

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

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 (www.ccad.org.uk).

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 (www.nice.org.uk/ip_140).

- 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,

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This guidance is written in the following context:

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

> 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 (see right).

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.

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.

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Chief Executive
July 2004

Information for the Public

The Institute 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. This information is available, in English and Welsh, from www.nice.org.uk/IPG076publicinfo

Sources of evidence

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

Interventional procedure overview of balloon dilatation with or without stenting for pulmonary artery or right ventricular outflow tract obstruction, April 2003

Available from: www.nice.org.uk/ip087overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0646. *Information for the Public* can be obtained by quoting reference number N0647 for the English version and N0648 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG076distributionlist

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