

Balloon angioplasty of pulmonary vein stenosis in infants

Interventional procedures guidance

Published: 28 July 2004

www.nice.org.uk/guidance/ipg75

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 the Institute'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 Department of Health runs the [UK Central Cardiac Audit Database](#) (UKCCAD) and clinicians are encouraged to enter all patients onto this database.
- 1.5 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute 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, refer to the Sources of evidence section.
- 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% (1/5) of patients; haemoptysis in 20% (1/5) of patients; death caused by infection in 33% (1/3) of patients; and puncture of the distal vein in 33% (1/3) of patients. For more details, refer to the Sources of evidence section.
- 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.

Andrew Dillon
Chief Executive
July 2004

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of balloon angioplasty of pulmonary vein stenosis in infants', March 2003.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

As part of the NICE's work programme, the current guidance was considered for review but did not meet the review criteria as set out in the IP process guide. This guidance therefore remains current.

8 May 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

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