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Balloon Dilation of Mitral Stenosis in Adult Patients: Postmortem and Percutaneous Mitral Valvuloplasty Studies

RAYMOND G. McKAY, MD, JAMES E. LOCK, MD, FACC, ROBERT D. SAFIAN, MD, PATRICIA C. COME, MD, FACC, DANIEL J. DIVER, MD, DONALD S. BAIM, MD, FACC, AARON D. BERMAN, MD, SANFORD E. WARREN, MD, VALERIE E. MANDELL, MD, HENRY D. ROYAL, MD, WILLIAM GROSSMAN, MD, FACC

Boston, Massachusetts

Preliminary reports have documented the utility of percutaneous balloon valvuloplasty of the mitral valve in adult patients with mitral stenosis, but the mechanism of successful valve dilation and the effect of mitral valvuloplasty on cardiac performance have not been studied in detail. Accordingly, mitral valvuloplasty was performed in five postmortem specimens and in 18 adult patients with rheumatic mitral stenosis, using either one (25 mm) or two (18 and 20 mm) dilation balloons. Postmortem balloon dilation resulted in increased valve orifice area in all five postmortem specimens, secondary to separation of fused commissures and fracture of nodular calcium within the mitral leaflets. In no case did balloon dilation result in tearing of valve leaflets, disruption of the mitral ring or liberation of potentially embolic debris.

Percutaneous mitral valvuloplasty in 18 patients with severe mitral stenosis (including 9 with a heavily calcified valve) resulted in an increase in cardiac output (4.3 ± 1.1 to 5.1 ± 1.5 liters/min, $p < 0.01$) and mitral valve area (0.9 ± 0.2 to 1.6 ± 0.4 cm^2, $p < 0.0001$), and a decrease in mean mitral pressure gradient (15 ± 5 to 9 ± 4 mm Hg, $p < 0.0001$), pulmonary capillary wedge pressure (23 ± 7 to 18 ± 7 mm Hg, $p < 0.0001$) and mean pulmonary artery pressure (36 ± 12 to 33 ± 12 mm Hg, $p < 0.01$). Left ventriculography before and after valvuloplasty in 14 of the 18 patients showed a mild (≤1+) increase in mitral regurgitation in five patients and no change in the remainder. Embolic phenomena were not observed in any patient.

Serial radionuclide ventriculography showed an increase in left ventricular peak filling rate (2.20 ± 1.20 to 2.50 ± 1.20 end-diastolic volumes per second [EDV/s], $p < 0.05$). Serial echocardiography/phonocardiography showed improvement in mitral valve excursion (11 ± 6 to 14 ± 6 mm, $p < 0.001$), mitral EF slope (7 ± 4 to 13 ± 5, $p < 0.001$), left atrial diameter (5.7 ± 0.9 to 5.3 ± 0.8 cm, $p < 0.001$), S_2-opening snap interval (0.07 ± 0.03 to 0.08 ± 0.02 second, $p < 0.02$) and mitral valve area (0.9 ± 0.2 to 1.5 ± 0.4 cm^2, $p < 0.0001$). All patients were discharged from the hospital with decreased symptoms after valvuloplasty.

It is concluded that percutaneous mitral valvuloplasty can be performed in adult patients with mitral stenosis, including patients with calcific disease, and can result in significant improvement in valvular function. The mechanisms of successful dilation include commissural separation and fracture of nodular calcium.

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The technique of percutaneous mitral valvuloplasty through a transseptal approach was first described by Lock et al. (1) and Rocchini et al. (2), who documented successful balloon dilation of the mitral valve in adolescents with critical mitral stenosis. Zaibag et al. (3) utilized a similar transseptal approach with a double balloon technique in successfully treating seven of nine adult patients with symptomatic, noncalcified mitral stenosis. More recently, our laboratory (4) and that of Palacios et al. (5) have extended the application of this technique to older patients with calcific mitral valve disease, including those in whom surgical intervention was deferred because of high expected surgical risk. Although all of these preliminary reports have suggested a favorable hemodynamic response to balloon dilation, the pathologic mechanism of mitral valvuloplasty and the effect of balloon

From the Charles A. Dana Research Institute and the Harvard Thorndike Laboratory of Beth Israel Hospital, Departments of Medicine (Cardiovascular Division) and Radiology, Beth Israel Hospital and Harvard Medical School, and from the Division of Cardiology, Children's Hospital, Harvard Medical School, Boston, Massachusetts.

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Address for reprints: Raymond G. McKay, MD, Cardiovascular Division, Beth Israel Hospital, 330 Brookline Avenue, Boston, Massachusetts 02215.

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dilation on cardiac function have not been previously studied in detail. Accordingly, the purpose of this study was to assess the effect of mitral valvuloplasty on valvular anatomy and ventricular function in five postmortem specimens and in 18 adult patients with symptomatic, rheumatic mitral stenosis.

Methods

Postmortem valve dilation. Five patients undergoing postmortem examination between August 1, 1985 and August 1, 1986 who had evidence of mitral stenosis were included in this study. The mitral valve was examined by a pathologist to determine the presence of commissural fusion, the presence of nodular calcification and the degree of leaflet distortion. Mitral valvuloplasty was accomplished subsequently with a 25 mm valvuloplasty balloon (Meditech) with a maximal balloon inflation to 3 atm for a 30 second period. After dilation, the valve was examined grossly for evidence of commissural separation, leaflet fracture, valve ring distortion, calcific debris and changes in leaflet mobility. In three of the five specimens, X-ray films were taken before and after valvuloplasty to identify calcific fractures.

Percutaneous mitral valvuloplasty study group (Table 1). Percutaneous balloon mitral valvuloplasty was performed in 18 patients with severe mitral stenosis. The study group consisted of 13 women and 5 men with a mean age of 49 years (range 23 to 75). All patients were symptomatic with congestive heart failure. Predominant symptoms reported by the study group included dyspnea on exertion in 18, orthopnea in 18 and weakness or fatigue in 7 patients. Each patient had previously undergone recent cardiac catheterization and coronary angiography. The origin of mitral stenosis was presumed to be rheumatic in all cases. Nine patients had fluoroscopic evidence of extensive mitral valve calcification, including mitral anular calcification. Five patients had atrial fibrillation and the remainder had normal sinus rhythm. Four patients had significant coronary artery disease, including two with severe three-vessel disease, one with two-vessel disease and one with one-vessel disease. The remaining 14 had normal coronary arteries. No patient had a prior history of stroke or embolic phenomena. Patients with evidence of left atrial thrombus on echocardiographic study were not considered candidates for balloon mitral valvuloplasty.

Each patient was evaluated by a cardiac surgeon and was offered mitral valve replacement, with an estimation of expected surgical risk. Fifteen patients were considered excellent surgical candidates. The remaining three (Cases 1, 3 and 17) were considered high risk surgical candidates, two because of severe obstructive chronic lung disease and severe pulmonary hypertension and the third because of severe three vessel coronary artery disease and pulmonary hypertension. All 18 patients refused surgical intervention. Each patient subsequently gave informed consent for percutaneous mitral valvuloplasty after being informed of the risks and potential complications of the procedure according to a protocol approved by the Beth Israel Hospital Human Investigations Committee.

Table 1. Clinical Characteristics of Patients Before Mitral Valvuloplasty

Patient No.	Age (yr) & Sex	Symptoms	Mitral Valve Area (cm^2)	Mitral Valve Calcification	Other Disease
1	75M	d,o,w	0.6	+	1 VD,COPD
2	42F	d,o	1.0	–	—
3	73M	d,o,w	0.6	+	3 VD,MI,AFIB
4	59F	d,o,w	1.0	+	AFIB
5	53F	d,o,w	1.2	–	—
6	54M	d,o,w	0.7	+	AFIB
7	56F	d,o	1.2	+	—
8	29F	d,o	0.8	–	—
9	71F	d,o,w	0.9	+	2 VD,AFIB
10	67M	d,o	0.8	+	3 VD
11	35F	d,o	0.9	–	AI
12	34F	d,o	1.3	–	—
13	27F	d,o	1.0	–	—
14	32F	d,o	0.8	–	—
15	46F	d,o	0.8	+	—
16	39F	d,o	1.4	–	—
17	63F	d,o,w	0.6	+	AFIB,COPD
18	23M	d,o	1.0	–	—

AFIB = atrial fibrillation; AI = aortic insufficiency; COPD = chronic obstructive lung disease; d = dyspnea on exertion; F = female; M = male; MI = prior myocardial infarction; o = orthopnea; 1 VD, 2 VD or 3 VD = one, two or three vessel coronary artery disease, respectively; w = weakness/fatigue.

Mitral valvuloplasty protocol (Fig. 1). After administration of a local anesthetic, the left femoral artery and left and right femoral veins were instrumented with 8F Hemokit sheaths. Left and right heart catheterization using a 7F pigtail catheter and a 7F balloon flotation catheter, respectively, was subsequently performed from the left groin. During the right heart catheterization, a diagnostic oxygen saturation series was obtained. After placement of the left and right heart catheters, measurements were made of systemic arterial, left ventricular, pulmonary capillary wedge and pulmonary artery pressures and of pulmonary artery and left ventricular oxygen saturations. Pulmonary capillary wedge pressure was confirmed by aspirating blood from the wedge position and subsequently documenting an arterial oxygen saturation. Oxygen consumption was measured using a metabolic rate meter (Waters). After the completion of pressure measurements, left ventriculography was performed in 14 of the 18 patients in the routine manner.

After prevalvuloplasty measurements, transseptal catheterization was accomplished by standard technique using a 8F Mullins transseptal sheath and dilator (USCI) and Brockenbrough needle (6). After entry into the left atrium, the needle and dilator were removed and a 7F balloon-tipped end-hole catheter (Critikon) was advanced through the sheath to the left atrium. Left heart pressures and transvalvular gradient were then measured directly to corroborate the previously obtained wedge pressure measurements. The 7F balloon catheter was then advanced through the mitral and aortic valves to the descending thoracic aorta, followed by insertion of an 0.038 inch (0.097 cm), 300 cm long Teflon-coated exchange guide wire through the flow-directed catheter. The sheath and balloon catheter were then removed, leaving only the guide wire in place.

Next, an 8F angioplasty catheter (Meditech) with an 8 mm balloon was advanced over the guide wire to the level of the interatrial septum and inflated to dilate the septal opening. After removal of this catheter, a 9F balloon dilation catheter with a 25 mm balloon was advanced across the septum to the left ventricle and positioned across the mitral anulus. The balloon was subsequently inflated for 10 to 15 seconds with a mixture of saline solution and radiographic contrast medium (Angiovist). Repeat inflations were made until a waist in the balloon at the level of the mitral valve was noted to disappear. Immediately after balloon valvuloplasty, all hemodynamic measurements were repeated, including determination of transvalvular gradient and cardiac output. Left ventriculography and a right heart oximetry series were also repeated to document changes in the degree of mitral regurgitation and to search for evidence of a new left to right shunt, respectively. Mitral valve area before and after valvuloplasty was calculated by the Gorlin formula using systemic blood flow for cardiac output, when appropriate (7).

In four patients (Cases 14 to 17), valve dilation was accomplished utilizing two (18 and 20 mm) valvuloplasty balloons, rather than a single 25 mm valvuloplasty balloon. In these patients, after placement of a single guide wire through the mitral orifice as described, a second guide wire was similarly placed using a double lumen 7F exchange catheter (Meditech) that accommodates two guide wires. The exchange catheter was subsequently removed, and the 18 and 20 mm dilation balloons were positioned over the two guide wires in the mitral apparatus before simultaneous inflation to effect valve dilation.

All patients were treated with a total of 10,000 units of intravenous heparin immediately after transseptal catheterization. All procedures were performed without surgical backup.

Serial radionuclide ventriculography. Serial radionuclide ventriculography was performed 24 hours before and 48 hours after mitral valvuloplasty. Each patient was injected with 0.75 GBq (20 mCi) of technetium-99M–labeled autologous red blood cells, with an in vitro technique used for labeling. Radionuclide ventriculograms were obtained

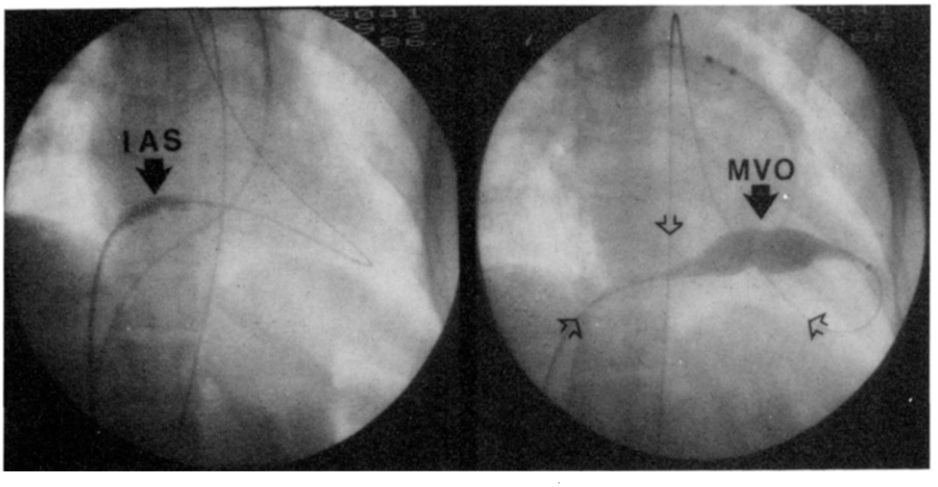

Figure 1. Left panel, Photograph of 8 mm balloon used to dilate the interatrial septum (IAS), marked by a waist in the inflated balloon profile (**dark arrow**). **Right panel,** Photograph of 25 mm balloon used to dilate the mitral valve orifice (MVO), marked by a waist in the inflated balloon profile (**dark arrow**). The balloon catheters used to dilate the interatrial septum and mitral valve are positioned over a guide wire (**light arrows**) that is placed by transseptal catheterization from the left atrium through the mitral and aortic valves to the descending aorta.

with the patient in a supine position in the anterior, left posterior oblique and modified left anterior oblique views using a mobile Anger camera computer system (Technicare 410) with an on-board VIP computer system. All radionuclide scans were obtained using a high sensitivity slant-hole collimator used to obtain 30° of cephalic angulation for the modified left anterior oblique view. Scans were obtained using a 64 × 64 matrix with a full fielded view (250 cm). Thirty-two frames per RR interval were acquired to a total of 10 million counts with an acquisition time of 5 to 8 minutes per view.

Left and right ventricular global ejection fraction, stroke/volume ratio and left ventricular peak filling rate were subsequently determined from each modified left anterior oblique view (8).

Serial echocardiographic studies. Phonocardiography and imaging/Doppler echocardiography were obtained 24 hours before and 48 hours after mitral valvuloplasty. M-mode echocardiograms were obtained using an Irex System II or ATL Mark 600 echocardiograph. Two-dimensional and Doppler studies were performed with the ATL equipment. The following data were subsequently determined in each patient: S_2-opening snap interval, presence of mitral valve thickening, mitral valve excursion, mitral EF slope and left atrial diameter (9).

Severity of mitral stenosis and mitral regurgitation was assessed using pulsed Doppler echocardiography (10). In the case of mitral regurgitation, the left atrium above both mitral leaflets was interrogated using parasternal long-axis and apical long-axis, four chamber and two chamber views. The severity of mitral regurgitation was graded as trace, mild, moderate or severe depending on the extension of the signal of mitral regurgitation from the mitral leaflets to the back wall of the left atrium.

From pulsed Doppler recordings within the stenotic mitral jet (obtained with sample volume placement on the ventricular side of the mitral valve using apical views), the pressure half-time was calculated, and mitral valve area (MVA) was then estimated from the formula (10)

$$\text{MVA (cm}^2\text{)} = 220/\text{pressure half-time (ms)}.$$

The diagnosis of atrial septal defect flow was made using pulsed Doppler or contrast echocardiography or both (11,12). For pulsed Doppler echocardiography, the sample volume was placed on the right atrial side of the interatrial septum, using a subcostal view. Shunt flow from the left to the right atrium was recognized by the presence of continuous turbulence, maximal during late systole and early diastole. Contrast echocardiography was performed after the injection of agitated saline solution, mixed with the patient's own blood, into an antecubital vein. A communication between the right and left atria was diagnosed if there was a subsequent negative contrast effect in the right atrium or a positive contrast appearance in the left heart chambers, or both.

Statistics. Mean and standard deviation were determined for all variables. Paired dimensional data were analyzed by either the paired *t* test or Wilcoxon signed-rank test where appropriate, for parametric and nonparametric distributions. A probability value of <0.05 was considered significant.

Results

Postmortem Valvuloplasty

Balloon dilation was performed in five postmortem hearts with calcific mitral stenosis. The mean age of the patients at the time of death was 79 years. All patients had critical mitral stenosis with a mean valve area of 0.9 ± 0.3 cm^2 documented before death. All five specimens demonstrated fusion of both commissures and extensive nodular calcification.

In each of the five cases, balloon dilation using a 25 mm balloon resulted in increased orifice area without tearing of valve leaflets, disruption of the valve ring or dislodgment of potentially embolic material. In four of the five cases, valvuloplasty resulted in complete or partial separation of the fused edges of both commissures; in the remaining specimen, balloon dilation resulted in complete separation of only one commissure. In two of the three cases in which radiographs were taken before and after dilation, valvuloplasty resulted in fractures of nodular calcium within the mitral leaflet. An example of postmortem specimen before and after dilation is shown in Figure 2.

Clinical Data

Hemodynamic changes associated with percutaneous valvuloplasty (Table 2). Hemodynamically successful balloon dilation was accomplished in all 18 patients as evidenced by a decrease in mean mitral gradient from 15 ± 5 to 9 ± 4 mm Hg ($p < 0.0001$), and an increase in cardiac output from 4.3 ± 1.1 to 5.1 ± 1.5 liters/min ($p < 0.01$) and calculated mitral valve area from 0.9 ± 0.2 to 1.6 ± 0.4 cm^2 ($p < 0.0001$). Immediately after valve dilation, there was a decrease in pulmonary capillary wedge pressure (23 ± 7 to 18 ± 7 mm Hg, $p < 0.0001$) and mean pulmonary artery pressure (36 ± 12 to 33 ± 12 mm Hg, $p < 0.01$), with no significant change in left ventricular pressure (119 ± 24/11 ± 5 to 114 ± 19/13 ± 5 mm Hg, p = NS) or pulmonary vascular resistance (252 ± 187 to 254 ± 131 dynes·s·cm^{-5}, p = NS).

In all 18 patients, a waist was noted to disappear in the dilation balloon or balloons during maximal inflation. During the 10 to 15 second period of balloon inflation, systemic arterial pressure dropped precipitously with the appearance of presyncopal symptoms in 5 of the 18 patients, followed by the return of baseline arterial pressures and disappearance

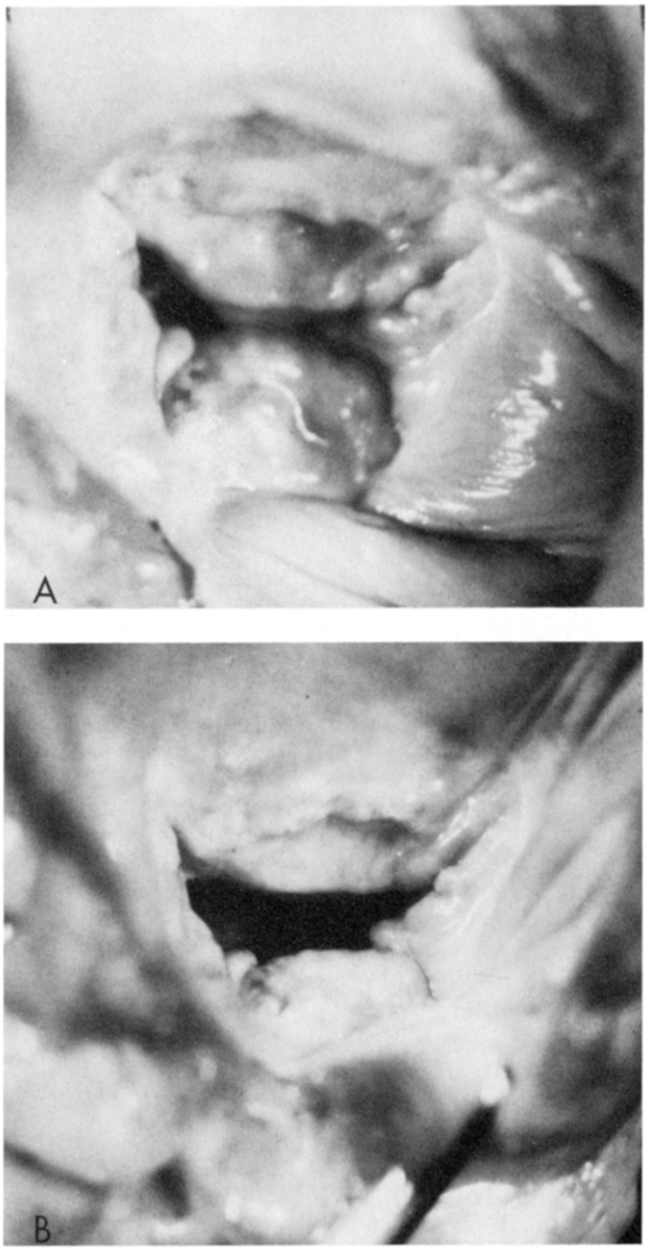

Figure 2. Photographs of postmortem specimen from a patient with rheumatic mitral stenosis before (**A**) and after (**B**) dilation with a 25 mm valvuloplasty balloon; note separation of fused commissures after valvuloplasty.

of presyncopal symptoms immediately on balloon deflation. In no case was balloon dilation accompanied by embolic phenomena.

Mitral regurgitation after valvuloplasty (Table 3). Left ventriculography was performed in 14 of the 18 patients before and after valvuloplasty. Before valvuloplasty, mitral regurgitation was considered to be absent in eight patients, trace in four patients, mild (1+) in one patient and moderate (2+) in one patient. After dilation, there was a mild ($\leq$1+) increase in mitral regurgitation in five patients and no change in the remaining nine.

Doppler echocardiographic studies obtained in 15 of the 18 patients demonstrated an increase in mitral regurgitation in 3 patients, a decrease in 2 and no change in the remaining 10.

Presence of an interatrial shunt after valvuloplasty (Table 4). Serial right heart diagnostic oxygen saturation series documented the presence of a significant right atrial oxygen "step-up" in 5 of the 18 patients; calculated pulmonary to systemic flow (Q_P/Q_S) ratios were 1.1, 1.1, 1.4, 1.8 and 2.3, respectively.

Doppler or contrast echocardiography performed in 15 of the 18 patients documented the presence of a small interatrial shunt in five patients, including one patient not detected by the oximetry series. There were no significant differences in hemodynamic changes after valvuloplasty in patients with or without an atrial septal defect.

Serial radionuclide ventriculography. This procedure was performed in 13 of the 18 patients. Balloon valvuloplasty resulted in no significant change in left ventricular ejection fraction (57 ± 16 to 56 ± 13%, p = NS), right ventricular ejection fraction (43 ± 18 to 41 ± 15%, p = NS) or stroke/volume ratio (1.30 ± 0.50 to 1.20 ± 0.40, p = NS). There was, however, a significant increase in left ventricular peak filling rate (2.20 ± 1.10 to 2.50 ± 1.20 EDV/s, $p < 0.05$).

Serial phonocardiography/echocardiography (Table 5). These studies were obtained in 15 of 18 patients. All patients were found to have abnormal mitral valve motion on M-mode and two-dimensional echocardiography, characteristic for rheumatic deformity. Mitral valve fibrosis was classified as mild in five patients, moderate in four and severe in six.

Balloon valvuloplasty resulted in significant changes in mitral valve excursion (11 ± 6 to 14 ± 6 mm, $p < 0.001$), mitral EF slope (7 ± 4 to 13 ± 5, $p < 0.001$), left atrial diameter (5.7 ± 0.9 to 5.3 ± 0.8 cm, $p < 0.001$), S_2-opening snap interval (0.06 ± 0.03 to 0.08 ± 0.02 second, $p < 0.02$) and mitral valve area determined by Doppler half-time pressure (0.9 ± 0.2 to 1.5 ± 0.4 cm^2, $p < 0.0001$).

Clinical follow-up. All 18 patients noted significant reduction in symptoms of dyspnea on exertion, orthopnea and weakness after valvuloplasty. One patient (Case 1) was recatheterized at 6 months and found to have progressive hemodynamic improvement, including no evidence of valve restenosis (valve area 0.6 cm^2 before dilation, 1.4 cm^2 immediately after dilation and 1.4 cm^2 6 months after dilation), a decrease in mitral regurgitation from moderate to trace and further decreases in pulmonary capillary wedge pressure and pulmonary vascular resistance. Nine patients (Cases 1 to 4, 7 to 11) had repeat echocardiographic studies 4 to 6 weeks after dilation with no evidence of valvular restenosis. Two patients (Cases 3 and 4) in whom balloon dilation resulted in a minimal increase in mitral valve area noted recurrent symptoms 3 months after dilation and subsequently underwent operative mitral valve replacement with

Table 2. Hemodynamics Before and After Valvuloplasty in 18 Patients

Patient No.	Mitral Gradient (mm Hg)		Cardiac Output (liters/min)		Mitral Valve Area (cm^2)		PCW (mm Hg)	
	Before	After	Before	After	Before	After	Before	After
1	18	12	3.3	4.7	0.6	1.4	28	23
2	18	15	5.6	9.6	1.0	2.2	26	25
3	15	12	3.0	4.0	0.6	1.0	26	22
4	13	9	4.5	5.2	1.0	1.3	28	28
5	8	5	4.4	4.8	1.2	1.8	10	8
6	15	11	4.0	6.0	0.7	1.2	30	24
7	7	6	3.9	4.2	1.2	1.7	16	8
8	15	7	5.1	5.6	0.8	1.6	29	16
9	10	4	3.3	3.5	0.9	1.5	24	18
10	21	14	4.3	4.4	0.8	1.2	25	18
11	23	13	5.6	6.0	0.9	1.5	30	20
12	10	3	5.8	4.9	1.3	2.1	14	12
13	10	5	3.5	3.8	1.0	1.5	14	9
14	16	8	3.7	5.3	0.8	1.8	25	19
15	18	11	4.0	4.6	0.8	1.4	26	16
16	16	7	6.9	6.6	1.4	2.4	15	7
17	14	10	2.9	3.0	0.6	0.9	19	23
18	25	9	4.1	5.3	1.0	1.6	35	24
Mean	15	9	4.3	5.1	0.9	1.6	23	18
SD	5	4	1.1	1.5	0.2	0.4	7	7
		**		*		**		**

Patient No.	LVSP (mm Hg)		LVEDP (mm Hg)		PA (mm Hg)		PVR (dynes·s·cm $^{-5}$)	
	Before	After	Before	After	Before	After	Before	After
1	113	108	10	15	54	50	630	460
2	112	122	14	18	43	46	243	175
3	95	80	15	12	52	49	693	540
4	190	166	15	19	42	44	249	246
5	150	129	7	5	23	19	236	183
6	113	127	14	17	50	48	348	320
7	102	95	6	7	23	20	143	228
8	103	97	14	15	48	38	298	314
9	116	116	24	15	30	28	145	229
10	121	108	10	15	44	35	353	309
11	102	108	10	15	44	35	200	200
12	120	112	6	12	25	24	152	195
13	110	112	9	15	18	16	91	147
14	106	110	11	14	27	26	43	106
15	136	136	11	8	38	36	240	348
16	85	92	2	1	17	10	23	36
17	143	117	7	16	32	34	359	293
18	130	120	8	12	40	40	98	242
Mean	119	114	11	13	36	33	252	254
SD	24	19	5	5	12	12	187	131
						*		

*$p < 0.01$; **$p < 0.0001$. Cardiac output reported here represents systemic blood flow calculated by the Fick method. When postvalvuloplasty oximetry series demonstrated an interatrial shunt, systemic blood flow was calculated using the formula of Flamm et al. (13). LVEDP = left ventricular end-diastolic pressure; LVSP = left ventricular systolic pressure; PA = mean pulmonary artery pressure; PCW = pulmonary capillary wedge pressure; PVR = pulmonary vascular resistance.

Table 3. Assessment of Mitral Regurgitation Before and After Valvuloplasty in 18 Patients

Patient No.	Ventriculography		Doppler	
	Before	After	Before	After
1	1+	2+	2+	2+
2	–	–	–	–
3	Trace	Trace	Trace	Trace
4	2+	2+	2+	2+
5	–	–	Trace	–
6	–	1+	–	1+
7	Trace	Trace	Trace	Trace
8	–	–	–	–
9	NA	NA	Trace	–
10	Trace	1+	–	1+
11	–	Trace	–	Trace
12	–	–	NA	NA
13	–	Trace	NA	NA
14	–	–	Trace	Trace
15	NA	NA	–	–
16	NA	NA	–	–
17	NA	NA	–	–
18	Trace	Trace	NA	NA

Mitral regurgitation is graded on a scale of trace, 1+ (mild), 2+ (moderate), 3+ (moderate to severe) and 4+ (severe). Doppler = Doppler echocardiography; NA = not assessed; – = absent.

a good result. At the time of surgery, there was incomplete separation of fused commissures in both of these patients suggesting inadequate balloon dilation. The remaining 16 patients have remained symptom free (the longest clinical follow-up has been 12 months).

Discussion

In previous series of percutaneous balloon mitral commissurotomy by a transseptal approach (1–3), patients with evidence of mitral regurgitation or mitral calcification were excluded. The present study complements these previous reports and indicates that mitral valvuloplasty may also be performed in adult patients with mild mitral regurgitation and severe calcific mitral stenosis, without embolic phenomena or major increases in valvular regurgitation. Improvement in valvular function has been documented by a decrease in mitral gradient and left atrial size, and by an increase in cardiac output, mitral valve area, mitral valve excursion, mitral EF slope, S_2-opening snap interval and left ventricular peak filling rate. Although immediate hemodynamic improvement occurred in all patients, two patients with minimal clinical improvement required valve replacement within 3 months after valve dilation.

Clinical indications. This study has not documented the efficacy of percutaneous mitral valvuloplasty as a routine treatment for adult patients with critical mitral stenosis, given the facts that mitral valve surgery can usually be performed with low risk and marked functional improvement (14), that our study group was small and that two patients eventually required mitral valve replacement. Additional studies will be needed to evaluate the role of percutaneous balloon dilation, including careful long-term follow-up to assess mitral valve restenosis. Nevertheless, at least two groups of patients theoretically may benefit from mitral valvuloplasty. First, in patients who are considered at high surgical risk for mitral valve replacement or who are refused surgery, mitral valvuloplasty may offer a potential nonsurgical alternative. This group may include, for example, patients with advanced age, severe pulmonary hypertension, coronary artery disease, associated aortic and tricuspid valve disease, renal failure and pulmonary dysfunction. A second group of patients in whom valvuloplasty may have a role includes younger patients who are not optimal candidates for placement of a porcine valve because of the high incidence of calcification of these valves (15), or for whom chronic anticoagulation is also undesirable (for example, young women who wish to become pregnant).

Anatomic mechanism of valve dilation. Postmortem valve dilations in this study have documented that successful balloon valvuloplasty may result from both separation of fused commissures and fracture of nodular calcium. It is presumably the former mechanism that is operative in young patients with noncalcified disease. Similar mechanisms of successful valvuloplasty have been noted by our laboratory in postmortem specimens of calcific aortic stenosis (16).

Single or double balloon technique. At least two techniques have been reported to be successful in the balloon dilation of stenotic mitral valves, both involving a trans-

Table 4. Detection of Left to Right Shunts After Valvuloplasty in 18 Patients

Patient No.	Q_P/Q_S by Right Heart Oximetry Series	Echocardiography Doppler/Bubble Study
1	1.8	+
2	–	+
3	1.1	+
4	–	–
5	–	–
6	1.1	+
7	–	–
8	–	–
9	2.3	+
10	–	–
11	–	–
12	–	NA
13	1.4	NA
14	–	–
15	–	–
16	–	–
17	–	–
18	–	–

Bubble = contrast echocardiography; NA = not assessed; Q_P/Q_S = pulmonary to systemic blood flow; + = present; – = minus.

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Table 5. Echocardiographic Results Before and After Valvuloplasty in 15 Patients

Patient No.	MV Excursion (mm)		EF Slope (mm/s)		S_2-OS (seconds)		MVA (cm^2)		LA Size (cm)	
	Before	After	Before	After	Before	After	Before	After	Before	After
1	7	8	13	10	NA	NA	0.6	1.5	5.8	5.8
2	13	17	4	14	0.06	0.08	0.8	1.7	5.6	4.9
3	6	10	1	9	0.05	0.05	0.9	1.4	5.9	5.6
4	6	13	8	12	0.12	0.10	0.8	0.9	7.1	6.0
5	19	24	7	12	0.11	0.10	1.1	2.0	5.4	5.4
6	7	9	9	15	0.04	0.07	0.7	1.2	6.5	6.0
7	12	17	10	14	0.09	0.09	0.8	1.2	5.0	4.3
8	18	23	7	12	0.04	0.10	0.6	1.2	5.1	4.5
9	6	9	10	6	0.08	0.08	0.9	1.4	7.8	7.2
10	8	8	0	6	0.04	0.06	1.1	1.5	5.8	6.0
11	16	16	0	10	0.03	0.07	1.0	1.6	5.9	5.3
12	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
13	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
14	23	21	7	21	0.09	0.10	0.8	1.8	4.5	4.1
15	9	12	10	19	0.09	0.11	1.1	1.7	5.3	5.2
16	15	15	8	23	0.04	0.07	1.4	2.3	4.5	4.2
17	3	8	12	18	0.05	0.07	1.0	1.6	5.3	5.2
18	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Mean	11	14	7	13	0.07	0.08	0.9	1.5	5.7	5.3
SD	6	6	4	5	0.03	0.02	0.2	0.4	0.7	0.8
		**		**		*		***		**

*$p < 0.02$; **$p < 0.001$; *** $p < 0.001$. EF slope = mitral valve EF slope; LA size = left atrial diameter; MV = mitral valve; MVA = mitral valve area by Doppler pressure half-time; S_2-OS = duration of S_2-opening snap interval.

septal approach. Our laboratory (4) and that of Palacios et al. (5) have reported using a single 25 mm balloon introduced after dilation of the interatrial septal puncture. Zaibag et al. (3) used a double-balloon technique involving two transseptal punctures to position two smaller balloons in the mitral anulus, thereby avoiding dilation of the atrial septum. Variations of both of these techniques are obviously possible. For example, in the four patients in the present study in whom two balloons were utilized, only one transseptal procedure was performed to place a single guide wire across the mitral apparatus; the second guide wire was subsequently positioned using a double lumen exchange catheter that could accommodate two guide wires simultaneously. Theoretic advantages of the single balloon technique include the need for only one transseptal procedure and the technical feasibility of placing only one guide wire and one balloon. Alternatively, the double balloon technique may not require dilation of the interatrial septum and may provide the largest dilating balloon volume with the use of two balloons.

Additional variations in the technique will presumably accompany technologic improvements in valvuloplasty equipment. As with coronary angioplasty, it is probable that the technique of mitral valvuloplasty will change dramatically with improvements in design and construction of balloon dilation catheters. Decreases in deflated balloon profiles, shortening of inflation and deflation time, changes in catheter stiffness and changes in balloon shape are all examples of potential balloon modifications that may make valvuloplasty easier to perform.

Complications. Six of the 18 patients in this series had evidence of an atrial septal defect either by oximetry series or by echocardiographic determination after valvuloplasty. It is possible that the presence of a new atrial septal defect in some patients may have partially contributed to the decrease in pulmonary capillary wedge pressure after valvuloplasty. The magnitude of the balloon-induced shunt, however, was small in four of the six patients, and four of the six also demonstrated an immediate decrease in pulmonary vascular resistance. Additional investigation will need to be done to assess the long-term hemodynamic effect of these shunts. Improvements in balloon catheter design and construction, resulting in substantially lower profiles for deflated balloons, may decrease the incidence of atrial septal defect in the future.

Several additional problems should be emphasized as potential complications of mitral valvuloplasty. The technique must be performed through a transseptal approach which, by itself, is associated with small but definite risk of cardiac perforation (17,18). Improper positioning of the dilation balloon (for example, through mitral chordae) could theoretically lead to chordal rupture and acute mitral regurgitation. Dislodgement of left atrial clot not detected by

prevalvuloplasty echocardiographic examination could potentially lead to embolic phenomena. Creation of a significant atrial septal defect secondary to septal dilation could theoretically expose the patient to a paradoxic embolus (19). Finally, valvular restenosis may develop in a significant number of patients. Because the incidence of restenosis after surgical commissurotomy has been estimated to range from 2 to 60%, with approximately 10% of patients requiring reoperation in 5 years and 60% within 10 years (20), it seems likely that significant rates of restenosis will also occur after balloon valvuloplasty. All of these technical considerations will have to be addressed to assess the true efficacy and safety of mitral valvuloplasty.

Conclusion. The present study demonstrates that mitral valvuloplasty can be accomplished successfully in older adult patients with moderate to severe calcification of the mitral valve. Significant lessening of symptoms may result from improvement in valvular function. The mechanism of successful valve dilation involves separation of fused commissures and fracture of nodular calcification. Additional studies will need to be done to assess the long-term efficacy of this procedure.

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