

Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction

1 Guidance

1.1 The evidence on percutaneous pulmonary valve implantation for right ventricular outflow tract (RVOT) dysfunction is limited to small numbers of patients but shows good short-term efficacy. There is little evidence on long-term efficacy. There are no particular safety concerns in the context of a condition that otherwise requires open cardiac surgery. Clinicians wishing to use this procedure should do so only with special arrangements for clinical governance, consent and for audit or research.

1.2 Clinicians should take the following actions:

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's long-term efficacy and that there will be a need for repeat procedures or operations. They should provide patients with clear, written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG237publicinfo).

1.3 The procedure should be performed only in specialist units and with arrangements in place for cardiac surgical support in the event of complications.

1.4 Patient selection should be carried out by a multidisciplinary team including a paediatric cardiologist, an interventional cardiologist, a radiologist and a cardiothoracic surgeon with a special interest in congenital heart disease.

1.5 This is a technically challenging procedure that should be performed only by clinicians with

special training and experience in interventional paediatric cardiology.

1.6 The Department of Health runs the UK Central Cardiac Audit Database (UK CCAD) and clinicians should enter details about all patients undergoing percutaneous pulmonary valve implantation for RVOT dysfunction onto this database (www.ccad.org.uk).

2 The procedure

2.1 Indications

2.1.1 RVOT dysfunction encompasses pulmonary valve stenosis, pulmonary valve incompetence (regurgitation) and combined (mixed) disease. It is usually associated with a congenital heart abnormality, such as tetralogy of Fallot. Depending on the severity of the condition and associated structural abnormalities of the heart, RVOT dysfunction causes varying degrees of right ventricular hypertrophy and right heart failure. If left untreated, it can be a life-limiting condition.

2.1.2 Some patients with RVOT dysfunction may have severe stenotic lesions or pulmonary valve incompetence and may require open surgical repair or replacement of the valve, particularly where valvuloplasty has failed.

2.1.3 Pulmonary valve surgery is a major cardiac procedure requiring cardiopulmonary bypass. It often involves insertion of a bioprosthetic pulmonary valve, either in situ or in a bypass conduit. Because patients undergoing this procedure are typically children or adolescents, the bioprosthetic valve will require revisions as the patient grows.

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This guidance represents the view of the Institute, which 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.2 Outline of the procedure

2.2.1 Performed under general anaesthesia, percutaneous pulmonary valve implantation is accomplished by insertion of a catheter system through a systemic vein. Using angiographic guidance, a guide wire is used to position a stent-mounted biological valve in the RVOT, usually within a pre-existing pulmonary conduit. The valve is then deployed by balloon inflation. The procedure can be repeated.

2.3 Efficacy

2.3.1 In two case series of 59 and 8 patients, percutaneous pulmonary valve implantation was successful in 98% (58/59) and 100% (8/8) of patients, respectively, at 10-month follow-up (specific outcome measures not stated).

2.3.2 The case series of 59 patients reported a statistically significant decrease in the mean pressure gradient across the RVOT immediately after the procedure (19.5 mmHg versus 33.0 mmHg at baseline; $p < 0.001$). In the case series of eight patients, the systolic pressure ratio between the right ventricle and aorta (RV peak systolic pressure) decreased from 74% at baseline to 47% following the procedure, and mean peak systolic pressure across the RVOT decreased from 74 mmHg to 44 mmHg (measures of significance not stated). For more details, refer to the 'Sources of evidence' section.

2.3.3 Three of the Specialist Advisers considered this procedure to be novel and of uncertain efficacy. Four Specialist Advisers commented that the mid- to long-term performance of the valve is of concern.

2.4 Safety

2.4.1 In the case series of 59 patients, severe bleeding with right haemothorax was reported in one patient (2%). Minor dissection of the existing homograft was also reported in one patient (2%).

2.4.2 In the case series of eight patients, the RVOT was completely obstructed by the valve delivery system in one patient (13%) requiring immediate deployment of the valve in a suboptimal position. In the case series of 59 patients, the distal tip of the valve delivery system became detached in 3% (2/59) of patients during implantation, the

clinical impact of which was not provided. For more details, refer to the 'Sources of evidence' section.

2.4.3 The Specialist Advisers listed theoretical adverse events as failed placement and migration of the valve stent, stent fracture, cardiac perforation, paraprosthetic leak, haemolysis, iatrogenic pulmonary stenosis, valve damage during delivery, valve failure and transient severe hypotension during valve placement. Death, coronary artery compression, endocarditis and femoral vein injury were also identified as theoretical adverse events.

2.5 Other comments

2.5.1 The Committee noted that the technology for this procedure is continuing to develop.

3 Further information

3.1 Adverse events, including stent fractures, should be reported to the Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk).

3.2 The Institute has issued interventional procedures guidance on balloon dilatation of pulmonary valve stenosis (www.nice.org.uk/IPG067) and radiofrequency valvotomy for pulmonary atresia (www.nice.org.uk/IPG095).

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November 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG237publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document. 'Interventional procedure overview of percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction', February 2007.

Available from: www.nice.org.uk/ip392overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1408. 'Understanding NICE guidance' can be obtained by quoting reference number N1409.

The distribution list for this guidance is available at www.nice.org.uk/IPG237distributionlist

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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