NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech guidance

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www.nice.org.uk/guidance/htg47

# 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 IPG76.

# 1 Recommendations

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 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 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). See also NICE's HealthTech guidance on balloon dilatation of pulmonary valve stenosis.

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 1 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 out of 79) for stent insertion and 60% (97 out of 162) for balloon dilatation in 1 study, and 53% (39 out of 74) for balloon dilatation in another study. 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 One of the studies reported a 3% (5 out of 162) complication rate for patients undergoing balloon dilatation. This included 1 femoral vein thrombosis, 3 pulmonary artery major dissections, and 1 transient pulmonary oedema. One study of stent implantation reported a complication rate of 1% (1 out of 79 – a pleural perforation with haemopericardium). For more details, see the overview.

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.

# 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 76 has been migrated to HealthTech guidance 47. The recommendations and accompanying content remain unchanged.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.