NICE National Institute for Health and Care Excellence

NICE guidance

Balloon dilatation of pulmonary valve stenosis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg67

1 Guidance

1.1 Current evidence on the safety and efficacy of balloon dilatation of pulmonary valve stenosis 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 Balloon dilatation of pulmonary valve stenosis should only be performed in a specialist unit where paediatric cardiac surgery is available.

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

2 The procedure

2.1 Indications

2.1.1 Pulmonary valve stenosis is narrowing of the pulmonary valve in the heart. It is usually congenital. The outflow of blood from the right ventricle of the heart to the lungs is obstructed. Symptoms include shortness of breath, chest pains, fainting and, in some instances, sudden death.

2.1.2 Balloon dilatation is an alternative to open surgical valvotomy.

2.2 Outline of the procedure

2.2.1 Balloon dilatation is a minimally invasive transvenous procedure to dilate the pulmonary valve orifice during cardiac catheterisation.

2.3 Efficacy

2.3.1 The evidence identified was limited to case series and one historical controlled study. All the studies reported a reduction in the residual pressure gradient across the pulmonary valve. In addition, the studies that reported data with more than 11 months follow-up showed that the reduction in pressure gradient persisted. In a case series of 533 children who received the procedure, an immediate residual gradient of less than 36 mmHg was reported in 74% (394/533) of patients. No clinical outcomes were reported. For more details, refer to the Sources of evidence section.

2.3.2 The Specialist Advisors considered this procedure to be established practice and had no concerns about its efficacy.

2.4 Safety

2.4.1 Most of the studies identified did not report safety findings in detail. The study that described safety findings in most detail reported the following

immediate complications among 811 patients: arrhythmia, 1% (8/811); bleeding from catheter site, 0.9% (7/811); femoral vein thrombosis, 0.6% (5/811); hypoxia, 0.4% (3/811); death, 0.2% (2/811); tricuspid regurgitation, 0.2% (2/811); femoral vein tears, 0.2% (2/811); arterial thrombosis, 0.2% (2/811); cardiac perforation, 0.1% (1/811); and respiratory arrest, 0.1% (1/811). For more details, refer to the Sources of evidence section.

2.4.2 The Specialist Advisors commented that pulmonary regurgitation was common after the procedure, but that the long-term effects of this were unknown. They considered the risks to be greater in neonates than in older infants and children. The Advisors also recommended that the procedure should be carried out only in paediatric cardiology units with special expertise.

2.5 Other comments

2.5.1 This procedure has become established practice on the basis of clinical experience. There is very limited research evidence published.

2.5.2 Most of the data relates to neonates and children, but the procedure can also be performed in adults.

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 pulmonary valve stenosis', March 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: 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.