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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Blocking the left atrial appendage of the heart to prevent stroke in non-valvular atrial fibrillation, using a catheter

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 treating non-valvular atrial fibrillation using a catheter to block the left atrial appendage (LAA) of the heart in the prevention of stroke can be used in the NHS. 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 the procedure is quite new. This means that there is not a lot of information yet about how well it 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 atrial fibrillation 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 8.

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What has NICE said?

This procedure can be offered routinely as a treatment option for people with non-valvular atrial fibrillation provided that doctors are sure that:

- the patient understands what is involved (particularly that the procedure can cause life-threatening complications in a small number of people) and agrees to the treatment, and
- the results of the procedure are monitored.

A team of healthcare professionals who are experienced in the management of atrial fibrillation and associated stroke should decide which patients should have this procedure. The team should include a cardiologist and other appropriate specialists. Patients should be considered for alternative treatments and be given relevant information.

This is a complicated procedure that should only be carried out by doctors with specific training and relevant experience, and in hospitals with facilities for emergency heart surgery.

NICE is asking doctors to send information about device-related complications to the Medicines and Healthcare products Regulatory Agency (MHRA) so that the safety of the procedure can be checked over time.

Other comments from NICE

NICE noted the use of different devices to block the LAA and that this may affect clinical outcomes. Also, new drugs to reduce the risk of blood clot complications associated with atrial fibrillation are being developed.

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This procedure may not be the only possible treatment for atrial fibrillation. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism'. The procedure is not described in detail here – please talk to your specialist for a full description.

Atrial fibrillation is the irregular and rapid beating of the upper 2 chambers of the heart (atria). It can cause symptoms such as palpitations, dizziness and breathlessness. People with atrial fibrillation have an increased risk of blood clots forming in the heart. These blood clots can form in the LAA (a small sac off the left atrium). Clots may break off from the LAA, travel to any part of the circulation and block a local blood vessel (thromboembolism).

Blood-thinning medicines are often given to reduce the risk of 'thromboembolic' stroke. Surgery to insert a special device that blocks the LAA may be another treatment option.

In this procedure the patient is usually under general anaesthesia. A thin tube (catheter) is inserted into a vein in the top of the leg (the femoral vein) and guided into the left atrium. A special device is moved up the catheter into place at the mouth of the LAA. This device stops any blood clots getting into the bloodstream. An imaging technique called transoesophageal echocardiography is used to confirm how well the device is working and its position in the LAA.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks this procedure is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve? What are the benefits?
- How good are my chances of getting those benefits?
- 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 operation?
- What happens if something goes wrong?
- What may happen if I don’t have the procedure?

Summary of possible benefits and risks

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 9 studies on this procedure.

How well does the procedure work?

In a study of 707 patients, strokes (of any type) occurred at rates of 2.3 and 3.2 per 100 patient-years in patients who received warfarin and those treated by the procedure respectively. Of the 463 patients selected for the procedure, the LAA was successfully blocked in 408.

A study of 111 patients reported stroke in 2 patients (after 173 and 215 days respectively). Transoesophageal echocardiography at 1 and 6 months showed no problems with the device in either patient. Two patients had a transient ischaemic attack (a ‘mini’ stroke).

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 how well the procedure works should be measured by key outcomes such as freedom from stroke, and other brain and heart complications.

Risks and possible problems

Blood collecting in the sac around the heart, which needed emergency open heart surgery within 4 hours of the procedure, was reported in 1 of 111 patients in 1 study. The patient later developed deep vein thrombosis and died 27 days after the procedure.

In a study of 73 patients, 1 needed open heart surgery due to a loose device. One patient died following cardiac arrest 30 minutes after the procedure. The reported cause was device embolisation (the device dislodging and entering the circulation).

In the study of 707 patients, device embolisation was reported in 3 of the 463 patients who had the procedure: 1 was detected during the procedure and 2 were detected on imaging after 45 days.

In the same study, pericardial effusion (blood escaping into the sac around the heart) needed draining in 22 patients. Pericardial effusion not needing draining was reported in 8 patients; and procedure-related irregular heartbeat was reported in 1 patient who had the procedure.

Another study reported surgical removal of a fractured delivery wire in 1 out of 75 patients. In the study of 111 patients, 1 patient had damage to the femoral artery and another had a blood clot in the left atrium during the procedure, preventing device implantation.

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. They said that other potential complications are emergency surgery to retrieve an incorrectly placed device, and a persistent ‘hole in the heart’.

More information about atrial fibrillation

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on atrial fibrillation, 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 occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG222

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2206). 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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