Use of a double balloon technique for percutaneous balloon pulmonary valvotomy in adults

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SUMMARY Percutaneous double balloon pulmonary valvotomy was performed on seven consecutive adult patients (mean age 26 years) with congenital pulmonary valve stenosis. The peak systolic transvalvar pressure gradient was significantly reduced from a mean (SD) of 104 (30) to 24.3 (6) mm Hg. This haemodynamic improvement was maintained at six week follow up. In six patients pulmonary infundibular spasm developed immediately after valvotomy; however, these patients showed considerable haemodynamic improvement at the six week follow up. During balloon inflation the heart rate did not fall below 60 beats/minute and the systemic aortic pressure was maintained above 90 mm Hg.

Early results indicate that percutaneous double balloon valvotomy in adults is an effective treatment for isolated pulmonary valve stenosis. Theoretically the two balloons provide a venting area during inflation. This has the advantage of preventing bradycardia or systemic hypotension during prolonged balloon inflation.

Percutaneous balloon pulmonary valvotomy with a single balloon was first performed by Kan et al in a child and by Pepine et al in an adult. Percutaneous balloon valvotomy has been the treatment of choice for congenital pulmonary valve stenosis in 96 consecutive children in our centre. We have already reported the use of the double balloon valvotomy technique for mitral valve stenosis. We now describe our experience in seven consecutive adult patients with congenital pulmonary valve stenosis in whom we used a double balloon technique for percutaneous pulmonary valvotomy.

Patients and methods

Seven consecutive adult patients (two women and five men; mean age 26 years, range 15–37) with congenital pulmonary valve stenosis (table 1) had transluminal double balloon pulmonary valvotomy. Their main complaints were palpitation and shortness of breath on exertion (class II New York Heart Association classification). All patients had a systolic thrill in the pulmonary area and a soft pulmonary second heart sound with a grade 4 to 5 or 6 ejection systolic murmur. In all patients the electrocardiogram showed right axis deviation with right ventricular hypertrophy. The cross sectional echocardiogram showed a domed pulmonary valve and right ventricular hypertrophy.

TECHNIQUE OF VALVOTOMY

Signed consent was obtained on a special procedure consent form. All the patients were given 10 mg oral diazepam as premedication, and the procedures were performed under local anaesthesia. A 7F sheath was introduced percutaneously through the right femoral vein. Two 7F sheaths were similarly introduced through the left femoral vein. A 7F pigtail catheter was introduced percutaneously via the right femoral artery into the aorta for continuous pressure monitoring. Heparin (5000 units) was given intraarterially.

A 7F Berman angiography catheter was advanced from the left femoral vein and positioned in the right ventricle to monitor the right ventricular pressure during the procedure and for right ventricular angio-
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Table 1 Clinical characteristics and pulmonary valve and balloon diameters in seven consecutive patients with congenital pulmonary valve stenosis

<table>
<thead>
<tr>
<th>Patient No</th>
<th>Age</th>
<th>Sex</th>
<th>Pulmonary valve diameter (mm)</th>
<th>Two balloon diameter (mm)</th>
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<tbody>
<tr>
<td>1</td>
<td>32</td>
<td>M</td>
<td>27</td>
<td>15 + 15</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>F</td>
<td>24</td>
<td>12 + 15</td>
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<td>3</td>
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<td>15 + 15</td>
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<td>4</td>
<td>28</td>
<td>F</td>
<td>18</td>
<td>12 + 12</td>
</tr>
<tr>
<td>5</td>
<td>18</td>
<td>M</td>
<td>19</td>
<td>(a) 10 + 10</td>
</tr>
<tr>
<td>6</td>
<td>37</td>
<td>M</td>
<td>28</td>
<td>(b) 15 + 15*</td>
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<tr>
<td>7</td>
<td>20</td>
<td>M</td>
<td>27</td>
<td>15 + 15</td>
</tr>
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</table>

*Two balloon combinations used; a, first combination; b, second combination.

graphy in the anteroposterior and lateral projections before and after valvotomy. Pulmonary artery, right ventricular, and aortic pressures were recorded simultaneously, followed by pull-back pressures from the pulmonary artery to right ventricle before and after dilatation and six days after the procedure.

We selected a balloon size that was appropriate to the diameter of the pulmonary valve annulus, which was estimated by cross sectional echocardiography and a biplane cinevideo angiogram. A grid was recorded on the angiogram so that the pulmonary valve annulus could be correctly measured. For all the patients the sum of the diameters of the balloon catheters used for successful valvotomy was approximately 3–5 mm more than the diameter of the pulmonary valve annulus. The first combination of balloons used on patients 5 and 6 failed to produce adequate dilatation (table 1). Two 7F Berman wedge pressure catheters were advanced from the right and left femoral veins and positioned in the left pulmonary artery. Through each catheter a 0.038 inch diameter pre-shaped Teflon coated exchange guide wire was introduced and positioned well into the pulmonary artery in the left lower lobe. The catheters and the introducer sheaths were then removed, leaving the guide wires in position in the left pulmonary artery.

We used paired t tests for statistical analysis.

CROSS SECTIONAL ECHOCARDIOGRAPHY

Before valvotomy, on the day after valvotomy, and 6–8 weeks later we obtained cross sectional echocardiograms using a Hewlett Packard phased array system with 3-5-5 MHz transducers. Standard views were obtained; the short axis left parasternal view was used to estimate the diameter of the pulmonary valve annulus and the excursion of the leaflets. The images were recorded for subsequent analysis. ATL pulsed Doppler was used to detect pulmonary regurgitation before valvotomy, immediately after valvotomy, and at a six week follow up.

Fig 1 Lateral projection of the heart with inflated balloons positioned across the pulmonary valve; note the indentation (arrowed) of the balloon produced by the stenotic valve.
Results

CLINICAL
At clinical evaluation immediately after pulmonary valvotomy the systolic thrill in the pulmonary area had disappeared in all but two patients (cases 2 and 7). In these patients the thrill had disappeared at the six week follow up. There was a snapping pulmonary second heart sound in all patients and no patient developed an early diastolic murmur after valvotomy. Furthermore, the duration and intensity of the systolic murmur decreased in all patients.

HAEMODYNAMIC, ANGIOGRAPHIC, AND ECHOCARDIOGRAPHIC RESULTS
After balloon valvotomy all seven patients had haemodynamic evidence of relief of the pulmonary valve stenosis. The peak systolic gradient across the pulmonary valve decreased from a mean of 104 (30) to 24·3 (6) mm Hg (p < 0·001). The improvement was maintained at the six week follow up study (fig 2). Right ventricular systolic pressure decreased from a mean of 120 (28) to 69 (25) mm Hg (p < 0·009) (table 2; fig 3).

Echocardiography and a right ventricular angiogram demonstrated that although the pulmonary valve still appeared to be thickened in all patients, there was good excursion of the valve leaflets (fig 4), indicating successful dilatation. Pulsed Doppler revealed mild pulmonary regurgitation in patients 1 and 4 after dilatation.

Pull back pressure measurements from the pulmonary artery to the right ventricular outflow and then to the right ventricular apex showed the presence of infundibular spasm in patients 2–7 immediately after successful pulmonary valvotomy; the gradient was small in patients 3–7. Haemodynamic follow up studies of patients 2–7 at six weeks showed that there was a further reduction in the right ventricular systolic pressures from the immediate post-valvotomy mean of 69 (25) to 47 (11) mm Hg, which was suggestive of relief of the infundibular spasm (table 2). This contrasts with the gradients across the pulmonary valve, where the major reduction occurred immediately after valvotomy (fig 2; fig 5). In patient 2 the infundibular spasm was severe, but was completely relieved during six weeks treatment with oral propranolol 20 mg three times a day.

During double balloon inflation, no patient had bradycardia (heart rates >60 beats/min) and aortic systolic pressure was maintained above 90 mm Hg (fig 6).

Table 2 Haemodynamic data before (B), immediately after balloon pulmonary valvotomy (A), and at six weeks’ follow up (F)

<table>
<thead>
<tr>
<th>Patient No</th>
<th>RVSP</th>
<th>PSPG</th>
<th>HR</th>
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</thead>
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<tr>
<td></td>
<td>B</td>
<td>A</td>
<td>F</td>
</tr>
<tr>
<td>1</td>
<td>120</td>
<td>40</td>
<td>—</td>
</tr>
<tr>
<td>2</td>
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<td>120*</td>
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<td>170</td>
<td>60*</td>
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<td>80</td>
<td>60*</td>
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</tr>
<tr>
<td>7</td>
<td>95</td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>120 (28)</td>
<td>69 (25)</td>
<td>47 (11)</td>
</tr>
</tbody>
</table>

p value: B vs A, < 0·001; B vs F, < 0·003; B vs A, < 0·001; B vs F, < 0·003; B vs A, NS; B vs F, < 0·001.

*Infundibular spasm.
RVSP, right ventricular (apical) systolic pressure; PSPG, peak systolic pulmonary valvar gradient; HR, heart rate.
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![Fig 3 Aortic (AO-P), right ventricle (RV-P), and pulmonary artery (PA-P) pressure tracing (a) before and (b) after pulmonary valvotomy. There was a considerable reduction of right ventricular pressure and gradient across the pulmonary valve (patient 3).](image)

**Discussion**

When Tynan *et al* used a single balloon for pulmonary valvotomy, hypotension developed in 26 of 27 patients during inflation of the balloon and severe bradycardia developed in 12 patients. This complication was confirmed in another recent study. When we used a double balloon technique neither bradycardia nor systemic hypotension developed in any of our patients. In all seven patients there was a dramatic improvement in the gradient across the pulmonary valve with no clinical evidence of pulmonary regurgitation.

The sum of the cross sectional area of two 10 mm balloon catheters (157 mm²) is 50% less than that of a single 20 mm balloon catheter (314 mm²) (fig 7). The double balloon technique thus theoretically provides a venting area between the balloons during inflation and thus ensures that the pulmonary valve orifice is not completely occluded, as it is by a single balloon. We presume that this is the mechanism by which bradycardia and hypotension are prevented during inflation. The procedure was successful when we used two balloons with a combined cross sectional area less than that of the single balloon which theoretically would otherwise have been required. It appears that the combined diameter of the two balloons, rather than their cross sectional area, is the determining factor for the success of valvotomy.

Ring *et al* demonstrated that over dilatation of the pulmonary valve annulus in lambs by single oversized balloons, with a diameter that exceeded that of the annulus by 20–40%, damaged the heart. In man Ben-Shachar *et al* demonstrated that balloons with diameters that were 20% larger than the diameter of the pulmonary valve annulus produced adequate dilatation with minimal damage to the subvalvar region. The use of a double balloon technique which allows the use of two balloons with smaller total cross sectional areas than a single balloon (fig 7) must improve the safety of the procedure.
Infundibular spasm has been reported after percutaneous balloon dilatation of the pulmonary valve,\(^9^{10}\) and also after surgical valvotomy.\(^11\) In six of our patients successful dilatation of the pulmonary valve was followed by infundibular spasm. In these patients the right ventricular pressure resembled the systemic pressure, as in the case reported by Ben-Shachar et al.\(^8\) Because β blockade in patient 2 relieved severe infundibular spasm after valvotomy it is conceivable that the use of prophylactic β blockade before valvotomy may prevent infundibular spasm. This requires further investigation.

In most adults the pulmonary valve annulus is bigger than the maximum available size of single balloon that is needed for successful dilatation, and two balloons will be necessary. We have shown that...
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Fig 7  Diagram comparing the cross sectional area of a 20 mm diameter balloon with that of two 10 mm balloons.

percutaneous double balloon pulmonary valvotomy in adults is a safe and effective treatment for isolated pulmonary valve stenosis. All the demonstrable advantages of the double balloon technique indicate that this should become the choice for this procedure in adults.

Addendum

Since the submission of this paper we have performed another five successful percutaneous double balloon pulmonary valvotomies with similar results to those reported in this paper.

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References