NICE guidance

Balloon dilatation of systemic to pulmonary arterial shunts in children

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg77

1 Guidance

1.1 Current evidence on the safety and efficacy of balloon dilatation of systemic to pulmonary arterial shunts in children appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 The procedure should only be undertaken in specialist paediatric cardiology units.

1.3 The Department of Health runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients into this database.

2 The procedure

2.1 Indications

2.1.1 Systemic to pulmonary arterial shunts are surgically created connections between the aorta and a pulmonary artery in children with cyanotic congenital heart disease, such as tetralogy of Fallot or tricuspid atresia. The shunts increase the blood supply to the lungs and the arterial oxygen saturation. The procedures are palliative. In some children, definitive surgery may be possible later. The most common type of systemic to pulmonary shunt is known as the Blalock–Taussig shunt.

2.1.2 Systemic to pulmonary shunts may become blocked or narrowed (stenosed) because of scarring or thrombosis. Stenosed systemic to pulmonary shunts may be treated by a repeat surgical systemic to pulmonary shunt operation.

2.2 Outline of the procedure

2.2.1 Balloon dilatation of systemic to pulmonary shunts is a palliative procedure carried out to relieve blockage or narrowing of pulmonary shunts. The procedure involves inserting a catheter into a large blood vessel (usually in the groin), passing it up into the chest under radiological guidance and inflating a balloon in the narrowed area. This may avoid the need for a repeat surgical systemic to pulmonary shunt procedure.

2.3 Efficacy

2.3.1 The evidence was limited to small uncontrolled case series. All these studies reported increases in mean oxygen saturation, ranging from 5% to 19%. One of the studies reported successful dilatation (> 20% increase in oxygen saturation) in 91% (42/46) of patients. For more details, refer to the Sources of evidence section.

2.3.2 The Specialist Advisors had no concerns regarding the efficacy of this

procedure.

2.4 Safety

2.4.1 Adverse events were poorly reported in the largest study, which included 46 people. The main adverse events reported in the next largest studies included: one patient with pulmonary hypertension and one death because of pneumonia (could not be weaned off ventilator) in a study of eight patients; and one patient with a thrombosed femoral artery, one patient with balloon rupture and one case of severe arterial vasospasm in a study of six patients. For more details, refer to the Sources of evidence section.

2.4.2 Potential adverse events noted by the Specialist Advisors included tearing of the vessel or shunt, death, complete shunt occlusion, rupture, thrombosis, haemorrhage, embolic stroke, and pulmonary embolism.

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 dilatation of systemic to pulmonary arterial shunts', April 2003.

Information for patients

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

4 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.

Changes since publication

8 May 2012: minor maintenance.

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.