

Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction

Interventional procedures guidance
Published: 23 January 2013

www.nice.org.uk/guidance/ipg436

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.

This guidance replaces IPG237.

1 Guidance

- 1.1 The evidence on percutaneous pulmonary valve implantation (PPVI) for right ventricular outflow tract (RVOT) dysfunction shows good short-term efficacy. There is little evidence on long-term efficacy, but it is well documented that these valves may need to be replaced in the longer term. With regard to safety there are well-recognised complications, particularly stent fractures in the longer term, which may or may not have clinical effects. Patients having this procedure are often very unwell and might otherwise need open heart surgery (typically reoperative) with its associated risks. Therefore, this procedure may be used with normal arrangements for clinical governance, consent and audit.
- 1.2 The procedure should be performed only in specialist units and with arrangements in place for cardiac surgical support in the event of complications.
- 1.3 Patient selection should be carried out by a multidisciplinary team including a cardiologist with a special interest in congenital heart disease, an interventional cardiologist and a cardiothoracic surgeon with a special interest in congenital heart disease.
- 1.4 This is a technically challenging procedure that should be performed only by clinicians with training and experience in interventional cardiology and congenital

heart disease.

- 1.5 Clinicians should enter details about all patients undergoing PPVI for RVOT dysfunction onto the [UK Central Cardiac Audit Database \(UKCCAD\)](#) run by the [National Institute for Cardiovascular Outcomes Research](#). They should audit and review clinical outcomes locally, and in particular collect information on long-term outcomes.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Right ventricular outflow tract (RVOT) dysfunction often occurs as part of complex congenital heart conditions, such as tetralogy of Fallot. It may take the form of pulmonary valve stenosis, pulmonary valve incompetence (regurgitation) or both. 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 Reconstruction of the RVOT, done as part of surgery for congenital heart disease, is likely to need revision in the long term as a result of growth of the child and/or degeneration of any replacement valve. Normally, revision involves repeat surgery with replacement of the RVOT and/or any previously placed conduit.
- 2.1.3 PPVI is an interim alternative to surgery for some patients. This approach is usually used for patients who have had a previous RVOT conduit or valve replacement. Many of the patients with this condition are adolescents or young adults, who may need multiple valve replacement procedures during their lifetime.

2.2 Outline of the procedure

- 2.2.1 The aim of percutaneous pulmonary valve implantation (PPVI) is to provide a less

invasive intervention than open heart surgery to improve pulmonary valve function and circulation to the lungs while reducing pressure in the right ventricle. The treatment strategy may be to delay the need for further surgical revision.

2.2.2 The procedure is done with the patient under general anaesthesia. PPVI is done by inserting a catheter system through a large vein (typically the femoral vein). Angiography is used to identify the anatomy of the RVOT and its relation to coronary arteries. A stent-mounted valve is introduced over a guidewire and is positioned in the RVOT, under fluoroscopic guidance. A balloon is then inflated to deploy the valve. Sometimes a plain stent is inserted first to dilate the RVOT and provide a regular surface onto which the stent-mounted valve can be fixed. This may decrease the risk of stent fracture, and thereby increase the longevity of the valve. The procedure can be repeated if necessary.

2.2.3 Most valves used in this procedure are derived from animal sources.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3.1 A non-randomised comparative study of 108 patients, 54 treated by PPVI alone and 54 treated by pre-stenting followed by PPVI, reported a significant decrease in mean right ventricular systolic pressure from 57 to 42 mmHg for patients treated by PPVI only (n=52; p<0.0001) and from 65 to 41 mmHg for pre-stenting followed by PPVI (n=54; p<0.0001) at 1-year follow-up (p=0.02 between groups).

2.3.2 In a case series of 155 patients, there was a significant reduction in mean right ventricular systolic pressure from 63 to 45 mmHg (p<0.001) and RVOT gradient from 37 to 17 mmHg 'after the procedure' (no further details; p<0.001).

2.3.3 In a case series of 102 patients, pulmonary regurgitation (assessed by magnetic resonance imaging) significantly decreased from a median of 16% to 1% 'after the procedure' (p<0.001).

- 2.3.4 In a case series of 36 patients, the percentage of patients with a New York Heart Association (NYHA) functional status of I (no limitation of physical activity) increased from 15% (5 out of 33) at baseline to 82% (27 out of 33) at 6-month follow-up and patients with NYHA functional status IV (inability to carry out any physical activity without physical discomfort) decreased from 6% at baseline to 0% at 6-month follow-up (absolute figures not reported).
- 2.3.5 In a case series of 28 patients, cardiopulmonary exercise testing showed that the oxygen uptake (peak VO₂) improved from 24 ml/kg/minute before treatment with PPVI (n=24) to 28 ml/kg/minute at median 6-month follow-up (n=19; p<0.0001).
- 2.3.6 In the case series of 155 patients, 93%, 86%, 84% and 70% of patients did not need to have further surgery and 95%, 87%, 73% and 73% did not need any further transcatheter reintervention at 10, 30, 50 and 70 months respectively (absolute figures not reported).
- 2.3.7 The Specialist Advisers listed the following additional efficacy outcomes: reduced pulmonary incompetence, avoiding a sternotomy incision and cardiopulmonary bypass, and shorter recovery time with less risk of postoperative infection and bleeding.

2.4 Safety

- 2.4.1 Death was reported in 4% (2 out of 54) of patients treated by PPVI alone and in 4% (2 out of 54) of patients treated by pre-stenting followed by PPVI in the non-randomised comparative study of 108 patients (1 death was within 30 days because of pulmonary oedema). In patients treated by PPVI alone, 1 patient died after a chest infection 2 months after the procedure and 1 patient with pulmonary hypertension died after 'presumed' arrhythmia 24 months after the procedure. In patients treated by pre-stenting followed by PPVI, 1 patient died because of pulmonary oedema 1 day after the procedure (as noted above) and 1 patient died because of 'presumed' arrhythmia 8 months after the procedure. Death within 30 days was reported in less than 1% of patients (1 out of 136) in a case series of 136 patients. The patient had coronary artery dissection and intracranial haemorrhage.

- 2.4.2 Bacterial endocarditis was reported in 1 patient in the case series of 102 patients. The valve was surgically removed and replaced by a homograft valve 6 months after the procedure. One patient developed endocarditis in a case series of 20 patients and the valve was explanted at 6 months.
- 2.4.3 Stent fractures were reported in 29% (15 out of 52) of patients treated by PPVI alone and in 17% (9 out of 52) of patients treated by pre-stenting followed by PPVI at 1-year follow-up in the non-randomised comparative study of 108 patients. Stent fractures occurred in 21% (absolute figures not reported) of patients in the case series of 155 patients. Nine patients had required reintervention (further details not reported) by median 28-month follow-up.
- 2.4.4 Valve migration was reported in 9% (3 out of 34) of patients in the case series of 36 patients. Two patients were treated by surgical pulmonary valve replacement. Valve migration during the procedure was reported in 1 patient who was treated by a further implantation during the same procedure (no further details reported).
- 2.4.5 Conduit rupture/tear (no further details) was reported in 2 patients in the case series of 136 patients at 6-month follow-up. One patient was treated by replacement conduit and the other by covered stent placement.
- 2.4.6 The valve had to be removed in 4% (2 out of 54) of patients treated by PPVI alone in the non-randomised comparative study of 108 patients. This was because of RVOT pseudoaneurysm in 1 patient (at 16 months) and endocarditis in 1 patient (at 19 months).
- 2.4.7 Complete atrioventricular block occurred in 1 patient during the procedure in the case series of 102 patients; the patient's heart rate reverted to sinus rhythm after 21 days.
- 2.4.8 The Specialist Advisers listed the following theoretical adverse events: pulmonary artery dissection and rupture, perforation of the heart, embolisation of the device, bleeding from the cannulation site, and vascular perforation.

2.5 Other comments

- 2.5.1 The Committee noted that the ages of the patients in the published studies varied. The number of previous procedures patients had undergone was often unclear: this may have influenced the outcomes of PPVI.
- 2.5.2 The Committee noted apparent duplication of patients in published studies.
- 2.5.3 The Committee recognised that stent fracture is a risk in the longer term and this underpinned the recommendation for continued data collection about long-term outcomes. It noted that devices continue to evolve and that developments in their design may have influenced long-term performance.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described 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 guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-6398-0

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).