NICE guidance

Endovascular atrial septostomy

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg86

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 endovascular atrial septostomy 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 Endovascular atrial septostomy should be undertaken only by specialist paediatric cardiology teams.

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 This procedure is undertaken to relieve the symptoms of cyanotic congenital heart disease by improving the flow of oxygenated blood to the systemic circulation. There are several types of cyanotic congenital heart disease for which this procedure is indicated. Among these is transposition of the great arteries, an uncommon congenital cardiac anomaly in which the aorta arises from the right ventricle and the pulmonary trunk arises from the left ventricle. This results in two separate circuits of blood flow, in which highly oxygenated blood recycles through the lungs, while oxygen-depleted blood recycles around the body. As a result, the baby develops a blue colour (cyanosis) shortly after birth. The baby can survive for a few days because the foramen ovale (a small hole in the fetal interatrial septum) allows some oxygenated blood to mix with the blood that is being recirculated around the body. However, the foramen ovale normally closes days after birth, and the only babies then likely to survive are those with a

congenital ventricular septal defect.

2.1.2 There is no reliable alternative to septostomy procedures in babies.

2.2 Outline of the procedure

2.2.1 Endovascular atrial septostomy is a procedure that is used to enlarge the foramen ovale. A catheter is passed through a large vein, usually in the groin, into the right atrium and through the foramen ovale to the left atrium. In simple balloon septostomy, a balloon at the end of the catheter is inflated and pulled back into the right atrium, so enlarging the foramen ovale. When this procedure is unsuccessful or contraindicated, static balloon atrial septostomy is used to enlarge an inter-atrial communication. The septum is cut using a catheter with a blade at its end. The balloon is then used to enlarge the opening in the septum. The procedure aims to prolong survival until definitive surgery can be performed.

2.3 Efficacy

2.3.1 No controlled studies were identified and many of the studies found were published more than 15 years ago. One of the studies reported an 'immediate haemodynamic effect' in 95% (508 out of 535) of patients. Another reported a mean increase in arterial oxygen saturation of 21%; two other studies reported increases of 21% and 16% in median systemic arterial oxygen saturation. For more details, see the overview.

2.3.2 The Specialist Advisors regarded this procedure as established practice. They also noted that the septostomy may close spontaneously, necessitating surgical septectomy.

2.4 Safety

2.4.1 Among the identified studies, mortality from the procedure ranged from 2% (2 out of 104, 3 out of 149) to 3% (3 out of 108). One study reported a minor

complication rate of 10% (26 out of 248) and a lethal complication rate of 1% (3 out of 248). For more details, see the overview.

2.4.2 The Specialist Advisors considered the main safety concerns to be death, transient arrhythmias and cardiac injuries.

2.5 Other comments

2.5.1 This procedure has become established as a life-saving measure for severely ill neonates, but clinical trial data are very limited.

2.5.2 The majority of the evidence relates to the simple balloon method.

2.5.3 The evidence on static balloon atrial septostomy is more limited.

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.