Experimental Balloon Valvuloplasty of Fibrotic and Calcific Mitral Valves

Nicolaus Reifart, MD, Bernd Nowak, MD, Doghan Baykut, MD, Peter Satter, MD, Wulf-Dirk Bussmann, MD, and Martin Kaltenbach, MD

This study evaluated the mechanism of valvular area expansion during single- and double-balloon valvuloplasty in fibrotic and calcific mitral valves. Special interest was focused on the morphological features of the valves treated. Mitral valves that appeared unsuitable for commissurotomy were excised in toto at the time of mitral valve replacement in 15 patients. The excised valves were mounted in a fluid-filled chamber with a window for photographic evaluation. The chamber was perfused continuously to ensure maximal valvular opening. The valve was photographed, and the orifice area was measured before and after balloon expansion. In addition, the specimens were examined macroscopically and radiographically with regard to calcium content and degree and localization of fibrosis. These data were correlated with splitting of commissures and with rupture of leaflets. Nine valves were fibrotic, and six were calcific. Dilatation was performed first with a single-balloon catheter (diameter, 2 cm) and then with a double-balloon catheter (diameter, 2 and 1.5 cm). After dilatation with one balloon, the average mitral valve area increased from 0.79 to 1.09 cm², and with two balloons, average area increased to 1.59 cm². The single-balloon technique caused commissural splitting in nine valves, stretching in three, partial leaflet rupture in one, and no change in two. After the double-balloon technique, commissural splitting occurred in 12 valves and three leaflets were ruptured where severe fibrosis and calcification were mainly located within the commissures. As a rule, after dilatation with the single-balloon technique, the remaining stenosis was still severe, and after dilatation with the double-balloon technique, the remaining stenosis was moderate. The results show that percutaneous mitral valvuloplasty might be successful despite severe fibrosis and calcification. In some patients, however, mitral regurgitation will probably develop because of tearing of the mitral valve leaflet. This seems to depend mainly on the distribution of advanced morphologic changes, not on their degree. (Circulation 1990;81:1005-1011)

Surgical mitral commissurotomy has been a standard procedure for several decades. In the last 3 years, the development of dilatating catheters with large balloons has made possible nonoperative dilatation of stenosed mitral valves with single- and double-balloon catheters. Recent reports demonstrated the successful application of mitral balloon valvuloplasty even in calcific mitral stenosis, with a noteworthy increased risk of restenosis.

Since our first report in 1985, several studies have focused on the same topic, namely the mechanism of mitral balloon valvuloplasty. Three investigations used the single-balloon technique, and one study compared the single- with the double-balloon technique. Some investigators focused only on the morphological changes induced at the valves, whereas others measured the increase in mitral valve area with a calibrated conus. This kind of measurement is probably not exact, because a bizarre mitral valve opening area might be distorted by an inserted conus.

In the present study, we tried to simulate in vivo conditions before and after single- and double-balloon mitral valvuloplasty to evaluate the mechanism of enlargement in mitral valve area. Special interest was focused on the morphological features of the treated valves and on the risk of rupturing the leaflets, which would cause severe mitral incompetence.

Methods

Mitral valves were excised in toto from 15 patients (age range, 36–69 years; average age, 55.8 years) at
TABLE 1. Morphological Features of Calcific and Fibrotic Mitral Valves

<table>
<thead>
<tr>
<th>Patient</th>
<th>Calcification</th>
<th>Localization</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.E.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>R.E.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>O.S.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>S.M.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>N.E.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>U.G.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>H.K.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>B.M.</td>
<td>Slight</td>
<td>1 leaflet</td>
</tr>
<tr>
<td>B.W.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>B.J.</td>
<td>Severe</td>
<td>1 commissure</td>
</tr>
<tr>
<td>R.F.</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>K.M.</td>
<td>Severe</td>
<td>1 commissure and 1 leaflet</td>
</tr>
<tr>
<td>M.S.</td>
<td>Severe</td>
<td>1 commissure</td>
</tr>
<tr>
<td>B.J.</td>
<td>Moderate</td>
<td>1 leaflet near both commissures</td>
</tr>
<tr>
<td>W.R.</td>
<td>Severe</td>
<td>1 commissure and tip of both leaflets</td>
</tr>
</tbody>
</table>

The time of mitral valve replacement for posthemor- 

tatic mitral stenosis. All patients were in New York 

Heart Association (NYHA) functional class III or IV. The surgical specimens were examined for cal- 

cium content by fluoroscopy and plain film with a 

scale. The degree of calcification was quantified as 

none, no calcification; slight, one to three areas of 

calcification with a maximum diameter of 5 mm each; 

moderate, more than three not conflating areas of 

calcification, or at least one area of calcification 

greater than 5 mm in diameter; and severe, conflu- 

ating areas of calcium greater than 10 mm in 

diameter.

By inspection and careful palpation of the valves, 

the degree of fibrosis was graded semiquantitatively 

as slight, thicker-than-normal valve tissue but with 

good mobility; moderate, marked thickening of the 

leaflet but still pliable; and severe, thickened and 

rigid leaflet without calcification. The morphologic 

features of all valves with the localization of fibrosis 

and calcium is listed in Table 1 and in Figure 1.

After examination, the valves were sewn onto a 

ring of thin synthetic fabric and mounted free of 

tension in a two-piece glass cylinder (Figure 2). A 

flow-steered pump was used to irrigate the glass 

cylinder with a warm water (37°C) flow that was 

continuously increased to a maximum of 15 l/min. 

With increased flow, the leaflets eventually separated 

until the valve reached its maximal opening area, 

which remained unchanged by a further increase in 

flow. Therefore, we assumed that this continuous 

flow was in the physiological range of the pulsatile 

flow in vivo.

The mitral valves were photographed together 

with a scale to measure orifice area (Figure 3). 

Planimetry of the opening area was performed with 

computer assistance (Cardio 80, Kontron). Each 

opening area was measured three times, and a 

mean value was established. This method was 

proven reliable in previous studies. A single- 

balloon catheter (diameter, 2 cm; dilating area, 3.14 

cm²; Meditech) was placed in the mitral orifice and 

slowly inflated with water for 3–5 seconds to a 

pressure of 200–250 kPa. The balloon was removed, 

and the valve was photographed again for measure- 

ment of orifice size.

The mechanism by which the mitral valve area 

changed was noted. A double-balloon catheter was 

then inserted (diameter, 2 and 1.5 cm; dilating area, 

4.9 cm²; Meditech). Both balloons were inflated 

simultaneously to a pressure of 200–250 kPa. The 

orifice of the mitral valve was photographed after 

removal of the catheters for the third planimetric 

measurement. Again, the mechanism of the further 

increase in mitral valve area was noted. Stretching 

of the valve was assumed when there was an increase 

in mitral valve area without a visible rupture of com- 

missures or leaflets.

Results

The degree of fibrosis and calcification and its 

localization within the leaflets or commissures is 

shown in Table 1 and Figure 1. There were four 

severe, one moderate, and one slightly calcific valve; 

nine valves were fibrotic but showed no calcification. 

Table 2 and Figures 1, 3, and 4 illustrate that dilatation with one balloon of a 2-cm diameter
improved the opening area in 13 of the 15 valves. In three valves, the improved opening was only caused by stretching. We noticed incomplete splitting in six valves, and in one valve, we noticed complete splitting within one of the commissures. In two valves, the increase in mitral valve area was due to splitting of both commissures, and in one valve, the increase was due to partial rupture of the anterior mitral leaflet with an extension of 5 mm. The mean mitral valve area increased by 38% (from 0.0 to 0.5 cm²; mean, 0.3 cm²) from 0.79 to 1.09 cm².

After insertion of a double-balloon catheter and simultaneous inflation of both balloons, one of the two previously unchanged mitral valves was split within one commissure, and the other valve was stretched in combination with an incomplete rupture of the anterior mitral leaflet with an extension of 6 mm. Two previously stretched valves were now split within one commissure. A deeper splitting of the commissures occurred in six. In two valves, a new splitting occurred within the previously unchanged commissure. In two valves, dilatation with the
double-balloon catheter led to a complete rupture of one mitral leaflet (Figure 5).

The valve with complete commissural splitting after dilatation with the single-balloon catheter was not treated with the double-balloon catheter. Intervention by means of the double-balloon technique further increased the mean mitral valve area to 1.59 cm² (more than twice the initial value). The results were independent of the degree of fibrosis or calcification (Figure 1). However, leaflet rupture occurred in three specimens with only slight or moderate fibrotic leaflets (U.G., R.F., and B.J.). Of note, in these patients, the advanced morphological changes (severe fibrosis or calcification) were assigned only to the commissures.

**Discussion**

Inoue et al. achieved excellent results in mitral balloon valvuloplasty using a single-balloon catheter with a diameter of 25–28 mm. The results we obtained in vitro, using the double-balloon technique, with excised valves in patients with mitral stenosis graded as NYHA class III and IV were less favorable. Dilatation with two balloons (diameter, 2 and 1.5 cm) reached at most 2.2 cm². Clinically, this indicates that a mild-to-moderate residual stenosis would have persisted. More favorable in vivo results with conventional commissurotomy have been reported by others. The reason for this discrepancy is that the material we used came from older patients with valves that required excision and were not suitable for commissurotomy by clinical, echocardiographic, angiographic, and surgical criteria. Maximal opening could not be achieved even with two balloons fully expanded. This finding is supported by recent clinical investigations.

Our study implies that with the use of only a single balloon with a diameter of 2 cm (balloon area, 3.1
TABLE 2. Mitral Valve Areas and Mechanisms of Expansion Before Dilatation and After Single-Balloon and Double Balloon-Valvuloplasty

<table>
<thead>
<tr>
<th>Patient</th>
<th>Patient (cm²)</th>
<th>Before</th>
<th>After single (cm²)</th>
<th>After double (cm²)</th>
<th>Mechanism</th>
<th>Single balloon</th>
<th>Double balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.E.</td>
<td>0.8</td>
<td>1.3</td>
<td>1.6</td>
<td></td>
<td>Splitting both commissures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R.E.</td>
<td>0.7</td>
<td>1.1</td>
<td>1.5</td>
<td></td>
<td>Splitting right commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>O.S.</td>
<td>0.7</td>
<td>1.0</td>
<td>1.4</td>
<td></td>
<td>Splitting right commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S.M.</td>
<td>0.8</td>
<td>1.0</td>
<td>1.7</td>
<td></td>
<td>Splitting both commissures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N.E.</td>
<td>0.9</td>
<td>1.2</td>
<td>1.4</td>
<td></td>
<td>Splitting right commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.G.</td>
<td>1.15</td>
<td>1.2</td>
<td>2.1</td>
<td></td>
<td>No change</td>
<td></td>
<td>Complete leaflet rupture</td>
</tr>
<tr>
<td>H.K.</td>
<td>0.9</td>
<td>1.2</td>
<td>1.4</td>
<td></td>
<td>Splitting left commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.M.</td>
<td>0.55</td>
<td>1.0</td>
<td>1.2</td>
<td></td>
<td>Splitting left commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.W.</td>
<td>1.0</td>
<td>1.4</td>
<td>1.6</td>
<td></td>
<td>Stretching</td>
<td></td>
<td>Splitting left commissure</td>
</tr>
<tr>
<td>B.J.</td>
<td>1.0</td>
<td>1.2</td>
<td>1.75</td>
<td></td>
<td>Stretching</td>
<td></td>
<td>Leaflet rupture (6 mm)</td>
</tr>
<tr>
<td>R.F.</td>
<td>0.75</td>
<td>0.9</td>
<td>1.5</td>
<td></td>
<td>Partial leaflet rupture</td>
<td></td>
<td>Complete leaflet rupture</td>
</tr>
<tr>
<td>K.M.</td>
<td>0.4</td>
<td>0.8</td>
<td>. .</td>
<td></td>
<td>Complete splitting right commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M.S.</td>
<td>0.55</td>
<td>1.0</td>
<td>1.2</td>
<td></td>
<td>Splitting right commissure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>W.R.</td>
<td>1.0</td>
<td>1.0</td>
<td>2.2</td>
<td></td>
<td>Stretching</td>
<td></td>
<td>Splitting left commissure</td>
</tr>
<tr>
<td>Mean</td>
<td>0.79</td>
<td>1.09</td>
<td>1.59</td>
<td></td>
<td>No change</td>
<td></td>
<td>Splitting right commissure</td>
</tr>
<tr>
<td>SD</td>
<td>0.21</td>
<td>0.16</td>
<td>0.29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Before, before dilatation; After single, after single-balloon valvuloplasty; After double, after double-balloon valvuloplasty.

cm²), severe residual stenosis would have remained in seven of 15 patients. This problem might be overcome with the use of a larger single balloon. Because simultaneous use of two balloons would have increased mitral valve area by at least 0.5 cm² in 14 of 15 patients, clinical improvement probably would have been ensured in these patients.

Thus, for successful dilatation in vivo, a balloon area of about 5.0 cm² (double-balloon technique) with a pressure of 1–5 atm for 5 seconds is probably sufficient. Until recently, only smaller-sized balloons were available, and some researchers have already successfully applied the double-balloon technique, some using even larger-sized balloons than we did in vitro.

Our in vitro results also show that balloon valvuloplasty may be successful even in severely calcific valves. Our impression was recently confirmed by others. Kaplan et al and Ribeiro et al used a calibrated conus to measure mitral valve area. This technique may lead to an overestimation, because the deformed mitral valve opening area is forced to follow an elliptical form. We determined the undistorted mitral valve area using a flow model. This may also explain why the opening area that resulted after dilatation in our study seems to be smaller compared with other reports.

As expected, in less fibrotic valves, the increase in mitral valve area was produced by splitting of the commissures. In severely fibrotic valves, however, dilatation with one balloon was achieved by stretching and, in some, by partial splitting. Stretching without splitting is probably a transient effect. This may explain why the mitral valve undergoes restenosis early in some patients after apparently successful percutaneous balloon commissurotomy.

FIGURE 4. Plot of results of in vitro balloon dilatation of severely stenotic mitral valves. A, before dilatation; B, after dilatation with the single-balloon catheter (20-mm diameter); C, after dilatation with the double-balloon catheter (20-mm and 15-mm diameter).
Until now, all in vitro investigations showed that the increase in mitral valve area by balloon valvuloplasty occurs exclusively through commissural splitting, even in severely calcific valves. However, we observed complete leaflet rupture in two fibrotic valves. (Once, an incomplete leaflet rupture occurred.) In these valves, the most advanced morphological changes were located within one or both commissures (U.G., R.F., and B.J.). Therefore, the leaflets, themselves, were less resistant than the commissures and were ruptured. This could have caused significant mitral regurgitation in vivo. Another cause for mitral incompetence may be over-separation of commissures. Our study design did not allow an assessment of this risk, because the valves we used were excised from their natural bases.

**Limitations**

The balloon we used for single-balloon valvuloplasty was smaller than that used by other investigators. This may be one cause for the less favorable results we achieved with single-balloon dilatation.

Pressures were not measured in this investigation; however, in a previous study in this model, we found good agreement between echocardiographic and anatomic data, suggesting that our flows are physiologically relevant.²³

Severity of mitral stenosis depends not only on the degree of morphological changes within leaflets and commissures but also on the involvement of subvalvular structures adversely affecting the results of mitral balloon valvuloplasty in vivo. Our model did not allow the assessment of subvalvular stenosis because the valves were removed from the papillary muscles and chordae tendineae during mitral valve replacement.

The absolute number of valves in which a leaflet rupture occurred in our study is low. Therefore, it is difficult to predict whether the distribution of advanced morphological changes is the only factor that contributes to the risk of leaflet laceration.

**Conclusions**

From this study, we conclude that 1) balloon valvuloplasty should be successful in most patients with severely fibrotic and calcified mitral valves; 2) the balloon area should be at least 4.9 cm² (i.e., balloon diameter, 2.0 and 1.5 cm); 3) enlargement of the mitral valve area is achieved by splitting of the commissures (60%), splitting and stretching (20%), and rupture within the leaflet (20%); and 4) a relatively high percentage of complete leaflet laceration (13%) occurred in our study. This may lead to significant mitral incompetence. We suspect this to depend mainly on the distribution of advanced morphological changes within leaflets and commissures.
changes and not on their degree. Further studies are needed to fully elucidate the mechanism of leaflet rupture in percutaneous mitral balloon valvuloplasty.

References

KEY WORD • valvuloplasty
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