NICE guidance

Radiofrequency valvotomy for pulmonary atresia

Interventional procedures guidance
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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.

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 National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients into 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 out of 12) and 93% (14 out of 15). The proportion of patients with establishment of a biventricular circulation was reported in four studies. In the comparative study, 63% (12 out of 19) of patients had a biventricular circulation established after radiofrequency valvotomy, compared with 50% (7 out of 14) after surgical valvotomy. In the other three studies, a biventricular circulation was established in between 42% (5 out of 12) and 53% (16 out of 30) of patients. For more details, see the overview.

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 out of 19), compared with 29% (4 out of 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 out of 30) and 33% (4 out of 12) of patients, and perforation of the right ventricular outflow tract in 17% (3 out of 18) of patients. For more details, see the overview.

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.

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.