NICE guidance

Percutaneous closure of patent foramen ovale for recurrent migraine

Interventional procedures guidance
Published: 15 December 2010

www.nice.org.uk/guidance/ipg370

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 patients ('Understanding NICE guidance') 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 Data on all patients having this procedure should be submitted to the UK Central Cardiac Audit Database.

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 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.

> 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 migraine- and embolism-related overviews.

2.3 Efficacy

2.3.1 Immediate closure of the PFO (confirmed with echocardiography) was reported in 99% (148/150), 89% (42/47), 97% (179/185), 100% (76/76) and 99.8% (823/825) 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 0–21+; higher score indicates more severe disability) between the procedure and sham groups (from 36 to 17 vs 34 to 18 respectively), or mean migraine headache days (from 26 to 19 vs 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, $p < 0.003$ vs 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% (5/825) and 1% (2/167) 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% (8/47) and 10% (5/48) 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 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). 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.

NICE has also written guidance on this procedure for:

- IPG371 Percutaneous closure of patent foramen ovale for the secondary prevention of recurrent paradoxical embolism in divers

- IPG109 Percutaneous closure of the patent foramen ovale for the prevention of cerebral embolic stroke

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.

Accreditation