NICE guidance

Percutaneous closure of patent foramen ovale for recurrent migraine

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg370

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 should be read in conjunction with IPG371 and IPG109.

1 Guidance

1.1 Current evidence on the efficacy of percutaneous closure of patent foramen ovale (PFO) for recurrent migraine is inadequate in quality and quantity. The evidence on safety shows a small incidence of well-recognised but sometimes serious adverse events, including device embolisation and device prolapse (each reported in less than 1% of patients). Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake percutaneous closure of PFO for recurrent migraine should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and the possibility of serious complications. Clinicians should provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection for percutaneous closure of PFO for recurrent migraine should be carried out by a neurologist or other specialist in headache followed by an interventional cardiologist. Use of this procedure should be restricted to patients who are severely affected by recurrent, refractory migraine.

1.4 The procedure should be done by an interventional cardiologist and supporting team with specific training in the procedure.

1.5 The procedure should only be carried out in units where there are arrangements for emergency cardiac surgical support in the event of complications.

1.6 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and data on all patients having this procedure should be submitted.

1.7 NICE encourages further research into this procedure, which should investigate the uncertainty surrounding the aetiology and natural history of migraine in patients with PFO. NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 A patent foramen ovale (PFO) is the persistence of an opening (the foramen ovale) in the septum between the right atrium and left atrium of the heart. In the fetus, the foramen ovale allows blood to bypass the lungs, directly from the venous to the arterial side of the circulation. After birth, the foramen ovale normally closes but in approximately 25% of people, it remains either fully or partially patent throughout life. Studies evaluating PFO closure to prevent paradoxical thromboembolism noted a change in the incidence of migraine amongst patients. Any physiological effect of PFO closure in migraine treatment is not understood.

2.1.2 Current treatment for patients with recurrent migraine is aimed at either preventing or aborting episodes through medical management. Invasive treatments such as nerve blocks or physical therapies such as acupuncture are sometimes used if medical therapy has failed.

2.2 Outline of the procedure

2.2.1 Percutaneous closure of PFO for recurrent migraine is carried out with the patient under local anaesthesia and intravenous sedation, or general anaesthesia. A guidewire and delivery sheath are introduced via a small incision in the femoral vein into the heart and across the PFO. A closure device is then inserted through the opening via the delivery sheath and released, closing the PFO.

2.2.2 A range of different devices are available for this procedure.

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 Immediate closure of the PFO (confirmed with echocardiography) was reported in 99% (148 out of 150), 89% (42 out of 47), 97% (179 out of 185), 100% (76 out of 76) and 99.8% (823 out of 825) of patients in studies across a range of indications.

2.3.2 A randomised controlled trial (RCT) of 147 patients treated either by the procedure (n=74) or a sham procedure (n=73) reported that 3 patients in each group had experienced no further migraines at 6-month follow-up. The study reported no significant difference in the reduction in median MIDAS score (a measure of migraine-related disability on a scale of 0 to 21+; higher score indicates more severe disability) between the procedure and sham groups (from 36 to 17 versus 34 to 18 respectively), or mean migraine headache days (from 26 to 19 versus 30 to 21 days respectively) over 6 months.

2.3.3 A non-randomised comparative study of 86 patients reported a significant reduction in mean MIDAS score in the 40 patients treated by the procedure and the 46 patients treated by medical therapy at a mean follow-up of 29.2 months (from 35.8 to 8.3, $p<0.003$ versus 22.6 to 19.1, $p=0.059$ respectively; significance of between-group difference not stated).

2.3.4 The Specialist Advisers listed key efficacy outcomes as evidence of complete closure, and frequency and severity of migraine.

2.4 Safety

2.4.1 The following safety data were obtained from studies of PFO closure for a range of indications because:

- safety data are likely to be similar for the various indications
- the larger numbers of patients provide more robust evidence on safety than those from studies specifically relating to migraine.

2.4.2 Cardiac tamponade requiring surgery was reported in 2 patients in a non-randomised comparative study of 280 patients: 1 occurred 5 weeks after the procedure because of left atrial laceration.

2.4.3 Late perforation of the aortic root by the device requiring pericardiocentesis and emergency cardiothoracic surgery occurred in 1 patient in a case report.

2.4.4 Device embolisation was reported in 0.6% (5 out of 825) and 1% (2 out of 167) of patients treated by the procedure in a case series of 825 patients and a non-randomised comparative study of 280 patients respectively (device removed percutaneously in the first study but no further details given for the second).

2.4.5 Post- or peri-procedural arrhythmia was reported in 17% (8 out of 47) and 10% (5 out of 48) of patients in non-randomised comparative studies of 121 and 92 patients respectively.

2.4.6 The Specialist Advisers considered an additional theoretical adverse event to be valve dysfunction.

3 Further information

3.1 NICE has also produced interventional procedures guidance on percutaneous

closure of patent foramen ovale for the secondary prevention of recurrent paradoxical embolism in divers and percutaneous closure of patent foramen ovale to prevent recurrent cerebral embolic events.

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.