TECHNOLOGY

Balloon dilatation of the mitral valve by a single bifoil (2 × 19 mm) or trefoil (3 × 15 mm) catheter

J Patel, S Vythilingum, AS Mitha

Abstract

The efficacy of balloon dilatation of the mitral valve by a bifoil (2 × 19 mm) or trefoil (3 × 15 mm) catheter (single catheter technique) was assessed in 53 patients (mean age 28) with mitral stenosis, most of whom were women. The procedure was unsuccessful in three patients. After balloon dilatation the left atrial pressure decreased from 22 mm Hg to 13 mm Hg and the mitral valve gradient from 12 mm Hg to 4 mm Hg. The mitral valve area increased from 0.7 cm² to 2.1 cm². Exercise time on the standard Bruce protocol increased from 3.9 minutes to 7.2 minutes. In 22 (44%) patients mitral regurgitation developed or the grade of regurgitation increased. Left to right shunts with pulmonary to systemic flow ratios > 1.5 were detected in four patients. Transient cerebrovascular episodes developed in two patients. One patient died after emergency valve replacement for severe mitral regurgitation.

Balloon dilatation of the mitral valve by the single catheter technique with the bifoil or trefoil catheters is an effective treatment for patients with mitral stenosis. Mild mitral regurgitation is a frequent complication of the procedure.

Since Inoue *et al*'s first description in 1984,¹ percutaneous balloon dilatation of the mitral valve has emerged as a new form of treatment for mitral stenosis. Dilatation with single² and double balloon techniques has been described.³⁻⁵ The double balloon technique was more effective in dilating stenotic mitral valves than the monofoil single catheter technique.^{6,7} The smaller (3 × 12 mm) trefoil catheter was used as part of the double balloon technique.⁸ But we found little information on the use of a single catheter technique with bifoil or trefoil balloons for dilatation.⁹ The catheter consists of two (bifoil) or three (trefoil) identical balloons mounted in parallel on a single 12F catheter. The balloons fill simultaneously when filled with saline.

The criteria, especially anatomical, for patient selection have received scant attention. We report our experience of balloon dilatation of the mitral valve by a bifoil or trefoil cath-

eter in 50 patients with mitral stenosis. We also studied the effect of various clinical, haemodynamic, and echocardiographic variables on the outcome of the procedure and on the development of mitral regurgitation.

Patients and methods

PATIENTS

From May 1988 to June 1989 balloon dilatation of the mitral valve was attempted in 53 patients with symptomatic (New York Heart Association class II-IV) pliable isolated mitral stenosis (table 1). We excluded those with active rheumatic carditis, extensive calcification, severe subvalvar disease, and more than mild mitral or aortic regurgitation. Technical reasons related to transseptal catheterisation prevented valve dilatation in two patients. In one patient the mitral valve could not be split despite repeated inflations. The final study group consisted of 50 patients of whom 41 were women and nine men (mean age 28 years (range 15-50)). Forty six were in sinus rhythm and four had atrial fibrillation. Sixteen patients had trivial (1+) and two mild (2+) mitral regurgitation. Fourteen patients also had mild aortic regurgitation. Ten patients had mitral restenosis after having had closed mitral commissurotomy 4-13 years before. Nineteen patients were in New York Heart Association class II, 30 in class III, and one in class IV. Fluoroscopy showed mild mitral valve calcification in 13 patients.

ECHOCARDIOGRAPHY

Cross sectional echocardiography was performed in all patients before and after the procedure. The structure of the mitral valve was examined for leaflet mobility, leaflet thickening, subvalvar disease, and calcification; a score was obtained for each valve as described previously.¹⁰ Out of a possible score of 16 (for a severely fibrotic valve with important subvalvar disease and calcification) the severity ranged from 3 to 9 (mean 5.3). This accords with our clinical findings that all patients had pliable mitral stenosis.

EXERCISE TREADMILL PERFORMANCE

All patients except one (New York Heart Association class IV) underwent symptom limited treadmill exercise (standard Bruce protocol) before and after (within one week) the

Cardiac Unit,
Wentworth Hospital,
Department of
Medicine, University
of Natal, Durban,
South Africa
J Patel
S Vythilingum
AS Mitha

Correspondence to
Professor A S Mitha,
Cardiac Unit, Wentworth
Hospital, P B Jacobs, 4026
Natal, South Africa.

Accepted for publication
15 May 1990

Table 1 Echocardiographic and haemodynamic characteristics of patients

Case	Sex	Age	CMV	Echo score	MVA (cm ²)	
					Pre	Post
1	F	29	—	3	0.9	3.9
2	F	29	—	8	0.7	1.5
3	F	47	—	6	0.7	2.1
4	M	15	—	7	0.3	1.0
5	F	17	—	5	0.5	3.2
6	M	35	+	7	0.9	4.7
7	F	27	—	7	0.6	1.7
8	F	26	—	4	0.4	2.7
9	F	28	—	5	0.5	1.1
10	M	20	—	9	0.3	—
11	M	23	—	7	0.4	2.4
12	F	15	—	4	0.5	1.8
13	F	36	—	5	1.0	2.7
14	F	20	—	6	1.1	2.7
15	F	23	—	5	0.8	1.8
16	F	43	+	6	1.2	3.5
17	M	28	—	6	0.9	2.7
18	F	22	—	3	0.8	1.8
19	F	37	—	4	0.4	2.6
20	F	46	—	4	0.5	1.3
21	F	23	+	7	1.1	2.2
22	F	49	+	5	1.4	2.2
23	F	18	—	4	0.7	2.1
24	F	27	—	4	1.0	2.0
25	F	34	—	6	0.7	1.2
26	F	44	—	5	0.6	1.5
27	F	24	—	5	0.6	1.9
28	F	24	—	3	1.3	2.1
29	F	27	+	3	0.6	1.4
30	F	21	—	6	0.6	1.1
31	F	38	—	5	1.2	2.8
32	F	22	—	4	0.6	2.4
33	F	46	+	6	0.9	3.3
34	M	27	—	4	0.8	2.1
35	F	18	—	5	0.5	1.0
36	F	18	—	7	0.6	1.0
37	F	42	+	8	0.9	1.9
38	F	16	—	4	0.6	1.6
39	F	21	—	5	0.7	1.6
40	F	50	—	7	1.5	3.1
41	F	26	—	5	0.4	2.3
42	F	25	—	8	0.7	1.5
43	M	32	—	5	0.7	3.5
44	F	33	+	7	0.8	1.6
45	F	36	+	5	0.9	2.8
46	M	36	—	7	1.2	2.0
47	F	17	+	6	0.7	2.2
48	F	20	—	8	0.8	1.7
49	F	31	—	8	0.9	1.8
50	M	24	—	5	0.8	2.3

CMV, closed mitral commissurotomy; Echo score, cross sectional echocardiographic score; MVA, mitral valve area; Pre, before balloon dilatation; Post, after balloon dilatation.

procedure. All were taking a β blocker at the time of the pre-dilatation test. The drug was stopped after the procedure so the patients were not taking β blockers for the post-dilatation treadmill test.

TECHNIQUE

All patients were given a β blocker for at least 48 hours as premedication before the procedure. Left and right heart catheterisation was performed from the left groin with measurement of cardiac output by thermodilution and left ventriculography immediately before dilatation. Transseptal puncture was performed via the right groin with a standard Brockenbrough needle and 8F Mullins sheath (USCI). A 7F balloon tipped flotation catheter with the balloon inflated was then introduced into the left atrium and then the left ventricle. Through this catheter a 0.038 inch extra-stiff guidewire (Cook) with a 2–3 cm handmade gentle curve at its tip was positioned in the left ventricular apex. The septum was dilated with a 10 mm balloon dilating catheter (Meditech). The mitral valve was dilated with either the bifoil (2 × 19 mm) or trefoil (3 × 15 mm) catheter (Schneider-Medintag). The dilatation catheter was introduced into the right femoral

vein through a 16.5 French introducer sheath in the first nine patients but not in the others. After haemodynamic measurements were obtained, we repeated the right heart oximetry series and left ventriculography in all patients. The measurement of cardiac output by thermomodulation was repeated with the deflated balloon across the septum so as to minimise any error due to atrial shunting. The mitral valve area was calculated by the original Gorlin formula. Mitral regurgitation was graded according to the method described by Sellers *et al.*¹¹ Heparin was administered via a peripheral vein (100 units/kg) after the left atrium had been entered. The anticoagulant effect was reversed with protamine sulphate (25 mg) at the end of the procedure.

STATISTICAL ANALYSIS

We calculated the mean and standard deviation and standard error for all variables. Haemodynamic changes before and after dilatation of the mitral valve were analysed by the paired *t* test. Stepwise multiple linear regression analysis (BMDP statistical package) was performed to establish a relation between the percentage increase in valve area or the development of mitral regurgitation and (a) balloon size, (b) balloon surface area per square metre body surface area, (c) balloon surface area per square centimetre mitral annulus area, (d) age, (e) severity of mitral stenosis, (f) echocardiographic score, (g) presence of mitral regurgitation before dilatation, and (h) mean pulmonary artery pressure.

Results

HAEMODYNAMIC CHANGES

The mitral valve gradient decreased from 12 (6) to 4 (3) mm Hg ($p < 0.001$) and the average left atrial pressure decreased from 22 (6) to 13 (5) mm Hg ($p < 0.001$). There was a significant increase in mitral valve area from 0.7 (0.3) to 2.1 (0.8) ($p < 0.001$) and increase in cardiac output from 3.2 (0.7) to 4.0 (0.8) l/min ($p < 0.001$). There was a significant immediate change in the mean pulmonary artery pressure (34 (14) to 31 (13) mm Hg, $p = 0.01$) but no significant change in pulmonary vascular resistance (365 (292) to 352 (265) dyn s cm⁻⁵). There was, however, a significant decrease in the systemic vascular resistance from 2043 (539) to 1664 (426) dyn s cm⁻⁵ ($p < 0.001$).

Stepwise linear regression analysis showed that mitral regurgitation (MR) was related to the presence of mitral regurgitation before dilatation ($p < 0.01$) and the severity of mitral stenosis ($p < 0.01$) ($MR = 1.786 - 1.379$ (mitral area pre-dilatation) + 0.932 (MR), $R^2 = 42\%$). Regression analysis also showed that the percentage increase in mitral valve area was related to the severity of mitral stenosis before the procedure ($p < 0.01$) (percentage increase in valve area = 371.870–223.728 (mitral area), $R^2 = 20\%$).

Figure 1 Mitral regurgitation (A) before and (B) after dilatation. 0 = nil, 1+ = trivial, 2+ = mild, 3+ = moderate, 4+ = severe. *No change in grade of regurgitation.

COMPLICATIONS

Mitral regurgitation was the most common complication (fig 1). In 22 (44%) of the 50 patients mitral regurgitation either developed for the first time or became worse. Most patients had trivial (5) or mild (12) regurgitation. In one patient severe regurgitation (grade 4) developed and he required emergency surgery. Mitral valve replacement was uneventful but he died in the postoperative period. Another patient with moderate mitral regurgitation (grade 3) underwent successful valve replacement for worsening cardiac failure four weeks after balloon dilatation. Of the remaining three patients with moderate regurgitation two were symptom free and one had grade II disablement at follow up 10 months later.

The development or increase in the grade of mitral regurgitation was predicted by the presence of regurgitation before dilatation and the severity of stenosis before the procedure. Cross sectional echocardiography immediately after the procedure showed a tear in the anterior mitral leaflet and chordal rupture in the patient with severe mitral regurgitation. Of the four patients with moderate regurgitation, chordal rupture was seen in two and a tear in the anterior cusp in one. None of the other patients with mitral regurgitation showed any abnormality on cross sectional echocardiography. The echocardiographic findings were confirmed in the two patients who had an operation.

A right heart oximetry series showed pulmonary to systemic flow ratios > 1.5 in four patients (1.6, 1.6, 1.7, and 1.9). There were transient ischaemic attacks in two patients, indicating embolic events. One had left

Figure 2 New York Heart Association functional class (A) before and (B) within one week of dilatation.

hemiparesis and the other internuclear ophthalmoplegia.

CLINICAL FOLLOW UP

In all but two patients symptoms improved. The New York Heart Association functional class (fig 2) improved to I in 45 patients, to II in three, and remained the same in two patients. It remained the same in the patient in whom severe mitral regurgitation (class IV) developed and in another who had moderate regurgitation after dilatation (class III). The average exercise time increased from 3.9 (2) to 7.2 (2) min ($p < 0.001$).

Discussion

Since the pioneer work of Harken *et al*,¹³ Bailey,¹⁴ and Baker *et al*,¹⁵ closed mitral commissurotomy has been the treatment of choice for rheumatic mitral stenosis. The technique has been perfected over the years and has become safe and effective. However, it has the drawback of being a surgical procedure. Over the past five years percutaneous balloon dilatation of the mitral valve has been tried as a treatment for stenotic mitral valves. The symptomatic and haemodynamic improvements after balloon dilatation by the single catheter technique (Inoue balloon catheter) and the double balloon technique have been well documented.¹⁻⁶ Experience with the bifoil or trefoil catheter has been limited.^{8,9}

Commissural splitting has been shown to be the mechanism responsible for a successful result.¹²⁻¹⁶ The size of the balloon has been shown to determine the area of the valve after dilatation.¹⁰ Smaller balloons probably just stretch the valve apparatus and a balloon with a larger effective dilating area is required for adequate commissural splitting. Palacios *et al* recommended a balloon dilating area > 4.9 cm².⁵ The average effective balloon dilating area in our series was 6.2 cm². Balloon dilatation with the bifoil catheter produced a larger mean (SD) valve area (2.2 (0.8) cm²) than the trefoil catheter (1.8 (0.5) cm²); but the difference was not statistically significant ($p = 0.2$). Our results are comparable to the calculated valve area achieved with the double balloon technique (table 2). The mean total duration of the procedure was 110 minutes (range 75-200) with a fluoroscopy time of 34 minutes (range 14-90). In the last 20 patients the mean fluoroscopy time was 19 minutes. A shorter fluoroscopy time is useful in pregnant patients with symptomatic mitral stenosis.

The severity of mitral stenosis was the only reliable predictor of outcome; the smaller the initial valve area, the larger was the percentage increase. Only five patients had valve area increase of $< 100\%$. Studies of surgical commissurotomy and in vivo and in vitro balloon dilatation^{10,17} showed that the structural features of the mitral valve determined the success of the procedure. Those with heavily calcified valves and subvalvar disease had smaller increases in valve area. Though the average increase in valve area was just over 200%, the range was wide (57-592%). We

Table 2 Results with double balloon technique

Authors	Mitral valve area (cm ²)		Percentage increase
	Before	After	
Al Zaibag <i>et al</i> ³	1.0 (0.3)	2.0 (0.8)	100
McKay <i>C et al</i> ¹²	1.0 (0.3)	2.4 (0.8)	140
McKay <i>C et al</i> ⁴	1.0 (0.3)	2.2 (0.7)	120
Kasab <i>et al</i> ⁷	0.8 (0.1)	1.8 (0.3)	125
Chen <i>et al</i> ⁶	0.8 (0.2)	1.9 (0.4)	138

failed to split the valve in one patient (fig 3) despite reasonable valve mobility and an echocardiographic score of 8. Partial splitting occurred in another five patients who had echocardiographic scores between 5 and 8. It is clear that some patients with good valve mobility have severe commissural fibrosis which results in a suboptimal result. We may also have underestimated the degree of subvalvar disease in this group of patients. In addition, some valves may merely stretch and recoil after balloon dilatation.

In the present series the pulmonary vascular resistance fell slightly but the fall was not statistically significant. The degree of relief of mitral obstruction does not necessarily correlate with the extent of the drop in the pulmonary vascular resistance after mitral valvotomy.¹⁸ Our experience¹⁹ and that of others¹⁸ showed a progressive drop in the pulmonary vascular resistance with time. The mechanism by which the resistance continues to drop is not certain but changes in lung compliance and relief of vasoconstriction could explain these findings.

Mitral regurgitation remains a potentially life threatening complication of balloon dilatation of the mitral valve. In published reports its incidence varies from 0 to 50%. Severe regurgitation, however, is uncommon. Of the 22 patients (44%) in our study in whom regurgitation increased or developed, 12 had a prior mitral leak. Regurgitation after balloon dilatation was trivial or mild in most cases (17 patients). All except one of the patients with

moderate (four cases) or severe regurgitation (one case) showed structural damage. Although the presence of mitral regurgitation before balloon dilatation predicted the development or worsening of regurgitation, most of these patients showed only a marginal increase in grade. Thus it seems that significant regurgitation will only occur when there is structural damage to the mitral valve. An oversized balloon catheter in the presence of significant stenosis (mean area = 0.7 cm²) may have played a role. In the patient with severe mitral regurgitation entanglement of the balloon with the chordae was believed to be the cause.

The incidence of significant left to right shunting at the atrial level, as in other series,⁴⁻⁶ was low. The long term effects of these shunts is unknown but there is some evidence that most atrial septal defects will close within 24 hours.³

The complications associated with the bifoil and trefoil catheters are similar to those experienced with the double balloon technique. Some say that it is easier and less damaging to introduce two small catheters into the femoral vein and across the valve. We did not have any technical difficulties introducing the bifoil and trefoil catheters into the femoral vein and across the valve and saw no bleeding or other complications at the venous puncture site. In fact the placement of two balloons may require more time and additional wire or catheter manipulation and we do not believe that the double balloon technique has any major advantages over the single catheter technique with the larger bifoil or trefoil catheters.

Balloon dilatation of the mitral valve has emerged as a definite alternative to surgical commissurotomy. The single catheter technique with the bifoil or trefoil catheter results in haemodynamic and clinical improvement that is comparable to that obtained with the double balloon technique. The average dilating area of the balloon (6.0–6.5 cm²) seems to be adequate in most cases. Additional studies need to be done to assess the safety and efficacy of percutaneous balloon dilatation with different techniques and catheters. We believe that the single catheter technique achieves acceptable valve areas, compares favourably with the double balloon technique, and may be more cost effective (because it uses fewer guidewires and catheters).

We thank Mrs Amelia Smyth for statistical guidance and the staff of the cardiac catheterisation and non-invasive laboratories for their technical assistance.

- 1 Inoue K, Owaki T, Nakamura T, Kitamura F, Miyamoto N. Clinical applications of transvenous mitral commissurotomy by a new balloon catheter. *J Thorac Cardiovasc Surg* 1984;87:394–400.
- 2 Lock JE, Khalibullah M, Shrivastara S, Bahl V, Keane JF. Percutaneous catheter commissurotomy in rheumatic mitral stenosis. *N Engl J Med* 1985;313:1515–18.
- 3 Al Zaibag M, Ribeiro PA, Alkasab S, Al Fagih MR. Percutaneous double balloon mitral valvotomy for rheumatic mitral stenosis. *Lancet* 1986;i:757–61.
- 4 McKay CR, Kawanishi DT, Rahimtoola SH. Catheter balloon valvuloplasty of the mitral valve in adults using a double balloon technique. *JAMA* 1987;257:1753–61.
- 5 Palacios I, Block P, Brande S, *et al*. Percutaneous balloon valvotomy for patients with severe mitral stenosis. *Circulation* 1987;75:778–84.
- 6 Chen C, Wang Y, Qing D, Kin Y, Lan Y. Percutaneous mitral balloon dilatation by a new sequential single and double balloon technique. *Am Heart J* 1988;116:1161–7.

Figure 3 Trefoil catheter across mitral valve showing persistence of waist despite full balloon inflation.

- 7 Kasab SA, Ribeiro PA, Zaibag MA, *et al.* Comparison of results of percutaneous balloon mitral valvulotomy using single and double balloon technique. *Am J Cardiol* 1989;63:135-6.
- 8 Vahanian A, Michel PL, Cornier B, *et al.* Results of percutaneous mitral commissurotomy in 200 patients. *Am J Cardiol* 1989;63:847-52.
- 9 Manga P, Chun R, Horak M, *et al.* Balloon mitral valvuloplasty: multicentre study [Abstract]. *J Am Coll Cardiol* 1989;13(suppl A):70A.
- 10 Wilkins GT, Weyman AE, Abascal VM, Block PC, Palacios IF. Percutaneous balloon dilatation of the mitral valve: an analysis of echocardiographic variables related to outcome and the mechanism of dilatation. *Br Heart J* 1988;60:299-308.
- 11 Sellers RD, Lery MJ, Amplatz K, Lillehei CW. Left retrograde cardiac angiography in acquired cardiac disease. Technic indication and interpretation in 700 cases. *Am J Cardiol* 1964;14:437-47.
- 12 McKay RG, Lock JE, Safian RD, *et al.* Balloon dilation of mitral stenosis in adult patients: post mortem and percutaneous mitral valvuloplasty studies. *J Am Coll Cardiol* 1987;9:723-31.
- 13 Harken DE, Ellis LB, Ware PF, Norman CR. The surgical treatment of mitral stenosis. *N Engl J Med* 1948;239:801-9.
- 14 Bailey CP. The surgical treatment of mitral stenosis (mitral commissurotomy). *Dis Chest* 1949;15:377-93.
- 15 Baker C, Brock RC, Campbell M. Valvotomy for mitral stenosis. *Br Med J* 1950;i:1283-93.
- 16 Ribeiro PA, Zaibag M, Rajendran V, *et al.* Mechanism of mitral valve area increase by in vitro single and double balloon mitral valvotomy. *Am J Cardiol* 1989;62:264-69.
- 17 Reid CL, McKay CR, Chandraratna PAN, Kawanishi DT, Rahimtoola SH. Mechanisms of increase in mitral valve area and influence of anatomic features in double-balloon, catheter balloon valvuloplasty in adults: a Doppler and two-dimensional echocardiography study. *Circulation* 1987;76:628-36.
- 18 Levine MJ, Weinstein JS, Direr DJ, *et al.* Progressive improvement in pulmonary vascular resistance after percutaneous mitral valvuloplasty. *Circulation* 1989;79:1061-7.
- 19 Patel J, Vythilingum S, Miha AS. Balloon mitral valvuloplasty: clinical and haemodynamic follow-up [Abstract]. *Philippine J Cardiol* 1990;19:11-97.