

Balloon dilatation of the pulmonary valve in the first year of life in patients with tetralogy of Fallot: a preliminary study

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SUMMARY Fifteen infants with tetralogy of Fallot, who would otherwise have required a palliative operation, underwent balloon dilatation of the right ventricular outflow tract. The mean period of palliation was 8.5 months (range 0-26 months). The procedure was performed without serious complications on 88% of occasions.

This preliminary study suggests that balloon dilatation may be useful in the management of tetralogy of Fallot.

Some centres believe that the optimum time for correction of tetralogy of Fallot is after two years of age. The need for a palliative operation before this is determined by the severity of cyanosis and the frequency of cyanotic spells, both of which are related to the degree of right ventricular outflow tract obstruction. Palliative operation, however, has an appreciable mortality. The systemic to pulmonary artery shunts may require revision because of shunt failure and this may increase the risks of the subsequent definitive operation.

Balloon dilatation is an established treatment for pulmonary valve stenosis. We have used this technique in the management of an unselected group of infants with tetralogy of Fallot who would otherwise have required a palliative operation.

Patients and methods

Between December 1983 and December 1986, 15 infants (nine boys and six girls) had 24 balloon dilatations of the pulmonary valve for tetralogy of Fallot. Five children required more than one balloon procedure—two children had two, two children had three, and one child had four balloon dilatations on separate occasions. Their mean age at the first procedure was 3.3 months (range 0.5-9 months).

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Tetralogy of Fallot was an isolated finding in nine children. Two children had an associated persistent arterial duct, two had a secundum atrial septal defect, one an atrioventricular septal defect, and one had an aorto-pulmonary collateral artery as the sole blood supply to the left pulmonary artery.

On 19 occasions balloon dilatation of the pulmonary valve was performed because the patients were becoming increasingly cyanosed and on five occasions it was performed because of frequent cyanotic spells. In our hospital, all patients with tetralogy of Fallot who were being considered for palliative treatment underwent balloon dilatation as the procedure of choice rather than a shunt. Early in the series, the pulmonary valve could not be crossed at cardiac catheterisation in five patients. Treatment with a β blocker (propranolol) was continued in patients already on this treatment but was not started for the first time at the time of balloon dilatation.

Cardiac catheterisation and angiocardiology were carried out under general anaesthesia in all cases. The mean systemic arterial oxygen saturation was 75% (range 46-97%) and the mean pulmonary artery oxygen saturation was 64% (range 46-80%). The mean right ventricular outflow tract gradient, measured on 15 occasions, was 70 mm Hg (range 56-83 mm Hg).

We used balloons with external diameters of 6-15 mm for dilatation. The size of the balloon was selected on the basis of the size of the pulmonary valve annulus measured from the lateral projection of the right ventricular angiogram. Early in the series dilatation was performed with balloons that we later recognised were too small. In the later cases we used

balloons with diameters that were approximately 33–40% larger than the pulmonary annulus. An exchange guide wire was passed through a 5 French Courmand or Multipurpose catheter and the tip was positioned in the distal right pulmonary artery. The balloon catheter was advanced over the guide wire until the midpoint of the balloon lay at the valve annulus. The balloon was inflated with dilute contrast to a pressure of 3–4 atmospheres and deflated immediately. For each dilatation procedure the balloon was inflated between two and four times. When we used larger balloons a constriction persisted at the site of the pulmonary valve annulus. The femoral artery pressure was monitored with a cannula whenever possible. The systemic and pulmonary oxygen saturations and right ventricular outflow tract gradient were measured at the end of the procedure.

Results

HAEMODYNAMIC FUNCTION

On 20 occasions the systemic arterial oxygen saturation increased by a mean of 18% (range 6–38%), on two occasions it remained the same, and on two occasions it deteriorated by 4% and 17%. Overall the systemic arterial oxygen saturation improved to a mean of 87% (range 65–98%; $p < 0.05$) after dilatation. The mean oxygen saturation in the pulmonary artery was 68% (range 52–89%) after dilatation and did not differ significantly from the value before dilatation. The mean residual systolic gradient across the right ventricular outflow tract was 64 mm Hg (range 45–83 mmHg). The gradient was increased in two patients by 10 mm Hg; however, the systemic artery saturation improved by 37% in one and by 12% in the other.

COMPLICATIONS

In all children there was a transient period of hypotension and bradycardia during balloon inflation, with spontaneous recovery within 30 seconds.

Table 1 Patients adequately palliated by balloon dilatation

	Case No						
	1	2	3	4	5	6	7
Age at presentation (mnth)	1.8	9	0.3	0.1	0.3	0.3	0.1
Age at first dilatation (mnth)	2	9	0.5	0.5	9	10	3
Age at follow-up (mnth)	20	18	4*	4.5	35	27	7
Period of palliation (mnth)	18	9	3.5	4	26	26	4

*Died.

Table 2 Patients who required systemic-pulmonary artery shunt after dilatation

	Case No			
	8	9	10	11
Age at presentation (mnth)	1.8	5	2	0.6
Age at first dilatation (mnth)	3	6	2.5	1
Age at shunt (mnth)	3	9	3	3
Period of palliation (mnth)	0	3	0.5	2

Two children required a short period of intermittent positive pressure ventilation after the procedure—one because of increasing cyanosis two hours after dilatation (11 days later a Waterston shunt was inserted) and the other because transient pulmonary oedema developed 18 hours after dilatation. In one patient group D streptococcal septicaemia developed after the procedure. This was treated with appropriate antibiotics. He died suddenly at home three months later, having been symptom free for three weeks; at necropsy vegetations were found on the tricuspid valve.

OUTCOME

Six children have not required further intervention during a mean follow up of 12.9 months (range 3.5–26 months). Four children have had a systemic to pulmonary artery shunt a mean of 1.6 months (range 0–3 months) after dilatation and four children have had a corrective operation six to 10 months (mean 8 months) after dilatation (tables 1–3).

OPERATIVE FINDINGS

The pulmonary artery and valve were inspected at the time of surgical correction. In two patients the valve was tricuspid without any evidence of tears affecting the cusps or commissures. The other two valves had tears; in one the valve was tricuspid and there was a split along the commissure between the posterior and the left cusps and in the second patient there was a tear of the posterior cusp itself. We saw no tears in the pulmonary arteries.

Table 3 Patients who had surgical correction after balloon dilatation of the pulmonary valve

	Case No			
	12	13	14	15
Age at presentation (mnth)	1	3	7	0.3
Age at first dilatation (mnth)	3	3	7	2
Age at correction (mnth)	13	12	13	9
Period of palliation (mnth)	10	9	6	7

Discussion

The mortality for total correction of tetralogy of Fallot is between 1% and 5%.¹ Although operation during infancy is associated with only a small increase in the frequency of early deaths, young age and small size remain important risk factors.¹ Many centres therefore recommend a staged approach with the creation of a systemic to pulmonary artery shunt before complete correction.²⁻⁴ This has the advantage of reducing the intensity of cyanosis and the frequency of cyanotic attacks. It also promotes the growth of the pulmonary valve annulus and the pulmonary arteries, which may reduce the need for insertion of transannular patches at the corrective operation and thus reduces the operative risks and achieves a better functional outcome.⁵⁻⁷

The creation of systemic to pulmonary artery shunts is, however, not without risk. The operative mortality of Blalock-Taussig and Waterston shunts varies between 0% and 13%.^{1,8-12} Approximately 10% of Blalock-Taussig shunts became occluded¹¹ and up to 16% of Waterston shunts produce kinking of the pulmonary arteries or pulmonary hypertension or both.¹²⁻¹⁴ Shunt failure may require either total correction before the optimum time or the formation of a second shunt; both procedures increase the risks of total correction.¹ In view of these problems there may be a place for an alternative form of palliation.

Balloon dilatation is now a recognised method of treatment for pulmonary valve stenosis and has recently been applied to pulmonary artery stenosis and hypoplasia.^{15,16} We have extended its use to infants with tetralogy of Fallot as an alternative form of palliation to systemic to pulmonary artery shunt operations. In this study adequate non-surgical palliation was achieved in 11 (73%) infants and four of them later had elective total correction. Dilatation is simple to perform and can be repeated if necessary. It requires an inpatient stay of only 48 hours compared with a stay of about seven days for a systemic to pulmonary artery shunt and does not need the resources of a cardiothoracic surgical centre. It also does not seem to increase the risks of subsequent corrective surgery.

Balloon dilatation for pulmonary valve stenosis, however, is not without risk. The potential immediate complications include the production of arrhythmias, haemorrhage, and femoral vein thrombosis.¹⁷ There are also reports of damage to the right ventricular outflow tract¹⁸ and the pulmonary valve,¹⁵ trunk,¹⁹ and branch arteries.¹⁶ Twenty one (88%) of our procedures were uncomplicated and of the four children who have undergone correction the only notable findings were splitting of the commissures. Previous balloon dilatation did not cause any

intraoperative complications.

We could not predict the subgroup of children who did not benefit from balloon dilatation. We are also uncertain of the effect of this procedure on the growth of the pulmonary annulus and arteries. Patients with a predominantly valvar component of the right ventricular outflow tract obstruction may benefit most from this procedure.

This preliminary study suggests that balloon dilatation may be useful in the management of infants with severe tetralogy of Fallot and that it should be considered for the initial palliative treatment.

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