Original article

Percutaneous Mitral valvotomy: Early Experience with New Single Dilation “Inoue Type” Balloon

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ABSTRACT
Percutaneous Mitral Commissurotomy: Initial Experience with the New Inoue-Type Balloon

Background: Percutaneous mitral commissurotomy (PMC) with a single balloon is the most used technique to treat symptomatic mitral stenosis. The objective of this study was to evaluate a new single balloon (Inoue-type) in patients with symptomatic mitral stenosis undergoing percutaneous mitral commissurotomy with a single balloon.

Method:
Patients undergoing PMC with a single balloon from March/2008 to September/2009 were included, comparing the group treated with the Inoue-type balloon to the group treated with Inoue’s classic balloon. Pre and post procedure echocardiogram and late follow up were carried out.

Results: Patients were divided into two groups for comparison:
A, Inoue-type balloon (n = 16) and B, original Inoue balloon (n = 10). Both groups presented similar clinical characteristics. Mitral valve area increased from 1.03 ± 0.24 cm ²to 1.75 ± 0.22 cm ²in group A and 1.08 ± 0.25 cm ²to 1.88 ± 0.41 cm ²in B (P = 0.33). There were no cases of cardiac perforation, cardiac tamponate and severe mitral insufficiency requiring surgery. Two group A patients presented hematoma > 10 cm (12.5% in group A vs. 0 in group B; P = 0.27). Event free survival was 100% in group A and 90% in group B (P = 0.21).

Conclusions:
Percutaneous mitral commissurotomy is safe and effective. The new Inoue-type balloon showed comparable results with Inoue’s classic balloon.

Descriptions: Mitral valve stenosis, Balloon dilatation, Heart catheterization, chocardiography.

Although the prevalence of rheumatic fever has been significantly reduced in the present day, cases mitral stenosis due to impairment rheumatism is still found in daily cardiology practice1. According to current guidelines, patients with symptomatic mitral valve area of less than 1.5 cm ²and valve apparatus are preserved Class I indication for treatment with mitral valvotomy percutaneous balloon [2, 3].

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Since the introduction of percutaneous mitral valvotomy with Inoue in 1984, several techniques have dilation been described. Despite the constant technological advances in the field of cardiology, percutaneous mitral valvotomy with the single balloon Inoue technique is mostly used in comparison to the double-balloon technique on two guides, the technique of double balloon on a guide system (Multi-track) and Cribier the device. Currently there are balloons with design similar to the original Inoue balloon, but specific results of each model have been scarcely reported.

The aim of this study is to evaluate the performance of new single balloon dilation "type Inoue" in patients undergoing percutaneous balloon mitral valvotomy mitral stenosis.

Method

Sample Selection

We selected all patients undergoing percutaneous mitral valvotomy with balloon only between March 2008 and September 2009 at the Institute of Cardiology of Rio Grande do Sul (Porto Alegre). All patients with clinical heart failure functional class II-IV New York Heart Association (NYHA) and moderate to severe mitral stenosis (mitral area <1.5 cm ^{2}).

Clinical evaluation before the procedure

Patients were assessed clinically by history, physical examination and electrocardiogram. Transthoracic echocardiography was performed in all patients, the severity of mitral stenosis measured by the mitral area (planimetry) and the maximum and medium gradients by Doppler echocardiography. Were also evaluated by echocardiography, the mitral valve and the Wilkins score and Block10 valvulopathy associated. Patients with heart rhythm of atrial and / or atrial flutter underwent further the transesophageal echocardiography to exclude any thrombus in left atrium. For the realization of percutaneous mitral valvotomy with balloon only, were used only tested the new balloon (group A) and Inoue balloon classic (group B).

Description of the balloon

The new single balloon dilation "type Inoue” (Shenzhen Shineyard Medical Device Co., Ltd. - Shenzhen, China) has a similar design to the classic Inoue balloon (Toray - Tokyo, Japan). This is a balloon in polyvinyl single body, which, when filled by contrast, has no uniform dilation. First is inflation of the distal balloon (more compliant) and is maintained as the injection of contrast medium inside the proximal portion of the balloon is dilated (Figure 1A).
The middle portion of the balloon ("waist ") determines its diameter, and sizes available ranging from 20 mm to 30 mm. The expansion joint consists of spiral-tipped guide, dilator, drawing board, director, caliper and syringe (Figure 1B). The balloon test is marketed in Brazil and is registered in the National Agency for Sanitary Vigilance Agency (Anvisa) under registration number 80102510259 (www.anvisa.gov.br).

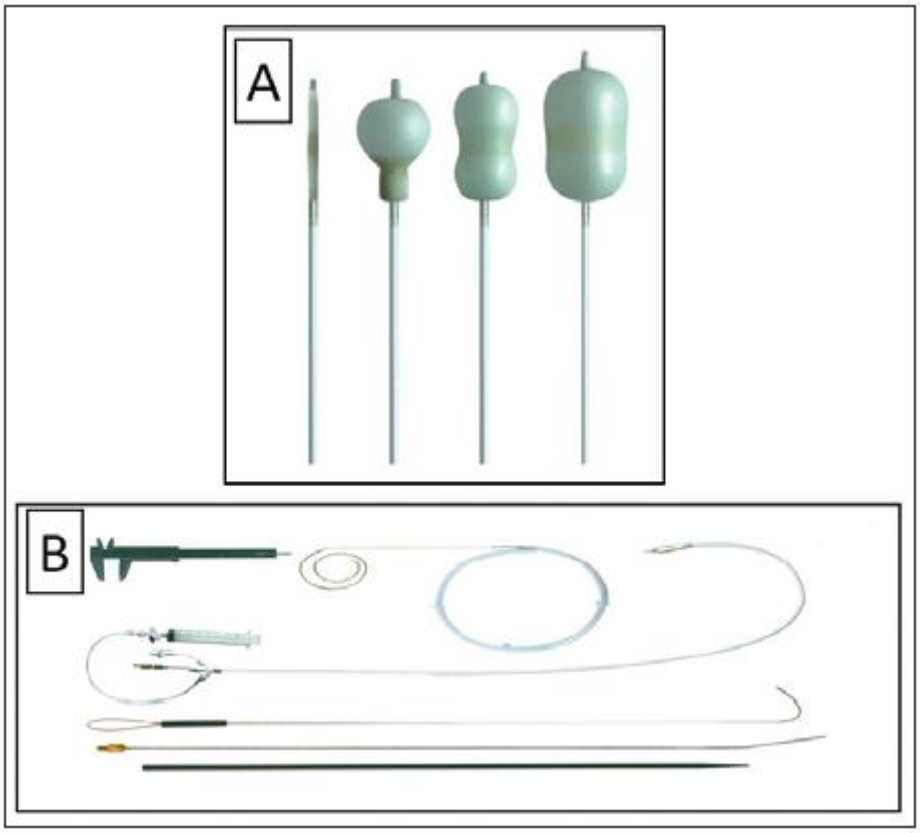

Figure 1 - In a new balloon "type Inoue" progressively inflated, noting that the distal to proximal inflation before. In B, the items that accompany the series: spiral guide, dilator, drawing board, director, and caliper syringe.

Percutaneous Procedure

The procedures were performed in the catheterization laboratory under local anesthesia and sedation. The percutaneous procedure is described in brief below: Intravenous right femoral vein were catheterized and pressures were recorded in the right heart chambers. Via left femoral arterial pressures were recorded in the aorta and left ventricle, and marked up the plan with valvular aortic pigtail catheter. Next, positioned himself Mullins sheath at the time of the atrial septum, puncturing it with Brockenbrough needle in left anterior oblique 45 degrees. After confirmation of proper position in the left atrium, dilated with the septal 14 F dilator and evaluated the transmitral gradient. Heparinize the patient with 5,000 U of intravenous heparin peripheral. Using the balloon valvotomy, dilated mitral valve progressively until a significant reduction in transmitral gradient. The procedure was completed with new blood pressure recording in the right and left heart chambers, left ventriculography in right anterior oblique 35 degrees to evaluate the mitral valve plane and removing the introducer tube. The calculation for selection of balloon size was based on the following fórmula11: [(height in cm ÷10) + 10].

Clinical follow-up
Patients underwent transthoracic echocardiography the day after the procedure to evaluate the outcome. Functional clinical evaluation was done through regular medical consultation, chart review or telephone contact.

Definitions
This study used the following definitions:

1) Success - mitral valve area after dilatation exceeding 1.5 cm ²in the absence of severe mitral regurgitation or other complications;
2) Partial success or a suboptimal outcome - mitral valve area <1.5 cm ²in the absence of severe mitral regurgitation or other complications;
3) Failure - inability or failure of the valve dilation of the atrial septum puncture;
4) Major complications - death, cardiac perforation with or without tamponade, stroke-related procedures, retroperitoneal hematoma and severe mitral regurgitation requiring surgery;
5) Minor complications - hematoma at the femoral puncture site> 10 cm in diameter, arteriovenous fistula, procedure-related arrhythmia and femoral pseudoaneurysm; and
6) Event-free survival - survival free of death, mitral valve replacement, new mitral or change of the NYHA degree.

Statistical analysis
Results are presented as mean, standard deviation and percentage. For comparison of categorical variables used the chi-square test, continuous variables are analyzed by Student t test when normally distributed, and nonparametric, in the case of non-normal distribution. Event-free survival was measured by the curve
Kaplan-Meier with log rank test. We considered the level of statistical significance two-tailed P value less than 0.05. The data were evaluated in version 11.0 of SPSS for Windows.

RESULTS
During the study period, there were 27 percutaneous mitral valvotomy with a single balloon. In one case it was not possible to puncture the atrial septum (global failure of puncture 3.7%). It was a patient with previous surgical commissurotomy with access via right thoracotomy. In this type of approach occurs incision of the atrial septum and posterior suture. The process of healing by fibrosis leads to thickening of the atrial septum, which hinders its punch.

In the 26 remaining patients could perform the procedure valve dilatation, 16 patients in Group A (new balloon) and 10 in group B (Inoue balloon).

Table 1 shows the clinical characteristics of patients included in the study and Table 2 shows the echocardiographic and electrocardiographic findings before the procedure. There were no differences between groups, except more patients with class IV heart failure and reduced complexity of the mitral valve echocardiographic score Wilkins and Block in group B.

Immediate results
Procedural success was 100% (16/16) in group A and 90% (9 / 10) in group B (P = 0.85). The only patient in whom it was not obtained mitral area> 1.5 cm ²in group B had an affair with a suboptimal outcome. The final patient had mitral valve area of 1.45 cm ², less than 1.5 cm ², as previously defined criterion of success.

We managed to mitral valve area increased from 69% in group A and 74% in group B. In Figure 2 are shown the results of the significant increase in the area after mitral balloon valvotomy 1.03

± 0.24 cm ²to 1.75 ± 0.22 cm ²in group A and 1.08 ± 0.25 cm ²for a , 88 cm ² ± 0.41 in group B (P = 0.33).

The results of manometry in both groups are presented in Table 3. Systolic and diastolic pulmonary artery, which is closely related to the severity of mitral stenosis, suffered acute changes after mitral valvotomy. The transmitral gradient was also reduced after the procedure, 16.1 ± 6.2 mmHg to 5.9 ± 2.9 mmHg in group A and 18.9 ± 9.1 mmHg to 5.2 ± 4.2 mmHg in group B (P = 0.68).

Late results

Late follow-up, performed in all patients, reveals a good clinical outcome in both groups. The event-free survival assessed by Kaplan-Meier analysis showed no statistical difference between groups (Figure 3). Only one patient in group B had recurrence of symptoms of heart failure just over four months after percutaneous mitral valvotomy with balloon only, with increased grade of regurgitation after the procedure (evolved from mild to moderate mitral regurgitation), compensated by using beta-blockers, diuretics and angiotensin converting enzyme conversion. The patient remains asymptomatic to date.

Table 1
Clinical characteristics of patients treated with percutaneous balloon mitral valvotomy

Clinical features, n(%)	**Group A (n = 16)**	**Group B (n = 10)**	**P**
Female	7/16 (43.75%)	8/10 (80%)	0.35
Age (years)	43.68 ±14.55	37.7 ±12.97	0.48
Weight (kg)	67.86 ±16.49	64.9 ±9.48	0.61
Height (cm)	162 ±7.44	158.7 ±8.02	0.26
Hypertension	6/16 (37.5%)	2/10 (20%)	0.48
Diabetes mellitus	0	2/10 (20%)	0.09
Dyslipidemia	4/16 (25%)	2/10 (20%)	0.81
Smoking	2/16 (12.5%)	1/10 (10%)	0.86
Previous stroke	1/6 (6.25%)	0/10 (0%)	0.43
Previous surgical repair	4/16 (25%)	0/10 (0%)	0.12
Previous percutaneous valve repair	0	0	N/A
Heart failure			0.01
Class II (NYHA)	3/16 (18.75%)	2/10 (20%)	
Class III (NYHA)	13/16 (81.25)	6/10 (60%)	
Class IV (NYHA)	0	2/10 (20%)	
Medication in use, n (%)			
Oral anticoagulant	4/16 (25%)	2/10 (20%)	0.81
Acetylsalicylic acid	6/16 (37.5%)	4/10 (40%)	0.93
Blocker	12/16 (75%)	6/10 (60%)	0.36
Inhibitor of angiotensin converting enzyme	7/16 (43.75%)	3/10 (30%)	0.63
Diuretic	12/16 (75%)	6/10 (60%)	0.72
Inhibitor of the angiotensin	1/16 (6.25%)	1/10 (10%)	0.74
Digoxin	4/16 (25%)	1/10 (10%)	0.42
Results presented as mean, standard deviation and percentage. CVA = cerebrovascular accident, n = number of patients, N / A = not applicable; NYHA = New York Heart Association			

Complications

There were no major complications (death, perforation with or without cardiac tamponade, stroke-related procedures, retroperitoneal hematoma and severe mitral regurgitation requiring surgery) in both groups

Between complications defined as minor, there was no presence of an arteriovenous fistula procedure-related arrhythmia and femoral pseudoaneurysm. There were two cases of hematoma related to the puncture site> 10 cm in diameter in group A (12.5% in group A vs. 0 in group B, P = 0.27). Both patients were suffering from chronic atrial fibrillation and, by decision of the cardiologist, began the use of oral anticoagulants about 24 hours after removal of the tube introducers. The hematomas were treated medically and resolved spontaneously.

Worsening of mitral regurgitation is a major complication of percutaneous mitral valvotomy with a single balloon. In this study, we observed differences between groups in relation to the worsening of mitral regurgitation after the procedure (group A vs 0. 3 patients in group B, P = 0.04). These patients in group B showed worsening of mitral regurgitation, mild to moderate, and evaluation with echocardiography identified a partial rupture of chordae tendineae in a mechanical complication and none in others. Moreover, these patients showed at the end of the procedure, mitral valve areas significantly larger than those that have not evolved with this complication (1.07 ± 0.24 cm ²to 2.12 ± 0.48 cm ²vs. 1.05 ± 0, 23 cm ²to 1.73 ± 0.21 cm ², P = 0.004). In group A, regression was observed in the degree of mitral regurgitation after percutaneous mitral valvotomy with a single balloon. It was a patient with severe mitral stenosis (area of 0.88 cm ²) and significant restriction of mobility of the anterior leaflet, which improved their function after valve dilation.

Percutaneous mitral valvotomy after surgical commissurotomy

Commissurotomy surgery was present in 4 patients (15% of the sample), all being treated percutaneously with the new balloon type Inoue "(25% in group A vs. 0 in group B, P = 0.21). In this subgroup (100% of patients with Wilkins and Block score below 8) increased the mitral valve area (1.03 ± 0.28 cm ²to 1.77 ± 0.24 cm ²), without being observed increased grade of regurgitation mitral after the procedure.

Table 2
Echocardiographic and electrocardiographic findings before the procedure in patients treated with percutaneous mitral valvotomy

	Group A (n = 16)	Group B (n = 10)	P
Echocardiographic findings, n (%)			
Mitral valve area (cm²)	1.03 ±0.24	1.08 ±0.25	0.62
Maximum transmitral gradient (mmHg)	20.29 ±7.10	21.91 ±6.17	0.58
Mean transmitral gradient (mmHg)	10.59 ±3.93	12.3 ±2.84	0.27
Wilkins and Block score			< 0.001
< 8	15/16 (93.75%)	10/10 (100%)	
9-11	1/16 (6.25%)	0	
> 12	0	0	
Left atrium (mm)	50.61 ±4.35	48.37 ±2.77	0.21
Ejection fraction (%)	65.42 ±7.2	64.42 ±4.42	0.65
Left atrial thrombus (%)	0	0	N/A
Associated valve, n (%)			
Mild aortic stenosis	2/16 (12.5%)	4/10 (40%)	0.20
Moderate to severe aortic stenosis	0	0	N/A
Mild aortic regurgitation	3/16 (18.75%)	9/10 (90%)	0.03
Moderate to severe aortic insufficiency	0	0	N/A
Mild mitral insufficiency	13/16 (81.25%)	9/10 (90%)	0.86
Moderate to severe mitral insufficiency	1/16 (6.25%)	0	0.43
ECG findings, n (%)			
Sinus rhythm	11/16 (68.75%)	8/10 (80%)	0.80
Atrial fibrillation or flutter	5/16 (31.25%)	2/10 (20%)	0.69
Left atrial enlargement	11/16 (68.75%)	8/10 (80%)	0.80
Left ventricular overload	4/16 (25%)	4/10 (40%)	0.56
Right ventricular overload	6/16 (37.5%)	1/10 (10%)	0.22

Results presented as mean, standard deviation and percentage.
n = number of patients, N / A = not applicable

DISCUSSION

This study sought to evaluate the performance of two balloons with the design and method of expansion valve similar. Both balloons were highly effective in increasing the mitral valve area after dilatation, with few complications. The procedure of percutaneous mitral valvotomy with a single balloon is universally held and its results are widely conhecidos2, 12. In patients with moderate to severe mitral stenosis with preserved valvular apparatus, the procedure of percutaneous mitral valvotomy with a single balloon has a class I indication about the procedure surgery2, 13, due to the extremely favorable results.

Although there are many techniques of dilatation with single balloon valvotomy is still the most used. A single balloon technique has some advantages over other methods dilatação14: shows less difficulty, because the manipulation of the catheter is easier to use and does not need a guide; the risk of cardiac perforation is also lower and, although obtain an area smaller than the double balloon, the late clinical outcome of both methods is semelhante15, 16. In this study, the new balloon dilation results overlapped those shown Balloon Classic Inoue, evidenced by similar success rate and low complication rate.

Severe mitral regurgitation after percutaneous mitral valvotomy with a single balloon is a major complication. It has been reported in 1.4% to 9.4%[7,17,18] of procedures, although cases requiring immediate surgery are even rarer. In this series, there were no reported cases of severe mitral regurgitation requiring surgery, occurring only worsens the degree of mitral regurgitation of mild to moderate in 3 patients treated with the Inoue balloon. Worsening of mitral regurgitation is relatively common after percutaneous mitral valvotomy with a single balloon. His appearance is related to various factors such as degree of mitral calcification, involvement of the subvalvular apparatus and the final area reached. Because patients with this complication showed adequate echocardiographic score (Wilkins and Block <8), it is believed that this finding has elapsed predominantly the significant increase in mean mitral valve area in this group. The mean final area in these patients was 2.12 cm^2 and higher valve areas have been related to this complication. Nevertheless, the clinical outcome is usually favorable and the clinical treatment has offset this group of patients.

Page 6

The natural evolution of patients treated either by surgical commissurotomy for mitral valvotomy and percutaneous balloon shows that only about 11% to 39% will have echocardiographic restenosis 7 to 15 years after the procedure. In another surgery is usually necessary, the return of symptoms. In surgically treated patients with low echocardiographic score, percutaneous mitral valvotomy with a single balloon can be safely performed. Previous studies demonstrate the efficacy and safety of this procedure, it becomes attractive for avoiding new non-surgical intervention. Patients treated by percutaneous mitral valvotomy with a single balloon may also have their valve procedures repeated by the same technique. Gomes et al. revealed that this procedure is safe for the balloon technique, even when repeated for the second and third time. However, it tends to get smaller valve areas.

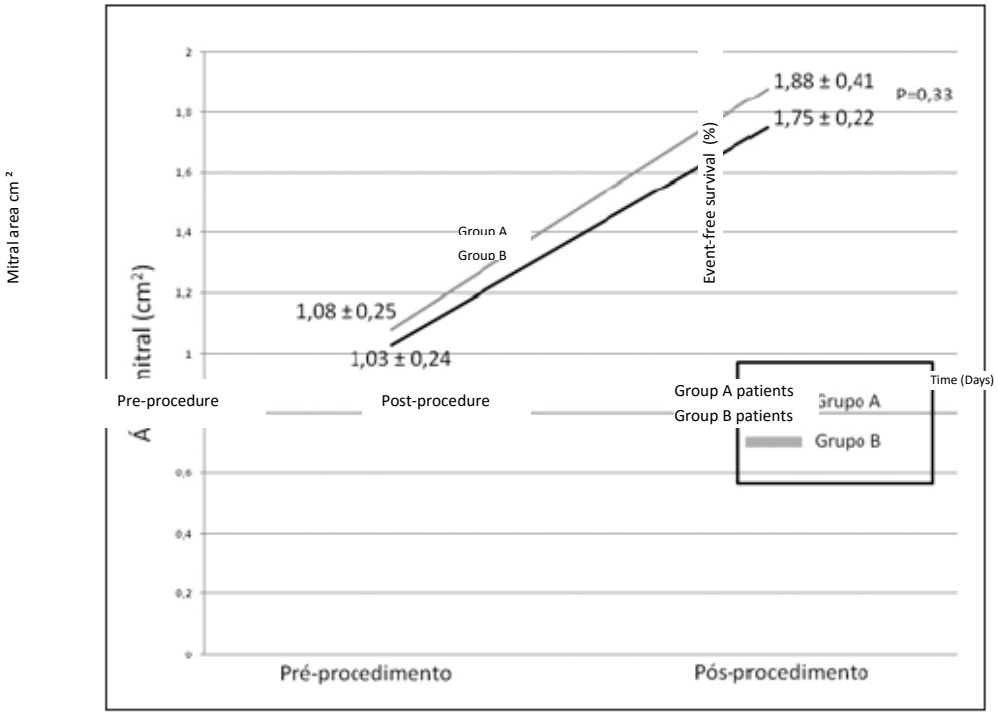

Figure 2 - Area mitral pre-and post-procedure in the groups undergoing percutaneous balloon mitral valvotomy.

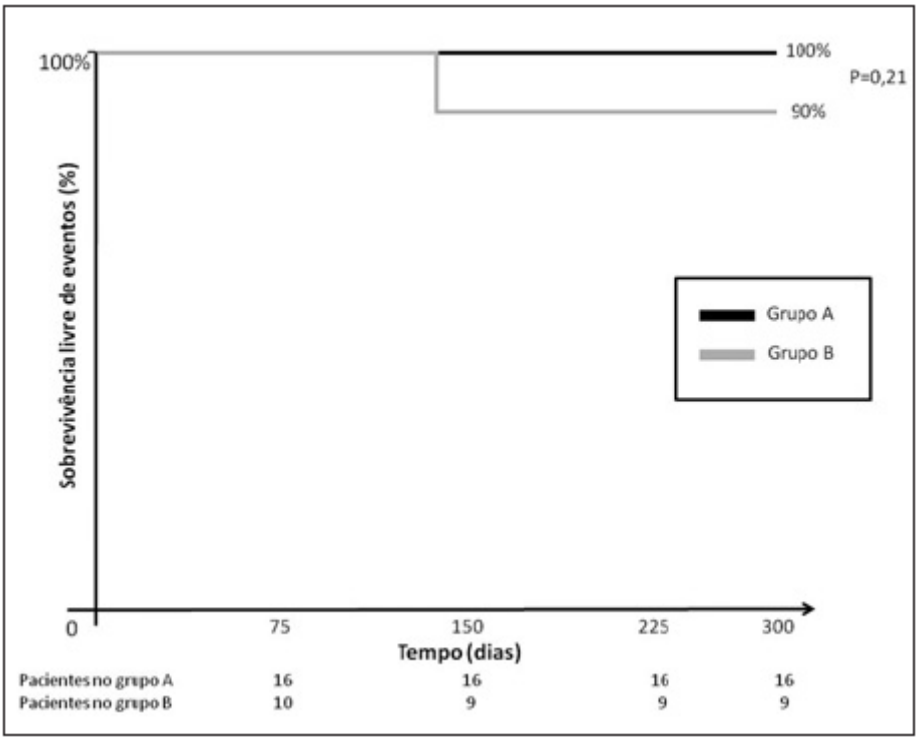

Figure 3 - Curve of event-free survival estimated by Kaplan-Meier.

Table 3
Manometry of the heart chambers before and after percutaneous mitral valvotomy

	Group A (n = 16)	Group B (n = 10)	P
Pre-procedure (mm Hg)			
Systolic pulmonary artery	52.33 ±14.37	50.95 ±13.15	0.80
Diastolic pressure in the pulmonary artery	28.53 ±8.56	28.7 ±17.60	0.97
Systolic pressure in left atrium	36.56 ±7	36.85 ±6.80	0.92
Diastolic pressure in left atrium	24.6 ±8.12	19.3 ±7.08	0.10
Transmitral gradient	16.1 ±6.2	18.9 ±9.1	0.37
Post-procedure (mmHg)			
Systolic pulmonary artery	45.75 ±14	46.9 ±10.78	0.83
Diastolic pressure in the pulmonary artery	23 ±6.72	22.6 ±4.86	0.87
Systolic pressure in left atrium	26.64 ±8.58	22.85 ±5.99	0.35
Diastolic pressure in left atrium	19.6 ±7.05	12.1 ±4.27	0.008
Transmitral gradient	5.9 ±2.9	5.2 ±4.2	0.68
Results presented as mean and standard deviation n = number of patients			

Follow-up in 12 months

The criterion for success of percutaneous mitral valvotomy is defined as valve area over 1.5 cm ^{2}. Although this area is less than the normal mitral valve area (3 cm ^{2} to 5 cm ^{2}), areas larger than 1.5 cm ^{2} is sufficient to leave the patient free of symptoms.

These findings were confirmed in this study, by means of event-free survival. No difference was observed between groups by Kaplan-Meier, suggesting that both balloons have had similar performance.

Study limitations

The limitations pertinent to the study are discussed below: 1) it is a single-center study with small number of patients, 2) the lack of randomization precludes determining the superiority of one over the other balloon, 3) although curve of event-free survival showed no difference between treatment groups, the absence of echocardiographic control limits any conclusion about long-term maintenance of outcomes in relation to the mitral area, and 4) due to the small number of patients included, it was not possible to determine early and late predictors.

CONCLUSIONS

The percutaneous balloon mitral valvotomy is a safe and effective procedure for treatment of moderate to severe mitral stenosis symptomatic. In this study, the new balloon dilation was shown to superimpose the results of Inoue balloon classic.

CONFLICT OF INTEREST

The authors declared no conflict of interest related to this manuscript.

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