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NHS
National Institute for Clinical Excellence

Balloon dilatation of pulmonary valve stenosis

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 (www.ccad.org.uk).

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 (see overleaf).

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

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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 (see right).

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.

Andrew Dillon
Chief Executive
June 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/IPG067publicinfo

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

Available from: www.nice.org.uk/ip140overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0600. *Information for the Public* can be obtained by quoting reference number N0601 for the English version and N0602 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/IPG067distributionlist

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