

Balloon dilatation with or without stenting for pulmonary artery or non-valvar right ventricular outflow tract obstruction in children

Interventional procedures guidance

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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. However, 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.

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.

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 dilatation with or without stenting for pulmonary artery or non-valvar right ventricular outflow tract obstruction 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 The right ventricular outflow tract includes the pulmonary valve and the tissue above and below it. Narrowing (stenosis) of this region may involve the area below the valve (subvalvar), the valve itself (valvar), or the area above the valve (supravalvar). [Balloon dilatation of valvar right ventricular outflow tract narrowing \(pulmonary valve stenosis\)](#) is covered in separate guidance.
- 2.1.2 Congenital subvalvar and supravalvar right ventricular outflow tract stenosis usually occurs with other cardiac defects, such as ventricular septal defect or tetralogy of Fallot. Postoperative right ventricular outflow tract obstruction may occur after surgery to create a conduit between the right ventricle and pulmonary artery in children with congenital anomalies. Narrowing may also occur beyond the right ventricular outflow tract, in one of the pulmonary arteries, or in their branches.
- 2.1.3 Standard treatment of non-valvar right ventricular outflow tract or pulmonary artery obstruction involves open chest surgery.

2.2 Outline of the procedure

2.2.1 Balloon dilatation is a minimally invasive procedure that involves inserting a catheter into a large blood vessel, usually in the groin, and passing it up to the area of narrowing under radiological guidance. A balloon is then inflated within the narrowing to dilate the obstruction. Stenting involves the insertion of a small tube into the narrow region following balloon dilatation, to maintain patency.

2.3 Efficacy

2.3.1 No comparative studies were identified. Reports of technical success rates (defined as > 50% increase in pre-dilatation diameter, > 50% decrease in pressure gradient or > 20% decrease in right ventricular to aortic peak pressure ratio) were 97% (77/79) for stent insertion and 60% (97/162) for balloon dilatation in one study, and 53% (39/74) for balloon dilatation in another study. 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 One of the studies reported a 3% (5/162) complication rate for patients undergoing balloon dilatation. This included one femoral vein thrombosis, three pulmonary artery major dissections, and one transient pulmonary oedema. One study of stent implantation reported a complication rate of 1% (1/79 – a pleural perforation with haemopericardium). For more details, refer to the Sources of evidence section.

2.4.2 The Specialist Advisors listed potential complications as arrhythmia, haemorrhage, stent migration, embolisation, balloon rupture, blood vessel damage and tricuspid valve damage.

2.5 Other comments

2.5.1 Fewer data were available on the use of the technique for non-valvar right ventricular outflow tract obstruction than for pulmonary artery or branch

pulmonary artery obstruction.

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 dilation with or without stenting for pulmonary artery or right ventricular outflow tract obstruction'](#), April 2003.

Information for patients

NICE has produced [information on this procedure for patients and carers](#) ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, 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.

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Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 033 7780

Endorsing organisation

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