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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating atrial fibrillation using heat energy delivered to the outside of the heart through a thin tube

NICE 'interventional procedures 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 to the outside of the heart by a thin, flexible tube (called a catheter) 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).

Interventional procedures 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 6.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. 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 and about 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. There should also be special arrangements for monitoring what happens to the patient after the procedure. NICE has said that a team of specialist doctors experienced in treating heart rhythm disorders should decide who has this procedure. It should include experts in the heart's electrical activity and in removing abnormal tissue. The procedure should only be carried out by cardiologists who have training in the heart's electrical activity, operating on the heart, and removing abnormal tissue. It should only be carried out in units with emergency cardiac surgery support.

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 UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor) so that the safety of the procedure and how well it works can be checked over time. NICE has encouraged further research into the procedure and may review the procedure if more evidence becomes available.

Treating atrial fibrillation using heat energy delivered to the outside of the heart through a thin tube

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 (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation'. 'Epicardial' refers to the outermost membrane of the heart and 'radiofrequency ablation' means using heat energy to remove tissue. The procedure is not described in detail here – please talk to your specialist for a full description.

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. The heart cannot then efficiently pump blood around the body. Some people don't have any symptoms, but if present, symptoms can include palpitations, dizziness, breathlessness and tiredness. 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. Ablation procedures can also be successfully carried out from the inside of the heart. Surgical procedures can be offered when medicine either does not work or cannot be tolerated.

The procedure is carried out with the patient sedated or under general anaesthetic. A special thin tube is inserted through the skin and positioned next to the epicardium (the outer layer of the heart wall). The surgeon uses X-rays to make sure it is positioned properly. Heat is passed to the tip of the thin tube and used to break down the parts of the heart where the abnormal electrical impulses are. The patient is given steroids to reduce the risk of inflammation around the heart. Ablation from the inside and outside of the heart may be combined.

What does this mean for me?

If your doctor has offered you this procedure 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. 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 two studies on this procedure.

How well does the procedure work?

In one study, five patients had the procedure after another heart operation had failed. Between 2 months and 15 months after the procedure four of them no longer had atrial fibrillation, and did not need medication. The fifth patient did not have atrial fibrillation but was still taking medication 4 months after the procedure. In a different study one person who had long-lasting atrial fibrillation had no symptoms 1 month after having the procedure.

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. One adviser said that the main success factor was freedom from atrial fibrillation. Another said that it is uncertain how well the procedure works because only a few cases have been reported.

Risks and possible problems

In the study of five patients, one patient developed a collection of blood in the sac around the heart. Another patient had a very fast heart rate (known as tachycardia) during the procedure, but this was cured by delivering more heat energy to the inside and outside of the heart.

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 theoretical problems were puncturing of the heart muscle and stomach; inflammation of the membranes around the heart; perforation of the heart; damage to the coronary artery, the throat, lungs and the nerve to the diaphragm, and to blood

vessels and organs in the abdomen. One adviser said that safety of the procedure in the long term was uncertain.

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. Interventional procedures 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 (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG294

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1836).

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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