Farhat et al. [31] reported that 7-year results were better for PMC and open surgery in comparison with closed commissurotomy, in terms of higher event-free survival, lower restenosis rate, and better MV area.

Conclusion

There is insufficient data in the literature on long-term (up to 15 years) implications, follow-up, and predictors of mortality in patients who undergo PMC for severe mitral stenosis.

In the current study, the encouraging results after prolonged follow-up led us to conclude that PMC indications are more robust and an excellent alternative to surgery in patients with favorable valve anatomy. Patients at a lower age and with Larger pre-surface area had the best survival results in our series. Lower Wilkins score and NYHA class are not likely to play a significant role in predicting mortality at this extended period of follow-up, especially in a relatively older population. Long-term results are comparable with the surgical approach. These data afford us better insight into the possible prognosis for patients with specific baseline characteristics who will undergo PMC.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Georges Ghanem, Lebanese American University Medical Center-Rizk Hospital, Gilbert and Rose Marie Chagoury School of Medicine, Zahar Street, Achrafieh P.O. Box 11-3288, Beirut, Lebanon. Tel: +(961)3622405; Fax: +(961) 1200816; E-mail: gghanemmd@gmail.com

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