Balloon dilatation of congenital aortic valve stenosis in infants and children: short term and intermediate results

MICHAEL VOGEL, LEE N BENSON, PATRICIA BURROWS, JEFFREY F SMALLHORN, ROBERT M FREEDOM

From the Department of Pediatrics, Division of Cardiology, The Variety Club Catheterization Laboratories, The Hospital for Sick Children, Toronto, Ontario, Canada

SUMMARY Percutaneous balloon dilatation of the aortic valve was attempted in 25 consecutive patients with stenosis. The aortic valve diameters were normal for age. The balloon catheters were placed retrogradely, and their diameters were within 1–2 mm of the valve diameter and 3 (13 patients) or 6 cm (recent 12 patients) long. After dilatation the pressure gradients across the aortic valve were reduced significantly and the valve areas, measured in 10 patients, increased. Aortic regurgitation was detected in six patients before (grade I) the procedure and in 15 patients (6 grade I, 6 grade II, 3 grade III) after the procedure. In one patient the aortic valve could not be crossed and in three there was no reduction in the pressure drop. Nine patients have a sustained reduction in Doppler assessed gradients. There were vascular complications in 12 and these required surgical intervention in three patients.

Balloon dilatation seems to be an effective short term palliative procedure in patients with congenital stenosis of the aortic valve.

The success of balloon dilatation of the stenosed pulmonary valve,\(^1\)\(^2\) has prompted the application of this technique to other heart lesions with varying success.\(^3\)\(^4\) It's application to congenital valvar aortic stenosis is recent, and there are few clinical studies outlining the technique, complications, and patient tolerance.\(^5\)\(^6\)

The purpose of this report is to outline the technique, complications, and short term results of balloon dilatation of the aortic valve and to examine short term follow up data on the gradient reduction and any improvement in ventricular function.

Patients and methods

CLINICAL DATA

From October 1985 up to and including March 1987 percutaneous balloon dilatation of congenitally stenosed aortic valves was attempted in 25 consecutive patients over six months of age (21 male, four female) (mean (SD) age 9·3 (5·4) (0·5–16·7) years and a mean (SD) body surface area of 0·87 (0·36) (0·3–1·4) m\(^2\)). In this period no patient had an operation as the initial form of management.

All patients had clinical and echocardiographic findings consistent with moderate to severe stenosis of the aortic valve\(^10\): 16 had an apical aortic click and in 18 there was a systolic ejection murmur associated with a precordial thrill. Six patients had a 1/6 early high frequency diastolic murmur of aortic regurgitation.

The mean (SD) cardiothoracic ratio on chest x ray was 0·5 (0·07) (0·43–0·7)%. Twenty one patients had evidence of left ventricular hypertrophy on the electrocardiogram associated with ST segment inversion at rest in 11. Six patients underwent a graded exercise test protocol with a mean (SD) endurance time of 9·6 (1·7) (7–11) minutes with > 2 mm ST-T wave depression as the end point. The mean echodoppler gradient was 71 (18) (40–100) mm Hg; the one patient with only a 40 mm Hg gradient was included in this study because of left ventricular strain on the electrocardiogram.

Two patients had previously undergone a sub-
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clavian flap angioplasty for repair of coarctation of the aorta; one had a supravalvar aortic ridge where the left aortic cusp had a superior attachment. Four patients had undergone previous open aortic valvotomy at a mean age of 8·8 (6) (1–14) years, a mean 3·3 (2·2) (0·5–8) years before balloon dilatation. These four had bicuspid aortic valves.

ECHOCARDIOGRAPHY

Cross sectional and Doppler echocardiographic studies were performed on all patients one day before and within 24 hours after the procedure. Nine patients had an additional study 9 (3) (3–13) months later. All studies were obtained at rest. Doppler interrogation of the left ventricular outflow tract was performed from both the suprasternal and apical four chamber aortic root views. Doppler gradients were calculated by a modified Bernoulli equation \( P = 4 v^2 \). In 12 patients, pulsed Doppler measurements of the maximal instantaneous pressure gradients were obtained simultaneously with catheter pressure measurements during catheterisation. The correlation coefficient between Doppler and haemodynamic (peak to peak) measurements was \( r = 0·96 \) with a standard error of the estimate of 6·96. The relation between Doppler and catheter gradient was: catheter pressure gradient = 1·07 (Doppler pressure gradient) + 0·8, and used to correct the so estimated Doppler derived gradients.

We measured the left ventricular dimensions on cross sectional echocardiograms targeted by means of M mode tracings. We graded aortic incompetence according to Quinones et al: as mild, if the diastolic back flow Doppler jet extended to the mitral valve leaffet; moderate, if the jet extended to the mid left ventricular cavity; and severe, if the jet extended to the apex during a single beat.

The study was reviewed and approved by the Human Subject Review Committee of the University of Toronto and The Hospital for Sick Children. Informed consent was obtained from all parents entering their children in the study.

STATISTICAL ANALYSIS

Data were expressed as mean (SD) and range. We used a two tailed Student’s \( t \) test to compare paired data. A \( p \) value of < 0·05 was regarded as significant.

TECHNIQUE OF BALLOON DILATATION

All studies were performed under general anaesthesia with either ketamine or fentanyl. Right heart catheterisation was performed in all patients and included a thermodilution determination of cardiac output. If necessary we also catheterised the left ventricle by trans atrial-septal puncture and a balloon tipped, side hole catheter (Berman angiocatheter; Critikon Inc, Tampa, Florida) placed in the left ventricle for constant monitoring during the procedure. We used a 21 gauge needle and a 6 French micro puncture sheath dilator set (Cook Inc, Bloomington, Illinois) to cannulate the femoral artery and we placed a side hole National Institute of Health (NIH) angiography catheter in the ascending aorta. Heparin sulphate (150 units/kg; maximal dose 5000 units) was given after arterial entry. We measured simultaneous arm blood pressure (by cuff) and aortic and left ventricular pressures and obtained ascending aortoangiograms of the 30° left anterior oblique and lateral projections. The position of the aortic valve was marked with a radio-opaque sticker on the chest before the angiogram and this was used as a reference throughout the procedure. We measured the diameter of the aortic valve at the hinge points from the left anterior oblique projection using the angiocatheter for magnification correction.

The retrograde NIH catheter was substituted for an end hole (Gensini angiocatheter, USCI, BARD, Inc) catheter and manoeuvred across the aortic valve over a straight guide wire. Once in position we removed the wire and replaced it with a Teflon coated exchange wire (0·035 inch, 0·889 cm; 260 cm, Cook, Inc) that curled in the ventricular apex. We removed the catheter and sheath from the femoral artery and positioned a balloon catheter 3 (12 patients) or 6 (13 patients) cm long across the outflow tract and valve over the guide wire. The balloons chosen were within 1 or 2 mm of the valve diameter as estimated from angiography.

It was always difficult to position the 3 cm length balloon across the aortic valve at full inflation and only slightly easier with the 6 cm long balloon.

Balloons of 10–20 mm in diameter were mounted on 8 or 9 French polyethylene catheter shafts (Mansfield Scientific Inc, Mansfield, Massachusetts). Once in position the balloon was inflated repeatedly (up to six times (mean 3)) until we could be certain that it was properly positioned across the valve at full inflation and the waist had disappeared. The balloon was then removed to the descending aorta while the wire was left in the ventricle. Systolic (by arm cuff) and left ventricular pressures were recorded. A second series of inflations were performed if there was no change or a change of < 20 mm Hg (four times) in the gradient or the balloon was exchanged for the next larger diameter (four patients). In one patient, with a 22 mm valve annulus, we used two 12 mm balloons; a single balloon technique was performed in the remaining patients. Inflation-deflation cycles lasted no longer than 15 seconds. Intraballooon inflation pressures were not monitored. None of the balloons ruptured.

After we removed the balloon catheter, we...
positioned an end hole catheter (Gensini type) high in the ascending aorta and measured simultaneous left ventricular and aortic pressures. We recorded the pressures during sinus rhythm 10–15 minutes after the end of dilatation, after the heart rate had returned to within 10% of baseline. We also measured cardiac output by thermodilution and obtained a further angiogram of the aortic root.

We calculated the aortic valve area from the Gorlin formula.\textsuperscript{13} The degree of aortic incompetence was graded angiographically by the criteria of Hunt et al\textsuperscript{14}: grade 1, a whiff of contrast was seen in the outflow tract only; grade 2, there was faint ventricular opacification with each diastole; grade 3, the ventricular chamber was outlined but contrast was less dense than in the aorta; grade 4, the left ventricle was densely opacified after three beats, and grade 5, the left ventricle became opacified within three beats.

Post-dilatation haemostasis was achieved and the leg pulse was assessed for possible thrombosis. The mean fluoroscopy times were 30 (11) (15–60) minutes and the mean duration of the catheterisations 142 (35) (85–200) minutes. All patients recovered in a post-anaesthesia area for four hours before returning to the cardiac ward.

Results

HAEMODYNAMIC DATA

Table 1 shows haemodynamic data before and immediately after balloon dilatation. Balloons ranged from 10 mm to 20 mm in diameter and were 97 (11) (69–116)% of the aortic ring diameter. The left ventricular systolic pressure was reduced by a mean of 27 (22) (0–55)% and the mean gradient across the aortic valve by 63 (21) (18–92)%. The valve area increased 96 (80) (23–270)%. Eleven patients had a gradient of <25 mm Hg after balloon dilatation, 11 between 25–50 mm Hg, and two had residual gradients of 60 and 64 mm Hg respectively. In one patient the transverse arch was tortuous and could not be transversed with a 3 cm long, 15 mm diameter balloon catheter. In two patients the pressure gradient was not reduced. In one the 3 cm long balloon was expelled from the left ventricle with each systole and could not be positioned across the aortic valve ring during inflation. In the other patient, balloon dilatation was attempted twice. In the initial attempt, the 3 cm balloon could not be stabilised in the left ventricle; at the second, three months later, we achieved an initial reduction in pressure gradient with two 6 cm long, 12 mm diameter balloons, but the cardiac index had fallen (from 2.7 to 1.71/min/m\textsuperscript{2}) and after 24 hours the left ventricular-aortic Doppler gradient was unchanged from the pre-valvotomy values.

Intermediate follow up

Before balloon dilatation the resting Doppler gradient was 71 (18) (40–100) mm Hg, with mild aortic regurgitation in eight patients. In the first 24 hours after dilatation the Doppler gradient had fallen to 41 (16) (16–64) mm Hg (p < 0.001).

After a mean 9 (3) (3–13) months follow up in nine patients, the Doppler gradient across the aortic valve was 30 (17) (10–58) mm Hg—a significant (p < 0.007) reduction from the pressure gradient before dilatation. The difference between gradients immediately after dilatation and after the longer term follow up were not significant (p < 0.8).

The left ventricular end diastolic dimension was on or below the 95th percentile in three and above the 95th percentile in the remaining 22 patients. In all the left ventricular posterior wall thickness was increased and in 22 the ventricular septum was hypertrophied. We found no differences in left ventricular end diastolic dimension or posterior wall and ventricular septal thicknesses immediately after dilatation.

Two patients had exercise tests after dilatation. These showed an improvement in endurance times and no ST-T wave depression, which had been present before dilatation.

Complications

Two patients developed transient left bundle branch block which resolved spontaneously within 24 hours. During placement of the balloon catheter occasional ventricular extrasystoles developed. During balloon inflation extrasystoles with short non-sustained runs of ventricular tachycardia were common; sinus rhythm returned when the balloon was deflated (fig 1). There were also transient ST-T changes (both depression and elevation) that reverted to a normal pattern within minutes of balloon deflation. We did not attempt to measure the rhythm or haemodynamic changes during balloon dilatation.

Vascular complications were frequent. Femoral artery occlusion manifested by an impalpable pulse occurred in 10 patients (40%) whose mean weight

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before</th>
<th>After</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>LV systolic pressure (mm Hg)</td>
<td>167 (32)</td>
<td>128 (25)</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>(125–240)</td>
<td>(95–190)</td>
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<tr>
<td>LV end diastolic pressure (mm Hg)</td>
<td>12 (6)</td>
<td>9 (4)</td>
<td>p &lt; 0.001</td>
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<tr>
<td>(5–30)</td>
<td>(5–22)</td>
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<tr>
<td>LV-AO pressure gradient (mm Hg)</td>
<td>66 (26)</td>
<td>24 (17)</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>(45–114)</td>
<td>(0–64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac index (1/min/m\textsuperscript{2})</td>
<td>4.3 (3)</td>
<td>4.3 (1)</td>
<td>NS</td>
</tr>
<tr>
<td>(2–4.6)</td>
<td>(2–1.6)</td>
<td></td>
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<tr>
<td>Valve area (cm\textsuperscript{2}/m\textsuperscript{2})</td>
<td>0.53 (0.3)</td>
<td>1.24 (0.2)</td>
<td>p &lt; 0.005</td>
</tr>
<tr>
<td>(10 patients)</td>
<td>(0.2–1.1)</td>
<td>(0.4–1.8)</td>
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LV, left ventricular; LV-AO, left ventricular-aortic.
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Fig 1  Left ventricular pressure tracing and electrocardiogram during balloon inflation. The arrow indicates the end of inflation.

was 11·4 (4) (5–20) kg. One patient recovered after a 24 hour infusion of heparin. In eight patients the femoral pulse returned after a 48–72 hour infusion of streptokinase and one patient (10 kg) needed surgical thrombectomy after an unsuccessful trial of thrombolytic treatment. Two further patients required operation—one for persistent femoral artery bleeding and one for repair of a false femoral artery aneurysm. The average hospital stay was three days in patients with an uncomplicated course and 4·3 (2) (2–8) days in those with vascular complications.

Six patients showed angiographic evidence of aortic incompetence before dilatation, and it was detected in 15 patients after dilatation. Only one patient without previous aortic incompetence and two patients with grade I aortic incompetence had severe regurgitation (grade III) after dilatation (fig 2). There were no significant differences in terms of worsening or newly acquired aortic incompetence between those patients who had a reduction of > 50 % in gradient and those in whom the reduction was less pronounced (p < 0·9). Aortic incompetence was detected in 15 by Doppler: it was mild in nine and moderate in six. Again there was no correlation between reduction in the pressure gradient and the acquisition of or degree of aortic incompetence.

FINDINGS AT OPERATION IN PATIENTS WITH UNSUCCESSFUL BALLOON DILATATION

Four patients had an operation 6 (5) weeks (3 days to 3 months) after attempted balloon dilatation. Operations were performed at a mean age of 10·8 (4·6) (4·2–14·2) years. All patients had unsuccessful balloon dilatation, in one patient the left ventricle could not be entered and one was found to have annular and supra-annular aortic narrowing.

Two patients had open valvotomies and bicuspid valves were found. The patient with supra-annular narrowing had a tricuspid valve whose area could not be enlarged and a 21 St Jude valve was implanted. In the fourth patient a bicuspid calcified valve was found and a Kono procedure performed. This patient died soon after. Permission was not given for necropsy. No alterations in valve leaflets or commissural tears were seen in the dilated valves. The valve rings were intact and the leaflets were not damaged.

Discussion

Although the optimal treatment for the heterogenous population of patients with aortic valve stenosis under the age of six months remains controversial, surgical valvotomy under direct vision on cardiopulmonary bypass has been the standard treatment for those aged more than six months, with an early
mortality of 1–2%. But surgical valvotomy is palliative. After valvotomy patients can have residual haemodynamically important valve obstruction, aortic regurgitation, or progressive outflow obstruction that requires reoperation. In the long term most will need valve replacement. The early clinical results of percutaneous balloon dilatation of the aortic valve compare well with the results of valvotomy. Table 2 summarises the studies to date. Overall there was a 57% reduction in mean gradient in the short term. This accords with our experience (45% of our patients had a gradient of < 25 mm Hg after dilatation). Short term follow up of our patients identified no restenosis detected by Doppler. These results compare favourably with the short term studies of surgical results in which the gradients after valvotomy ranged from 25 to 50 mm Hg.

There was mild to moderate aortic incompetence in 60% of patients after balloon dilatation, compared with 24% before dilatation. The overall incidence of newly acquired incompetence in three series and ours, reporting a total of 71 patients, was 35%. Incompetence became worse in four of six, and was present in nine who did not have incompetence before study. The degree, however, was trivial to mild in most cases (fig 2), also reflected in other reported series. We were unable to relate the onset or degree of regurgitation to the extent of gradient reduction, although Helgason et al found a weak correlation.

In surgical valvotomy series the rate of moderate to severe postoperative incompetence varies, with a mean of 30–40%. In this regard, follow up of this procedure has been too brief to determine if balloon induced incompetence will be progressive although logically one would not expect a different long term course. Indeed, in one surgical series, progressive insufficiency was the major reason for late reoperation.

In our study arterial complications were frequent (40%); however, only three patients required surgical intervention: one each for arterial thrombosis, persistent arterial bleeding, and the development of a false aneurysm. In the others medical treatment restored arterial flow. These events appear to be more frequent in children weighing < 12 kg and seem to be related to the redundant balloon material on the catheter and the French gauge of the shaft. Bundle branch block and ST-T wave depolarisation abnormalities seem to be transient and well tolerated in our experience and that of others.

**TECHNICAL CONSIDERATIONS**

Because of the duration of the procedure and the size and number of catheters used, we prefer to perform balloon dilatation under a general anaesthetic. We found that either a ketamine infusion or fentanyl during spontaneous ventilation was effective and safe. Neither caused complications or lengthened hospital stay.

We also prefer to have a second catheter in place in the left ventricle allowing left ventricular pressures and transvalvar gradients to be monitored before, during, and after the procedure. Because of earlier problems, we now exclusively use long balloons (5–6 cm) to ensure satisfactory positioning of the balloon across the valve during inflation. The use of the stiff guide wire (Amplatz Extra Stiff Interventional Exchange wire, 260 cm, Cook, Inc) also helps to prevent the balloon shifting position when it is inflated—others have reported this difficulty.

A single balloon, with a diameter that does not exceed the annulus when it is inflated was effective in animal experiments and clinical series. Aortic tears have been described when larger single balloons were used. None the less, a larger transverse diameter than the annulus can be accommodated by the pulmonary and aortic valves when two balloons are used side by side, provided that total ring circumference of the balloons is no greater than that of the undistended annulus.

Our data indicate that balloon dilatation of the stenosed aortic valve is a safe procedure if the balloon does not exceed the annulus diameter by more than 1–2 mm. In most patients the pressure gradient can be reduced with an increase in the effective valve area, and clinically significant aortic regurgitation is uncommon, although mild incompetence develops in most. Short term follow up suggests that reduction in
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pressure gradient is sustained. The number of patients studied needs to be expanded but encouraging results, particularly in older children, suggest that this form of initial management is as effective as surgical valvotomy. Technical improvements and changes in the procedure may improve results and reduce complications.

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**References**

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