Operative findings after percutaneous pulmonary balloon dilatation of the right ventricular outflow tract in tetralogy of Fallot

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Abstract
Since 1983 percutaneous balloon dilatation of the right ventricular outflow tract has been performed as an alternative to surgical palliation in selected cases of tetralogy of Fallot at the Royal Liverpool Children's Hospital. From 31 December 1984 to 31 December 1988, 27 of these patients underwent subsequent surgical correction. Age at operation ranged from 7 to 58 months (median 2.7 years). The mean interval between balloon dilatation and correction was 15.6 months (range 3–39 months). Two patients had a systemic pulmonary shunt operation performed before dilatation and a further five required one afterwards. Overall 20 (74%) patients had some anatomical alteration as the result of balloon dilatation, while in seven (26%) there was no discernible change in the right ventricular outflow tract. There was no consistent relation between the ratio of balloon size to pulmonary annulus diameter and the morphological findings.

Balloon dilatation may obviate the need for systemic-pulmonary shunt at the expense of some structural damage, particularly to the posterior cusp. The present data suggest that dilatation does not bring about growth of the annulus to such an extent that transannular patch is no longer needed at intracardiac repair.

Since percutaneous pulmonary balloon dilatation was introduced in 1953, it has become the treatment of choice for pulmonary valve stenosis in many centres. As suggested initially by Semb et al2 and Kan et al,3 the haemodynamic results compare favourably with those of surgery, especially when dysplastic valves are excluded. Because of this, few patients come to operation and the numerous published series4–8 contain little information on the morphological effects of dilatation of the right ventricular outflow tract.5 8

In our hospital, percutaneous pulmonary balloon dilatation has been practised as an alternative to or in combination with surgical palliation in selected patients with tetralogy of Fallot.9 Because most of these patients will eventually undergo operation we were presented with an opportunity to observe the anatomical consequences of dilatation of the right ventricular outflow.

Patients and methods
From 31 December 1984 to 31 December 1988, 27 patients underwent correction of tetralogy of Fallot after previous balloon dilatation of the right ventricular outflow tract. This includes 15 of those reported in the original clinical series.9 We reviewed the clinical notes; the operative reports; and, when available, the necropsy specimens.

The median age of the patients at operation was 33 months (range 7–58 months). Twenty one of them had one pulmonary dilatation, four had two procedures, and two patients had three and four balloon dilatations. The mean age at the first dilatation was 10.0 months (range 0.5–30); for all dilatations the median age was 14.6 months (range 0.5–56). Balloon sizes ranged from 5 to 15 mm (mean 13 mm). Surgical correction was undertaken 3 to 39 months (mean 15.6 months) after dilatation.

At operation the surgeon classified the pulmonary valve leaflets as follows: (a) intact, when there was no observable effect of dilatation; (b) detached, when the leaflet was separated from its hinge-point for a variable length, starting from one of the commissures; (c) split, when a vertical tear was found, usually in mid-portion of the leaflet dividing it in two segments (in no case was a split identified at a commissure); (d) fused, when the leaflets were fused to the pulmonary artery wall, probably after initial detachment.

The pulmonary ventriculo-arterial junction (pulmonary annulus) was described as: (a) intact, where there was no observable effect of dilatation; or (b) split, when there was a tear usually originating at the hinge-point of the leaflet and extending a variable distance into the main pulmonary artery and its right branch.

The computerised records of all the other patients (113) who underwent correction of tetralogy of Fallot over the same period (31 December 1984–31 December 1988) and who did not have balloon dilatation were reviewed to determine how many later had systemic-pulmonary shunt operations performed at our hospital or elsewhere and how many required a transannular patch at the time of correction.

All patients underwent intracardiac repair of tetralogy of Fallot by standard surgical techniques on conventional cardiopulmonary bypass. In most patients we used accepted criteria for the predicted ratio of postoperative right and left ventricular pressures to decide whether or not a transannular patch was required. The ventricular septal defect usually was closed through the right atrial approach.
We used simple logistic regression analysis to examine whether the ratio of balloon size to pulmonary artery diameter predicted morphological changes in the pulmonary artery. We analysed the frequency of transannular patch and shunt operations in patients treated by dilatation and those who were not by the \( \chi^2 \) test. We regarded \( p \) values of between 0.05–0.1 as statistically significant. We calculated the 70% confidence intervals for all percentages.

**Results**

Table 1 shows the findings at operation. Figure 1 is an example of a split leaflet. Overall 20 of the patients (74%) (70% CI 63%–83%) had gross evidence of damage caused by balloon dilatation. Seven patients (26%) (70% CI 17%–37%) had an intact outflow. Only five (19%) (70% CI 11%–29%) had evidence of changes that extended to more than one morphological category. No valve was found to have been split along a commissure and most valves described as “intact” were still obstructive with fused commissures. In five (19%) (70% CI 11%–29%) there was a posterior split of the pulmonary arterial wall (fig 2), starting at the ventriculo-arterial junction and often extending into the right branch. In one of the patients who died, gross and microscopical examination showed extensive disruption of the tissues (fig 3). The endothelial continuity was lost posteriorly at the depressed and uneven area that corresponded with the macroscopic tear, although the adventitia remained intact. Subendocardial fibrosis and elastosis were conspicuous in all sections of the adjacent right ventricular outflow septum in this patient.

Table 2 shows the relation between the ratio of the balloon size to the angiographic diameter of the pulmonary annulus and the frequency of...
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non-dilatation group \( (\chi^2 = 3.12, p = 0.08) \), and fewer patients had surgical palliation when balloon dilatation had been performed. A transannular patch was required in 62 (55%) of the group without prior balloon dilatation (70% CI, 50%–60%) and in 18 (67%) of 27 of the dilatation group (70% CI, 55%–77%) \( (\chi^2 = 27, p = 0.27) \).

Discussion

Balloon dilatation of the pulmonary valve is an invasive, non-surgical technique\(^1-3\) used to relieve obstruction of the right ventricular outflow tract.\(^4,5\) The ideal balloon size, the number and pressure of inflations, and patient selection vary among different centres. Except for the report on the effect of balloon dilatation of the pulmonary annulus on newborn lambs from Ring and colleagues\(^6\) and mention of isolated surgical cases in series of pulmonary valve dilatations,\(^7\) there is little information available on the morphological consequences of the procedure on the right side of the heart. This, in part, attests to its relative safety and effectiveness, because few patients who have undergone dilatation of isolated pulmonary valve stenosis required later surgery.

Ring showed that balloon inflation severely damaged the right ventricular outflow tract in newborn lambs particularly when the balloon diameter was >50% bigger than the pulmonary artery diameter.\(^8\) In animals killed 83 and 111 days after dilatation the damaged area was occupied by small patches of fibrosis. We did not find distinctive signs of this type of trauma in our patients at operation but in most patients with tetralogy of Fallot the endocardium in areas of turbulence is usually whitened and fibrotic. We have not examined enough patients to know whether fibrosis along the right ventricular outflow (which cannot be solely attributed to the dilatation scar) will predispose to ventricular arrhythmias—as was suggested by Ring\(^9\) commenting on the clinical-pathological study by Deanfield and colleagues.\(^10\) By using simple logistic regression analysis, we were unable to show any significant relation between the size of the balloon and occurrence of morphological changes (table 2), except for the general trend shown in fig 3. However, in one four month old patient, who has not yet come for correction (and therefore is not included in this report) sudden and severe hypotension and hypoxia after balloon dilatation required urgent systemic-pulmonary artery anastomosis. After the chest was opened, blood was evacuated from a tense pericardium and we found disruption of the anterior right ventricular outflow tract with a large subadventitial haematoma extending across the annulus into the left pulmonary artery. Follow up catheterisation showed a small, round diverticulum protruding from the anterior aspect of the right ventricular outflow tract, confirming an extensive structural deformity.

The major changes in our series were confined to the valve leaflets; 20 (74%) of patients (70% CI, 63%–83%) had one or more of the changes described, while 22 (81%) (70% CI,
71%-89%) were free of annular/pulmonary artery disruption. The frequency of the three categories of cusp alterations was very similar (table 1). It is striking that most of the morphological changes were found on the posterior leaflet and the posterior wall of the pulmonary trunk. We had difficulty for our artery patch remain to be determined. However, accumulating evidence suggests that continuing pulmonary regurgitation may be detrimental to right ventricular function.

We found that balloon dilatation tended to split the posterior pulmonary valve leaflet or detach it from the hinge point, with or without a dehiscence in the posterior wall of the pulmonary artery. This may obviate the need for a systemic-pulmonary shunt, possibly at the expense of some anatomical damage and loss of valvar function at later correction. In view of these findings, we advise that the balloon size should be limited to 120%-140% of the diameter of the pulmonary annulus. From our present data, we cannot tell whether dilatation has any effect on the growth of the pulmonary arteries, but the procedure did not seem to alter the need for a transannular patch at the time of intracardiac repair.

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