

Radiofrequency valvotomy for pulmonary atresia

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg95

1 Guidance

- 1.1 Current evidence on the safety and efficacy of radiofrequency valvotomy for pulmonary atresia with intact interventricular septum is limited due to the rarity of the condition, but appears adequate to support the use of the procedure for the treatment of seriously ill neonates, provided that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Radiofrequency valvotomy for pulmonary atresia with intact interventricular septum should be performed in carefully selected patients in specialist centres with paediatric cardiac surgery facilities.
- 1.3 The Department of Health runs the [UK Central Cardiac Audit Database](#) (UKCCAD) and clinicians are encouraged to enter all patients onto this database.

2 The procedure

2.1 Indications

- 2.1.1 Radiofrequency valvotomy is used to treat pulmonary atresia, a congenital malformation of the pulmonary valve in which the valve orifice fails to develop. The valve is completely closed, thereby obstructing the outflow of blood from the heart to the lungs. Babies with this type of cyanotic congenital heart disease survive only for the first few days of life. During those first few days, if there is no operation to open the pulmonary valve or to make a shunt between the aorta and the pulmonary arteries, the condition is fatal.
- 2.1.2 The standard treatment for pulmonary atresia is open heart surgery that includes the Fontan procedure (the surgical creation of a right ventricular bypass by directly connecting either the right atrium or the superior or inferior vena cava with the pulmonary artery) and the Blalock-Taussig shunt (a palliative procedure in which a shunt is created to allow blood to pass from the aorta to the pulmonary artery by dividing the left subclavian artery and connecting it to the left pulmonary artery). Further open heart surgery may include open surgical valvotomy.

2.2 Outline of the procedure

- 2.2.1 Radiofrequency valvotomy is a minimally invasive cardiac catheterisation procedure that involves creating an opening in the blocked pulmonary valve followed by dilatation using balloon angioplasty. It avoids the need for open surgery but some children will later need a permanent shunt procedure or surgical relief of pulmonary valve obstruction.

2.3 Efficacy

- 2.3.1 The evidence was limited to one small nonrandomised comparative study and four small uncontrolled studies. The success rate of the procedure varied between 75% (9/12) and 93% (14/15). The proportion of patients with establishment of a biventricular circulation was reported in four

studies. In the comparative study, 63% (12/19) of patients had a biventricular circulation established after radiofrequency valvotomy, compared with 50% (7/14) after surgical valvotomy. In the other three studies, a biventricular circulation was established in between 42% (5/12) and 53% (16/30) of patients. For more details, refer to the Sources of evidence section.

- 2.3.2 One Specialist Advisor commented that proper patient selection was important in order to achieve good clinical outcomes.

2.4 Safety

- 2.4.1 In the comparative study, the mortality rate for patients who underwent radiofrequency valvotomy was 16% (3/19), compared with 29% (4/14) for patients who underwent surgical valvotomy. The largest non-comparative study (of 30 patients) reported three postoperative deaths and two late deaths. Other complications reported in the studies included perforation of the pulmonary artery in between 3% (1/30) and 33% (4/12) of patients, and perforation of the right ventricular outflow tract in 17% (3/18) of patients. For more details, refer to the Sources of evidence section.
- 2.4.2 The Specialist Advisors considered the main risks of the procedure to be death, perforation of the heart, cardiac tamponade, cardiac or pulmonary artery perforation/rupture, arrhythmias, infection and multiple organ failure.

2.5 Other comments

- 2.5.1 In making its recommendations, the Advisory Committee was influenced by the specialist advice that the procedure is established treatment for severely ill neonates who may otherwise die.

Andrew Dillon
Chief Executive
October 2004

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 radiofrequency valvotomy in pulmonary atresia', March 2003.

Information for patients

NICE has produced information on this procedure for patients and carers. 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 2012: 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](#).