

Percutaneous closure of patent foramen ovale to prevent recurrent cerebral embolic events

Information for the public

Published: 1 December 2013

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What has NICE said?

This procedure is safe enough and works well enough for use in the NHS. Some serious complications are possible, but these are rare.

The procedure should only be carried out in hospitals that can deal quickly with complications needing heart surgery.

What does this mean for me?

Your doctor should fully explain what is involved in having this procedure and discuss the possible benefits and risks with you. You should also be told how to find more information about the procedure. All of this should happen before you decide whether you want to

have this procedure or not.

If you decide to have the procedure your health professional might ask you if your details can be included in a database.

Other comments from NICE

NICE said that the procedure is at least as effective as drug treatment for preventing stroke and transient ischaemic attack, and may be even more effective. Patients should be able to decide if they want to have this procedure based on the risks and benefits compared with drug treatment.

NICE also said that it's not certain if it's useful to use drugs that reduce the risk of blood clots forming after the procedure, or for how long.

The condition

The foramen ovale is a hole in the wall that divides the 2 sides of the heart. It is present in the heart of a developing fetus, but normally it closes up soon after birth. If it doesn't close up, it's known as a patent foramen ovale. There is a small risk that blood clots from the veins might pass through this opening and travel to the brain, causing a stroke or transient ischaemic attack.

To reduce the risk of stroke and transient ischaemic attack, patients are often given drugs such as warfarin or aspirin, which reduce blood clotting.

NICE has looked at using percutaneous closure of the patent foramen ovale as another treatment option in people who have had a stroke or a transient ischaemic attack. Click on to the next page to find out more.

The procedure

The aim of the procedure is to close the hole in the heart, and so prevent clots from passing through it to the brain.

The patient is given a sedative and a local anaesthetic, or a general anaesthetic. A

puncture is made in a vein in the groin, and a small device is passed into the vein, up through the body and into the heart. The doctor usually uses an ultrasound picture to help guide the device into place and close the hole in the heart.

Benefits and risks

When NICE looked at the evidence, it decided that there was enough evidence on how well it worked and how safe it was to be used in the NHS. The 12 studies that NICE looked at involved a total of 18,560 patients.

Generally, they showed that, compared with patients who had drug therapy, patients who had percutaneous closure of the patent foramen ovale had fewer strokes, transient ischaemic attacks and other related problems, during the 4 years after the procedure.

The hole in the heart was still successfully closed in at least three-quarters of patients 1–2 years after the procedure.

The studies showed that the risks of percutaneous patent foramen ovale closure included:

- fluid around the heart, which can sometimes be life threatening
- damage to the heart during the procedure
- the device being positioned wrongly
- bleeding
- air getting into the bloodstream
- an infection in the heart
- blood clots elsewhere in the body (heart, legs and lungs)
- an abnormal hole forming between an artery and one of the upper chambers of the heart
- development of an abnormal heart rhythm (although this was temporary in most patients).

In general, the risk of having a serious reaction or complication with the procedure was similar as with having medical treatment.

A small number of people died as a result of the procedure (8 in around 8000 people).

NICE was also told about some other possible risks: the device wearing away the tissue around it, and temporary worsening of migraines.

If you want to know more about the studies see the [guidance](#). Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- 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?

Medical terms explained

Percutaneous

Through a small hole in the skin.

Stroke

A serious medical condition that occurs when the blood supply to part of the brain is cut off.

Transient ischaemic attack

A temporary disruption in the blood supply to part of the brain. Sometimes called a 'mini stroke'.

About this information

NICE [interventional procedures guidance](#) advises the NHS on the safety of a procedure and how well it works. This information applies to people who use the NHS in England, Wales, Scotland and Northern Ireland.

ISBN: 978-1-4731-7919-6

Accreditation

