

PERCUTANEOUS BALLOON VALVULOPLASTY IN MITRAL RESTENOSIS AFTER PREVIOUS SURGICAL COMMISSUROTOMY

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ABSTRACT

Objectives: The aim of this study was to determine the safety profile, mitral valve outcome and follow-up functional status after percutaneous balloon mitral valvuloplasty (PBMV) in patients with mitral restenosis post-surgical commissurotomy.

Methods: Sixteen patients with symptomatic mitral restenosis after previous surgical commissurotomy underwent valvuloplasty using the Inoue balloon stepwise dilatation method. Echocardiography was performed before and after the procedure to evaluate the mitral valve area.

Results: All procedures were successfully completed without cardiac perforation, thromboembolism, resultant severe mitral regurgitation or death. The mitral valve area improved from 0.9 ± 0.2 to 1.6 ± 0.3 ($p=0.0001$), accompanied by a significant immediate reduction in the left atrial pressure and transmitral gradient. Compared with PBMV in patients without past mitral surgery, patients with mitral restenosis undergoing PBMV experienced less valve area improvement but the difference was not significant ($p=0.137$). Optimal valve enlargement resulting in mild mitral stenosis was achieved in 12 of the 16 patients. Midterm symptomatic benefit was observed in almost all patients.

Conclusions: In view of the excellent success rate, low complication risk, the optimal haemodynamic results and favourable functional outcome afforded by mitral balloon valvuloplasty in patients with mitral restenosis after prior surgical commissurotomy, it is logical that balloon mitral valvuloplasty, where available, should be the initial treatment modality in this group of patients with suitable valve morphology before considering repeat mitral surgery.

Keywords: balloon valvotomy, surgical commissurotomy, mitral stenosis, restenosis.

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INTRODUCTION

Rheumatic mitral stenosis remains a common problem, especially in less developed countries where rheumatic fever is endemic. In the past, mitral surgery (closed or open commissurotomy and valve replacement) was the only therapeutic option available for patients requiring relief of the valvular obstruction. Restenosis

after surgical commissurotomy (SC), unfortunately, is an inevitable process and has been estimated to occur in 10%-30% of patients within 5-10 years after surgery⁽¹⁻⁴⁾. Although mitral reoperation is feasible, it is, nevertheless, associated with a higher morbidity and mortality compared with the initial procedure^(1-3,5,6). Percutaneous balloon mitral valvuloplasty (PBMV), in contrast, is a relatively non-traumatic procedure that splits the fused mitral commissures in a manner similar to that of its surgical counterpart⁽⁷⁾. Not unexpectedly, the short- and long-term results afforded by PBMV have been shown in various observational⁽⁸⁻¹⁴⁾ and randomised studies⁽¹⁵⁻¹⁹⁾ to be either comparable or better than those of SC in selected patients. PBMV is now considered the treatment of choice in patients with post-surgical mitral restenosis. Despite this assumption, only a few reports⁽²⁰⁻²²⁾ in the past have specifically addressed the outcome of PBMV in mitral restenosis after SC. Accordingly, this study analyses our experience of PBMV in this group of patients.

METHODS

Patient population

Between June 1990 to March 1994, 114 consecutive patients with symptomatic mitral stenosis without $\geq 2/4$ angiographic mitral regurgitation or thrombus within the left atrial cavity or attached to the interatrial septum underwent PBMV. Of these, 16 (14%) were patients with recurrent mitral stenosis 16 years (range, 7-30) after SC (11 closed, 5 open); they formed the basis of this report. Two patients had strokes in the past with residual hemiparesis. The baseline characteristics are depicted in Table I.

PBMV technique

A 1-stage diagnostic cardiac catheterisation and PBMV procedure was performed in all patients as described previously^(11,13,14). After transeptal access was achieved and baseline haemodynamic measurements made, the mitral

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valve was dilated (Fig 1) using the Inoue stepwise dilatation technique^(11,13,14). Selection of the appropriate balloon size was made in accordance with the method previously described by Hung and coworkers^(11,13). The procedure was terminated when a satisfactory reduction in transmitral gradient was obtained or when significant mitral regurgitation was suspected from a combination of auscultatory findings, the appearance of giant v waves in the left atrial pressure or an increase in mean left atrial pressure. Left ventriculography was performed before and after the procedure to document the mitral regurgitation status, the grading of which was based on Sellers' criteria⁽²³⁾.

Echocardiography

All patients underwent a complete transthoracic echocardiographic assessment before, soon after PBMV and at follow-up of ≥ 6 months. Measurements were performed according to the recommendations of the American Society of Echocardiography⁽²⁴⁾. The mitral valve morphologic features were evaluated based on the Wilkins scoring system⁽²⁵⁾ which generated a 4-point score of each of 4 anatomic subcomponents (leaflet mobility, thickening, calcification and subvalvular thickening) and a total cumulative score. Higher scores implied more severe disease. Transoesophageal echocardiography was performed routinely 1 to 2 days before PBMV to exclude the presence of left atrial thrombus. Non-protruding left atrial appendage thrombus was not considered a contraindication to the procedure in our institution.

Table I – Baseline characteristics and haemodynamic results of PBMV patients

No. of patients	16		
Female (%)	75		
Age (years)	48 \pm 10		
(range)	(34-66)		
Atrial fibrillation (%)	75		
Echo score	8 \pm 2		
(range)	(4-12)		
	Pre	Post	*p value
LAP (mmHg)	19 \pm 6	13 \pm 4	0.0003
(range)	(7-26)	(5-22)	
Gradient (mmHg)	11 \pm 3	4 \pm 1	0.0001
(range)	(6-16)	(2-7)	
MVA (cm ²)	0.9 \pm 0.2	1.6 \pm 0.3	0.0001
(range)	(0.6-1.7)	(1.2-2.5)	

Data expressed as mean \pm SD

*for comparisons between pre- and post-PBMV haemodynamics

LAP: left atrial pressure; MVA: mitral valve area.

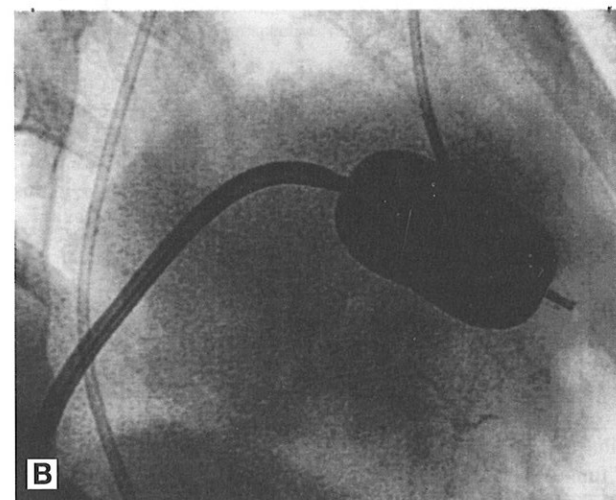
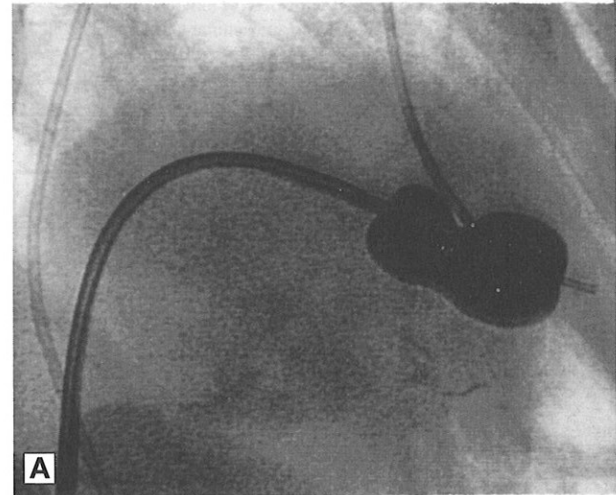
Statistical analysis

Continuous variables are expressed as mean \pm SD. Measurements before and after PBMV were compared using Student's paired t test. A p value < 0.05 was considered statistically significant.

RESULTS

PBMV was technically successful in all 16 patients, resulting in immediate improvement in the transmitral gradient and left atrial pressure (Table I). All patients experienced an improvement in haemodynamic and mitral valve area measurements following PBMV. The mitral valve area increased from 0.9 ± 0.2 cm² to 1.6 ± 0.3 cm² (p=0.0001); this magnitude of valve enlargement was not significantly less than that produced by PBMV in patients without previous mitral surgery (0.8 ± 0.2 to 1.7 ± 0.4 , p=0.137)⁽¹⁴⁾. An optimal result, defined arbitrarily as a $\geq 50\%$

Fig 1 - Angiographic freeze-frames in the right anterior oblique projection showing an inflated Inoue balloon across the mitral valve. (A) Initial balloon inflation demonstrates the mid-balloon constriction at the site of the stenosed valve. Subsequent careful dilatations of the valve by progressively bigger balloon sizes achieved by increasing the amount of diluted contrast in the balloon (stepwise dilatation technique) result in obliteration of the balloon "waist" and complete splitting of the fused mitral commissures (B).

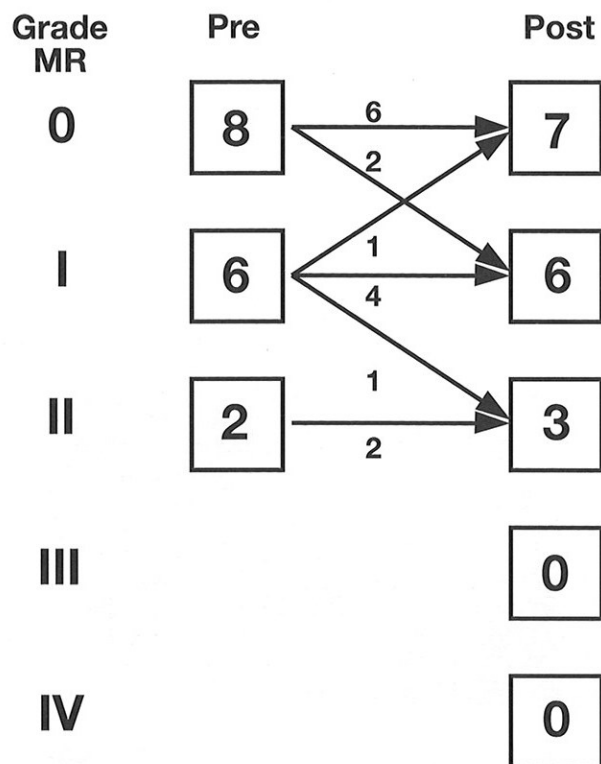


increment in mitral valve area with a final valve area ≥ 1.4 cm² and without an increase of $\geq 2/4$ mitral regurgitation, was obtained in 12 patients (75%). The result of PBMV was independent of the type of previous SC (closed vs open) used.

The change in mitral regurgitation is shown in Fig 2. An increase in mitral regurgitation of ≥ 1 grade was observed in 4 patients (25%). No patient developed grade 3/4 mitral regurgitation or required mitral valve surgery as a result of it. Atrial septal defect after PBMV was noted in 2 patients; the shunts in both were small. There was no procedure-related cardiac tamponade, cardioembolism or death in this series of patients.

Follow-up echocardiography at a mean of 11 months was performed in 4 patients (33%). Restenosis (arbitrarily defined as a loss of $\geq 50\%$ of the initial gain in valve area) was observed in one patient. However, favourable functional class (NYHA class I and II) was maintained in 15 patients at a mean follow-up of 7 months post-PBMV with 78% of patients experiencing symptomatic improvement of ≥ 1 NYHA class.

Fig 2 – Angiographic mitral regurgitation (MR) before (pre) and after (post) percutaneous mitral valvuloplasty.



DISCUSSION

This present study extends and confirms a number of findings from earlier reports on PBMV in mitral restenosis after SC, namely that the procedure is extremely safe and effective in this scenario.

Technical success rate and complications

Although the overall technical failure rate in PBMV is extremely low, particularly when performed by experienced operators^(8,26), in one study⁽²²⁾ involving 27 patients with post-surgical mitral restenosis undergoing PBMV, a 4% failure rate (due to inability to cross the mitral valve with the balloon) was observed. Furthermore, the much thicker interatrial septum and eccentric "funnel-shaped" mitral valve not uncommonly encountered in such patients may make the technical aspects of the procedure more demanding than PBMV in those without past mitral surgery. In the present study, however, all procedures were successfully completed.

Cardiac perforation with tamponade - occasionally causing death - due mainly to erroneous transseptal puncture of adjacent cardiac structures other than the interatrial septum occurs in about 1% of procedures^(8,26). The transseptal technique described by Hung⁽²⁷⁾ and used by us is most suitable for the Inoue PBMV approach. There was no cardiac perforation in this series. Hung has only encountered one cardiac perforation in more than 800 PBMV procedures (personal communication). An additional site of cardiac perforation is that of the left ventricle, only encountered with the double-balloon technique because of either perforation by the left ventricular guide wires or the stiff-tip of the Mansfield balloons⁽⁸⁾. In sharp contrast, this dreaded site of perforation has never been described in > 15,000 Inoue PBMV procedures⁽²⁸⁾.

Mild mitral regurgitation after PBMV is often, detectable in 25%-83% of patients^(8,14). This is usually due to commissural splitting and inadequate leaflet coaptation, and is of no clinical consequence, with the majority resolving within months⁽⁸⁾. In

contrast, severe mitral regurgitation - albeit infrequent and only occurs in 3%-5% of patients - due mainly to leaflet tear and/or excessive subvalvular disruption, poses a key limiting factor to PBMV with some requiring emergency valve replacement^(8,14). In this study, a 25% incidence of an increase in mitral regurgitation was noted but fortunately, none was severe or required surgery. This lack of significant mitral regurgitation could be attributed to our patient selection, and the stepwise dilatation and balloon sizing methods we used in the study. In a recent study by Lau and Hung⁽¹³⁾, no severe mitral regurgitation was created in patients with favourable valve characteristics (pliable, noncalcified) using the same balloon sizing method adopted in the present study.

Cardioembolism is currently exceedingly rare during PBMV⁽⁸⁾. Undoubtedly, this is attributable to the vital role played by pre-PBMV transoesophageal echocardiography in excluding the presence of left atrial thrombus. Not surprisingly, because of our routine application of transoesophageal echocardiographic assessment just before each PBMV procedure, not one systemic embolism was observed in the study.

The overall mortality associated with PBMV is now < 1% in most studies from high-volume skilled centres staffed with trained operators⁽⁸⁾. In this study (and in our total experience of > 150 cases) there was no death related to the procedure. In contrast, with redo mitral surgery, the patients are exposed to a 3%-10% risk of operative mortality, and the trauma of a second thoracotomy and its related morbidity⁽¹⁻⁶⁾. Perhaps, making PBMV even more attractive are convincing data from recent landmark randomised trials comparing PBMV and SC showing similar or better short- and long-term results in terms of mitral valve area and symptomatic improvements with PBMV⁽¹⁵⁻¹⁹⁾.

Mitral valve enlargement

The present study also demonstrates the efficacy of PBMV in patients with mitral restenosis. The absolute gain in mitral valve area obtained in our study is comparable with those from previous studies⁽⁸⁾. Optimal valve dilatation resulting in generally mild residual mitral stenosis was obtained in 75% of our patients. Based on our definition of optimal dilatation, Rediker et al⁽²⁰⁾ obtained a 67% success rate. Serra and co-investigators⁽²²⁾ using the fixed-balloon systems (Bifoil balloons, Schneider or 2 Mansfield double-balloons), obtained optimal results (defined as an increase in mitral valve area of $\geq 25\%$ with a valve area $\geq 1.5 \text{ cm}^2$) in 67% of their 27 patients with mitral restenosis, results which were similar to those without previous SC undergoing primary PBMV. In contrast, Hermann et al⁽²⁹⁾ noted a smaller valve enlargement after PBMV in patients with vs those without previous SC (55% vs 94%, $p=0.01$). Similarly, Davidson et al⁽²¹⁾ found an echo-determined valve area improvement of 45%-54% after PBMV in patients with post-surgical mitral restenosis compared with a slightly larger gain in valve area of 54%-64% in those without prior SC.

Midterm results

Over a 6-month follow-up period, sustained symptomatic improvement was observed in 80% of patients. Recent studies^(8,18,30,31) have, indeed, confirmed that symptomatic benefits after successful PBMV are usually maintained in the majority of patients, even in those of restenosis. Furthermore, in those with symptomatic restenosis, PBMV can be repeated with equal safety and efficacy as the initial procedure^(8,9). Thus, PBMV can effectively delay the need for surgical intervention. After all, one must recognise that all interventional procedures, whether PBMV or mitral valve surgery, are only palliative and not a one-time definitive treatment strategy.

Limitations

Although the percent increase in mitral valve area following PBMV in the present study is comparable with other studies^(8,20-22), the final mitral valve area (1.6 cm²) at first glance appears small. This is due to the method - echocardiographic rather haemodynamic measurements - we employed in determining the valve area after PBMV. Estimations of mitral valve area have recently been shown to be substantially smaller when determined by echocardiographic than by haemodynamic methods^(21,32,33). This significant disparity in results between the 2 methods was due to the atrial septal defect created during PBMV, thereby causing an increase in cardiac output and concomitant increase in calculated valve area. Once the atrial septal defect was occluded the difference in valve area between the 2 methods no longer existed. In the studies by Petrossian et al⁽³²⁾ and Davidson et al⁽²¹⁾, the haemodynamic-derived mitral valve area was consistently 0.2 to 0.3 cm² larger than that determined echocardiographically when haemodynamic measurements of the valve area were made without occlusion of the iatrogenic atrial septal defect (1.9 vs 1.6 cm² and 1.8-2.0 vs 1.6-1.7 cm², respectively). Our valve area outcome (0.9 to 1.6 cm²) was similar to that of the NHLBI Balloon Valvuloplasty Registry⁽²¹⁾ (1.1 to 1.8 cm²) using echocardiographic measurements of valve area.

Another limiting factor of the present study is the small sample size of 16 patients. However, most past studies^(20,22,29), similarly, have small patient numbers. All studies^(20-22,29) including ours have, nevertheless, demonstrated the feasibility, the high safety-profile, and short- and long-term haemodynamic and clinical benefits of PBMV in patients with post-SC mitral restenosis.

CONCLUSIONS

Our study demonstrates the high success rate, low adverse-effect profile and excellent early haemodynamic and long-term clinical improvements associated with PBMV in patients with symptomatic mitral restenosis after previous SC. Because of these promising results, PBMV should be considered the preferred and initial treatment strategy for this group of patients.

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