

Percutaneous Mitral Valvotomy in Patients Eighteen Years Old and Younger. Immediate and Late Results

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Objective – To analyze immediate and late results of percutaneous mitral valvotomy (PMV) in patients ≤ 18 year.

Methods - Between August '87 and July '97, 48 procedures were performed on 40 patients. The mean age was 15.6 years; 68.7% were females four of whom were pregnant.

Results – Success was obtained in 91.7% of the procedures. Immediate complications were severe mitral regurgitation (6.3%) and cardiac tamponade (2.0%). Late follow-up was obtained in 88.8% of the patients (mean value = 43.2 ± 33.9 months). NYHA functional class (FC) I or II was observed in 96.2% of the patients and restenosis developed in five patients, at a mean follow-up of 29.7 ± 11.9 months. Three patients presented with severe mitral insufficiency and underwent surgery. Two patients died.

Conclusion - PMV represents a valid therapeutic option in young patients. In these patients, maybe because of subclinical rheumatic activity, restenosis may have a higher incidence and occur at an earlier stage than in others persons.

Key words: mitral valvotomy, restenosis, teenagers.

Rheumatic valvar disease is still relatively frequent in developing countries, occurring in 25% to 40% of patients with cardiac diseases¹. Surgical treatment through closed mitral commissurotomy, was initially proposed by Cutler et al² in 1923. As an alternative to surgical treatment, Inoue et al³ in 1984, described a technique for percutaneous mitral valvotomy using a balloon catheter created by themselves and an antegrade access. Using this via, a valvar opening is created by the separation of the commissures by the centrifugal force generated by the balloon at the level of the mitral valvar ring. Immediate and late results obtained with percutaneous treatment throughout the years have been found to be similar to those obtained with classical surgical treatment, with the advantage of having a lower rate of morbidity and mortality⁴⁻⁶. Therefore, percutaneous mitral valvotomy is now the first therapeutical choice for treating mitral stenosis in selected patients.

Patients with rheumatic mitral stenosis who undergo surgery during childhood or adolescence, need to undergo other procedures during the follow-up of their disease due to the incidence of rheumatic attacks at this early age⁷. These new interventions may increase morbidity and mortality in this young group. Taking these data into consideration, we decided to use PMV as a first-choice therapy at our institution in patients ≤ 18 years.

The objective of this study was to describe early results and late clinical follow-up of patients at this young age who underwent PMV for treatment of rheumatic mitral stenosis.

Methods

Between August '87 and July '97, 882 percutaneous procedures for mitral valve openings were performed at our institution in patients previously selected. Forty-eight (5.4%) were performed in 40 patients ≤ 18 years. In this group, mean age ranged from 10 to 18 years, with a mean age of 15.6, and 33 (68.7%) were females. All patients were in sinus rhythm, and only one patient had had a previous surgical mitral valve commissurotomy. It is important to note that four patients

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(8.3%) were pregnant and did not respond to conventional clinical therapy, necessitating the intervention between the 13th and 34th weeks of pregnancy. Before percutaneous mitral valvotomy, six patients (15%) were in NYHA functional class (FC) IV, 21 (52.5%) in FC III and 13 (32.5%) in FC II (table I).

The indications for the procedure were a mixture of clinical, radiological and echocardiographic findings, that is, symptomatic patients with a mitral valve area $\leq 1\text{cm}^2$ and a score ≤ 12 points by echocardiographic criteria⁸. The presence of thrombus in the left atrium (LA) and/OR, associated mitral regurgitation $>2+/4+$, according to Seller's classification⁹ were considered exclusion criteria.

A Doppler echocardiogram was performed in all patients before the procedure, 48 hours afterwards and once a year during late follow-up. Valve anatomy, peak and mean diastolic gradients, and mitral valve area (MVA) calculated by planimetry were assessed in all patients. Morphology of the mitral valve and subvalvular apparatus was analyzed according to the criteria proposed by Wilkins et al⁸, and mitral regurgitation was quantitated when present.

All selected patients underwent a Cardiac Catheterization both before and after the procedure. This study included right and left heart catheterization performed through the puncture of the right femoral vein and left femoral artery. Manometry was obtained, including right chamber pressures and the gradient between mean LA pressure and left ventricular end diastolic pressure. Left ventriculography was performed at 30° in the oblique anterior view to analyze the mitral subvalvular apparatus and to quantitate mitral regurgitation, when present. Aortography at 45° in the left anterior oblique view was obtained to assess associated aortic lesions. After valvotomy and consequent opening of the mitral valve, left atrigraphy at 30° in the left anterior oblique view was obtained to analyze LA emptying and another left ventriculography was performed to detect mitral regurgitation at this view.

Valvotomy was always performed using the antero-graduate access through the puncture of the atrial septum, as described by Brockenbrough¹⁰. Heparin (100U.i/kg) was given to all patients after puncture of the atrial septum. Both the double balloon and the Inoue techniques were used (table II).

The procedure was considered successful when the mitral valve area became $\geq 1.5\text{cm}^2$ and when no complications, such as severe mitral regurgitation or left-to-right shunt $>1.5:1$ through the residual atrial septal defect (ASD), occurred.

Age (years)	10-18 (mean = 15.5±2.2)
Sex	Female 33 (68.7%) Male 15 (31.3%)
Sinus rhythm	48
Previous commissurotomy	1 (2.0%)
Pregnancy	4 (8.3%) 13°-34° week. (mean=27.7±8.5)
Echocardiographic score	5-10 (mean = 7.7±1.3)
Functional Class (NYHA)	
II	13 (32.5%)
III	21 (52.5%)
IV	6 (15.0%)

Restenosis was defined as a loss of $>50\%$ of the mitral valve area obtained right after the procedure.

Results

Immediate Results - A transseptal puncture was performed without complications in 47 of the 48 procedures, and the mitral valve was successfully dilated in 44 (91.7%) patients. In only one patient could the procedure not be completed due to a complication of the transseptal puncture with subsequent hemopericardium and signs of cardiac tamponade.

The mean mitral valve area assessed by planimetry and by the pressure half-time method increased from 0.86 ± 0.21 to $2.03\pm 0.50\text{cm}^2$ after percutaneous mitral valvotomy ($p<0.00001$). Doppler echocardiography showed a decrease in peak and mean gradients of 26.0 ± 7.1 to $13.7\pm 3.9\text{mmHg}$ and from 15.3 ± 5.4 to 6.0 ± 2.5 ($p<0.00001$) respectively, right after the procedure.

Manometry data obtained at right and left catheterization showed a decrease in mean LA pressure: 29.0 ± 7.3 to $12.5\pm 6.1\text{mmHg}$ ($p<0.00001$). The same happened to the mean diastolic gradient and the mean pulmonary pressure, which decreased respectively from 21.7 ± 6.08 to $4.4\pm 3.0\text{mmHg}$ ($p<0.00001$) and from 42.1 ± 15.6 to $28.7\pm 11.5\text{mmHg}$ ($p<0.005$) (table III).

Regarding mitral regurgitation, which represents the most frequent complication of this procedure, of 37 patients with no previous mitral regurgitation, 28 did not have it at the control ventriculography. Five patients developed a $1+/4+$ mitral regurgitation, according to Seller's classification, one a $2+/4+$, two a $3+/4+$ and one $4+/4+$. Of nine procedures with previous $1+/4+$ mitral regurgitation, six did not show any change while three increased their regurgitation to a $2+/4+$. In the only procedure with an initial $2+/4+$ mitral regurgitation, no change occurred in the degree of regurgitation at a control ventriculo-

1) Double balloon *	- 36 procedures (76.6%)
•	20 + 20 = 20
•	20 + 18 = 8
•	18 + 15 = 4
•	18 + 18 = 3
•	20 + 15 = 1
EBDA/BSA (cm^2/m^2) = 3.6 ± 0.29 (effective balloon dilation area/body surface)	
(2) Inoue	- 11 procedures (23.4%)

Echocardiogram	Pre	Post	P
MVA (cm^2)	0.86 ± 0.21	2.03 ± 0.50	<0.00001
Peak Gradient (mmHg)	26.0 ± 7.1	13.7 ± 3.9	<0.00001
Mean Gradient (mmHg)	15.3 ± 5.4	6.0 ± 2.5	<0.00001
Catheterization			
LA (mmHg)	29.0 ± 7.3	12.5 ± 6.1	<0.00001
Mean Gradient (mmHg)	21.7 ± 6.8	4.4 ± 3.0	<0.00001
Mean PA pressure (mmHg)	42.1 ± 15.6	28.7 ± 11.5	<0.005

MVA- mitral valve area; LA – left atrium; PA- Pulmonary Artery pressure

graphy (fig. 1). Therefore, mitral regurgitation was found to develop to appear or increase in intensity in 12 (25.4%) of the 47 completed procedures, being 3+/4+ and 4+/4+ in 3 (6.3%).

The development and the measurement of the ASD were assessed by oximetry (QP/QS<1.5/1) and by Doppler echocardiogram. In 10 procedures where a left-to-right shunt was detected, the ASD was not greater than 3mm in diameter.

There were no embolic events or hospital deaths in this group of patients.

Success was not obtained in four procedures in one perforation of the LA free wall occurred during the atrial septal puncture with consequent cardiac tamponade that required emergent surgery. In the remaining three, after balloon valvotomy, severe mitral regurgitation was detected by left ventriculography, and all three patients underwent urgent mitral valve replacement surgery

Late results – Late follow-up was obtained in 32 (80%) of the 40 patients who underwent percutaneous mitral valvotomy. Twenty-four (75%) were females and mean follow-up was 43.2±33.9 months.

Of these 32 patients (fig. 2), three were referred for elective valve replacement surgery (two because of mitral insufficiency and one because of restenosis). In the remaining 29 patients,

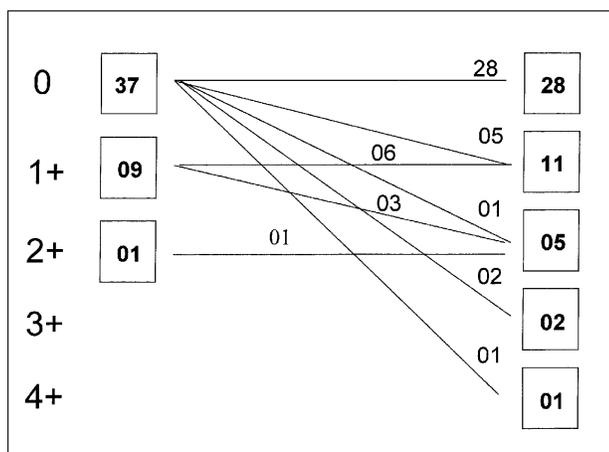


Fig. 1 – Mitral insufficiency (47 procedures).

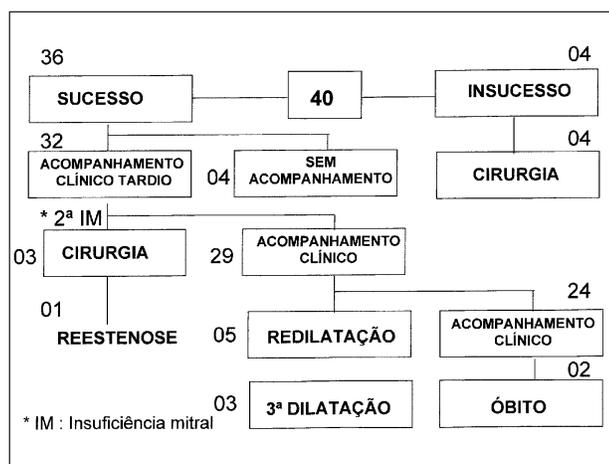


Fig. 2 – Population (40 patients).

five developed restenosis in a mean period of 29.7±11.9 months and were successfully redilated. In three of these a third redilatation was performed due to a new restenosis. Therefore, eight redilations were performed in five patients.

In this group of 40 patients, two late deaths occurred, one probably due to restenosis (acute pulmonary edema) and the other due to a non related cause (septicemia).

A better NYHA FC at follow-up was observed with significant improvement in the quality of life of these patients. In the observed follow-up period, 24 (75%) patients were in NYHA FC I and only three (11.2%) were in FC II or III. At follow-up, 30 patients remained in sinus rhythm, and only two developed atrial fibrillation. All four pregnant women had a term cesarean delivery while in FC I and no fetal deaths or associated malformations occurred.

Echocardiographic parameters of MVA and peak and mean gradients at follow-up are described in table IV.

Discussion

Data reporting the immediate results obtained in this group of patients do not differ significantly from those observed in the general population undergoing this type of procedure¹¹. The efficacy of this method in this age group was demonstrated by the final MVA, the reduction of mean LA pressure, of the pulmonary artery pressure and of the mean diastolic transmitral gradient.

As for immediate complications, a residual ASD was observed in 21.2% of the patients by a Doppler echocardiogram performed 48 hours after the procedure, a phenomenon also reported in the majority of published studies¹⁰. In our experience, the created defect was always small, and a significant residual shunt was not observed in any of the cases. We think that the persistence of this defect occurs mainly in those patients where final results of the MVA are considered suboptimal (<1.5cm²), due to the persistence of an elevated pressure in the left atrium¹².

The incidence of mitral regurgitation (27.2%) is similar to that observed by us in the general population(29.2%)¹¹. As is well known, the main predictors of this complication are oversizing of the balloon¹³, commissural or leaflet calcification or both and the intensity of the involvement of the mitral subvalvar apparatus¹⁴. In our series of patients, the development of severe mitral regurgitation was directly related to the degree of valvar involvement before valvotomy, especially when MVA was ≤0.9cm².

In this group, because patients were young, calcification was uncommon, and the involvement of the subvalvar apparatus was usually mild, our main concern was the exact diameter of the balloon, especially when MVA was <0.9 cm².

Echocardiogram	Post	Late	P
Mitral valve area (cm ²)	2.03±0.50	1.91±0.50	NS *
Peak gradient (mmHg)	13.7±3.9	11.5±4.9	NS
Mean gradient (mmHg)	6.0±2.5	4.8±2.6	NS

*NS- nonsignificant.e

Therefore, when the double balloon technique was employed, we used an EBDA/BSA < 3.5 relation and, when the Inoue balloon was the one chosen, we used the formula suggested by the author and subtracted 1 mm. Even having done that, three procedures were followed by a 3+/4+ or 4+/4+ mitral regurgitation, which required urgent surgery. Some degree of involution of acute mitral insufficiency has been described in the literature in a certain percentage of patients¹⁵ and is probably related to the elastic retraction of the mitral ring, to commissural fusion and fibrosis and to the improvement of posttraumatic dysfunction (edema) of the papillary muscles caused by the balloon. However, this phenomenon was not observed in this group of patients.

Late follow-up data obtained at a mean period of 43.2±33.9 months showed that the great majority of the patients (88%) were in NYHA FC I and atrial fibrillation occurred in only two patients.

No statistically significant difference occurred between immediate and late echocardiographic parameters, such as MVA, mean LA pressure, mean pulmonary artery pressure and, finally, mean transmitral diastolic gradient, which demonstrates the efficacy of the procedure in the medium-term follow-up.

We believe that the relatively high index of restenosis (15.6%) detected in five of the 32 patients in a relatively short period of time (29.7±11.9 months) is above the observed in the index described in the literature for the general population, which is around 10% in five years, both for percutaneous or surgical treatment¹⁵⁻¹⁷. The observed re-stenosis in the present study is probably not directly related to the use of undersized balloons in both techniques, because our immediate results do not differ significantly from those previously observed by us.

Predisposing factors related to development of restenosis classically described are: old age, atrial fibrillation and a high echocardiographic score index (mainly the degree of thi-

ckening and the presence of calcium in the leaflets)¹⁸. In this group, these findings were uncommon because of the young age of the patients, and we think that restenosis may have been caused by recurrent subclinical rheumatic attacks, which usually can not be detected clinically or by laboratory tests.

Based on these results and considering the problem imposed by future re-interventions, we believe that percutaneous treatment should be the primary intervention, because its immediate and late results are similar to those obtained by surgery⁴⁻⁶, which has a higher morbidity. Another advantage of the percutaneous procedure is that redilatations can be performed without technical difficulties in the additional procedures and without a higher incidence of complications.

It is well known that rheumatic disease has a chronic and progressive course and young patients are prone to undergoing more than one valvular procedure during their lifetime. Therefore, when this becomes necessary, surgery can be performed without the inherent risks of a previous thoracotomy.

Analyzing these data, we believe that percutaneous mitral valvotomy is a valid therapeutic option for the treatment of severe rheumatic mitral stenosis in patients under 18. In this population, the incidence of restenosis is relatively higher and occurs earlier than in the general population. This is probably related to the occurrence of subclinical attacks of rheumatic disease or to a more malign valvar involvement of the disease in this age group.

It has also been demonstrated that the technique can be repeated in cases of restenosis without additional technical implications or more complications. We therefore conclude that percutaneous mitral valvotomy should be the method of choice for the treatment of severe rheumatic mitral stenosis in patients under 18 years of age.

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