

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

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg371

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 IPG370 and IPG109.

1 Guidance

- 1.1 Current evidence on the efficacy of percutaneous closure of patent foramen ovale (PFO) for the secondary prevention of recurrent paradoxical embolism in divers is inadequate in quality and quantity, and the evidence on safety shows that there is a possibility of serious complications. 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 the secondary prevention of recurrent paradoxical embolism in divers should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and the possibility of complications, and that they understand alternative options which may include modifying their diving practice to reduce the risk of gas bubble formation. Clinicians should provide patients with clear written information. In addition, the use of NICE's information for the public is recommended.
- 1.3 Patient selection for this procedure should only be carried out by clinicians with

- specific expertise in decompression sickness, in liaison with an interventional cardiologist.
- 1.4 The procedure should only be carried out in units where there are arrangements for emergency cardiac surgical support in the event of complications.
- 1.5 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.
- 1.6 NICE encourages further research into this procedure. Studies should document the recurrence of neurological decompression sickness in patients treated by this procedure compared with recurrence among those in whom the PFO is not closed. Outcomes should include details of the depth and duration profile of dives undertaken.

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. Usually a PFO causes no symptoms, although a 'shunt' or movement of blood from the right to left side of the heart may be demonstrable using specialist tests.
- 2.1.2 During a dive, inert gas (usually nitrogen or helium) accumulates within blood and tissues. On ascent, provided that appropriate decompression schedules are followed, excess gas is excreted via the lungs. However, during deep or long duration dives, venous gas emboli (VGE) often form, and in the presence of a PFO, VGE may become arterialised, resulting in neurological symptoms that may resemble a stroke (termed 'neurological decompression illness').

- 2.1.3 There is currently no consensus on the optimal management of divers with a PFO and a history of neurological decompression sickness.

2.2 Outline of the procedure

- 2.2.1 Percutaneous closure of PFO for the secondary prevention of recurrent paradoxical embolism in divers 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 case series of 29 divers treated by percutaneous closure of PFO for neurological decompression sickness reported that 79% (23 out of 29) had returned to diving (3 had only recently had closure and 3 had not returned to diving for other unrelated reasons). In the 23 who returned to diving, no recurrences of decompression sickness were reported.
- 2.3.3 The Specialist Advisers stated that a key efficacy outcome is adequate closure of the PFO assessed by a suitable technique (such as bubble contrast echocardiography).

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 divers.
- 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.

2.5 Other comments

- 2.5.1 The Committee noted that an episode of neurological decompression sickness might influence subsequent diving activity whether a PFO is present or not. This could confound evaluation of the effect of PFO closure.

3 Further information

- 3.1 NICE has also produced [interventional procedures guidance on percutaneous closure of patent foramen ovale \(PFO\) for recurrent migraine](#) and [percutaneous closure of PFO 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](#).