Influence of Balloon Size on Short-Term and Long-Term Results of Balloon Pulmonary Valvuloplasty

P. Syamasundar Rao, M.D.

This article studies the relationship between the size of the balloon used for balloon pulmonary valvuloplasty (BPV) and the degree of relief of pulmonary stenosis. Twenty-six BPVs in 22 patients were divided into two groups: (A) those in which the balloon/pulmonary annulus ratio was 1.0 or less and (B) those in which the ratio was more than 1.0. In group A (which consisted of 9 BPVs), the mean ratio was 0.89 (range, 0.79 to 1.0, whereas in group B (which included 17 BPVs), the mean ratio was 1.32 (range, 1.01 to 1.69). The two groups had similar pre-BPV pulmonary valve (PV) gradients [93 ± 41 (mean ± SD) vs 103 ± 40 mm Hg] ($p > 0.1$). Immediately after BPV, neither the absolute residual PV gradient (43 ± 29 vs 37 ± 21 mm Hg) nor the percentage of residual PV gradient (44 ± 14 vs 36 ± 17 percent) differed significantly ($p > 0.1$) from group to group. However, long-term follow-up (which ranged from 6 to 28 months, with a mean of 12 months), showed the residual PV gradient in group B (18 ± 8 mm Hg) to be lower ($p < 0.02$) than that in group A (80 ± 52 mm Hg). Similarly, the percentage of residual gradient (83 ± 41 vs 20 ± 10 percent) was also lower in group B. Repeat BPV was required in four patients from group A, but in none from group B.

Although the immediate results of BPV are similar with either small or large balloons, balloons larger than the PV annulus appear to produce more sustained relief of pulmonary stenosis. Therefore, balloons larger than the PV annulus are recommended for pulmonary valvuloplasty. ***(Texas Heart Institute Journal 1987; 14:57-61)***

Key words: Pulmonary valve stenosis; heart valve diseases, pulmonary; heart catheterization.

PERCUTANEOUS BALLOON pulmonary valvuloplasty (BPV) is now widely used for the treatment of moderate-to-severe pulmonary stenosis. The immediate results of BPV have been well documented.[1-11] Several studies have also attempted to document the long-term effectiveness of BPV.[3,8-11] Varying degrees of either immediate or late failure have been reported.[3,9-11] Inadequate balloon size and dysplasia of the pulmonary valve leaflets have been implicated in such failure.[3,9-11] This article examines the relationship between the size of the balloon used for BPV and the effectiveness of relief of pulmonary valvular stenosis.

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PATIENTS AND METHODS

During a 30-month period ending in March 1986, 22 patients, aged 4 months to 20 years (mean, 6 years), underwent 26 BPVs for the relief of isolated pulmonary valvular stenosis. Informed consent was obtained from the parents of each patient. The data obtained and the technique of balloon dilatation are described in detail elsewhere[7,11]; the technique is similar to that used by others.[2,3] Catheters ranging from 5 to 9 Fr, with 6- to 20-mm balloons, were used, depending on the size of the pulmonary valve annulus. Two balloons were used simultaneously for pulmonary valvuloplasty in six patients whose annular diameter was larger than 20 mm.

During our initial experience with this technique,[7] we intentionally limited the size of the balloon so as not to exceed the size of the pulmonary valve annulus; during the later part of our experience, we intentionally used larger balloons. However, the availability of balloons (or lack of them) during our recent experience sometimes forced us to use balloons no larger than the pulmonary valve annulus. The size of this structure and the size of the inflated balloon were measured from cineangiographic views taken in the lateral projection. In most cases, correction of magnification was made by comparing any structure shown in the cineangiogram with a marker of known size (1.0 cm) on the catheter used for right ventricular angiography. When no such marker was present, the magnification factor was derived from the catheter's diameter. Care was taken to avoid parallax error. When the measured size of the balloon was compared with the size listed by the manufacturer, the ratio was 0.95 ± 0.09 (mean ± SD), with a range of 0.87 to 1.08. Because this was close to unity and the difference was within the range of error of measurement, the balloon size listed by the manufacturer was used for final computation of the ratio of balloon size to pulmonary valve annulus. When two balloons were used simultaneously, the total balloon diameter was calculated according to the following formula:

$$\frac{D_1 + D_2 + \pi\left(\frac{D1}{2} + \frac{D2}{2}\right)}{\pi}$$

where D_1 and D_2 are the diameters of the balloons used.

Balloon dilatation procedures were divided into two groups, based on the ratio between the balloon size and the size of the pulmonary valve annulus: In group A, the ratio was 1.0 or less; in group B, it was more than 1.0.

Repeat cardiac catheterization was performed in 19 of the 26 cases, 6 to 28 months (mean, 12 months) after BPV. Pressure pullback recordings from the main pulmonary artery to the right ventricle were obtained in all cases. Cardiac output determinations, which were based on thermodilution in most cases (and on the Fick technique in the remainder), showed no difference ($p > 0.1$) between pre-BPV values, (3.6 ± 1.9 L/min/m^2), those obtained immediately after BPV (3.5 ± 1.1 L/min/m^2), and those obtained several months after BPV (3.4 ± 0.5 L/min/m^2).

Student's *t*-test was used for comparing data between groups, as well as data obtained before and after BPV. The level of statistical significance was set as $p < 0.05$.

RESULTS

There was a total of 26 balloon dilatations in 22 patients; in 19 of these cases, long-term follow-up data were available. In group A, which consisted of 9 dilatations, the balloon/annulus ratio ranged between 0.79 and 1.0 (mean, 0.89); in group B, which consisted of 17 dilatations, the ratio ranged between 1.01 and 1.69 (mean, 1.32).

When the two groups were compared, neither the pre-BPV right ventricular peak systolic pressures (110.9 ± 38.5 vs 121.5 ± 40.2 mm Hg) nor the pulmonary valve (PV) peak systolic pressure gradients (93.3 ± 41.4 vs 102.6 ± 40.4 mm Hg) were significantly different ($p > 0.1$) (Fig. 1). Immediately after BPV, neither the absolute residual right ventricular pressure (67.8 ± 27.2 vs 64.5 ± 22.4 mm Hg) and the residual PV gradient (43.4 ± 29.4 vs 37.1 ± 21.2 mm Hg) nor the percentage of residual right ventricular pressure (61.2 ± 13.0 vs 53.6 ± 12.0 percent) and the percentage of residual PV gradient (44.4 ± 14.0 vs 35.9 ± 16.5 percent) differed significantly from group to group. These data suggest that both groups involved a similar degree

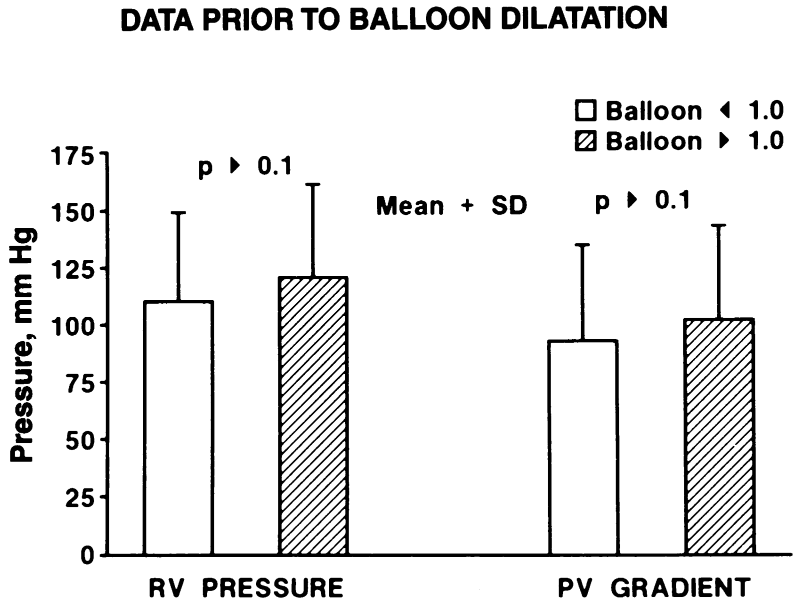

Fig. 1 The right ventricular peak systolic pressure and pulmonary valvular peak systolic pressure gradient in groups A (balloons smaller than the pulmonary valve annulus) and B (balloons larger than the pulmonary valve annulus) were similar ($p > 0.1$) before balloon dilatation of the pulmonary valve; this finding suggests that the severity of pulmonary valve stenosis was similar in both groups.
PV = pulmonary valvular; RV = right ventricular

of pulmonary valve obstruction and that the immediate results of pulmonary valvuloplasty were good, irrespective of the balloon/annulus ratio (within the range of balloon sizes used in the study, of course).

Nevertheless, long-term follow-up (at 6 to 28 months, with a mean of 12 months), showed that the right ventricular pressure in group B (the large-balloon group) (39.4 ± 7.5 mm Hg) was significantly lower ($p < 0.02$) than that in group A (the small-balloon group) (103.2 ± 53.0 mm Hg). Similarly, the PV gradient (80.0 ± 52.2 vs 17.9 ± 7.6 mm Hg) was also lower ($p < 0.02$) in group B, as was the percentage of residual right ventricular pressure (91.8 ± 34.6 vs 35.0 ± 10.0 percent) and PV gradient (82.7 ± 41.3 vs 19.6 ± 10.0 percent) ($p < 0.01$). Serial pressure changes in both groups are depicted in Figure 2. Repeat balloon dilatations with a larger balloon were required in four of the nine group-A patients but in none from group B. Doppler studies showed mild pulmonary insufficiency in six group-B patients. No other significant complications were encountered in either group.

DISCUSSION

In previously reported studies,[3,8-10] varying numbers of patients have had significant residual pulmonary valve stenosis, either immediately after BPV or several months later. Inadequate balloon size or dysplasia of the pulmonary valve leaflets has been the most commonly offered explanation for lack of success.[3,8-10] Our study was designed to investigate the role of balloon size in the effectiveness of BPV. The immediate results of valvuloplasty were fairly similar with both large and small balloons. At long-term follow-up, however, there was a significant difference between the groups. Persistent relief was associated with the use of large balloons, whereas significant restenosis was associated with the use of small balloons. All four patients who required repeat BPV were from the group in which small balloons were used. In the other group, pulmonary insufficiency, although mild, developed in a significant number of patients. These data suggest that large balloons produce sufficient tearing (one hopes in the valve raphes)

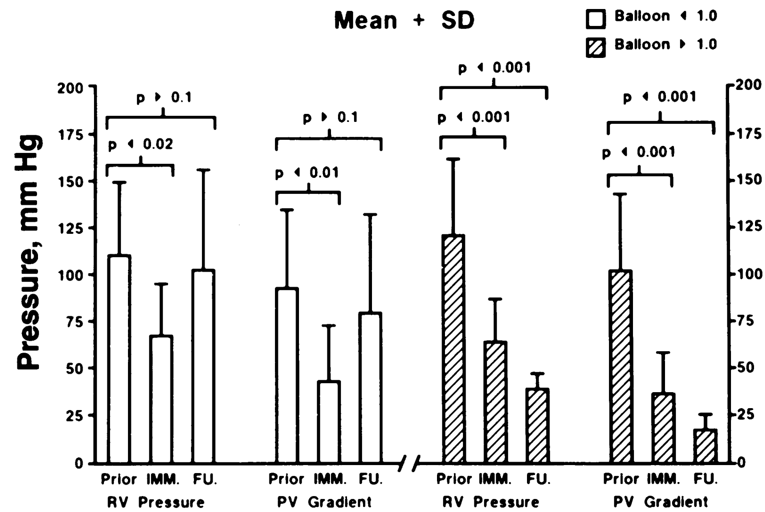

Fig. 2 The immediate and long-term effects of balloon dilatation on the right ventricular peak systolic pressure and pulmonary valvular peak systolic pressure gradient in both groups are shown. In group A, in which the balloon/PV ratio was less than 1.0, there was a significant decrease ($p < 0.02$ to 0.01) in RV pressure and PV gradient immediately after balloon dilatation; long-term follow-up showed that these valves returned toward predilatation levels ($p > 0.1$). In group B, in which the balloon/PV ratio was greater than 1.0, an improvement ($p < 0.001$) in RV pressure and PV gradient was seen both immediately after BPV and at long-term follow-up.
FU = follow-up; IMM = immediately; PV = pulmonary valvular; RV = right ventricular

to produce both short- and long-term relief. Large balloons also increase the risk of pulmonary insufficiency, but this finding was not hemodynamically significant. Based on these data, balloons larger than the pulmonary valve annulus are recommended for pulmonary valvuloplasty. Attempts to break down group B into subgroups of 1.0 to 1.2, 1.2 to 1.4, and 1.4 to 1.6 resulted in too small a number of procedures in each subgroup to reach a valid conclusion. Because of damage to the right ventricular outflow tract produced by oversized (ratio > 1.5) balloons,[12] the use of very large balloons is not advisable. Perhaps the best compromise will be to use balloons 1.2 to 1.4 larger than the pulmonary valve annulus.

Dysplastic pulmonary valves have been invoked as an explanation for BPV failure.[3,8-10] In our series, two patients appeared to have dysplastic valves. In one patient, dilatation with a balloon larger than the pulmonary valve produced excellent relief of the obstruction, both immediate and long-term. In the other patient, a balloon slightly smaller than the pulmonary valve annulus (ratio, 0.9) produced good results immediately after BPV. On recatheterization 15 months later, however, severe stenosis had recurred, with a suprasystemic right ventricular systolic pressure. This patient underwent repeat balloon dilatation with a balloon larger than the annulus (ratio, 1.3) and had excellent immediate relief, which was seen to persist at another repeat study 12 months after the second BPV. These observations, although anecdotal, would suggest that pulmonary stenosis in patients with dysplastic pulmonary valve leaflets does respond favorably when balloons larger than the pulmonary annulus are used. Therefore, balloon dilatation is still the initial treatment of choice, even with dysplastic leaflets.

In conclusion, although the immediate results of BPV are similar whether a small or a large balloon is used, larger balloons appear to produce more sustained relief of pulmonary stenosis. Therefore, balloons larger than the pulmonary valve annulus are recommended for pulmonary valvuloplasty. Because oversized balloons tend to damage the right ventricular outflow tract, a compromise would involve the use of balloons 1.2 to 1.4 times the size of the pulmonary valve annulus.

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