Percutaneous transluminal balloon valvuloplasty for pulmonary valve stenosis

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ABSTRACT Transluminal balloon valvuloplasty was used to treat congenital pulmonary valve stenosis in 20 patients. Follow-up cardiac catheterization was performed in 11 patients at intervals of from 2 to 12 months after the procedure. Peak systolic pressure gradient across the pulmonic valve decreased from 68 ± 27 to 23 ± 5 mm Hg (p < .001) after valvuloplasty. There were no complications. Follow-up catheterization demonstrated persistent relief of right ventricular hypertension in the patients with typical pulmonary valve stenosis.


TRANSLUMINAL BALLOON ANGIOPLASTY has been successfully used in the treatment of patients with stenoses of the coronary and peripheral circulations since 1976. Recently transluminal angioplasty has been applied in pediatric cardiology to treat pulmonary valve stenosis, peripheral pulmonary artery stenosis, coarctation of the aorta, and coarctation restenosis. Our experience with transluminal balloon angioplasty in 20 patients with pulmonary stenoses and the follow-up in 11 of these patients is included in this report.

Methods

**Clinical material.** Twenty patients with congenital pulmonary valve stenoses underwent transluminal balloon valvuloplasty at the Johns Hopkins Hospital between May 1981 and September 1983. The patients ranged in age from 3 months to 56 years. All 20 patients were referred to the Cardiovascular Diagnostic Laboratory for evaluation because of clinical evidence of significant pulmonary stenosis. Eleven of the patients underwent diagnostic cardiac catheterization at Johns Hopkins Hospital (seven patients) or at another institution (four patients) before being scheduled for balloon valvuloplasty. Nine patients underwent diagnostic catheterization and balloon valvuloplasty during the same procedure. Balloon valvuloplasty was presented to the patients and their parents as an investigational procedure approved by the Joint Committee for Clinical Investigation. Informed consent was obtained in writing for each patient before the procedure.

Eighteen of the patients had typical pulmonary valve stenoses with domed stenotic pulmonary valves that were apparent on cineangiograms. One patient had a dysplastic pulmonary valve.

One patient with pulmonary atresia and a hypoplastic right ventricle underwent a Brock procedure during the neonatal period. At 1 year of age she had evidence of persistent right ventricular outflow tract obstruction.

**Technique of valvuloplasty.** The method of valvuloplasty was the same for each patient, regardless of age. Both groins were prepared and draped. A No. 7F sheath was introduced percutaneously into the right femoral vein. A No. 5F sheath was introduced into the left femoral vein, and a Teflon arterial cannula was introduced into the left femoral artery. Heparin (100 units/kg) was administered intravenously. Cardiac output was measured by the thermal dilution technique. Femoral arterial, right ventricular, and pulmonary arterial pressures were recorded.

A No. 7F balloon-tipped wedge pressure catheter was advanced from the right femoral vein to the left pulmonary artery. An 0.035 inch diameter (200 cm length) angioplasty J guidewire* was introduced through the catheter and positioned with the J well into the left lower lobe pulmonary artery. The No. 7F catheter and introducing sheath were removed, leaving the guide wire in place in the left pulmonary artery. While the catheter was being withdrawn care was taken to avoid advancing excess guidewire, so that the wire course would remain straight and there would be no looping of the wire in the heart. The right femoral vein was dilated with a No. 9F dilator.

Selection of the appropriate balloon† size was based on measurement of the dimension of the valve anulus, as determined from the cineangiogram. The magnification factor of the cineangiogram was determined by comparing the angiographically determined diameter of the catheter to its actual diameter. The actual dimension of the valve anulus was thus equal to:

\[
\text{Measured anulus diameter} \times \frac{\text{Actual catheter diameter}}{\text{Measured catheter diameter}}
\]

For the first six patients a balloon diameter 1 to 2 mm less than the dimension of the pulmonary valve anulus was selected to minimize the risk of rupture of the pulmonary artery. For the subsequent 14 patients a balloon diameter equal to or 1 mm

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*Rosen wire (Cook, Inc., Bloomington, IN).
†Medi-Tech, Watertown, MA.
greater than the dimension of the valve anulus was selected. Modification of the balloons, based on the experience with the first 10 patients, permitted rapid inflation and deflation to minimize the time of occlusion of the right ventricular outflow tract. Modifications included shortening balloon length from 4 to 3 cm and increasing the cross-sectional area of the balloon inflation lumen.

The balloon used for dilation was attached through a pressure gauge to a 20 ml syringe that was filled with diluted (30%) contrast material. All air was evacuated from the balloon and as a test it was filled and emptied several times. It was then wrapped around the catheter in a clockwise direction. The balloon-forming tool, which is packaged with the balloon, was temporarily placed on the balloon to maximize wrapping around the catheter for easier percutaneous insertion.

The catheter used for dilation was advanced over the 0.035 inch guidewire and introduced into the right femoral vein with a counterclockwise rotation as the balloon entered the vein. The guidewire was held taut to avoid looping in the heart and the catheter was advanced into the right ventricular outflow tract with thestenotic valve at the center of the balloon. The guidewire was left in position in the left pulmonary artery to stabilize the tip of the stiff catheter during the balloon inflation. This made it possible to adjust the position of the balloon rapidly and to minimize the possibility of damage to the pulmonary artery.

A No. 5F catheter was passed into the right ventricle from the left femoral vein to monitor right ventricular pressure during balloon inflation. The electrocardiogram, femoral arterial pressure, and right ventricular pressure were recorded continuously during dilatation.

The balloon was inflated by hand pressure. The "waisting" (visible indentation of the balloon caused by the stenotic valve) of the balloon was observed by fluoroscopy and the inflation pressure required to eliminate the indentation of the balloon was noted by an assistant. Disappearance of the waist occurred suddenly as the valve was opened. Peak inflation pressure usually ranged from 45 to 60 psi. The balloon was rapidly deflated and then reinfated twice subsequently to document that there was no waisting of the balloon at the early phase of inflation. Figure 1 shows the inflated balloon during valvuloplasty in one of the patients. Oxygen (by mask) and intravenous atropine (0.01 mg/kg) were administered if bradycardia was observed during the first balloon inflation (three patients).

The dilatation balloon catheter was withdrawn and removed from the vein with a counterclockwise rotation while suction was applied to the balloon to maximally deflate it. Hemostasis was achieved by direct compression of the right groin. A thermal dilution catheter was advanced to the pulmonary artery from the left femoral vein and cardiac output was again measured, as were the pulmonary arterial, right ventricular, and femoral arterial pressures. The venous catheter and arterial cannula were removed from the left groin and hemostasis was achieved by direct compression. The heparinization was not reversed at the end of the procedure and no long-term anticoagulation therapy was instituted.

The ages of the patients and balloon sizes are shown in chronologic order according to timing of the procedure in table 1. There were no complications in performing valvuloplasty in any of these patients.
Follow-up cardiac catheterization was performed in 11 of the patients at intervals of 2 to 12 months after the valvuloplasty (mean, 7 months). In each of these the follow-up catheterization was performed percutaneously through the right femoral vein. There was no evidence of venous occlusion from the previous balloon valvuloplasty. At follow-up the cardiac output was measured by the thermal dilution technique. Pulmonary arterial, right ventricular, and femoral arterial pressures were measured. The remaining nine patients are scheduled for follow-up cardiac catheterization at between 6 to 12 months after their valvuloplasties.

**Results**

**Typical pulmonary valve stenosis.** All 18 patients with typical pulmonary valve stenoses had hemodynamic evidence indicating relief of pulmonary stenosis after the balloon valvuloplasty. The right ventricular pressures before and after the valvuloplasty and at follow-up are shown in table 2. Right ventricular pressure decreased from $86 \pm 26$ to $42 \pm 8$ mm Hg after the

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**FIGURE 1.** Valvuloplasty balloon during inflation. *A.* The balloon catheter across the pulmonary valve in an early phase of inflation. The balloon is indented by the stenotic valve. Note the guidewire placement deep in the left pulmonary artery. *B.* The balloon catheter fully inflated with the waist of the balloon abolished.
TABLE 3
Right ventricular to pulmonary arterial systolic pressure gradient (SPG) and cardiac index (CI) before and after valvuloplasty and at follow-up in patients with typical pulmonary valve stenoses

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>SPG (mm Hg)</th>
<th>CI (l/min/m²)</th>
<th>SPG (mm Hg)</th>
<th>CI (l/min/m²)</th>
<th>SPG (mm Hg)</th>
<th>CI (l/min/m²)</th>
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<tr>
<td>Mean ± SD</td>
<td>68 ± 27</td>
<td>4.4 ± 1.9</td>
<td>23 ± 8</td>
<td>4.1 ± 1.8</td>
<td>22 ± 5</td>
<td>4.2 ± 0.8</td>
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NA = not available.

valvuloplasty (p < .001). The peak systolic pressure gradients between the right ventricle and pulmonary artery before and after valvuloplasty and at follow-up are shown in table 3. The right ventricular to pulmonary arterial peak systolic pressure gradient decreased from 68 ± 27 to 23 ± 8 mm Hg* after the valvuloplasty (p < .001).† Analysis of cardiac index along with each systolic pressure gradient suggests that the decrease in gradient was not caused by a drop in cardiac output related to the procedure.

During the period of full balloon inflation peak right ventricular pressure ranged from 88 to 238 mm Hg (mean 141 ± 49).

To compare patients of various ages and with different systemic arterial pressures, the right ventricular pressure was expressed as a percentage of systemic pressure (right ventricular pressure/femoral arterial pressure × 100). The values for the 18 patients with typical pulmonary valve stenoses are shown in figure 2. Mean right ventricular pressure/femoral arterial pressure (%) decreased from 80 ± 26% to 38 ± 7% (p < .001) after the valvuloplasty.

In three patients right ventriculography was performed immediately after valvuloplasty. Their pulmonary valves still appeared thickened, but a much broader front of contrast material entered their pulmonary arteries with each systole, suggesting that the pulmonary valves had been opened (figure 3). Follow-up catheterization in nine patients with typical pulmonary valve stenoses demonstrated persistent relief of right ventricular hypertension. Peak systolic pressure gradients, right ventricular pressures, and cardiac in-

*Mean values ± 1 SD are given for this and all subsequent results.
†Significance was determined by paired t test.

Vol. 69, No. 3, March 1984
dexes were not significantly different from the results immediately after valvuloplasty.

By clinical evaluation each of the 18 patients with typical pulmonary valve stenosis had a decrease in the intensity of the systolic murmur with a change in quality of the murmur to a lower frequency with early systolic peaking. None of the patients developed an early diastolic murmur either immediately after valvuloplasty or at serial follow-up examinations. This suggests that no significant pulmonary valve insufficiency was created by the balloon valvuloplasty.

**Dysplastic pulmonary valve.** The one patient with a thick nodular pulmonary valve and no poststenotic dilatation, as demonstrated by angiography, was diag-

![FIGURE 3](http://circ.ahajournals.org/)

**FIGURE 3.** Right ventricular cineangiograms obtained before and after valvuloplasty. *A,* The lateral right ventriculogram before the valvuloplasty shows the domed stenotic pulmonary artery. *B,* After the valvuloplasty the pulmonary valve is less stenotic. Residual infundibular narrowing is still apparent.
nosed to have a dysplastic pulmonary valve (figure 4). Balloon valvuloplasty was performed and resulted in an initial fall in the right ventricular pressure from 78% to 54% of systemic pressure. At follow-up catheterization the right ventricular pressure had increased to 71% of systemic pressure. Balloon valvuloplasty was again attempted and there was a fall in the right ventricular pressure to 44% of systemic pressure. However, at subsequent follow-up the right ventricular pressure had again increased to 62% of systemic pressure.

**Pulmonary atresia: status after Brock procedure.** The 11-month-old girl with pulmonary atresia and a hypoplastic right ventricle underwent a Brock procedure in the neonatal period. Cardiac catheterization revealed a right ventricular pressure that was 100% of systemic pressure. She had a moderate initial response to valvuloplasty with a fall in right ventricular pressure to 54% of systemic pressure. At follow-up her right ventricular pressure had increased to 71% of systemic pressure. Her cineangiogram demonstrated redundant tissue in the valve area with apparent subvalvular narrowing (figure 5). She was referred for surgical reconstruction of the right ventricular outflow tract.

**Discussion**

Transluminal balloon valvuloplasty appears to be an effective method for relieving typical congenital pulmonary valve stenosis. Although the right ventricular pressures remain mildly elevated, all of the nine patients who have undergone follow-up cardiac catheterization have right ventricular pressures that are sufficiently low so that these patients would not be considered candidates for surgical correction of the residual mild pulmonary stenosis.

It is not surprising that the desired result was not obtained in the patient with a dysplastic pulmonary valve. The stenosis caused by such a valve does not respond to simple valvotomy, but requires valve resection to provide relief of obstruction.12

In several patients the right ventricular pressure did not drop immediately after the valvuloplasty. After inflation of the balloon the right ventricular pressure remained slightly elevated and then fell slowly to its lowest level 15 min after valvuloplasty. In these patients we speculate that the hypercontractility of the hypertrophied right ventricle was responsible for the delay in right ventricular pressure decrease. In patients with severe infundibular hypertrophy we would expect further drops in right ventricular pressure as the hypertrophy regresses.

Long-term results will need to be evaluated before transluminal valvuloplasty can replace open heart surgery for the management of pulmonary valvular stenosis. The preliminary results suggest that balloon...
valvuloplasty provides palliative if not permanent improvement. The early surgical experience with the Brock procedure showed that once the stenotic valve was opened manually in an operative procedure, this effect was lasting. If parallels can be drawn to surgical valvuloplasty, balloon valvuloplasty should also provide a permanent effect.

We extend our gratitude and appreciation to Mrs. R. M. Cherry for manuscript preparation.

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Circulation. 1984;69:554-560
doi: 10.1161/01.CIR.69.3.554
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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