

Understanding NICE guidance

Information for people who use NHS services

Treatment of atrial fibrillation using high-intensity focused ultrasound in association with other cardiac surgery

NICE 'interventional procedure guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how **high-intensity focused ultrasound** (or HIFU, for short) can be used to treat people with atrial fibrillation in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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.

Interventional procedure guidance makes recommendations on the safety of a procedure and how well it works. 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.



What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use HIFU, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the 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 after the procedure.

Patient selection and follow-up should be carried out by a multidisciplinary team, and the cardiac surgeons using the procedure should have specialist training.

More information on the safety of HIFU and how well it works will be helpful. NICE may look at this procedure again if more information becomes available.

Other comments from NICE

The technique and the settings used for HIFU can vary. Also, it may be difficult for surgeons to know when they have produced enough scarring across the heart tissue.

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.

High-intensity focused ultrasound

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

Atrial fibrillation is the irregular and rapid beating of the upper two chambers of the heart (the atria). Symptoms, if present, can include palpitations, dizziness, breathlessness and fatigue.

Treatments include medicine to control the heart rhythm and rate, or to stop blood clots forming, and electrical cardioversion to reset the heart's rhythm. Heat (radiofrequency, microwave), cold (cryotherapy), laser or ultrasound can be used to stop abnormal electrical impulses in the heart.

Surgery to isolate and stop the abnormal electrical impulses is another option. It is usually done at the same time as open heart surgery to repair other problems.

In HIFU an ultrasound device is placed outside the left atrium of the beating heart. This sends a focused beam of ultrasound energy across the wall of the heart. The heart absorbs the energy, causing the temperature to rise. The heat destroys the chosen area of cardiac tissue and disrupts the transmission of the abnormal electrical impulses.

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 one study on this procedure.

How well does the procedure work?

The evidence about how well the procedure works is based on one study of 103 patients. This study found that 85% (80/94) of patients who had the procedure did not have atrial fibrillation at 6 months follow-up. This result was found in 80% (for example, 80 people in 100) of patients who had permanent atrial fibrillation and in all the patients who had intermittent atrial fibrillation.

The expert advisers said that the key issues on how well the procedure works should include normalisation of heart rhythm, persistence or recurrence of atrial fibrillation, and quality of life.

Risks and possible problems

This procedure is done during open heart surgery; therefore it is difficult to know which problems are specifically related to HIFU ablation.

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

What does this mean for me?

If your doctor has offered you HIFU for atrial fibrillation, he or she should tell you that NICE has decided that the benefits and risks are uncertain. 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.

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 operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Evidence on safety was based on the same study of 103 patients. Early (up to 30 days after the operation) and late (more than 30 days after the operation) problems were reported, but none was considered to be related to the device or the procedure. Early problems included: bleeding that required more surgery to investigate, in 6% (6/103); stroke in 3% (3/103); serious deep wound infection in 1% (1/103); complete heart block (affects electrical impulses passing through the heart) in 4% (4/103) and sinus node dysfunction in 1% (1/103) of patients. Patients with these last two problems needed to have permanent pacemakers. Late complications included: multiple organ failure in 1% (1/103) of patients; delayed cardiac tamponade (compression of the heart) in 1% (1/103); transient ischaemic attack (like stroke but lasting less than 24 hours) in 1% (1/103) and sinus node dysfunction requiring a permanent pacemaker in 3% (3/103) of patients.

In this study 6% of people (6/103) had died at 6 months follow-up: 4% (4/103) were early deaths and 2% (2/103) were late non-cardiac deaths.

The expert advisers noted that possible problems included excess damage to the heart muscle, damage to nearby structures and an increase in surgical risk due to prolonged bypass time (if bypass is required).

More information about atrial fibrillation

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

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. 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/about/guidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG184

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1083).