NICE National Institute for Health and Care Excellence

NICE guidance

Balloon dilatation of systemic to pulmonary arterial shunts in children

HealthTech guidance
Published: 28 July 2004

www.nice.org.uk/guidance/htg48

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.

Contents

This guidance replaces IPG77.

1 Recommendations

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 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.

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 out of 46) of patients. For more details, see the overview.

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: 1 patient with pulmonary hypertension and 1 death because of pneumonia (could not be weaned off ventilator) in a study of 8 patients; and 1 patient with a thrombosed femoral artery, 1 patient with balloon rupture and 1 case of severe arterial vasospasm in a study of 6 patients. For more details, see the overview.

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.

3 Further information

Sources of evidence

The evidence considered by the committee is 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 decision made, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 77 has been migrated to HealthTech guidance 48. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8783-2

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.