

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

1 Guidance

- 1.1 Current evidence suggests that there are no major safety concerns and that percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke is efficacious in achieving closure of the foramen. However, its efficacy in preventing future strokes has not been clearly shown.
- 1.2 Clinicians wishing to undertake percutaneous closure of patent foramen ovale should take the following actions.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended.
 - Audit and review clinical outcomes of all patients having percutaneous closure of patent foramen ovale.
- 1.3 The procedure should be performed in units where there are arrangements for cardiac surgical support in the event of complications.
- 1.4 The Department of Health runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients onto this database (www.ccad.org.uk).
- 1.5 Further research will be useful and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 A patent foramen ovale is the persistence of a hole (the foramen ovale) in the wall (septum) between the right atrium and left atrium of the

heart. Before birth, the fetal heart has a structural communication, called the foramen ovale, between the two atria. This normal passage allows blood to bypass the lungs and be directed straight to the left side of the circulation, supplying blood to the brain and body before it returns to the placenta. The foramen ovale usually closes spontaneously after birth; however, in as many as one out of four people, the foramen ovale does not close completely and remains patent throughout life.

- 2.1.2 In most people, the persistence of a patent foramen ovale does not cause any complications. However, there have been a number of studies suggesting an association between patent foramen ovale and cerebral embolic stroke. It is believed that a thrombus from the venous circulation can pass into the arteries through the patent foramen and so causing an embolism in the brain. The presence of atrial septal aneurysms may increase the risk of embolism.
- 2.1.3 For patients with a patent foramen ovale as an isolated finding, no special treatment is given. Treatment is aimed at preventing recurrent thromboembolic events such as strokes. Treatment options include medical treatment with anticoagulation therapy, surgical closure (open heart surgery), and percutaneous closure of the patent foramen ovale.

2.2 Outline of the procedure

- 2.2.1 The procedure may be done using general anaesthesia or intravenous sedation with local anaesthesia. A small incision is made in the groin and a guidewire and delivery sheath are introduced via the femoral vein into the heart and across the patent foramen ovale. A closure device is then inserted through the defect via the delivery sheath and released, closing the foramen ovale.

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

2.2.2 Echocardiography and fluoroscopic guidance are used to determine the size and position of the defect and to place the occluder device.

2.3 Efficacy

2.3.1 The evidence for this procedure is based on case series assessing the secondary prevention of thromboembolic events (such as transient ischaemic attacks, stroke or peripheral embolism) following percutaneous closure of the patent foramen ovale. In a systematic review of ten studies of percutaneous closure using a variety of devices, reported rates of recurrent events ranged from 0% to 4.9% at 1 year. In one study of 307 patients with a follow-up of 24 months, 5 patients (1.6%) experienced recurrent events. This converted to an annual recurrence risk of 0.6% for transient ischaemic attack, 0% for stroke and 0.2% for peripheral embolism. In a second study of 457 patients with a mean follow-up of 19.6 months, the incidence of recurrent embolic events following the procedure was 1.9%, compared with 3.2% before percutaneous closure. For more details, refer to the Sources of evidence.

2.3.2 Although there are a number of large case series, follow-up in these does not go beyond a mean of 24 months and, in many, patient characteristics and devices differed, making comparisons difficult. For more details, refer to the Sources of evidence.

2.3.3 The Specialist Advisors commented that this procedure had become established, but that efficacy uncertainties remain in certain clinical situations. There is also some uncertainty about the long-term effects of the procedure.

2.4 Safety

2.4.1 Complication rates varied among the studies. In the systematic review of ten studies including 1355 patients, the rate of major and minor complications was 1.5% and 7.9%, respectively. Major complications included death, haemorrhage requiring blood transfusion, cardiac tamponade, the need for surgical intervention, and pulmonary embolus. Minor complications included bleeding, arrhythmia, device arm fracture, device embolisation, air embolism and arteriovenous fistula formation.

In another study of 100 patients, 9 (9%) were observed to have complications following the procedure, including two patients with device embolisation and one patient with arteriovenous fistula and cardiac tamponade. The use of different devices in reported series makes it difficult to assess complication rates attributable to each. For more details, refer to the Sources of evidence.

2.4.2 The Specialist Advisors noted that serious adverse events were uncommon: these included device embolisation, air embolism, thromboembolism from the device, and pericardial effusion. Minor side effects included migraine, minor arrhythmias and local bruising at the catheter puncture site.

2.5 Other comments

2.5.1 These recommendations apply only to the use of the procedure to treat patients with a history of previous cerebral embolic events. There may be other indications, but the evidence for these has not been reviewed.

Andrew Dillon
Chief Executive
January 2005

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from www.nice.org.uk/IPG109publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedures overview of percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke, January 2004.

Available from: www.nice.org.uk/IP237overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0795. *Information for the public* can be obtained by quoting reference number N0796 for the English version and N0797 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at www.nice.org.uk/IPG109distributionlist

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National Institute for Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA, website: www.nice.org.uk

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