Comparison of the Inoue and Single Balloon Techniques During Long Term Percutaneous Balloon Mitral Valvoplasty Follow-Up. Analysis of Risk Factors for Death and Major Events

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Summary

Objective: **To analyze the long term evolution of patients undergoing percutaneous balloon mitral valvoplasty comparing the Inoue and Balt single balloon methods, and to identify predictors of death and major events (death, repeat balloon mitral valvoplasty or mitral valve surgery).**

Methods: **The follow-up for the single and Inoue balloon groups were 54 ± 31 (1 to 126) months and 34 ± 26 (2 to 105) months, respectively (p < 0.0001). The Balt single balloon was used in 254 (84.1%) patients and the Inoue balloon in 48 (15.9%).**

Results: **The following data were found for the Inoue and single balloon groups, respectively: age, 36.9 ± 10.4 (19 to 63) years and 38.0 ± 12.6 (13 to 83) years (p = 0.5769); echocardiographic score, 7.5 ± 1.3 points and 7.2 ± 1.5 points (p = 0.1307); female gender, 72.9% and 87.4% (p = 0.0097); atrial fibrillation, 10.4% and 16.1% (p = 0.4275); mortality during follow-up, 2.1% and 4.3% (0.6984); and major events, 8.3% and 17.7% (p = 0.1642). Univariate and Kaplan-Meier curve analyses revealed no differences between the Inoue and Balt single balloon techniques in relation to survival and major event free survival. In the multivariate analysis, age ≥ 50 years and an echocardiographic score > 8 were independent predictors of death; and an echocardiographic score > 8 and post operative mitral valve area < 1.50 cm² were predictors for major events.**

Conclusion: **No differences were found in the long term evolution of patients undergoing the Inoue versus the single balloon technique. Predictors of death and/or major events were: age ≥ 50 years, echocardiographic score > 8 and mitral valve area < 1.50 cm² after the procedure. (Arq Bras Cardiol 2007; 89(1) : 46-53)**

Key words: **Mitral valve stenosis; balloon dilatation; rheumatic fever.**

Introduction

It has been established that the mitral valve area after balloon valvoplasty is similar for all balloon techniques in use[1-4], which is roughly 2 cm².

The immediate results using the single balloon are similar to the Inoue balloon[1] and it is more economical[4]. There are other lower cost balloon alternatives[5] in comparison to the Inoue technique, which is expensive even though it is used throughout the world, this led to the introduction of the now obsolete Cribier valvulotome, a metal device designed to reduce procedure costs.

Survival and major event free survival rates vary among the study groups due to clinical and echocardiography characteristics, as well as to the patients follow-up[6-13]. Accounts in literature of mortality rates during evolution range from 0 to 18%.

The main objective of this study was to analyze whether or not the single and Inoue balloon techniques in percutaneous balloon mitral valvoplasty produce similar results or if one of the techniques, in relation to the other, is a risk factor for death and events during long term evolution. The secondary objective was to conduct a comparative study of the long term results of percutaneous balloon mitral valvoplasty using the Inoue and single balloon, analyze the results of the entire population and identify factors that predict death and major events (death, repeat mitral balloon valvoplasty and mitral valve surgery.)

Methods

A prospective longitudinal observational study was conducted on patients at *Cinecor – 4º Centenário* undergoing percutaneous balloon mitral valvoplasty through the Inoue and single balloon techniques. Exclusion criteria included incomplete procedures, and complete procedures that

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were not followed by one month of evolution due to loss of patient contact, unsuccessful procedures or complications and subsequent major events that prevented follow-up for more than one month. Follow-up was discontinued in the case of death, repeat balloon mitral valvoplasty or mitral valve surgery.

Between July, 1987 and December 2004, 518 procedures were performed and there were no per-procedure deaths. In the initial study period (July 1987 to March 1990), during the learning curve of the method, 25 procedures were performed, of which 16 were not completed as the balloon was not positioned and the valve was dilated. Therefore these were incomplete procedures and there was one in-hospital death. During the same follow-up, nine procedures were performed with balloon placement in the mitral valve after dilatation. A 20mm diameter Meditech single balloon was used for three procedures with one in-hospital death; a double balloon was used for six procedures for a total of eight successful procedures with no complications.

Between April 1990 and December 2004, there was one incomplete procedure, in which the balloon was not positioned in the mitral valve after dilation. Another 492 procedures were performed during this period with no deaths during the procedure. A Balt single balloon was used in 403 procedures with two in-hospital deaths and one successful mitral valve repair surgery due to severe per-procedure mitral regurgitation. The Inoue balloon was used for 89 procedures.

Long term follow-up was conducted for 302 procedures out of those performed between April 1990 and December 2004 using the single and Inoue balloon techniques. Balloon diameters of 25mm, 25mm followed by a 30mm balloon and 30mm were used in 254 (84.1%) single balloon procedures, and 24mm to 28mm Inoue balloons in 48 (15.9%) procedures. The Balt single balloon diameters used in the 254 procedures measured a maximum of 25mm in five (2.0%) procedures and of 30mm in 249 (98.0%) procedures.

The Balt single balloon was used for most of the Single Health Care System patients, since, as a rule, the Inoue balloon was not authorized for reimbursement. And, even after authorization, the reimbursement amount was not widely accepted by the suppliers in state of Rio de Janeiro. The Inoue balloon was used in almost all of the patients with private health care plans. Occasionally, the selection depended on the availability of these balloons in the market.

All patients were submitted to an echocardiography before the balloon mitral valvoplasty and in 223 cases the test was performed at the end of the evolution. The mitral valve area was obtained using planimetry or pressure half-time. Mitral valve morphology was evaluated using the Wilkins score[14]. The degree of mitral regurgitation was evaluated with Doppler echocardiography, in accordance with the extent of regurgitation (mild, moderate or severe) in the left atrium. Mitral regurgitation before the valvoplasty or surgery, new mitral regurgitation or worsening of the degree of prior per-procedure mitral regurgitation were quantified angiographically in accordance with the criteria of Sellers and associates[15], in which a score of 3 or 4+ was considered to be severe. The gradient was measured using planimetry of the gradient area and the mitral valve area was established before and after the dilatation. Cardiac output was determined using thermodilution and the Gorlin & Gorlin[16] formula. At the start and end of the procedure, the mitral valve area was calculated using hemodynamics[16]. Follow-up was conducted by telephone or written correspondence and new consultations were scheduled as required. Factors evaluated included New York Heart Association (NYHA) functional class, mortality and cause of death, medications in use and whether the patient had undergone mitral valve surgery or repeat balloon mitral valvoplasty. The clinical evolution of the study patients was considered starting from the month of the procedure.

The patients were divided into two groups according to the balloon technique used: single or Inoue balloon.

Success was defined as mitral valve area $\geq$ 1.50 cm^2 after the procedure, using hemodynamic calculation, with no severe mitral regurgitation.

The Student's t-test was used to compare the continuous variables with normal distribution and the Mann-Whitney test for those with abnormal distribution. The chi-square test, Yates chi-square test and Fisher exact test were used to compare the categorical variables depending on event frequency. The software program EPI INFO (version 6, Centers for Disease Control and Prevention, Atlanta, USA) was used for the calculations and as a databank. For multivariate analysis, the Cox regression model was used in stages, so as to identify the independent factors that predicted death and major events (death, repeat mitral balloon valvoplasty and mitral valve surgery) during long term evolution with the software program SPSS for Windows (version 10.0, SPSS Inc., Chicago, Illinois, USA). The variables that demonstrated probability of error less than or equal to 10% ($p \leq 0.10$) in the univariate analysis were submitted to the mutlivariate analysis (forward conditional). Kaplan-Meier curves were used for the independent variables that predicted survival or major event free survival for the two balloon techniques.

The categorical variables studied were: age (< 50 years or $\geq$ 50 years), gender, prior mitral commissurotomy, prior mitral valvuloplasty, rhythm (sinus or atrial fibrillation), echocardiography score ($\leq$ 8 and > 8 points), maximum diameter of dilatation balloon ($\leq$ 29 mm and > 29 mm), actual mitral valve dilatation area ($\leq$ 6 cm^2 and > 6 cm^2), presence of mitral regurgitation before the procedure, echocardiography mitral valve area before the procedure (< 1 cm^2 and $\geq$ 1cm^2), mitral valve area calculated by hemodynamics before the procedure (< 1 cm^2 and $\geq$ 1 cm^2), mitral valve area calculated using hemodynamics after the procedure or success (< 1.5 cm^2 and $\geq$ 1.5 cm^2), mean pulmonary artery pressure before mitral valvuloplasty (< 40 mmHg and $\geq$ 40 mmHg), systolic pulmonary pressure before the balloon mitral valvuloplasty (< 60 mmHg and $\geq$ 60 mmHg), and type of dilatation balloon (Inoue or Balt single balloon). The variables with $p \leq 0.10$ in the univariate analysis were included in the multivariate survival or event free survival model.

Results

The clinical and echocardiographic characteristics and follow-up are shown in table 1. The NYHA functional class in the single and Inoue balloon groups before the balloon mitral valvoplasty and at the end of the follow-up is shown in table 2. The hemodynamic characteristics, procedure results and complications, evolution findings such as mortality and major events, are described in table 3. The multivariate analysis results with the independent variables for survival and major event free survival are shown in table 4. Kaplan-Meier curves were used for the significant variables in the multivariate analysis for survival and major event free survival (table 5). The survival curves for age, echocardiography score and balloon technique used (single Balt or Inoue balloon) are shown in figures 1 to 3.

Discussion

In the present study, the Balt single balloon and Inoue balloon techniques were compared. No differences were found in relation to death and major events during the long term evolution of the two groups. The immediate results of the two techniques have already been reported[1,4]. By means of a univariate and multivariate analysis model, it was demonstrated that the type of balloon used had no significant effect on survival and major event free survival.

In literature, studies with follow-up that ranged from one to twelve years after the balloon mitral valvuloplasty were observed[6,9,12,13,17-22].

In the present study the age of the patients in the single balloon valvoplasty group was 38.1 ± 12.4 years and in the Inoue balloon group, 36.9 ± 10.4 years, with no significant difference, an intermediate value when compared to younger patients from countries such as Índia[23], Tunisia[3] and Egypt[24] and older patients from Europe[8,19,25], the United States[10,12,26] and Japan[20].

In accordance with literature, there were more females in both study groups[3,12,18,20,22] and a greater percentage in the single balloon group in the present study.

Also in accordance with literature, most of the study patients were NYHA functional classes III and IV[12,19], and the Inoue balloon group presented fewer symptoms before the procedure. At the end of the follow-up, there was no difference between the groups, and 76.8% of the patients were NYHA functional classes I and II, of which 89.6% were from the Inoue balloon group and 74.4% from the single balloon group, even though the follow-up for the single balloon group was longer. Currently, balloon mitral valvuloplasty indications are accepted for NYHA functional class II patients, and in very

Table 1 – Clinical and echocardiographic characteristics

Variable	Single balloon (Balt) (n = 254)	Inoue balloon (n = 48)	p
Female gender (n, %)	222 (87.4)	35 (72.9)	0.0097
Age (years)	38.0 ± 12.6 (13 to 83)	36.9 ± 10.4 (19 to 63)	0.5769
Evolution follow-up (months)	54 ± 31 (1 to 126)	34 ± 26 (2 to 105)	< 0.0001
Prior commissurotomy (n, %)	22 (8.7)	5 (10.4)	0.9083
Prior valvoplasty (n, %)	8 (3.1)	2 (4.2)	0.6628
Atrial fibrillation rhythm (n, %)	41 (16.1)	5 (10.4)	0.4275
Score > 8 (n, %)	31 (12.2)	12 (25.0)	0.0356
Score (points)	7.2 ± 1.5	7.5 ± 1.3	0.1307
MVA pre-MBV echo (cm^2)	0.93 ± 0.21	0.96 ± 0.19	0.2745

n - number of patients; Score - echocardiographic score; MVA - mitral valve area; BMV - balloon mitral valvoplasty.

Table 2 – New York Heart Association (NYHA) functional class before balloon mitral valvoplasty and in the follow-up

	Group (n)	FC I (n, %)	FC II (n, %)	FC III (n, %)	FC IV (n, %)	Death (n, %)	p
Pre-PMBV	Balt (254)	1 (0.4)	63 (24.8)	168 (66.1)	22 (8.7)	-	0.0050
	Inoue (48)	3 (6.3)	16 (33.3)	25 (52.1)	4 (8.3)	-	
	Total (302)	4 (1.3)	79 (26.2)	193 (63.9)	26 (8.6)	-	-
Evolution	Balt (254)	117 (46.1)	72 (28.3)	51 (20.1)	3 (1.2)	11 (4.3)	0.2377
	Inoue (48)	28 (58.3)	15 (31.3)	4 (8.3)	0 (0.0)	1 (2.1)	
	Total (302)	145 (48.0)	87 (28.8)	55 (18.2)	3 (1.0)	12 (4.0)	-

FC - New York Heart Association functional class; n - number of patients; Balt - single Balt balloon group Balt; Inoue - Inoue balloon group; Pre-PMBV - before percutaneous mitral balloon valvoplasty; Total - total group of 302 patients.

Table 3 – Hemodynamic characteristics of the procedure and evolution

Variable	Single balloon (Balt) (n = 254)	Inoue balloon (n = 48)	p
Systolic pulmonary pressure pre (mmHg)	58 ± 20	52 ± 19	0.1162
Mean pulmonary pressure pre (mmHg)	38 ± 14	36 ± 15	0.1912
Systolic pulmonary pressure post (mmHg)	43 ± 15	40 ± 12	0.3388
Mean pulmonary pressure post (mmHg)	27 ± 10	25 ± 8	0.2293
Mean LA-LV gradient pre (mmHg)	20 ± 7	17 ± 6	0.0602
Mean LA-LV gradient post (mmHg)	5 ± 3	6 ± 3	0.4769
MVA pre-BMV echo (cm^2)	0.93 ± 0.21	0.96 ± 0.19	0.2745
MVA pre-BMV hemo (cm^2)	0.91 ± 0.21	0.93 ± 0.22	0.5525
MVA post-BMV hemo (cm^2)	2.02 ± 0.37	2.04 ± 0.53	0.9936
Maximum balloon diameter (mm)	29.9 ± 0.7	27.8 ± 0.6	< 0.0001
Effective dilatation area (mm^2)	7.02 ± 0.30	6.09 ± 0.27	< 0.0001
Pre-BMV mitral regurgitation (n, %)	47 (18.5)	3 (6.3)	0.0365
Post-BMV severe mitral regurgitation (n, %)	2 (0.8)	0 (0.0)	1.0000
Success (n, %)*	239 (94.8)	37 (90.2)	0.4193
Follow-up (months)	54 ± 31 (1 to 126)	34 ± 26 (2 to 105)	< 0.0001
MVA at the end of the follow-up (cm^2)	1.54 ± 0.50	1.68 ± 0.39	0.1364
Restenosis (n, %)**	90 (44.8)	9 (27.3)	0.0593
New severe MR (n, %)***	17 (8.3)	5 (14.7)	0.3748
New MBV (n, %)	12 (4.7)	1 (2.1)	0.7001
Mitral surgery (n, %)	27 (10.6)	3 (6.3)	0.4403
Clinical treatment (n, %)	209 (83.3)	44 (91.7)	0.2078
No medication (n, %)****	67 (28.3)	14 (31.1)	0.6994
Total deaths (n, %)	11 (4.3)	1 (2.1)	0.6984
Cardiac related death (n, %)	9 (3.5)	1 (2.1)	1.0000
Non-cardiac related death (n, %)	2 (0.8)	0 (0.0)	1.0000
Major events (n, %)	45 (17.7)	4 (8.3)	0.1642

Single Balt Balloon, n = 252; Inoue Balloon, n = 41. ** 201 patients with mitral area measured in the single balloon group and 33 patients in the Inoue Balloon Group. * 206 patients with echocardiographic in the follow-up in the single balloon group and 34 patients in the Inoue balloon group. **** 237 patients described in the single balloon group and 45 in the Inoue balloon group. n - number of patients; LA - left atrium; LV - left ventricle; MVA - mitral valve area; BMV - balloon mitral valvoplasty; echo - echocardiographic; hemo - hemodynamics, or in other words, measuring the cardiac output with thermodilution and using the Gorlin formula; MR - mitral regurgitation.*

Table 4 – Multivariate analysis: survival and event free survival

				Confidence interval (95%)	
Variable	Status	Significance	Hazard ratio	Low	High
Age	Survival	0.011	0.219	0.068	0.707
Echo score	Survival	< 0.001	0.102	0.032	0.325
Rhythm*	Event Free Survival	0.053	0.525	0.273	1.008
Echo score	Event Free Survival	0.038	0.471	0.231	0.958
Post MVA hemo	Event Free Survival	< 0.001	0.147	0.062	0.349

** Near statistic significance. Echo - echocardiographic; MVA - mitral valve area; MVA hemo - hemodynamic mitral valve area or in other words, measuring the cardiac output with thermodilution and using the Gorlin formula; Post - after balloon mitral valvoplasty.*

Table 5 - Kaplan-meier survival and event free survival curves

Variable	Event free survival	Group 1 (%)	Group 2 (%)	Log rank	Total group (%)
Age*	Death	97.27	89.13	0.003	96.03
Echo score*	Death	98.07	83.72	< 0.001	96.03
Balloon used	Death	95.67	97.92	0.709	96.03
Echo score*	Events	84.97	76.74	0.043	83.77
Post MVA hemo*	Events	58.82	84.78	< 0.001	83.28
Balloon used	Events	82.28	91.77	0.752	83.77

** Independent Variables, that presented significance for survival and/or event free survival in the multivariate analysis. Post MVA hemo - mitral valve area after the procedure measured hemodynamically, or in other words, measuring the cardiac output with thermodilution and using the Gorlin formula; echo - echocardiographic. Post MVA hemo: group 1 = mitral valve area < 1.50 cm² (unsuccessful); group 2 = mitral valve area ≥ 1.50 cm² (successful). Balloon used: group 1 = single Balt balloon; group 2 = Inoue balloon. Echo Score: group 1 = echocardiographic score ≤ 8 points; group 2 = echocardiographic score > 8 points. Age: group 1 = age < 50 years; group 2 = age ≥ 50 years.*

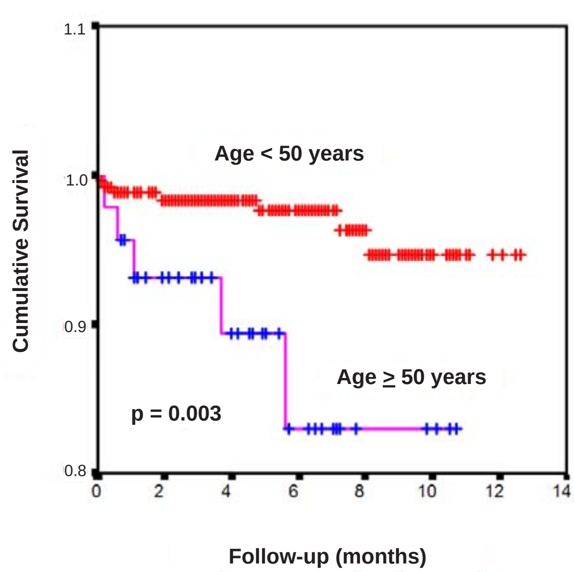

***Fig. 1** - Kaplan-Meier survival curve by age: < 50 years (red) and ≥ 50 years (blue). Log rank = 0.003.*

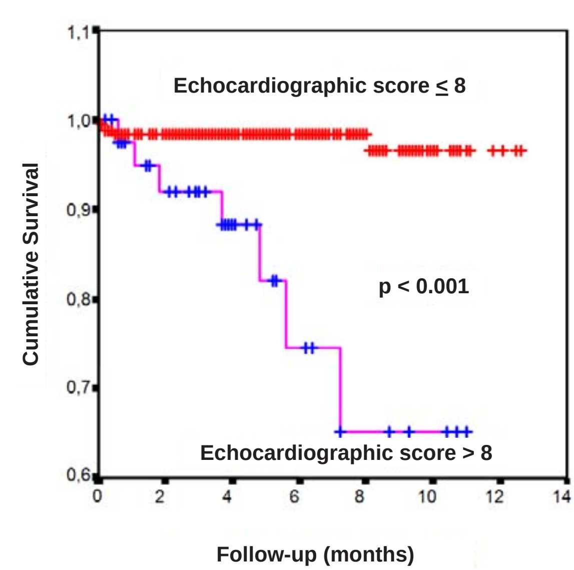

***Fig. 2** - Kaplan-Meier survival curve by echo score: ≤ 8 points (red) and > 8 points (blue). Log rank = 0.001.*

few cases functional class I[27], with excellent immediate and long term results as seen in the present study[28]. Functional classes I and II, at the end of the follow-up, ranged from 36% to 95% depending on the population characteristics and length of the follow-up[3,8,10].

Most of the patients in this study had sinus rhythm when they were indicated for the procedure and there was no difference between the groups. Farhat and associates[3] in a study with a young population, reported that 71% of the patients were in sinus rhythm before the procedure. Generally speaking, older populations[12] present higher echocardiographic scores and a greater incidence of atrial fibrillation. For some authors, the presence of atrial fibrillation is a predictor of events during long term follow-up[8,10,12,29,30], but others disagree[12,18,19,31,32].

As per observations in this study and literature[3,6,11,14,33], pulmonary and left atrium pressures drop immediately following balloon mitral valvoplasty which was similar for both study groups.

In both study groups, and in agreement with literature[12,18,34,35], the echocardiographic score ≤ 8 was prevalent and offered a more favorable evolution. But even though the results were not as positive, the group with echocardiographic scores > 8 also presented satisfactory results and evolution[13,18], particularly those with a score ≤ 11[13]. In the single and Inoue balloon groups, the echocardiographic scores presented similar averages even though the percentage of patients with a score > 8 was higher in the Inoue balloon group.

In the present study, the presence of mitral regurgitation before the procedure was greater in the single balloon group; however there was no difference in relation to severe mitral regurgitation after the procedure between the single and Inoue balloon group patients during long term evolution

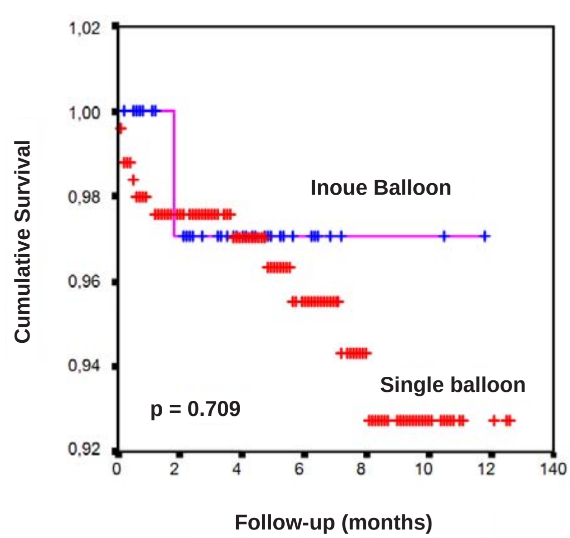

Fig. 3 - Kaplan-Meier survival curve for the 25mm and 30mm diameter single Balt balloons (red) and the 22mm to 28mm diameter Inoue balloons (blue). Log rank = 0.709.

or the onset of severe mitral regurgitation at the end of the evolution. The occurrence of severe mitral regurgitation during the procedure predicted events during long term evolution in other studies[11,12,13,19,22,32,35] and mitral regurgitation can be predicted by a specific echocardiographic score[36]. Mitral regurgitation before the valvuloplasty is a predictor of reduced event free survival[11]. Kaul and associates[23] found severe mitral regurgitation immediately following the procedure in 3.3% of the patients, of which 55% required urgent valve replacement; at the end of the follow-up they observed that 8.4% of the patients had severe mitral regurgitation, of which 37.7% required mitral valve surgery.

In this study the mitral valve area before and after the procedure and at the end of the follow-up was similar for the two groups. It has been established that similar mitral valve areas can be obtained after percutaneous balloon mitral valvoplasty using either of the current balloon technique practices as long as the actual balloon dilatation areas are comparable[1-5].

At the end of the follow-up there were 12 (4.0%) deaths, 11(4.3%) in the single balloon group and one (2.1%) in the Inoue balloon group, with no significant difference. Mortality in literature ranges from zero[37] to 18%[12,18-20,26,38] during follow-up of one to ten years and is greater in groups with higher echocardiographic scores[12,13], reaching as high as 17% to 18%[9,18] depending on unfavorable characteristics or longer follow-up. The follow-up period for the single balloon group (54 ± 31 months) was greater than that of the Inoue balloon group (34 ± 26 months). The statistical methods used in this study corrected the evolution time.

During long term follow-up, the survival rate varied substantially (82% to 100%) for follow-up of five to seven years[6,9,12,17,19,20,39]. The long term results are less favorable in Europe and the United States[12,25], where the patients are older and the mitral valve anatomies are more altered. Survival in this study at the end of evolution was 95.7% in the single balloon group and 97.9% in the Inoue balloon group. Major event free survival was 82.3% in the single balloon group and 91.7% in the Inoue balloon group in comparison to the findings in literature between 16% and 90% during follow-up of four to twelve years[6-12,19,25,38,39] due to differences in the patient groups.

In the univariate analysis, no differences were found in relation to the technique used (single or Inoue balloon) and this variable did not meet the criteria for inclusion in the multivariate model. In the multivariate analysis, echocardiographic scores > 8 and age $\geq$ 50 years were the only independent predictors of death during long term evolution. In literature, older patients, higher echocardiography scores, higher functional classes before and after the procedure, elevated systolic pulmonary pressure and left ventricle end diastolic pressure and severe mitral regurgitation during the balloon valvoplasty procedure have been cited as independent variables to predict death[12,13,38].

In the multivariate analysis, the independent factors that predicted events during long term evolution in this study were echocardiographic score > 8 and an unsuccessful procedure (mitral valve area < 1.50 cm^2). In literature the independent factors for events are: reduced mitral valve area after the procedure[8,13,19,22,25,40], atrial fibrillation before the procedure[8,10,11,13,29,30], prior mitral commissurotomy surgery[12,13,25,26,32] (even though the restenosis group after valve repair surgery or balloon valvoplasty can present satisfactory results and evolution[34,41]), presence of severe mitral valve regurgitation after the procedure[8,12,13,19,21,26,32,40], elevated functional class before the procedure[8,10,12], elevated echocardiographic score before the procedure[11,12,18,19,22], advanced age[8-12], unfavorable mitral valve anatomy[8-11,24], elevated mean pulmonary pressure after the procedure[9,12,22], elevated mitral transvalvular gradient after the procedure[8,10,26,30], elevated left atrium pressure after the procedure or increased left atrium[18,26], male gender[18], increased cardiothoracic index[9,25] and presence of comorbidities[18].

There are very few studies and reports on populations undergoing mitral valvoplasty that compare low cost large diameter single balloons with Inoue balloons[1,4,5].

One of the limitations of this study was the loss of patient contact during long term evolution; nevertheless, the study population for this type of procedure is widespread and is the largest documented population for the use of the large diameter single balloon technique. The fact that it was not a randomized study is another limitation; however, the study variables (clinical, echocardiographic and hemodynamic characteristics) in the two groups, for the most part, did not present any significant statistical differences and both techniques were performed during the study period.

Conclusion

No difference was observed in relation to immediate results and long term evolution between the Inoue and single large diameter Balt balloon techniques in the univariate analysis or Kaplan-Meier curves for survival and event free survival. In the long term evolution, age $\geq$ 50 and echocardiographic score > 8 were independent variables to predict death and an echocardiographic score > 8 and mitral valve area after the procedure < 1.50 cm^2 were independent variables to predict major events, and atrial fibrillation was near statistic significance.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association with Graduate Work

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