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Original Article

Percutaneous balloon mitral valvuloplasty: experiences at the "Cardiocentro" in Santiago de Cuba

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Abbreviations
LAP: left atrial pressure
MS: mitral stenosis
MVA: mitral valve area
PBMV: percutaneous balloon mitral valvuloplasty

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ABSTRACT

Introduction: Percutaneous balloon mitral valvuloplasty has flourished as a mainstream therapy (mostly in developed countries) for treating patients with medical indication and those suffering from rheumatic mitral stenosis. This procedure is performed at the "Cardiocentro" in Santiago de Cuba since July 2008.
Objectives: To describe the results of percutaneous balloon mitral valvuloplasty in the study participants.
Methods: A descriptive, single-centered and observational study including 91 patients treated by this procedure was conducted at the "Cardiocentro" in Santiago de Cuba from July 2008 to June 2019. Clinical/epidemiological, echocardiographic and hemodynamic variables were assessed, as well as immediate procedure outcomes.
Results: Young individuals (60.4% between 15-44 years), female (86.8%), with a history of rheumatic fever (48.4%), NYHA (New York Heart Association) functional class III (64.8%) and sinus rhythm (86.8%) predominated. An average increase in valve area of over double (0.99 vs. 2.12 cm^2) the initial value and a reduction in atrial pressure of more than 50% (25 vs. 11.76 mmHg) was achieved; thus evidencing that the treatment was effective in 95.6% of the patients. A significant association (Fisher Test ≤ 0.05) was identified between Wilkins score ≤ 8 and satisfactory outcome of the procedure.
Conclusions: The results of percutaneous balloon mitral valvuloplasty in the medical center were successful and consistent with those achieved nationally and internationally.
Keywords: Balloon Valvuloplasty, Percutaneous mitral valvuloplasty, Structural heart intervention, Mitral valve stenosis, Rheumatic Fever

Valvuloplastia mitral percutánea con balón: experiencia en el Cardiocentro de Santiago de Cuba

RESUMEN

Introducción: La valvuloplastia mitral percutánea con balón actualmente es el primer procedimiento terapéutico que se contempla en el mundo desarrollado para los pacientes con estenosis mitral reumática e indicación para ello, y se realiza en el Cardiocentro de Santiago de Cuba desde julio de 2008.
Objetivo: Describir los resultados de la valvuloplastia mitral percutánea con balón en los pacientes estudiados.
Método: Se realizó un estudio observacional y descriptivo, unicéntrico, que incluyó a 91 pacientes tratados mediante este procedimiento en el Cardiocentro de Santiago de Cuba, desde julio de 2008 hasta junio de 2019. Se evaluaron variables

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clínico-epidemiológicas, ecocardiográficas y hemodinámicas, así como el resultado inmediato del procedimiento.
Resultados: Predominaron los pacientes jóvenes (60,4% entre 15-44 años), del sexo femenino (86,8%), con antecedentes de fiebre reumática (48,4%), en clase funcional III (64,8%) de la NYHA (New York Heart Association) y en ritmo sinusal (86,8%). Se logró un aumento promedio del área valvular de más del doble (0,99 vs. 2,12 cm^2) del valor inicial y una reducción de la presión auricular mayor de 50% (25,0 vs.11, 76 mmHg), lo que permitió evaluar de satisfactorio el tratamiento en el 95,6% de los pacientes. Se identificó una asociación significativa (Prueba de Fisher ≤ 0,05) entre la puntuación de Wilkins ≤ 8 y el resultado satisfactorio del procedimiento.
Conclusiones: Los resultados de la aplicación de la valvuloplastia mitral percutánea con balón en el centro fueron satisfactorios y congruentes con los referidos nacional e internacionalmente.
Palabras clave: Valvuloplastia con balón, Valvuloplastia mitral percutánea, Intervencionismo cardiaco estructural, Estenosis de la válvula mitral, Fiebre reumática

INTRODUCTION

Percutaneous mitral valvuloplasty is currently the first therapeutic procedure indicated in developed countries to patients with rheumatic mitral stenosis (MS)[1]. With the reduction in the incidence of rheumatic fever, particularly in temperate climates and developed countries, the incidence of MS considerably decreased in recent decades, but in developing countries, and especially in those located in tropical and semi-tropical climates, it remains a major problem[2].

In Cuba, it still constitutes a disease of primary importance. In 2015, according to data from the statistical yearbook of the Ministry of Public Health, 150 patients died due to chronic rheumatic heart diseases, for a rate of 1.3 deaths per 100 000 inhabitants[3].

About 25% of all patients with a rheumatic heart disease have an isolated MS and about 40% have mitral regurgitation and mitral stenosis combined; on the other hand, the predominant cause of MS is rheumatic fever, and rheumatic changes are observed in 99% of the mitral stenosed valves removed at the moment of the valve replacement[4]. Although medical treatment can alleviate symptoms, it does not influence the degree of the valve obstruction. During many years, this disease could only be corrected with a closed commissurotomy and later, with an open one (with the use of cardiopulmonary bypass). However, as stated by Otto and Bonow[5], the development of percutaneous balloon mitral valvuloplasty (PBMV) by Inoue in 1984, and Lock in 1985, has opened new horizons in the treatment of this valve disease.

This interventional technique consists of the insufflation of one or more balloons through the mitral valve. It is accessed through the right femoral vein, reaching the atrium on the same side and, via transeptal, reaching the left atrium, where the fused commissures are opened, thus decreasing the gradient, increasing the mitral valve area (MVA) and improving the symptoms[6]. Generally, with PBMV, the MVA can be doubled and the gradient decreased in a 50-65%. Technical success and complications are related to the patients' selection process and the operator´s experience. Good initial results, which are achieved in more than 80% of cases, are defined by an MVA higher than 1.5 cm^2 (or higher than 1.0 cm^2 per square meter of body surface), without mitral regurgitation > 2/4 and a decrease in left atrial pressure (LAP) below 18 mmHg[6].

The indications in patients with unfavorable anatomy continue to be discussed; in these cases, for decision making, the multifactorial nature of the technique's results prediction and the relative experience of the center in these procedures should be taken into account[7].

The published mortality, according to most authors, is between 1-2%; but with the increase in the experience of the working teams and thanks to a more accurate patients' selection process, a mortality rate of less than 1% has been achieved.

In Cuba, until 1998, the treated cases were scarce and carried out by foreign medical personnel. From then on, the technique began to be developed by Cuban doctors, and from the very beginning, Doctor Echarte Martínez and his collaborators[8] published the successful results of the first percutaneous mitral valvuloplasties carried out in Cuba. Later on, studies carried out in the country have continued to be pub-

lished, which evidence the convenience of carrying out this technique that, besides achieving satisfactory clinical results, has also shown favorable economic outcomes, with an average institutional cost lower than that of surgical valvuloplasty[9].

In Santiago de Cuba, the PBMV has been carried out since July 2008, in the Hemodynamics Laboratory of the *Cardiocentro* from Santiago de Cuba, which belongs to the *Hospital Provincial Saturnino Lora*. Based on all the above, the current research was proposed, with the aim of describing the results of percutaneous mitral valvuloplasty in patients who had this procedure at the mentioned institution; besides, with this work we meet some objectives of the National Program for the Control of Cardiovascular Diseases, which represents a priority research task for the Department of Cardiology from the referred center.

METHOD

An observational, descriptive case series study was carried out, where the 91 patients who have had percutaneous mitral valvuloplasty at the *Cardiocentro* from Santiago de Cuba were included, since this technique was started in July 2008 until June 2019.

Epidemiological variables (age, sex), clinical variables (main symptoms, functional class, basal heart rhythm), as well as echocardiographic and hemodynamic variables, were studied. Complications associated with the procedure and its immediate results were also taken into account.

The aim of percutaneous mitral valvuloplasty is to increase MVA, since this decreases the gradient, LAP, and the symptoms improve or disappear. The echocardiography plays an important role in the assessment of the procedure's final results, and in these patients, it was used to determine the MVA. The LAP was measured during the hemodynamic study.

Averages, standard deviations, and percentages were calculated as summary measures of the information, and the Chi square test of independence was applied to identify the statistical association among the variables of interest, with a significance level of α=0.05 (which was considered statistically significant when $p<\alpha$); in addition, a 95% confidence interval was estimated in the patients' population for the percentage of the satisfactory outcome after the procedure.

RESULTS

When patients were distributed according to age and sex, the age group between 15 and 44 years old (60.4%) and the female sex (79 patients, 86.8%) were predominant. The 48.4% of the patients taking part in the study had a history of rheumatic fever, followed by recurrent tonsillitis (33.0%). It is noteworthy that 24.2% of patients did not report any pathological history of interest.

The distribution of patients according to their main symptoms (**Table 1**) shows that dyspnea (remarkably predominant [90.1%]), palpitations (24.2%) and easy fatigue (18.7%) were more frequent.

It is interesting to note that there was a predominance of classes II (29.7%) and III (64.8%), according to the New York Heart Association's functional classification; and most of the patients in the studied series were in sinus rhythm (86.8%), only 12 of the 91 cases had atrial fibrillation.

Table 1. Distribution of patients according to main pre-procedure symptoms (n=91).

Symptoms	Nº	%
Dyspnea	82	90.1
Palpitations	22	24.2
Easy fatigue	17	18.7
Chest pain	7	7.7
Hemoptysis	3	3.3
Cough	2	2.2

In **table 2** is shown the mean value of the echocardiographic and hemodynamic parameters before the procedure. It can be observed that the peak and mean gradients (14.93 ± 5.36 mmHg), the diameter of the left atrium (43.18 ± 5.14 mm), the LAP (25.00 ± 6.93 mmHg), and the systolic pressure of the pulmonary artery (51.21 ± 12.75 mmHg) are increased; on the other hand, the mean MVA was less than 0.99 cm^2.

The MVA and LAP, before and after the valvuloplasty (**Figure**)show that the procedure allowed more than double the MVA (0.99 vs. 2.12 cm^2) and to

Table 2. Echocardiographic and hemodynamic parameters observed in the patients before the valvuloplasty.

Parameter	Mean	SD
Left atrium diameter (mm)	43.18	5.14
Peak gradient (mmHg)	24.88	7.46
Mean gradient (mmHg)	14.93	5.36
Mitral annulus (mm)	28.02	1.71
Left ventricular ejection fraction (%)	67.27	7.49
Wilkins score	7.54	1.39
Mitral regurgitation jet area (cm^2)	0.81	1.26
PA systolic pressure (mmHg)	51.21	12.75
Left atrial pressure (mmHg)	25.00	6.93
Mitral valve area(cm^2)	0.99	0.17

PA, pulmonary artery

Table 3. Distribution of patients according to the procedure immediate result.

Result	Nº	%
Successful	87	95.6*
Non successful	4	4.4
Total	91	100

* p=0.028

decrease the LAP in more than the 50% (25.0 vs. 11.76 mmHg).

The immediate assessment of the PBMV results could be defined as successful, since in 87 of the 91 patients (95.6%) who underwent it, it was satisfactory (95% CI [89.2 - 98.2]); in only four patients (4.4%) the procedure did not have favorable results (**Table 3**). In one of them, the dilatation could not be completed due to technical problems, in another the dilatation failed, and in the remaining two there was a severe mitral regurgitation that was solved with elective surgery. This was the only major complication recorded in our series.

The analysis of the association between Wilkins score and the outcome of the valvuloplasty (**Table 4**) shows that, in 72 of the 91 patients who underwent the procedure (79.1%; p=0.028), this score was ≤ 8, and in 98.6% of them (71/72), the valvuloplasty was successful. In contrast, of the four complicated patients, in whom the procedure was considered failed, three had a Wilkins score between 9 and 11 points.

DISCUSSION

It is known that the time interval between the episode of rheumatic carditis and the onset of symptoms is usually prolonged, generally about 20 years, and although there are individuals with disabling symptoms in the third and fourth decades of life, most patients develop these clinical manifestations after the age of 40 years old[10]. This may explain the predominance of the age groups observed in our series, similar to those obtained by authors such as Sarmiento *et al*[11] in Argentina, and Dighero *et al*[12] at the Hospital San Juan de Dios from Chile.

In the national and international reviewed literature, it is agreed that rheumatic MS is a disease that occurs more frequently in women[5], which explains a greater number of valvuloplasties in females, a data

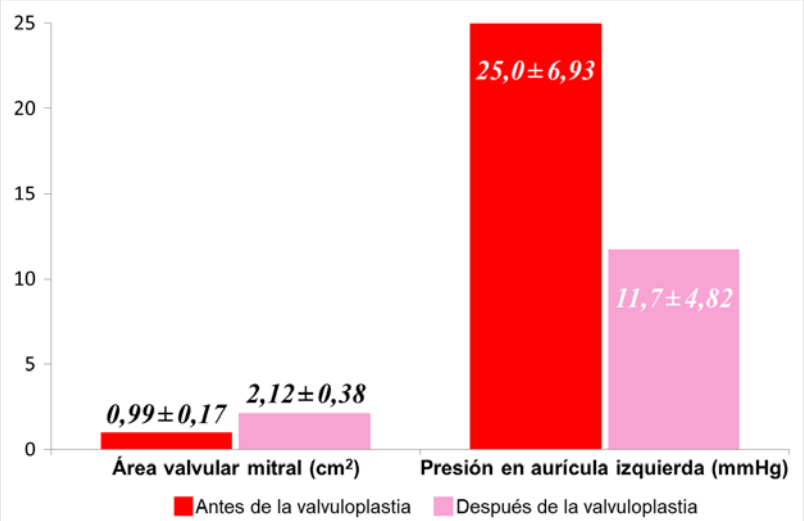

Figure. Variations in the mitral valve area and the left atrial pressure with the performance of the procedure.

Table 4. Distribution of patients according to Wilkins score and the valvuloplasty result.

Wilkins score	Result				Total	
	Successful		Failed			
	Nº	%	Nº	%	Nº	%
Less or equal to 8	71	98.6	1	1.4	72	79.1*
From 9 to 11	16	84.2	3	15.8	19	20.9*
Total	87	95.6**	4	4.4**	91	100

* Percentage calculated based on the total number of patients
** Fisher's exact test (p=0.028)

also referred to by other authors[2,8,11,13], which coincides with the results of this study. Furthermore, it also justifies the fact that rheumatic fever and recurrent tonsillitis were the most frequent antecedents; and, although some patients did not have a history of interest, the rheumatic cause should not be ruled out because this is missing in half of them[6], which only means that the patients were not aware of having suffered the disease.

Although dyspnea is a subjective symptom that is difficult to quantify, studies carried out by other authors have shown that this is the main symptom in patients with MS[14], which coincides with what was obtained in this research. Particularly in these patients, the dyspnea is secondary to the elevation of the left ventricular filling pressure, due to the valve obstruction, which determines an increase of the mean pressure of the atrium and the pulmonary capillary and venous pressures.

Regarding palpitations, different values have been reported in the medical literature in relation to this symptom; which, being subjective, has a great variability depending on multiple factors and does not represent a cardinal symptom in most of the reviewed studies; however, in this series it occupied the second place among the symptoms presented by the patients.

Easy fatigue is considered to be one of the common symptoms in this disease, but most of our patients did not refer to present it; a result that is thought to be due to the fact that once the patients were diagnosed, no studies were carried out to demonstrate true exercise intolerance.

These findings of our study are in line with the main symptoms of the disease referred to in the medical literature, as well as with those found by Echarte *et al*[8] in their research. These symptoms are sometimes bothersome and disabling and, according to the NYHA classification, are grouped into four functional classes. In relation to this, our research differs from that found in foreign studies such as those of Sarmiento *et al*[11] and Dighero *et al*[12], in which the highest percentage of patients is found between functional classes I and II. However, it coincides with the Cuban studies of Echarte *et al*[8] and López Ferrero *et al*[2], in which most of patients were between functional classes III and IV.

The absence of cardiac rhythm alterations previous to the procedure is a good prognosis factor, as it is referred to in nowadays bibliography. The rhythm in the patients' electrocardiograms in our study was similar to that one found by Sarmiento *et al*[11] and Martinez *et al*[13], where sinus rhythm predominated in 69.7% and 55.6% respectively, although somehow lower than that one observed in this research.

The MS results in significant hemodynamic alterations in patients who suffer from it, which explains that −in the studied patients− there was an increase in the peak and mean gradients, the diameter of the left atrium, the LAP, the systolic pressure of the pulmonary artery, and that the MVA was below 1 cm^2. These parameters are consistent with those expected in patients with MS, with an indication for valvuloplasty and those referred to in other studies[2,8,11,13]. It is also evident that a good selection of patients who had few predictors of bad results was made.

The immediate increase in MVA and LAP after the procedure is higher than those found in similar national and international studies. For example, Sarmiento *et al*[11] and Castillo Guzmán *et al*[9] reported an increase in the MVA from 0.9 cm^2 before the procedure to 1.71 cm^2 and 1.9 cm^2 respectively, after the valvuloplasty. Dighero *et al*[12] reported an increase

from 1.0 cm^2 to 1.71 cm^2 in their research and in the studies by Martínez *et al*[13] and Echarte *et al*[8], the increase in the MVA after valvuloplasty was also inferior. The results observed in this research could be a consequence of a right patients' selection process by the team that carried out the procedure and an adequate operator's technique.

According to what is referred to by different authors, this technique is considered to be effective when the MVA increases, at least in a 50% regarding the pre-valvuloplasty area, and there are no severe complications such as: death, cardiac tamponade, stroke, acute myocardial infarction, peripheral vascular damage requiring surgery, severe mitral regurgitation or significant interatrial communication[7,15]. In the current study, the procedure was successful in most of cases, which confirms what was referred to by authors, that percutaneous mitral valvuloplasty brings about an immediate clinical and hemodynamic improvement in most of patients with rheumatic MS[4,16,17].

The success in this research was superior to that one referred to by other authors: 71.7%[9], 78.8%[11] and 82.9%[12]; but lightly inferior to the 96.36% achieved by Echarte *et al*[8] at the *Instituto de Cardiología y Cirugía Cardiovascular* of Cuba.

The Wilkins score plays a key role in the assessment of patients with rheumatic MS, to determine the feasibility of carrying out the valvuloplasty and to predict complications. It has been widely assessed in a great number of patients and it has proved its predictive capacity for both, the immediate and the long term results. Its significant association with the procedure outcome observed in the current series is in correspondence with what is referred to in medical literature, which is explained due to the fact that the scores ≤ 8 corresponds with less compromise of the valve apparatus and, therefore, with better conditions for its repairment by this technique[7,8,14-17].

CONCLUSIONS

The results of percutaneous balloon mitral valvuloplasty were successful and consistent with those referred nationally and internationally. A significant increase in the mitral valve area and a decrease in the left atrial pressure were achieved. The success of the procedure was related to the low frequency of predictive factors of poor prognosis, due to the adequate selection of patients.

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