

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

**Understanding NICE guidance –
information for people considering the
procedure, and for the public**

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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0797.

A version in English only is also available, quote reference N0796.

The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0795.

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke. It is not a complete description of what is involved in the procedure – the patient’s healthcare team should describe it in detail.

NICE has looked at whether percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke is safe enough and works well enough for it to be used routinely.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of percutaneous closure of patent foramen ovale and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE’s work on ‘interventional procedures’ (see ‘Further information’ on page 12).

About percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke

The foramen ovale is a hole in the wall that divides the two sides of the heart. It's present in the heart of a developing fetus, but normally it closes up soon after the baby is born. If it doesn't close up, it's known as a patent foramen ovale.

In most people, a patent foramen ovale doesn't cause any problems. But some studies have shown there could be a link between having a patent foramen ovale and having a stroke. A stroke happens when a part of the brain becomes starved of blood because the blood supply is blocked. It's possible that a blood clot circulating round the body could pass to the brain more easily, and cause this type of blockage, if the person has a patent foramen ovale. For this reason, if a person has had some problems with blood clots (perhaps they've already had a stroke), and they have a patent foramen ovale, their doctor may offer them some treatment. The options include medicines that make the blood less likely to clot and surgery to close up the hole.

Percutaneous closure of a patent foramen ovale is a way of closing the foramen ovale without opening up the chest. A small cut or incision is made in the groin area. A narrow tube called a

catheter is passed into the incision and into a blood vessel. The catheter contains a wire with a special closing device attached, and this is passed up through the blood vessels to the heart. The closing device is moved into position in the foramen ovale and then released so that it fits into the hole and closes it. The wire is removed. During the procedure, ultrasound and X-rays are used to check the size and position of the hole, and to check the closing device is in the right place.

The standard operation to close a patent foramen ovale involves opening up the chest to get to the heart.

How well it works

What the studies said

Studies have looked at how many people who had the procedure went on to have more problems caused by blood clots. In one study, no one had any more problems with blood clots in the first year after having the procedure. But in another study, 5% had more problems in the first year (5% is the same as saying 5 people in 100, which is the same as 1 in 20).

In another study, 5 out of 307 people had more problems in the 2 years following surgery (as a percentage this is under 2%).

A study involving 457 people compared the numbers of problems people had before they had the procedure with the number they had after the foramen ovale was closed (this information was taken an average of 20 months after the surgery). After the procedure, the number of problems per year was roughly half what it was before patients had the procedure (1.9% of patients had a problem in 1 year after the procedure compared with 3.2% per year before the hole was closed).

NICE has commented that it's difficult to compare the results from different studies because they involved different groups of patients and different closing devices were used. Also, most studies stopped after a maximum of around 2 years, so little is known about what happens after this time.

What the experts said

The experts said that although many surgeons use this procedure, it's still not clear how well it works in certain patients. They also said that the long-term effects weren't completely clear.

Risks and possible problems

What the studies said

One report combined the results from ten studies. It showed that 1.5% of people had serious problems and nearly 8% had minor problems caused by the surgery.

The serious problems included: bleeding (haemorrhage) that meant the person needed a blood transfusion; a condition called cardiac tamponade, where fluid builds up around the heart and compresses it so that it can't work properly; blood clots on the lungs; and problems that meant the person needed more surgery. Some patients died.

The minor complications included: bleeding; effects on the heartbeat; problems with the device breaking, or with clots forming on the device; air bubbles in the blood; and the formation of fistulas between nearby blood vessels (fistulas are abnormal connections that can form).

In another report, 9 out of 100 patients had problems after the surgery. These included two people with blood clots on the device, and one person with connections between blood vessels and cardiac tamponade.

What the experts said

The experts said that serious problems after the surgery were rare. But there was a possibility of clots forming around the device, and then possibly breaking off and getting into the general circulation. Air bubbles in the blood were another potential problem, and fluid could build up around the heart causing compression (cardiac tamponade).

According to the experts, the potential minor problems were migraine headache, minor problems with the heartbeat and bruising around the incision in the groin.

What has NICE decided?

NICE has decided that if a doctor wants to carry out percutaneous closure of patent foramen ovale, he or she should make sure that the patient understands what is involved and that there are still uncertainties about how much protection the person has from future strokes. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

Percutaneous closure of patent foramen ovale should be carried out in units that can provide emergency heart surgery if there's a problem.

NICE has encouraged doctors to send information about every patient who has the procedure and what happens to them afterwards to a central store of information. This is so the safety of the procedure and how well it works can be checked over time. The central store of information is called the UK Central Cardiac Audit Database, and it is being run by the Department of Health. NICE may look at the procedure again if more information is published.

Other comments from NICE

NICE has stressed that its recommendations on this procedure apply only to people who have already had a stroke caused by a clot. The procedure may be suitable for other groups, but NICE has not looked at the evidence on safety or how well the procedure works in these groups.

What the decision means for you

Your doctor may have offered you percutaneous closure of patent foramen ovale. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits of percutaneous closure of patent foramen ovale which you need to understand before you agree to it. Your doctor should discuss these with you.

NICE has also encouraged doctors to collect some details about every patient who has this procedure in England and Wales. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to go ahead with the percutaneous closure, you may be asked to agree to your details being entered into an electronic database for this purpose. The doctor looking after you will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you will still be able to have the procedure.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on percutaneous closure of patent foramen ovale for the prevention of cerebral embolic stroke is on the NICE website (www.nice.org.uk/IPG109guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0795. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on heart problems, a good starting point is NHS Direct, telephone 0845 46 47, or NHS Direct Online (www.nhsdirect.nhs.uk).

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