

Treatment of atrial fibrillation using heat energy delivered through keyhole surgery to the heart

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 heat energy delivered through keyhole surgery to the heart can be used in the NHS to treat people with atrial fibrillation. 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 7.



What has NICE said?

There is some evidence that this procedure works in the short term and is safe, but the studies only involved small numbers of patients and the measures used to judge success varied. NICE has decided that if a doctor wants to use this procedure, 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 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.

Patients should be selected by teams of specialist doctors including a cardiologist and a cardiac surgeon, both with training and experience in the use of surgery to treat heart rhythm disorders. The procedure should only be carried out by surgeons with special training and experience in keyhole surgery through the chest wall and also in using heat energy to destroy tissue. NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at the NHS Information Centre for Health and Social Care, so that the safety of the procedure and how well it works can be checked over time. NICE has encouraged further research and may review the procedure if more evidence becomes available.

Treatment of atrial fibrillation using heat energy delivered through keyhole surgery

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 procedure is not described in detail here – please talk to your specialist for a full description. The medical name for this procedure is ‘Thoracoscopic epicardial radiofrequency ablation for atrial fibrillation’. ‘Thoracoscopic’ means keyhole surgery through the chest wall. ‘Epicardial’ refers to the outer surface of the heart and ‘radiofrequency ablation’ means using heat energy to destroy tissue.

Atrial fibrillation is a condition that affects the heart, causing an irregular pulse. It occurs when the electrical impulses controlling the heartbeat become disorganised, so that the heart beats irregularly and too fast. When this happens, the heart cannot efficiently pump blood around the body. Atrial fibrillation increases the risk of blood clots, stroke and death. Treatments include medicine to control the heart rhythm and rate, or to stop blood clots forming. Surgical procedures can be offered when medicine either does not work or cannot be tolerated. There are two types of atrial fibrillation: paroxysmal, in which the bouts of abnormal heart rhythm last for a short time and then end, and persistent, in which the abnormal rhythm continues indefinitely. This procedure is carried out with the patient under general anaesthesia. Small incisions are made in the chest wall, through which a camera and instruments are inserted. The right lung is deflated to gain access. Selected areas of the heart are destroyed using an instrument that delivers heat energy. The aim of the procedure is to prevent the abnormal electrical activity.

What does this mean for me?

If your doctor has offered you this procedure, 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.

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 operation?
- 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 seven studies on this procedure.

How well does the procedure work?

In four studies involving a total of 138 patients, 81–93% had a normal heart rhythm when they were reviewed 6–18 months after the procedure. The largest study involved 70 patients; 42 had paroxysmal atrial fibrillation and 28 had persistent atrial fibrillation. By 3 months after the procedure, 43% of patients with paroxysmal atrial fibrillation and 61% of patients with persistent atrial fibrillation still needed their medication. By 12 months after the procedure, things had improved so that 14% of patients with paroxysmal atrial fibrillation and 38% of patients with persistent atrial fibrillation still needed their medication.

In a study of 27 patients, 23 patients' progress was monitored for 3 months after the procedure. Of the 23 patients, 15 no longer needed their medication 3 months after the procedure. In another study of 26 patients, 21 had a normal heart rhythm 6 months after the procedure and of these, 12 patients no longer needed their medication. Two other studies, involving 42 patients, followed the patients' progress for longer (up to 18 months) and showed that 88% of patients were able to stop their medication.

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 aims are to reduce the need for medication and reduce symptoms of atrial fibrillation. One adviser stated that the long-term effects of the procedure are not certain.



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Risks and possible problems

The study of 70 patients reported that 2 patients needed further surgery because of complications. One patient needed a procedure to repair an abnormal passageway (fistula) which had developed between the heart and the oesophagus (gullet) and another patient needed a procedure to widen a narrowed artery. In the study of 27 patients, 1 had pneumothorax (air in the chest cavity, causing the lung to collapse) and another had a suspected inflammation of the tissues surrounding the heart. In the study of 26 patients, 1 had a build up of fluid in the tissues of the lungs. 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 possible complications are: injury to the heart, bleeding, blockage or narrowing of the heart's arteries, and an increased risk of abnormal heart rhythm after the procedure.



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.

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 'Thoracoscopic epicardial radiofrequency ablation for atrial fibrillation'. This leaflet and the full guidance aimed at healthcare professionals are available at

www.nice.org.uk/HTG180

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1782).

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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National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

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