Original Article

Balloon Valvuloplasty Outcome of a Group Previously Submitted to Mitral Percutaneous or Surgical Valve Repair versus First-time Valvuloplasty Patients. Evolution of the Group Previously Submitted to Valve Repair Procedures

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OBJECTIVE

To evaluate 501 procedures of mitral balloon valvuloplasty and the differences among the group already submitted the prior surgical or balloon valvuloplasty, with 59 procedures and the group without previous intervention, with 442 procedures.

METHODS

It was used the single balloon in 403, Inoue balloon in 89 and a double balloon in six, with no difference between the 2 groups (p=0.6610).

RESULTS

The prior surgical or balloon valvuloplasty group was older, with higher echo score and higher atrial fibrillation rate and of its 59 patients, 48 had been submitted only to mitral surgical commissurotomy, 8 only to mitral balloon valvuloplasty and 3 to surgical commissurotomy and after submitted to balloon valvuloplasty because of restenosis. In prior surgical or balloon valvuloplasty and mitral balloon valvuloplasty without previous intervention groups pre valvuloplasty there were respectively: echo mitral valve area 0.99 ± 0.21 and 0.94 ± 0.21 cm^2 (p=0.0802) and mitral valve area (Gorlin) 0.94 ± 0.18 and 0.91 ± 0.21 cm^2 (p=0.2518) and post mitral valvuloplasty 1.95 ± 0.44 and 2.05 ± 0.42 cm^2 (p=0.1059).

CONCLUSIONS

The hemodynamic and angiographic outcome of the prior surgical or balloon valvuloplasty group were similar to the group without previous intervention. The evolution was satisfactory in the prior valvuloplasty subgroup with long-term follow-up.

KEY WORDS

Percutaneous mitral balloon valvuloplasty, previous commissurotomy surgery, previous balloon valvuloplasty, mitral stenosis.

Mitral balloon valvuloplasty was introduced in 1984 by Inoue et al[1]. In 1986, McKay et al[2] and Palacios et al[3] put it into practice in the United States. Also in 1986, in Saudi Arabia, Al Zaibag et al[4], began using the double balloon technique with a transseptal approach. In Brazil, the dilation is described in 1987, with a retrograde approach[5,6] and a transseptal approach[7-9].

It has now been proved that one can achieve the mitral area with post percutaneous mitral balloon valvuloplasty similarly to any of the techniques in use[10-14].

Overall and event free survival rates varied among the groups studied, due to the patients' clinical and echocardiographic traits[15-22]. Factors that contribute to a better evolution include a younger age, satisfactory valve anatomy with an echocardiograph score less than or equal to 8 points, presence of a sinus rhythm, no mitral regurgitation before the procedure and no previous commissurotomy surgery before the procedure.

The transseptal mitral balloon valvuloplasty was initiated in Brazil in 1987 using a single balloon, followed by the double balloon and Inoue balloon, returning to the single balloon technique using a balloon with a larger diameter and lower profile[7-11,23]. Generally speaking, the studies documented in medical literature report similar results with the techniques mentioned[8-13,24-26]. In our case, the results attained in patients who had previously undergone commissurotomy surgery depended on the state of the mitral valve (Wilkins score)[27] and not on the previous surgical treatment; however, despite the positive immediate results[28,29], and satisfactory evolution, the first-time group presented a better evolution[30-32].

In the present paper, we analyzed the immediate results of percutaneous mitral balloon valvuloplasty in a group of patients that had undergone previous percutaneous or surgical mitral valve repair procedures and compared them to the results obtained with first-time valvuloplasty patients. We also relate the evolution of the group of long-term follow-up patients that had undergone previous valve repair procedures.

METHODS

Among the 518 mitral balloon valvuloplasty procedures performed between July 6, 1987 and December 31, 2004, 17 procedures were excluded as the balloon was never inflated in the mitral valve. All but one of these procedures were performed during the introductory stage of the technique. Consequently, the results of the 501 complete procedures where mitral valve dilation was successful were included in this paper. The group that was first submitted to mitral balloon valvuloplasty included 442 patients that underwent the procedure between August 4, 1987 and October 14, 2004. The remaining 59 patients, submitted to mitral balloon valvuloplasty for restenosis, had undergone previous valvuloplasty for surgical commissurotomy or percutaneous interventions between January 2, 1992 and October 15, 2001.

The 17 procedures that were excluded from the study included 16 procedures that were not completed and one that presented complications and hindered the effectiveness. Sixteen were first-time procedures and one was a redilation. However the exclusion of these 17 procedures did not interfere with the end results as the mitral valve was never dilated and therefore there were no results to analyze.

The techniques used for the 501 procedures included the Inoue balloon for 89 procedures, the Balt low profile single balloon for 403, the Meditech conventional single balloon in three and the double balloon in six. In the valvuloplasty post intervention restenosis group, the Inoue balloon was used in nine procedures and the low profile single balloon in fifty; while in the first-time mitral balloon valvuloplasty group the Inoue balloon was used in eighty procedures, the low profile single balloon in 353, the double balloon in six and the conventional single balloon in three (p= 0.6610).

After mitral dilation, a left heart ventriculography in a right anterior oblique projection was always performed as well as a new left and right catheterization and a new measurement of the gradient between the left atrium and left ventricle was taken. The gradient between the left atrium and left ventricle were measured simultaneously immediately before and after the mitral valve dilation. The protodiastolic, mesodiastolic and telediastolic gradients were measured. The average gradient was calculated using the three point method and the mathematical average of the three previous measurements[33] and during the second phase by gradient area planimetry[33]. The mitral valve area was calculated before and after the dilation. The mitral valve area was measured before the valvuloplasty using an echocardiograph. During the procedure the mitral valve area measurements were taken, before and after the procedure, using the thermodilution cardiac output followed by the Gorlin & Gorlin[34] formula to calculate the area. Mitral failure was graded according to the semiquantitive criteria of Sellers et al[35]. Success was defined as a mitral valve area ≥ 1.50 cm^2 after the procedure.

Data used in the study included age, gender, rhythm, NYHA functional class before the procedure, mitral valve echocardiograph score[27], mitral valve echocardiographic area before the procedure, hemodynamic mitral valve area before and after the procedure, mitral valve regurgitation before and after the valvuloplasty and success rates. None of the 501 patients selected died during the procedure.

A subgroup of 34 patients was selected from the 59 patients in the post valvuloplasty intervention restenosis group for long-term follow-up and evolution assessment. After the evolution period, the following data was studied: evolution time and functional class, echocardiographic mitral valve area, mitral competency, new serious mitral valve failure and events related to the new percutaneous

valvuloplasty or mitral valve surgery and fatality rates.

Comparison of the data collected before the procedure and the results immediately following the procedures, for both groups, was conducted using the chi-square test for categorical variables and the Student's t-test for quantitative variables. The program EPI-INFO version 6[36] was used as a database and for statistical analysis.

RESULTS

The 501 mitral balloon valvuloplasty procedures were performed on 59 patients that had already undergone percutaneous or surgical valve repair procedures that suffered restenosis during the evolution period and 442 first-time surgical intervention or balloon valvuloplasty patients.

From the 59 patients that had already undergone interventions, 48 had been submitted to commissurotomy surgery, eight to balloon valvuloplasty and three to commissurotomy surgery and subsequent balloon valvuloplasty for restenosis; 52 patients were female and seven were male. The 442 patients in the mitral balloon valvuloplasty group without previous surgery were divided into 365 females and 77 males (p = 0.2832) which did not present a significant difference.

The age of the post intervention restenosis group was 42.7 ± 11.4 years and the mitral balloon valvuloplasty group without previous interventionwas 37.0 ± 12.6 years (p = 0.0009). Therefore, the post intervention restenosis group was older.

The NYHA functional class for the valvuloplasty post intervention restenosis group was level I in one procedure, II in fifteen, III in 37 and IV in six, while in the mitral valve balloon valvuloplasty without intervention group the functional class was I in seven procedures, II in 101, III in 287 and IV in 47 (p = 0.9771). Therefore there was no significant difference between the groups.

From the 501 procedures studied, only eight patients were within the NYHA functional class I, with a mitral valve area less than 1.25cm^2 during the echocardiograph test before the valvuloplasty, a mitral valve area ≤ 1.10cm^2 when measured using the Gorlin & Gorlin[34] formula and a significant holodiastolic gradient during catheterization. In addition to the previous findings a later development showed a serious gradient increase in the volume-overload test. All the patients wanted to become pregnant and/or perform physical activity, seven had a score ≤ 8 points, and one patient in this subgroup who had undergone a previous valve repair procedure had a score of ten points. There were no complications in the procedures performed.

In the post intervention valvuloplasty restenosis group, 45 (76.3%) patients had a sinus rhythm and 14 (23.7%) had atrial fibrillation. In the mitral balloon valvuloplasty without intervention group, 388 (87.8%) had a sinus rhythm and 54 (12.2%) had atrial fibrillation (p= 0.0153). Therefore, the post intervention valvuloplasty restenosis group had a higher percentage of atrial fibrillation.

The echocardiograph score[27] in the post intervention restenosis valvuloplasty group was 7.91 ± 1.64 (4 to 12) points and in the mitral balloon valvuloplasty without intervention group was 7.28 ± 1.44 (4 to 14) points (p = 0.0018). Therefore the post intervention restenosis valvuloplasty group had higher echocardiograph scores. The mitral valve area before the valvuloplasty was calculated using the echocardiograph half pressure time and was 0.99 ± 0.21 cm^2 for the post intervention restenosis valvuloplasty group and 0.94 ± 0.21 cm^2 for the mitral valve balloon valvuloplasty without intervention group (p = 0.0802).

Comparison of the mitral valve area hemodynamic results between the two groups using the Gorlin formula revealed a mitral valve area before the mitral balloon valvuloplasty of 0.94 ± 0.18 per procedure for the post intervention restenosis valvuloplasty group and 0.91 ± 0.21 cm^2 per procedure for the valvuloplasty without intervention group (p = 0.2518), while the mitral valve area after the percutaneous mitral balloon valvuloplasty was 1.95 ± 0.44 and 2.05 ± 0.42 cm^2 respectively (p = 0.1058). There was no significant difference between the valve areas for the two groups.

The mitral valve before the percutaneous mitral balloon valvuloplasty was competent in 49 of the post intervention restenosis valvuloplasty group procedures and in 377 of the balloon valvuloplasty without previous intervention group procedures. Mitral valve failure of +/4 ocurred in ten post intervention restenosis procedures and 64 balloon valvuloplasties without previous intervention and one patient of the balloon valvuloplasty without previous intervention group had mitral failure of 2+/4 (p = 0.8273). The mitral valve after the percutaneous mitral balloon valvuloplasty for the post intervention restenosis group was competent in 44 procedures, +/4 in 10, 2+/4 in 3 and 3+/4 in 2 and for the balloon valvuloplasty without intervention group the mitral valve was competent in 311, +/4 in 93, 2+/4 in 30, 3+/4 in 4 and 4+/4 in 4 (p = 0.4059).

There were ten cases of serious mitral valve failure, two post intervention restenosis patients and eight patients of the balloon valvuloplasty without previous intervention group. The failures occurred both before and after the percutaneous mitral valve balloon valvuloplasty and did not have any significant statistical difference.

The mitral valve area was measured after the procedure in 480 of the 501 procedures studied, of which 56 were from the post intervention restenosis group (3 measurements were not made), four procedures were unsuccessful (mitral valve area < 1.50 cm^2) and 424 were from the 442 patients in the balloon valvuloplasty without previous intervention group; 24 procedures were unsuccessful (p = 0.7437).

From the group of 59 patients that had undergone previous valve repair procedures, 34 patients were submitted to a balloon valvuloplasty and long-term follow-

up with an evolution time of 48.9 ± 32.3 (4 to 126) months. There were 30 female patients (88.2%). Before the procedure, there were eleven (32.4%) functional class II patients; eighteen (52.9%) functional class III; and five (14.7%) functional class IV. Twenty-four (70.6%) patients had undergone previous surgical valve repair procedures, seven (20.6%) had undergone previous balloon valvuloplasty and three (8.8%) had previously undergone both procedures. Twenty-six (76.5%) patients had a sinus rhythm, an echocardiograph score of 8.0 ± 0.3 (5 to 12) points, an echocardiographic mitral valve area of 0.96 ± 0.04 (0.60 to 1.50) cm^2 before the procedure and the hemodynamic mitral valve area and mitral pre-dilation, calculated using the Gorlin formula, was 0.94 ± 0.03 (0.60 to 1.40) cm^2 per procedure.

The subgroup noted above, who had long-term follow-up, had a hemodynamic mitral valve area and mitral post dilation, calculated using the Gorlin formula, of 1.96 ± 0.07 (1.40 to 3.10) cm^2 per procedure. At the end of the evolution, the echocardiographic mitral valve area (half pressure time) was 1.37 ± 0.07 (0.70 to 2.00) cm^2; fifteen (44.1%) patients were in functional class I; nine (26.5%) in functional class II; seven (20.6%) in functional class III; three (8.8%) died during the evolution period and five (16.7%) were not taking any drugs.

Three (8.8%) patients presented new serious mitral failure during the evolution. Three (8.8%) patients were submitted to valve surgery, two for mitral restenosis and one for mitral failure, with one valve repair and two valve replacements. Four (11.8%) patients underwent new balloon valvuloplasty procedures. The three (8.8%) deaths were cardiac related, one during mitral valve replacement surgery and two due to acute pulmonary edema. Nine (26.5%) patients had major events (new balloon valvuloplasty, mitral valve surgery and/or death).

DISCUSSION

The percutaneous mitral balloon valvuloplasty introduced by Inoue[1], quickly became the treatment of choice for serious mitral stenosis. It was concluded at first that mitral balloon valvuloplasty using the double balloon technique produced a larger mitral valve area than the conventional single balloon[24,37]. Currently, the efficiency of various balloon types has been proven and mitral valve areas can be obtained after a mitral balloon valvuloplasty with similar balloons using any of the balloon techniques available, that is, the double balloon, the Inoue balloon or the low profile balloon (single balloon) as long as the effective balloon dilation areas are compatible[9-11,14,38-40].

Recent studies have shown an average mitral valve area greater than or equal to 2 cm^2, regardless of the technique used[10,37]. In the groups studied, the average mitral valve area obtained after the percutaneous intervention was 1.95 ± 0.44 cm^2 in the group previously submitted to percutaneous balloon commissurotomy or

previous surgery and who suffered restenosis, and 2.05 ± 0.42 cm^2 in the mitral valve balloon valvuloplasty without intervention group which does not present a significant statistical difference as from a clinical and echocardiographic viewpoint both groups had minimal residual lesions.

The incidence of mitral valve failure is lower when the effective balloon dilation area is corrected for body surface area, and is less than or equal to 4.0 cm^2[41]. For Roth et al[42], only the relation between the effective area of the balloon dilation and the body surface area could predict an increase in mitral valve regurgitation. The study by Aurora et al[43] concluded that the size of the balloon, the degree of subvalvular blockage or the seriousness of the mitral stenosis have no relation with the appearance of mitral failure. Later, new echocardiographic score was developed that predicts the appearance of mitral failure[44,45].

Despite the elevated effective dilation area used in this study, the incidence of significant mitral failure was low[8-11]. In the present study there was no significant difference for the incidence of mitral regurgitation after balloon valvuloplasty in the groups studied, of which the incidence rate of serious mitral valve failure among the 501 patients was 1.99%.

It has been shown that percutaneous mitral valve balloon valvuloplasty can be performed with the same degree of efficiency or at least with good results in groups of patients submitted to the procedure for restenosis after mitral commissurotomy surgery[28,29,46-49] or percutaneous mitral balloon valvuloplasty[50].

In the present study, the group that had previously undergone percutaneous balloon valvuloplasty or previous surgery was older, had a higher echocardiograph score and a higher percentage of atrial fibrillation than the balloon valvuloplasty without intervention group. There were no differences in the functional class ratings before the procedure, mitral valve area before or after the procedure and mitral valve failure after the procedure. The echocardiograph score was higher for the patients that had previously undergone interventions which agrees with other studies[51].

The increase in the mitral valve area after mitral balloon valvuloplasty found by Lee et al[46] was lower for their mitral balloon valvuloplasty group for restenosis after commissurotomy surgery; however the difference was not significant, while our findings indicate a significant difference in the same situation[29]. In a report published afterwards, Lau et al[48], from the same group as Lee et al[46], found similar mitral gradients, mitral valve areas, mitral failure rates and restenosis rates during follow-up of post commissurotomy surgery and mitral valvuloplasty without intervention patients. Nevertheless, both authors obtained valve areas much lower (1.6 cm^2) than those obtained in our present and previous studies[29,49]. Sharma et al[51] and Medina et al[52] found similar results in their two patient groups, for both the hemodynamic data and mitral failure

rates even though the post commissurotomy mitral group of Sharma et al[51] had a higher echocardiograph score.

Results similar to ours were found by Ha et al[53], that obtained lower average mitral valve area values, but without statistical significance, and similar mitral valve failure rates. However, in a previous study with fewer patients we obtained a lower mitral valve area after valvuloplasty that was statistically significant[29] for a mitral valvuloplasty for restenosis group after commissurotomy surgery, even though, from a clinical perspective, both groups had positive results.

In the subgroup of long-term follow-up patients submitted to mitral valvuloplasty for restenosis after surgical or balloon valve repair procedures, 24 (70.6%) patients had a satisfactory evolution and were rated as functional classes I and II, however nine (26.5%) patients suffered major events (new valvuloplasty, mitral valve surgery and/or death) and three (8.8%) died. In previous studies we discovered during the long term evolution that surgical valve repair was not an independent factor to predict death, however it was an indication for major events and a higher number of reinterventions[30-32]. Others have shown the influence of the Wilkins[27] echocardiograph score in the mitral valvuloplasty results[29,49,54], for both immediate results[29,49,54] and long term evolution[30,31,54-56], and the group of patients that had previously undergone valve repair procedures presented a higher echocardiograph score.

In conclusion, mitral balloon valvuloplasty was an efficient treatment for serious mitral stenosis in the group that had undergone previous percutaneous balloon or surgical valve repair procedures and suffered restenosis. The immediate results were comparable to the valvuloplasty without intervention group. In agreement with medical literature, the long term evolution of the post intervention group was inferior to the valvuloplasty without intervention group; nevertheless, the evolution was satisfactory.

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

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