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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating recurrent neurological decompression sickness in divers by closing a patent foramen ovale using a device inserted via the groin

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how closing a patent foramen ovale (PFO) using a device inserted via the groin can be used in the NHS to treat recurrent neurological decompression sickness in divers. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because there is not a lot of information yet about how the procedure works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe neurological decompression sickness or the procedure in detail – a member of your healthcare team should also give you full

information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 6.

What has NICE said?

There is not much good evidence about how well this procedure works. The evidence on safety shows that there is a possibility of serious complications. If a doctor wants to close a PFO using a device inserted via the groin to treat recurrent neurological decompression sickness in divers, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks of the procedure. This should include discussing alternative options, which may include changing their diving practice to reduce risks, and explaining the possibility of complications with this procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

A team including healthcare professionals with experience of decompression sickness along with a cardiologist should decide which patients should have this procedure.

The procedure should only be carried out in units with access to emergency heart surgery in case of complications.

NICE has encouraged further research into this procedure.

Treating recurrent neurological decompression sickness in divers by closing a PFO using a device inserted via the groin

The medical name for this procedure is 'percutaneous closure of patent foramen ovale for the secondary prevention of recurrent paradoxical embolism in divers'.

This procedure may not be the only possible means of treating recurrent neurological decompression sickness in divers. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The procedure is not described in detail here – please talk to your specialist for a full description.

The foramen ovale is a small hole between the two upper chambers of the heart that is present during development in the womb. It normally closes after birth but in some people it remains open (patent). This usually causes no symptoms, but tests may show abnormal movement of blood between the normally separate heart chambers.

If a diver ascends too quickly, gas which has dissolved in the blood and tissues can form bubbles in the circulation of the veins. If these bubbles cross the PFO into the arteries, it may cause brain damage with symptoms resembling a stroke known as neurological decompression sickness.

The procedure is performed using a local anaesthetic and sedation, or general anaesthesia. A guidewire and catheter are inserted through a vein in the groin into the heart and through the PFO using imaging guidance. A device is then inserted via the catheter, closing the hole.

What does this mean for me?

NICE has decided that there are uncertainties about how well this procedure works, and there is a risk of serious complications. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision. NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 14 studies on this procedure. Some of the studies looked at patients who had the procedure for reasons other than preventing neurological decompression sickness in divers.

How well does the procedure work?

In 5 studies including a total of 1283 patients who had the procedure for a number of different conditions, the PFO was immediately closed in 1268 patients (99%).

In a study of 29 divers treated by the procedure for neurological decompression sickness, 23 had returned to diving and experienced no more decompression sickness, and 6 were not diving (3 as they had only recently had the procedure, and 3 for reasons unrelated to the procedure).

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that a key indicator of success is adequate closure of the PFO assessed by a suitable heart scan.

Risks and possible problems

In a study of 280 patients, a collection of blood around the heart which interfered with its pumping (cardiac tamponade) was reported in 2 patients who both required further surgery.

The device used to close the PFO caused a tear in a large blood vessel of the heart requiring emergency surgery in 1 patient. The device fell out and entered the circulation in 7 of a total of 992 patients in 2 studies (the device was removed from patients in 1 of these studies; no further details were given for the second).

Abnormal heart rhythm during or after surgery was reported in 13 of 95 patients in 2 studies of a total of 213 patients.

As well as looking at these studies, NICE also asked expert advisers for their views who said that in theory, a problem with the heart valves could occur.

More information about PFO

Your local patient advice and liaison service (usually known as PALS) may be able to give you further information and support. For details of all NICE guidance on PFO, visit our website at www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. This guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'percutaneous closure of patent foramen ovale for the secondary prevention of recurrent paradoxical embolism in divers'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG243

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2387). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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