

# Balloon angioplasty of pulmonary vein stenosis in infants

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg75](http://www.nice.org.uk/guidance/ipg75)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 1 Guidance

- 1.1 Current evidence on the safety and efficacy of balloon angioplasty of pulmonary vein stenosis in infants does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. The available evidence suggests that the procedure is not efficacious. However, there are no special concerns about the safety of the procedure, especially in the context of very ill infants for whom it is used.
- 1.2 Clinicians wishing to undertake balloon angioplasty of pulmonary vein stenosis in infants should take the following actions:
  - Inform the clinical governance leads in their Trusts.
  - Ensure that the parents of patients understand that the limited available evidence indicates a lack of efficacy. Parents should be given clear written information. Use of NICE's information for the public is recommended.
  - Audit and review clinical outcomes of all patients having balloon angioplasty of pulmonary vein stenosis in infancy.
- 1.3 This procedure should only be offered to gravely ill infants with a very poor prognosis, and in the setting of a specialist paediatric cardiology unit.
- 1.4 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients into this database.
- 1.5 Publication of safety and efficacy outcomes will be useful in reducing the current

uncertainty. NICE may review the procedure upon publication of further evidence.

## 2 The procedure

### 2.1 Indications

- 2.1.1 Pulmonary vein stenosis (narrowing) may be congenital or may be acquired after surgery to correct other congenital cardiac anomalies. It is rare and often associated with other cardiac abnormalities. Untreated, it leads to severe lung damage.
- 2.1.2 There is currently no reliable alternative treatment.

### 2.2 Outline of the procedure

- 2.2.1 Balloon angioplasty of pulmonary vein stenosis, sometimes combined with stenting, is a palliative treatment for children with a very poor prognosis, or is sometimes a temporary measure for children awaiting further interventions. The procedure involves inserting a catheter into the narrowed area under radiological guidance. A balloon is then inflated to relieve the narrowing. A stent may be inserted after dilatation to maintain patency.

### 2.3 Efficacy

- 2.3.1 The evidence was limited to four very small, poor-quality case series, the largest including only five patients. The two largest studies found no benefit from the procedure in any patients. Another study of three patients found an immediate reduction in pulmonary vein pressure in all the patients, as well as angiographic evidence of relief of stenosis in one patient. However, this patient died of infection within 36 hours of surgery. For more details, see the [overview](#).
- 2.3.2 The Specialist Advisors considered that this procedure may have only short-term

efficacy (if any at all), and that recurrence rates may be high. They also noted, however, that there was almost no role for surgery in this condition, and that even a partial result from this procedure may offer palliation in this group of patients.

## 2.4 Safety

- 2.4.1 Some of the main adverse events reported in the studies included: venous tear leading to mediastinal haemorrhage in 20% (1 out of 5) of patients; haemoptysis in 20% (1 out of 5) of patients; death caused by infection in 33% (1 out of 3) of patients; and puncture of the distal vein in 33% (1 out of 3) of patients. For more details, see the [overview](#).
- 2.4.2 The Specialist Advisors considered the main potential adverse events to be death, rupture of myocardium, rupture of pulmonary vein, cerebral or other systemic embolism, arrhythmias and sepsis.

## 3 Further information

### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

### Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).