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Percutaneous Balloon Valvotomy of Congenital Pulmonary Stenosis Using Oversized Balloons

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Percutaneous balloon valvotomy was attempted in 27 patients (aged 6 days to 19 years, median 2 years, 11 months) with unoperated typical valvular pulmonary stenosis using a balloon 7 to 60% (mean 30%) larger than the valve anulus. One patient had undergone a previous balloon valvotomy elsewhere. To achieve an oversized dilation diameter in three larger patients, two balloons were inflated side by side. Their "effective dilation diameter" was determined by the diameter of the circle with the same area as that of the oval enveloping the two balloons.

A significant reduction of the transvalvular gradient occurred in all patients (mean ± SD = 74.3 ± 14.7%, range 33 to 100%). The average gradient of 65.0 ± 19.0 mm Hg (mean ± SD) fell to 15.9 ± 7.6 mm Hg (0 to 30 mm Hg). Twenty-five of 27 patients had a residual transvalvular gradient of less than 25 mm Hg. The calculated valve orifice area increased by an average of 183 ± 80%. No significant complications occurred. It is concluded that percutaneous balloon valvotomy with a balloon 20 to 40% larger than the valve anulus is the treatment of choice for typical congenital valvular pulmonary stenosis.

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Several studies (1–6) have indicated that percutaneous balloon valvotomy can reduce the transvalvular gradient in congenital pulmonary stenosis. The reported average gradient reduction ranged from 53 to 68%, which is somewhat less than that provided by standard surgical procedures (7). In these previous studies the balloon used for percutaneous valvotomy was either smaller than the valve anulus (3–6) or about the same size as the anulus (2). Successful use of a larger or so-called oversized balloon (that is, a balloon significantly larger than the adjacent "normal" cardiovascular structures) in other lesions (8,9) suggested the possibility of further gradient relief with this technique. After an experimental study in newborn lambs showed that balloons 20 to 40% larger than the pulmonary valve ring can safely be inflated across the anulus (10), we decided to study the safety and efficacy of oversized balloons for percutaneous valvotomy in congenital pulmonary stenosis.

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Methods

Patients. Beginning in May 1984 we used oversized balloons to attempt percutaneous balloon valvotomy in 26 patients with unoperated pulmonary valvular stenosis (Table 1). Patients 1 and 2 underwent balloon valvotomy with an oversized balloon before May 1984, and we included their results. One patient with classic findings of a dysplastic valve was excluded from further analysis. His gradient reduction was 60% with a residual gradient of 40 mm Hg. Each of the 27 patients (aged 6 days to 19 years, median 2 years, 11 months) fulfilled the classic diagnostic criteria for typical valvular pulmonary stenosis: a 3-4/6 systolic ejection murmur, variable systolic ejection click and, no diastolic murmur on auscultation, and right axis deviation and right ventricular hypertrophy on the electrocardiogram. Two-dimensional and Doppler echocardiography provided a gradient estimation and ruled out pulmonary regurgitation. Patient 13 had undergone prior balloon valvotomy at another institution and had a residual transvalvular gradient of 35 mm Hg.

Valvotomy procedure. After standard premedication, local anesthesia, percutaneous placement of an arterial and single venous catheter and hemodynamic evaluation, a right ventricular angiocardiogram in the anteroposterior and lateral projections was recorded to rule out valvular dysplasia and to determine anular and subvalvular diameter. Addi-

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JACC Vol. 8, No. 4
October 1986:909–15

Table 1. Pertinent Hemodynamic and Balloon Data in 27 Patients

Case	Age (yr,mo)	Valve Anulus Diameter (mm)	Nominal Balloon Diameter (mm)	Balloon/ Anulus Ratio	Post/Pre Output Ratio	Systolic Infundibular Diameter (mm)		Transvalvular Gradient			Valve Orifice Ratio (post/pre)
						Pre	Post	Pre (mm Hg)	Post (mm Hg)	Reduction (%)	
1	4,10	15	20	1.33	0.8	—	—	75	18	76	2.4
2	4,6	12.5	20	1.60	1.2	3.0	—	50[d]	15[d]	70	2.7
3	0,10	10	15	1.50	—	2.6	—	100	30	70	—
4	4,2	12	15	1.25	1.2	—	—	45	20	56	2.1
5	4,11	12.5	20	1.60	1.4	—	—	40	15	63	2.8
6	5,8	15	20	1.33	1.0	2.0	1.5	56	24	57	1.9
7	2,1	14	15	1.07	0.8	2.7	1.8	60[c]	5[c]	92	3.8
8	1,6	13	18	1.38	1.0	6.2	2.6	85	15	82	3.8
9	1,8	10	15	1.50	1.1	4.5	4.5	60	20	67	2.5
10	6 days	9	10	1.11	—	5.2	—	93	16	83	—
11	18,10	22	35[a]	1.59	1.1	—	—	39[f]	26[f]	33	1.5
12	0,10	12	15	1.25	1.2	5.9	—	55	20	64	2.5
13	13,9	22	27[b]	1.23	1.1	—	—	35[g]	0[g]	100	2.9
14	6,2	15	20	1.33	0.9	4.9	4.2	90	20	78	3.2
15	2,11	16.5	20	1.21	1.0	—	—	45	17	62	1.6
16	0,8	10.5	12	1.14	1.1	5.2	4.7	70[h]	5[h]	93	4.5
17	0,10	11	15	1.36	1.0	3.8	3.8	60	16	73	2.6
18	2,0	14	15	1.07	1.0	9.0	8.0	73	22	70	2.6
19	11,5	16	20	1.25	0.9	7.0	6.0	68	18	74	2.4
20	15,4	22	30[c]	1.36	—	6.9	5.6	64	24	63	—
21	0,9	12	15	1.25	1.2	6.9	4.8	72	4	94	4.5
22	4,10	17.5	20	1.14	0.9	5.0	3.0	44[i]	5[i]	89	2.8
23	5,1	15.5	20	1.29	0.9	9.0	—	49	10	80	2.7
24	5,8	13.5	18	1.33	1.1	7.5	—	66	23	65	2.8
25	0,7	11	12	1.10	1.0	7.5	4.5	90[j]	5[j]	94	—
26	1,8	13	15	1.15	0.9	7.0	6.5	70	15	79	3.6
27	1,2	10	15	1.50	—	6.0	—	100	20	80	—
Mean	2,11*	13.9	18.2	1.30	1.03	—	—	65.0	15.9	74.3	2.83
± SD		3.6	—	0.16	0.15	—	—	19.0	7.6	14.7	0.80

*Median. Dual balloons: [a]25 and 12 mm; [b]18 and 18 mm; [c]20 and 20 mm. Infundibular pressure gradients before and after dilation (mm Hg): [d]20/20; [e](60 assumed)/60; [f]0/6; [g]0/15; [h]5/16; [i]0/17; [j]0/30. Post and pre = after and before valvotomy, respectively.

tional analgesia (morphine, 0.1 mg/kg body weight) and local anesthesia were administered routinely just before valvotomy. Using a 7F balloon-tipped end-hole catheter, a 0.035 inch (0.089 cm) exchange guide wire was positioned in either the left or right lower lobe pulmonary artery. With the guide wire left in place, we removed the end-hole catheter and sheath, and the balloon valvotomy catheter (Mansfield Scientific) was inserted. Particular care was taken to keep the guide wire taut, with its tip still in the peripheral pulmonary artery as the dilation catheter was advanced to the upper inferior vena cava. Using diluted (20 to 30%) contrast material, the balloon was flushed to remove the air. We then advanced the deflated balloon across the pulmonary valve and rapidly inflated it by hand under fluoroscopic and pressure control until the indentation ("waist") caused by the stenotic valve disappeared (3 to 7.5 atm). After rapid deflation a second inflation was performed to document the absence of a waist at low (2 atm) inflation pressure. Inflation-deflation cycles lasted approximately 10 seconds.

The dilation catheter was removed and exchanged for a balloon-tipped end-hole catheter for repeat pressure measurements and determination of cardiac output. The pressure gradient was determined on pullback as a peak to peak systolic gradient. In the presence of a distinguishable subvalvular pressure gradient (Patients 2,7,11,13,16,22 and 25) we used the actual transvalvular gradient for data analysis. Ratios of valve orifice area before valvotomy to that after valvotomy were calculated on the basis of cardiac output and mean gradient using the Gorlin formula for semilunar valves. After replacement of the end-hole catheter by an angiographic catheter, a post-dilation right ventricular angiocardiogram was recorded to demonstrate the subvalvular dimension and valvular morphology. Catheters were removed and hemostasis was achieved by compression. All patients over 6 months of age were discharged on the day after valvotomy. The neonate (Patient 10) who had critical valvular pulmonary stenosis and right to left atrial shunting was discharged 4 days after valvotomy.

Selection of balloon size. The balloon diameter was selected according to the estimate of anular size made from the video replay of the lateral angiocardiogram (corrected for magnification by a predetermined factor). The anulus was defined by the valve leaflet hinge points. In the neonate and in older patients with suprasystemic right ventricular pressure, the first valvotomy was performed with a small balloon to reduce the risk of hemodynamic compromise that might be caused by advancing a large catheter through a severely stenotic valve. The final balloon diameter (range 10 to 35 mm, mean 18.2) was chosen to be 10 to 40% larger than the anulus, as estimated from the monitor replay. After the procedure all anular diameters were remeasured from the cineangiographic films (corrected for magnification). These postprocedure measurements were used for further analysis. For data analysis the nominal balloon diameters (as stated by the manufacturer) were taken as the actual balloon diameters. In 12 patients, we measured the used balloons (n = 17) directly at an inflation pressure of 4 atm. A variation as large as 1.5 mm (+ 8 to − 12.5%) was found between the actual and stated balloon sizes (mean difference = 0.8 mm). The balloon length was 3 cm (manufacturer's specifications) except in the neonate for whom we used a 2 cm balloon.

To achieve an oversized balloon dilation diameter in larger patients, a dual balloon technique was needed in three patients. In those, we inserted a second dilation catheter from the left groin in a similar fashion to that described. Both balloons were inflated and deflated simultaneously (Fig. 1). The "effective dilating diameter" was determined by calculating the cross-sectional area of the oval enveloping the two balloons and then taking the diameter of the circle with the same area (see Appendix). All values and measurements are expressed as mean ± SD.

Results

Gradient reduction. In our study anular diameter ranged from 9 to 22 mm (mean 13.9) and the ratio of balloon to anular diameter ranged from 1.07 to 1.60 (mean 1.30 ± 0.16). All patients had a significant reduction in transvalvular gradient ranging from 33 to 100% (mean reduction 74.3 ± 14.7%) (Table 1). The mean prevalvotomy gradient of 65.0 ± 19.0 mm Hg was reduced to 15.9 ± 7.6 mm Hg (0 to 30) after valvotomy. Ninety-three percent (25 of 27) of patients left the catheterization laboratory with a transvalvular gradient of less than 25 mm Hg (Fig. 2). The calculated valve orifice area increased by an average of 183% (range 50 to 350%). Gradient reduction was found to be a reliable index of success because in most instances cardiac output remained unchanged, with a mean postdilation/predilation cardiac output ratio of 1.03 ± 0.15 (n = 23).

There was no apparent relation between patient age and gradient reduction. A significant correlation between degree of balloon oversize and gradient reduction (or residual gradient) was not found by comparing patients in the study group. However, in six patients, valvotomy was performed sequentially with two different sized balloons, the second being larger than the first, and the transvalvular gradient was measured after both the first and the second procedure. The increase in balloon size resulted in a further gradient reduction in all six patients (Fig. 3).

Reactive infundibular stenosis. In 14 patients, it was possible to measure the systolic infundibular diameter during sinus rhythm before and after dilation. In these patients, the systolic diameter after valvotomy tended to be smaller (0 to 57%) than before valvotomy, with an average decrease in systolic subvalvular diameter of 21 ± 17% ($p < 0.05$)

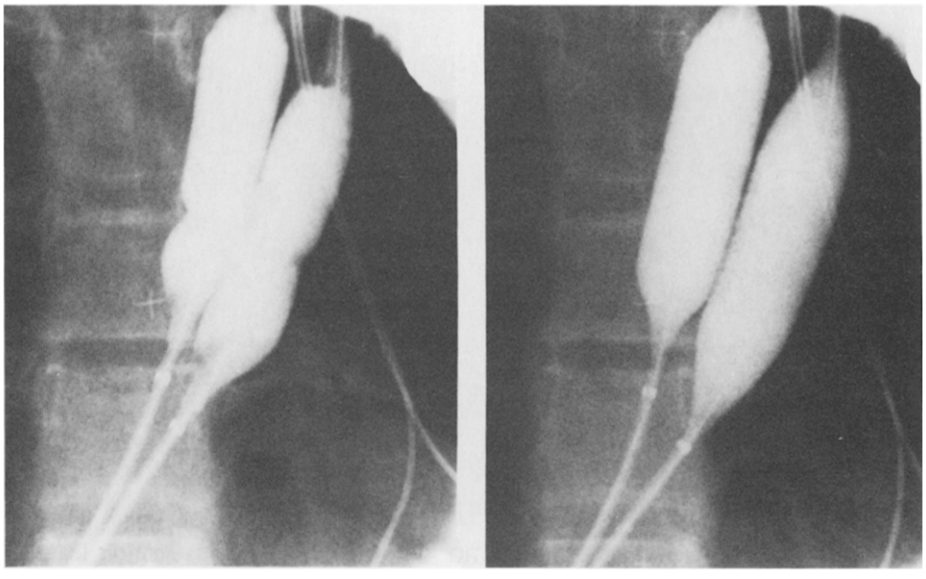


Figure 1. Patient 13. Dual balloon technique. The two balloons (diameter = 18 mm) inflated simultaneously across the stenotic pulmonary valve are shown in the anteroposterior projection before (**left**) and after (**right**) disappearance of the indentation ("waist") caused by the stenotic valve.

JACC Vol. 8, No. 4
October 1986:909–15

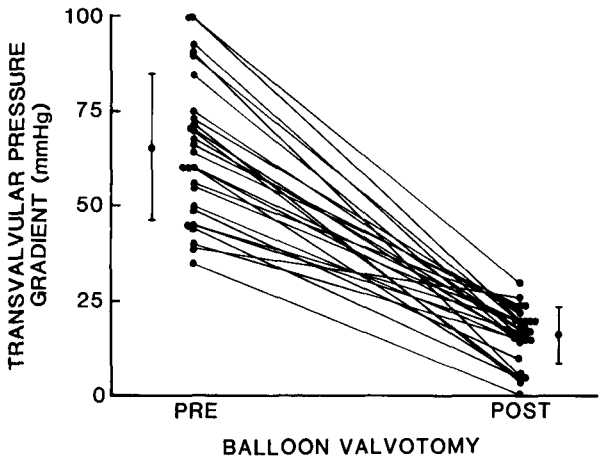
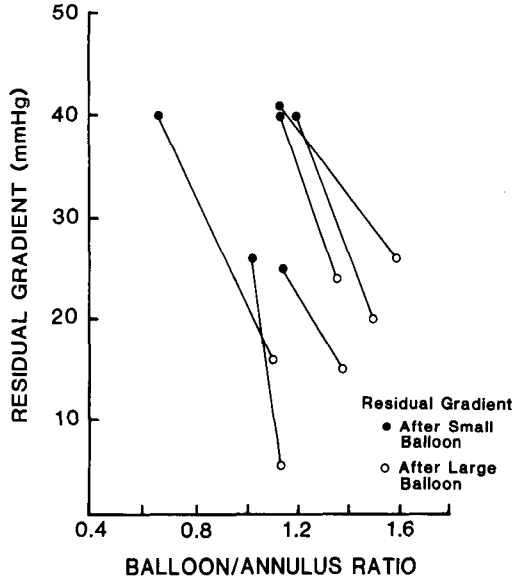


Figure 2. Transvalvular peak to peak pressure gradients before and after percutaneous balloon valvotomy of unoperated congenital pulmonary stenosis (n = 27) with mean pre- and postvalvotomy gradients and standard deviation.

subvalvular diameter, the subvalvular/valve ring diameter ratio and the balloon/anulus diameter ratio.

In seven patients (Patients 2,7,11,13,16,22 and 25), postdilation pressure pullback showed a minimal transvalvular but a significant infundibular gradient (Fig. 5). Comparison with predilation measurements revealed an increased subvalvular gradient in five patients and an unchanged infundibular gradient in one patient (Table 1). A distinction between a subvalvular and a valvular component was not possible in one patient's predilation pressure pullback, so we assumed an unchanged infundibular gradient. Subsequent catheterization in the patient with the largest infundibular gradient (60 mm Hg) documented almost complete resolution of the subvalvular stenosis after 1 year.

Figure 3. Sequential use of small and large balloons. The residual gradient after the "small" balloon (**closed circles**) was significantly reduced by the oversized balloon (**open circles**).



Safety. No significant complications occurred. Postvalvotomy angiocardiograms demonstrated slightly improved leaflet motion, accentuated infundibular contraction (Fig. 4) and no myocardial staining or extravasation.

Pulmonary regurgitation. On immediate follow-up (1 day) a decrease of the systolic murmur from grade 3-4/6 to 2-3/6 was noted. A new 1-2/6 diastolic murmur was detected in 5 (19%) of the 27 patients.

Discussion

Terminology. Although "percutaneous balloon valvuloplasty" is the term most often used to address the method used in this study we prefer the term "valvotomy" because it more accurately describes the actual mechanism, that is, tearing of tissue (although not cutting) and the absence of any shaping process (other than in percutaneous angioplasty).

Safety. This study indicates that oversized balloons can be used for percutaneous valvotomy in congenital pulmonary stenosis without apparent clinical morbidity. On the basis of the experimentally identified mechanisms of potential damage (10), especially to the right ventricular infundibulum, shorter balloons and a somewhat more distal position were employed to reduce anterior protrusion of the proximal balloon end. The apparent safety of oversized balloons in the pulmonary anulus is supported by a case report of surgical observation after use of a balloon 20% larger than the valve anulus (11). This report demonstrated only minor subendocardial hemorrhage directly underneath a valve cusp. Another surgical observation (12) after use of a balloon 10% larger than the anulus revealed no damage at all.

Balloon size. The large degree of actual balloon oversize in some patients (up to 60%) compared with an intended balloon/anulus ratio of 1.1 to 1.4 was due to the inaccuracy of estimation of anular size from video replay on the monitor. As a result of this experience we have begun to use the echocardiographic measurement as a further estimate of anular size. In this report balloon size was defined to be the nominal size according to the manufacturer's specification. Measurements after dilation at an inflation pressure of 4 atm actually revealed a variation of ± 1.5 mm ($+8$ to -12.5%) compared with the specified diameters. Consequently, even high precision in anular measurement does not necessarily lead to realization of the intended balloon/anulus ratio.

Because the maximal available balloon diameter was 25 mm, a dual balloon technique was necessary to provide adequate dilation diameters in adolescents. This technique did not cause any specific problems or complications, and may in fact reduce hemodynamic compromise, at least during maximal inflation, when both balloons gain a circular cross section leaving two triangular openings for residual

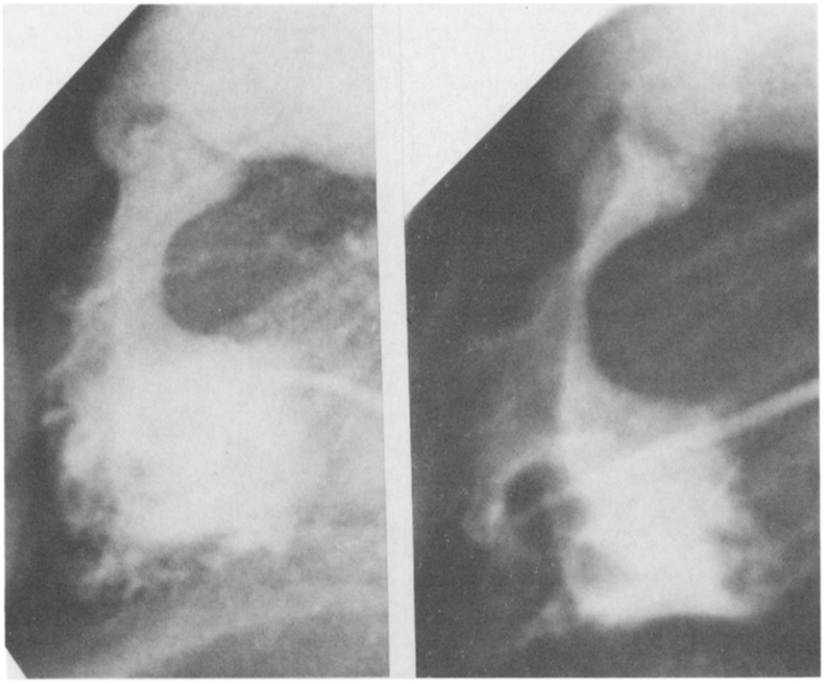


Figure 4. Patient 8. Dynamic infundibular stenosis after balloon valvotomy. End-systolic lateral angiocardiogram before (**left**) and after (**right**) balloon valvotomy.

transvalvular blood flow. It may be regarded as an alternative to a very large single balloon. The effect of inhomogeneous pressure and tension distribution on the valve and valve anulus caused by two balloons is not known.

Gradient reduction and balloon size. The use of oversized balloons appeared to be more effective in reducing gradients when compared with the use of smaller balloon diameters in other studies (Table 2). Using balloons approximately 14% smaller than the anulus, Rocchini et al. (5) found residual gradients of 39 ± 5 mm Hg with an overall gradient reduction of 53 ± 13%. No patient had a residual gradient of less than 25 mm Hg. No subvalvular stenosis was found on pullback. Kan et al. (2) achieved a gradient reduction of 58 ± 19% using a balloon/anulus ratio of 0.9 to 1.1, leaving a mean residual gradient of 23 ± 8 mm Hg across the valve. Walls et al. (6) used a balloon anulus ratio of 0.9 to 0.95 and found residual transvalvular gradients of 27 ± 15 mm Hg with a gradient reduction of 68%. Seventy percent of their patients had a residual gradient of less than 25 mm Hg. In our study the application of balloon anulus ratios ranging from 1.07 to 1.6 resulted in a gradient reduction of 74 ± 15%, leading to an average residual transvalvular gradient of 16 ± 8 mm Hg with 25 (93%) of 27 postdilation gradients below 25 mm Hg. The achieved increase in calculated valve orifice area was 183 ± 80% compared with the previously reported increases of 67 (5) and 95% (2). The increase in calculated valve orifice area, however, has to be regarded as a rough estimate of success because in addition to the inherent shortcomings of the Gorlin formula, pulmonary regurgitation after valvotomy was not quantified and accordingly not included in the transvalvular systolic flow. In these instances the valve orifice area after valvotomy was underestimated.

Figure 5. Patient 16. Infundibular pressure gradient after balloon valvotomy. Pullback from main pulmonary artery (MPA) to right ventricular outflow tract (RVOT) and right ventricular body (RV) with an end-hole catheter.

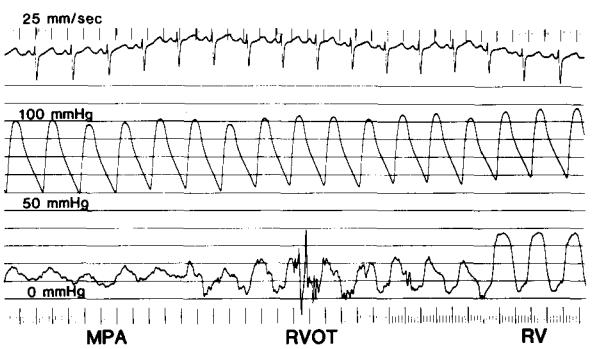


Figure 6. Calculation of the "effective dilation diameter" for the dual balloon technique.

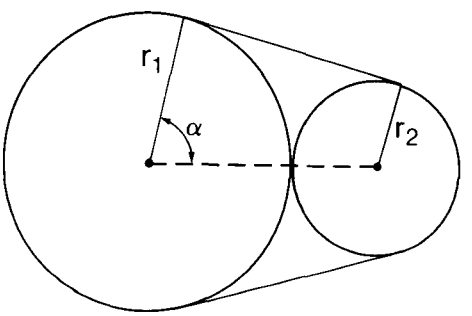


Table 2. Balloon Valvotomy With Different Balloon Sizes: Comparison Among Studies

	Median Patient Age (yr,mo)	Balloon Size		Valve Orifice Area Increase (%)	Gradient Reduction (%)	Residual Gradient (mm Hg)	Patients With a Residual Gradient <25 mm Hg (%)
		Balloon/ Anulus Ratio	Balloon Diameter (mm)				
Rocchini (5) (n = 7)	4,7	0.86	13 ± 3	67	53 ± 13	39 ± 5	0
Kan (2) (n = 19)	3,5	0.9 to 1.1	14.6 ± 4.1	95 ± 63	58 ± 19	23 ± 8	68
Walls (6) (n = 33)	6,0*	0.9 to 0.95	12 to 20	—	68	27 ± 15	70
Present study (n = 27)	2,11	1.30	18.2	183 ± 80	74 ± 15	16 ± 8	93

*Mean. Results are ranges or means ± SD.

Recent surgical observations after percutaneous balloon valvotomy (11,12) provided some evidence of improved efficacy of balloon valvotomy using oversized balloons: complete opening of the valve by two paracommissural tears extending to the anulus was seen after use of a 20% oversized balloon in one patient and an almost complete opening by one tear after use of a 10% oversized balloon was noted in another patient. A previous report of surgical valvotomy indicated that 81% of the patients had a residual gradient of less than 25 mm Hg several years postoperatively (7). In our study this proportion was 93% immediately after balloon valvotomy.

Pulmonary regurgitation. A new murmur of pulmonary regurgitation without hemodynamic significance has been noted in 57% of patients after surgical valvotomy (7). Griffith et al. (13) reported an even higher incidence (70%) in a more recent series. In our series, 5 (19%) of the 27 patients developed a murmur of mild pulmonary regurgitation. Although smaller balloons were employed, Kveselis at el. (14) found a pulmonary regurgitation murmur in two (20%) of seven patients and Benson et al. (12) reported clinical and echocardiographic evidence of trivial pulmonary insufficiency in one (13%) of eight patients.

Reactive infundibular stenosis. Our study supports the previous observations that operative (15) or balloon (11) valvotomy may be associated with a significant subvalvular stenosis immediately after the procedure. We found an average decrease of the smallest systolic infundibular diameter of 21% (0 to 57%) after balloon valvotomy. An increase in the subvalvular gradient could be identified in five patients. Follow-up studies after surgical valvotomy have suggested that this subvalvular stenosis is very likely to resolve (15).

Conclusion. Our study demonstrated that an immediate gradient reduction equivalent to long-term results of surgery can be achieved with percutaneous balloon valvotomy using oversized balloons (7 to 60% larger than the anulus) without significant morbidity and with a tolerable incidence of pulmonary regurgitation. We therefore conclude that balloon valvotomy is the treatment of choice for typical congenital valvular pulmonary stenosis. In view of errors in anulus measurement and variations in actual balloon diameter we recommend choosing balloons 20 to 40% larger than the valve ring.

Appendix

The calculation of the "effective dilation diameter" (d_{eff}) for the dual balloon technique (Fig. 6) is:

A_{ENV} = area of oval enveloping the two balloons with radius r_1 and r_2.

r_{eff} = radius of the circle with the same area (A_{ENV}).

$A_{ENV} = r_1^2\pi - (r_1^2 - r_2^2)\cdot\text{radians alpha} + 2(r_1 + r_2)\sqrt{r_1 r_2}$

with

$$\cos \text{alpha} = \frac{r_1 - r_2}{r_1 + r_2}$$

and

$$d_{eff} = 2r_{eff} = 2\sqrt{\frac{A_{ENV}}{\pi}}.$$

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