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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 a balloon catheter to freeze parts of the heart

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how people with atrial fibrillation can be treated in the NHS using a balloon catheter to freeze parts of the heart. 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 document 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 document 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 9.

What has NICE said?

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

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

Only specialists who are experts in the heart's electrical activity, and in complex procedures to treat heart problems using a catheter (interventional cardiologists), should decide which patients might benefit from the procedure and should carry it out. It should only be done in units with arrangements for emergency heart surgery in case any complications arise during treatment.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a database at the UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor) so that the safety of the procedure and/or how well it works can be checked over time.

NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) looking at how this procedure compares with other procedures for treating atrial fibrillation.

Other comments from NICE

NICE noted that this procedure is likely to be more effective in patients with paroxysmal atrial fibrillation (short bouts) than in patients with persistent (long-lasting) atrial fibrillation.

It also noted that changes (possible small strokes) have been seen on the brain scans of some patients who have had this procedure but they have no symptoms and the effect it might have on the patient is unknown.

Treating atrial fibrillation using a balloon catheter to freeze parts of the heart

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 balloon cryoablation for pulmonary vein isolation in atrial fibrillation'.

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

Atrial fibrillation is abnormal heart rhythm caused by the irregular and rapid beating of the upper two chambers of the heart (the atria). There are three types of atrial fibrillation: paroxysmal (comes and goes and usually stops within 48 hours without any treatment), persistent (lasts for longer than 7 days – less when treated) or permanent (present all the time). Electrical impulses 'trigger' the abnormal rhythm. These abnormal electrical impulses usually start where the large blood vessels carrying blood from the lungs (the pulmonary veins) enter the heart. Some people don't have any symptoms but, if they do, they include palpitations (a fluttering or pounding heartbeat), tiredness, breathlessness and chest pain.

People with atrial fibrillation have an increased risk of stroke. Blood-thinning drugs are often given to reduce this risk. Drugs can also be given to help control and regulate the heart rate, or may be used after electrical cardioversion (when an electrical 'shock' is used to reset the heart's rhythm). Surgery may also be an option.

If drug treatment doesn't work or if a person can't take drugs because of side effects or other reasons, there are several procedures that can be used which may affect the electrical activity of the tissue causing the

irregular heartbeat. These include using radiofrequency ablation (which uses heat) or cryoablation (freezing).

Balloon cryoablation uses a balloon catheter to freeze tissue in one of the chambers on the left side of the heart. The aim is to produce scarring, which may interrupt the electrical signals that come from the pulmonary veins, and so help to maintain a normal heartbeat.

For this procedure the patient is usually given a general anaesthetic, or a local anaesthetic with sedation. Catheters (thin tubes), one with a small balloon attached, are inserted into one or both of the veins at the top of the legs (the femoral veins) and guided into the heart. The freezing balloon and a device used to record electrical signals are passed into the left side of the heart and the balloon is inflated to fix it in the correct position at the entrance to the pulmonary vein. The freezing balloon is cooled in several-minute bursts until the abnormal electrical signals are stopped. This is repeated for each of the pulmonary veins.

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 using a balloon catheter to freeze parts of the heart 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 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?

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 8 studies on this procedure.

How well does the procedure work?

A review of 23 studies with a total of 1308 patients looked at whether the procedure (balloon cryoablation) succeeded in stopping the electrical signal from the veins. This happened in 99% of 924 patients across a total of 19 studies.

Two studies looked at whether the procedure succeeded in maintaining a normal heartbeat without the need for drugs. In the first study, 30 patients treated with the procedure were compared with 29 who had radiofrequency ablation and 35 who had radiofrequency ablation carried out with the help of a robot. When they were checked after an average of 13 months, the procedures had been successful in two thirds of the patients in each treatment group. In the second study, 346 patients with paroxysmal or persistent atrial fibrillation were treated with the procedure. The procedure was successful in 74% of patients with paroxysmal atrial fibrillation and 42% of patients with persistent atrial fibrillation.

The review of 23 studies also looked at how many patients had a year with no atrial fibrillation after having the procedure. This was 73% for 519 patients with paroxysmal atrial fibrillation from 5 studies, 60% for 316 patients with paroxysmal atrial fibrillation from 3 studies, and 45% for 62 patients with persistent atrial fibrillation from 2 studies.

Two other studies also looked at whether the atrial fibrillation returned after the procedure. In the first study of 141 patients, the atrial fibrillation returned in 71 of 139 patients who were checked after 457 days. In the second study of 177 patients, the atrial fibrillation returned in 17 patients

treated with the procedure and 12 patients treated with radiofrequency ablation.

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 the main success factors include stopping the electrical impulse coming from the pulmonary veins, reducing the time the procedure takes, no more atrial fibrillation, avoiding repeat procedures, and less need for drugs to maintain normal heart rhythm.

Risks and possible problems

During the procedure two patients in the study of 346 developed a collection of fluid in the sac around the heart, which put pressure on the heart. The fluid was drained without the need for surgery. Fluid also collected around the heart (but without pressure on the heart) in another study of 133 patients. This happened within 24 hours in 5 out of 46 patients who had the balloon cryoablation procedure and in 14 out of 87 patients treated with radiofrequency ablation (one patient in each treatment group needed drainage – all the others got better without treatment).

Twenty-six patients in the study of 346 had a phrenic nerve (the nerve to the diaphragm that helps breathing) damaged during the procedure. Two recovered during the procedure and the rest had fully recovered within a year.

In a study of 74 patients, 6 out of 35 patients treated with the balloon cryoablation procedure were found to have ulcers in their oesophagus (gullet) when they were checked after a week. None of the patients had symptoms and the ulcers healed within 3 months. None of the

7 patients in the same study who were treated with another procedure using a freezing catheter had ulcers.

In the review of 23 studies only 4 out of 1241 patients had a stroke or transient ischaemic attack (a ‘mini stroke’). Three of these happened in one study and they got better within 24 hours.

In the study of 141 patients, two patients said they had coughed up blood during the first month after the procedure. Both were successfully treated by temporarily stopping blood-thinning drugs.

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 things that could go wrong include narrowing of the pulmonary vein, blood collecting in the tissues where the catheter was inserted in the groin, and gas bubbles in the blood. They also said that, in theory, other risks were death, stroke, the opening of an abnormal passage (a fistula) between the heart and the oesophagus, permanent paralysis of the phrenic nerve, damage to structures near the pulmonary veins, and a blood clot in the vein (deep vein thrombosis).

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. 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 document is about 'Percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/IPG427

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 document in their own information about this procedure.

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