

Comparison of Open Commissurotomy and Balloon Valvuloplasty in Mitral Stenosis. A Five-Year Follow-up

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Objective

To compare clinical and laboratory data in patients with mitral stenosis undergoing open commissurotomy or balloon valvuloplasty, who were followed up for 5 years.

Methods

Eighty-one patients were prospectively assessed prior to the procedure (PRE) and immediately after the procedure, in the immediate postoperative period (IPO), and followed up yearly for 5 years (PO12M, PO24M, PO36M, PO48M, and PO60M). They were randomized into the following 2 groups: GC (group undergoing open commissurotomy): 37 patients (32.4 ± 7.2 years; 89.2% females); and GV (group undergoing balloon valvuloplasty): 44 patients (32.9 ± 9.5 years; 90.9% females). The patients' assessment comprised the following items: functional class, occurrence of events, electrocardiography, and Doppler echocardiography.

Results

A significant improvement in functional class occurred in most patients. Three patients in GC and in GV were in functional class III in PO60M. No difference in the mitral gradient was observed between the groups. A difference in the mean mitral valve areas was observed between the groups during the entire evaluation. No patients died. In regard to the IPO of GC, 3 patients had moderate mitral insufficiency (MI), and 3 had bleeding (1 was reoperated upon). In the IPO of GV, 4 patients had moderate MI, 1 had severe MI, 2 had cardiac tamponade, and 1 patient required surgery due to severe MI. Over 60 months, 9 GV patients evolved to moderate or severe MI, while 6 GC patients evolved to moderate or severe MI, and 2 other GC patients required surgery due to double mitral dysfunction.

Conclusion

The rate of success in open mitral commissurotomy and balloon mitral valvuloplasty was 100%, and the rate of complications was low. During follow-up, a mild elevation in mitral gradient and a drop in mitral valve area were observed in both groups.

Key words

mitral valve stenosis, rheumatic fever,
mitral commissurotomy, balloon mitral valvuloplasty

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In recent years, the treatment of rheumatic mitral stenosis has significantly changed^{1,2}. Balloon mitral valvuloplasty, introduced by Inoue et al³ in 1984, has become an attractive method with good results for certain patients⁴⁻⁶. Although the comparison of immediate and short-term results between open commissurotomy and balloon valvuloplasty in mitral stenosis has had similar results, the comparison of long-term results between these 2 methods has not been frequently performed.

Our study compared data obtained through noninvasive clinical and laboratory assessment – electrocardiography and Doppler echocardiography – about the use of open commissurotomy or balloon valvuloplasty in randomly selected patients with symptomatic mitral stenosis. Those data referred to the periods immediately after the procedure and a 5-year follow-up.

Methods

Eighty-one patients with mitral stenosis registered in the outpatient clinics for Valvular Heart Diseases at InCor of the Hospital das Clínicas of the Medical School of the University of São Paulo were selected with the following characteristics: a) symptoms of pulmonary veno-capillary hypertension, ie, New York Heart Association functional classes II, III, and IV; b) echocardiographic score $7 \leq 9$; c) age ≤ 60 years; d) absence of mitral insufficiency beyond a mild degree; e) no other heart disease with a surgical indication; f) no previous embolism; g) no image compatible with intracavitary thrombus on transthoracic Doppler echocardiography.

The patients were distributed into 2 groups according to randomization in a table of numbers generated by a software program as follows: a) group undergoing commissurotomy (GC) – composed by 37 patients referred for open mitral commissurotomy performed by the same surgeon; b) group undergoing valvuloplasty (GV) – composed of 44 patients undergoing mitral balloon valvuloplasty performed by the same hemodynamics technician.

After asepsis, the access route to the heart was performed through a median thoracotomy or right anterolateral thoracotomy in the 4th intercostal space, and extracorporeal circulation was installed with separated cannulas for the superior and inferior venae cava. The arterial cannula was always placed in the ascending aorta, even in lateral thoracotomies. Myocardial protection was provided with moderate hypothermia at 28°C, induced by extracorporeal circulation and crystalloid cardioplegia in all patients. Access to the mitral valve was through a left atriotomy, mitral commissurotomy being then performed, and, when pertinent, section of the papillary muscle and exeresis of the valvular calcium as well.

Balloon mitral valvuloplasty was performed through a transeptal puncture according to the previously reported technique⁸. Three (6.8%) patients underwent balloon mitral valvuloplasty according to the double-balloon technique recommended by Al Zaibag et al.⁹. The number of inflations was determined by the following: the visual aspect of the disappearance of the negative impression left by the mitral valve on the balloons; the drop in the gradient between the left atrium and the left ventricle; improvement in heart auscultation; and the absence of significant mitral insufficiency or other complications. Seven (15.9%) patients underwent mitral valvuloplasty with the bifoil balloon (Schneider Medintag), and 34 (77.2%) underwent balloon mitral valvuloplasty according to the Inoue technique³.

The patients were studied in the following clinical periods: a) prior to the procedure (PRE); b) immediately after the procedure and before hospital discharge (IPO); c) at every 12 months of follow-up (PO12M, PO24M, PO36M, PO48M, and PO60M).

Clinical and laboratory assessment comprised the following: a) data about functional class, IPO and late complications, in addition to the occurrence of an event during any period of the study; b) 12-lead electrocardiogram obtained in the PRE and PO60M periods; and c) transthoracic Doppler echocardiography performed by the same technician. The incidences, measurements, and interpretations abided by the recommendations of the American Association of Echocardiography. Electronic 3.5/2.0 MHz and 2.5 MHz transducers and mechanical 3.0 and 2.0 MHz transducers were used, respectively, for M-mode Doppler echocardiography, 2-dimensional echocardiography, and color-flow mapping. Thermo-sensitive paper was used for the recordings during the entire study.

Data referring to age, sex, functional class, cardiac rhythm, and Doppler echocardiography in the PRE period are shown in table I.

For the analysis of the efficiency of the procedures, the classical criterion of success was used, ie, the mitral valve area calculated in the IPO period on Doppler echocardiography should be ≥ 1.5 cm² or at least 50% greater than that prior to the procedure.

The descriptive analysis for quantitative variables consisted of the calculation of the means and standard deviation, and the descriptive analysis for qualitative variables consisted of the calculation of the absolute and relative frequencies. For quantitative variables, the means were compared by using the Student *t* test for independent samples. For qualitative variables, the hypothesis of the homogeneity of proportions between the 2 groups was

evaluated by using the McNemar test, chi-square test, or Fisher exact test. The Doppler echocardiographic variables in GC and GV during all periods studied were compared by using repeated-measures analysis of variance.

Results

The evolution of the functional classes in the PRE, IPO, and PO60M periods in both groups is shown in figure 1. A significant improvement in functional class was observed in both groups.

In GC, 3 (8.1%) patients were in functional class I/II, and 34 (91.9%) patients in functional class III/IV in the IPO period. Assessment in the PO60M period showed maintenance ($P < 0.0001$) of the functional class in most patients, 34 (91.9%) of whom evolved to functional class I/II, and 3 (8.1%) to functional class III/IV. The evolution of the functional class between the IPO and PO60M periods and between the PO12M and PO60M periods was compared, and no statistical difference between the 2 periods was observed ($P < 0.2482$), showing maintenance of the clinical results obtained immediately after the procedure. All 3 patients in functional class III/IV in the PO60M period were diagnosed with mitral restenosis; 2 were waiting for a new procedure and another underwent balloon mitral valvuloplasty.

In GV, 40 (91.9%) patients were in functional class I/II and 2 (8.1%) in functional class III/IV in the IPO period. However, a significant improvement in functional class was observed in the PO60M period ($P < 0.0001$) as follows: 37 (92.5%) patients in functional class I/II and only 3 (7.5%) patient in functional class III/IV. Two (5.0%) patients underwent mitral valve replacement

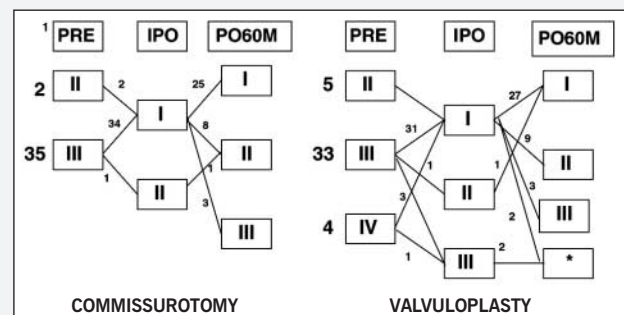


Fig. 1 – Evolution of the NYHA functional class in both groups prior to the procedure (PRE), immediately after the procedure and before hospital discharge (IPO), and after a 60-month follow-up (PO60M). * = Surgery.

Table I - Demographic characteristics of the patients in both groups prior to the procedures.

Characteristics	Commissurotomy (n= 37)	Valvuloplasty (n = 44)	<i>p</i>
Age (years)	32.5 ± 7.2 (20-54)	32.9 ± 9.5 (15-54)	NS
Sex (Female)	33 (89.2%)	40 (90.9%)	NS
NYHA functional class *			NS
II	3 (8.1%)	4 (9.0%)	
III/IV	34 (91.9%)	40 (91.0%)	
Cardiac rhythm			NS
Sinusal	32 (86.5%)	41 (93.2%)	
Atrial fibrillation	5 (13.5%)	3 (6.8%)	
Echocardiographic score †	7.1 ± 1.3	7.1 ± 1.1	NS
Mitral gradient (mm Hg)	12.0 ± 5.1	12.2 ± 6.7	NS
Mitral valve area (cm ²)	0.94 ± 0.20	1.1 ± 0.2	0.0005

* NYHA = New York Heart Association; † According to the criteria of Wilkins et al.⁷.

Table II – Doppler echocardiographic variables prior to and after the procedures.

	Mitral Valve Area (cm ²)		Mitral Gradient (mm Hg)	
	Commissurotomy	Valvuloplasty	Commissurotomy	Valvuloplasty
PRE	0.94 ± 0.20	1.10 ± 0.20	12.0 ± 5.1	12.2 ± 6.7
IPO	2.60 ± 0.44	2.20 ± 0.30	5.4 ± 2.3	4.7 ± 2.5
PO12M	2.20 ± 0.30	2.10 ± 0.40	5.0 ± 2.2	5.4 ± 3.2
PO24M	2.00 ± 0.40	2.00 ± 0.40	5.4 ± 1.7	5.5 ± 2.6
PO36M	1.90 ± 0.40	2.00 ± 0.40	5.5 ± 2.0	5.8 ± 3.2
PO48M	1.90 ± 0.40	1.80 ± 0.30	5.6 ± 2.2	6.1 ± 3.4
PO60M	1.70 ± 0.40	1.80 ± 0.40	5.6 ± 2.7	5.0 ± 2.4

PRE= prior to the procedure; IPO= immediately after the procedure; PO12M= 12 months after the procedure; PO24M= 24 months after the procedure; PO36M= 36 months after the procedure; PO48M= 48 months after the procedure; PO60M= 60 months after the procedure. P values are shown in figures 2 and 3.

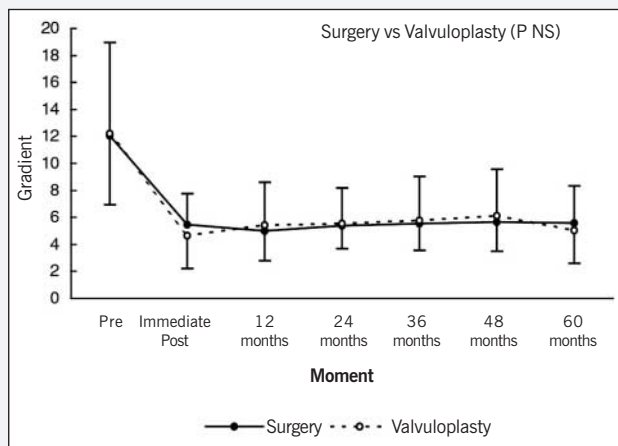


Fig. 2 – Behavior of the mean mitral transvalvular gradient (mm Hg) on echocardiogram in both groups during the study.

with a bioprosthesis due to double mitral dysfunction, 1 (2.5%) underwent mitral valvuloplasty due to significant mitral insufficiency during the IPO period, and another underwent mitral commissurotomy due to mitral restenosis. When comparing the functional class evolution in GV between the IPO and PO60M periods and between the PO12M and PO60M periods, no significant difference (P=1.0000) was observed, showing maintenance of the clinical results observed after the procedure.

The behavior of the mean mitral transvalvular gradient showed a similar behavior between the groups throughout the study (P=0.56799) (tab. II and fig. 2). The mean values were different between the periods assessed (P=0.0001). A difference between the means of the PRE and all other periods studied was observed (P=0.0001).

A 100% success rate was observed in both groups. The behavior of the mean values of the mitral valve area throughout the assessments between GC and GV showed a statistically significant difference (P=0.0005). The results are shown in figure 3 and table II.

Data on the evolution of cardiac rhythm in both groups between the PRE and PO60M periods revealed that most (91.9%) patients in GC had no change in cardiac rhythm; however, of the 2 (2.7%) patients with junctional rhythm in the PRE period, 1 (2.7%) evolved to sinus rhythm and the other to atrial fibrillation rhythm in the PO60M period. On the other hand, 1 (2.7%) patient who had sinus rhythm evolved to atrial fibrillation rhythm at the PO60M. No GV patient had changes in cardiac rhythm throughout the 60 months of follow-up.

In regard to the IPO period, in GC, moderate mitral insufficiency was recognized in 3 patients (2 of whom did not have it in the PRE period) and mild mitral insufficiency in 11 (7 of whom did not have it in the PRE period, and 2 already had mild mitral insufficiency in the PRE period). In regard to the PO60M period, of the 14 patients diagnosed with mitral insufficiency on Doppler echocardiography in the IPO period, 7 (50.0%) patients had a reduction in the degree of mitral insufficiency, while 4 (28.6%) had an increase in it. Mitral insufficiency appeared in 13 (56.5%) of the 23 patients who did not have it in the IPO period.

In regard to the IPO period, in GV, the Doppler echocardiographic study allowed the identification of the following degrees of mitral insufficiency: severe in 1 patient, who did not have it in the PRE period and was referred for mitral valvuloplasty; moderate mitral insufficiency in 4 patients, 3 of whom did not have it and 1 had it to a mild degree in the PRE period; and mild mitral insufficiency in 23 patients, 17 of whom did not have it and 6 with a mild degree in the PRE period. In regard to the PO60M period, of

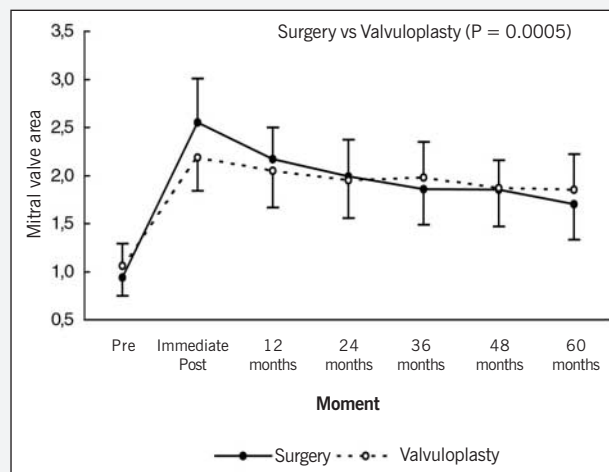


Fig. 3 – Behavior of the mean mitral area (cm²) on Doppler echocardiogram in both groups during the study.

Commissurotomy		Valvuloplasty	
Moment	P value	Moment	P value
Pre vs Immediate Post	0.0001	Pre vs Immediate Post	0.0001
Immediate Post vs 12 months	0.0001	Immediate Post vs 12 months	0.0176
12 months vs 24 months	0.0025	12 months vs 24 months	NS
24 months vs 36 months	0.0462	24 months vs 36 months	NS
36 months vs 48 months	NS	36 months vs 48 months	0.0081
48 months vs 60 months	0.0036	48 months vs 60 months	NS



the 27 patients with mild or moderate mitral insufficiency in the IPO period, a reduction in the insufficiency degree was observed in 10 (35.7%) patients, while an increase was observed in 4 (14.3%) patients, 2 of whom had a bioprosthesis implanted, 1 had undergone mitral valvuloplasty, and another had undergone mitral commissurotomy.

No statistically significant difference was observed between the groups in regard to the behavior of the mitral insufficiency ($P=0.0233$).

In regard to GC, 3 (8.1%) patients experienced bleeding, 1 of whom required reoperation, and the other (2.7%) underwent implantation of a transient pacemaker due to junctional bradycardia. In regard to GV, 2 (4.6%) patients had cardiac tamponade and 2 others (4.6%) had perforation of cardiac chambers with no cardiac tamponade, undergoing, then, pericardial drainage.

No patients died during the 60-month follow-up. In GC, 1 (2.7%) patient had an ischemic stroke due to chronic atrial fibrillation with no oral anticoagulant use, and 2 others (5.4%) evolved with paroxysmal atrial fibrillation. In GV, 2 (4.6%) patients evolved with double mitral dysfunction and underwent bioprosthesis implantation on the 42nd day and 45th month of follow-up. One (2.3%) patient evolved with mitral restenosis and underwent mitral commissurotomy 48 months after balloon mitral valvuloplasty. One (2.3%) patient evolved with paroxysmal atrial fibrillation, and another (2.3%) had a transient ischemic episode, despite his sinus rhythm, oral anticoagulation then being introduced.

Discussion

Currently, patients with isolated mitral stenosis are very frequently encountered in clinical practice. Surgical treatment through open or closed mitral commissurotomy has provided excellent results with the mortality rate not exceeding 3% and varying according to the clinical status of the patient and the experience of the surgical team¹⁰⁻¹². From 1984 onwards, balloon valvuloplasty has been incorporated to daily practice for the treatment of patients selected with mitral stenosis³.

In our study, only ideal candidates for balloon mitral valvuloplasty were selected. The analysis of the echocardiographic score showed no difference between the groups indicating that the valve morphology features had no influence on the comparison between groups.

In regard to functional class, the results provided by balloon mitral valvuloplasty are similar to those obtained with open commissurotomy^{13,14}. However, Patel et al¹⁵ and Shrivastava et al¹⁶ reported that the results of balloon mitral valvuloplasty were better than those of closed mitral commissurotomy. The procedures of section of the papillary muscle, decalcification, and removal of left atrium thrombi performed during open commissurotomy are believed to influence the results of the mitral valve area.

On the other hand, the causes determining nonregression of the functional class after the procedure are nonsuccess and development of mitral regurgitation or restenosis.

The hemodynamic improvement expressed as a significant and similar drop in the mitral transvalvular gradient (mmHg) in both groups in the IPO period and its maintenance throughout the 60-month follow-up shows the capacity of the 2 therapeutic methods to immediately relieve the pressure in the left atrium, and, consequently, in the pulmonary circulation. Measurement of

the mitral valve area is the most important criterion to assess the degree of success of the therapeutic intervention. In addition, the value of the mitral valve area in the IPO period is related to long-term prognosis. Some authors¹⁷ have shown that a mitral valve area close to 2.0 cm² immediately after balloon valvuloplasty was associated with a lower chance of restenosis.

The 100% rate of success obtained in both groups may have resulted from the application of the upper limit of 9 of the echocardiographic score to all patients.

After the first promising results of balloon mitral valvuloplasty, the first studies comparing the results of the surgical procedure and that new percutaneous technique^{18,19} began to be reported. Our results do not agree with those found by Patel et al¹⁵, who compared the results of balloon mitral valvuloplasty with those of closed commissurotomy. Our results also do not agree with those found by Reyes et al²⁰, who reported a mitral valve area after balloon valvuloplasty greater than that obtained with mitral commissurotomy by using hemodynamics. We believe that this divergence occurred due to differences in the techniques and methods used for obtaining the mitral valve area.

In our study, throughout the 60-month follow-up, a reduction in the mitral valve area was observed in both groups. This confirms that neither of the 2 methods leaves the mitral valve free from progression, which may be of a scarring nature. This process of reduction in the mitral valve area was more evident in the GC.

Balloon mitral valvuloplasty had more complications than mitral commissurotomy did, mainly those related to transeptal puncture and manipulation of guidewires and catheters inside the cardiac cavities. Currently, the mortality rate in several series has ranged from 1 to 2%, which may be even minimized with improvement in the learning curve. Recent studies²¹ have shown that this limit is currently below 1%. The experience of the hemodynamics technician, the appropriate selection of patients, and the improvement in the technique used have contributed to decrease the rate of complications.

Significant mitral insufficiency during commissurotomy and in its postoperative period¹ may appear in 4% of patients, being influenced by the presence of mitral insufficiency and calcification in the leaflets in the preoperative period. After balloon mitral valvuloplasty, approximately one third to 50% of patients²² may have mild mitral insufficiency. However, the presence of greater degrees of mitral insufficiency may range from 4 to 8%.

In our study, significant mitral insufficiency in the IPO period was observed on Doppler echocardiography in only 1 (2.3%) GV patient, who underwent surgical repair of the mitral valve. The need for surgical correction of significant mitral insufficiency following balloon valvuloplasty usually leads to valve replacement. However, depending on the mechanism that caused the mitral insufficiency, a conservative surgery may be possible.

The incidence of cardiac tamponade after balloon mitral valvuloplasty may range from 0 to 9.3%²³, and it has been decreasing since the beginning of the experience with this method. This decrease in the incidence of cardiac tamponade may be attributed to the learning curve with the transeptal puncture technique. In our series, 2 patients had cardiac tamponade diagnosed later, after the end of the procedure, which required only pericardial drainage without complementation with mitral commissurotomy.

Despite the extensive literature, the determination of predictive

factors of medium- and long-term good results in patients undergoing balloon mitral valvuloplasty is still controversial. Chen and Cheng²⁴ reported indices of restenosis of 5.2%. In France, Lung et al²⁵ identified the following predictive factors of long-term good evolution: echocardiographic score, functional class, cardiothoracic index, and valve area prior to the procedure. In our study, 1 (2.3%) patient evolved with restenosis, undergoing open mitral commissurotomy 48 months after balloon valvuloplasty. On the other hand, the occurrence of 2 (4.6%) patients evolving with double mitral dysfunction and requiring surgery on the 42nd day and in the 45th month after balloon valvuloplasty is below that reported in the literature²⁶. The occurrence of a reduction in the valvular opening in both groups shows that the scarring process probably caused by the action of the blood jet on the mitral valve is inherent to both methods. This finding has also been observed in a study by Cardoso

et al²⁷ with a similar case series in the second year of clinical follow-up, confirming that the 2 methods do not necessarily cause definitive changes in the progression of the valvular heart disease.

In conclusion, both methods provided a 100% rate of success and a low rate of complications associated with a drop in functional class and mitral gradient, and an increase in mitral valve area in the IPO period. During follow-up, the functional class did not change in most patients, and a mild elevation in the mitral gradient and a decrease in the mitral valve area were observed in both groups, mainly in the patients undergoing commissurotomy.

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