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Percutaneous radiofrequency ablation for atrial fibrillation

Understanding NICE guidance –
information for people considering
the procedure, and for the public



Ordering information

You can download the following documents from www.nice.org.uk/IPG168

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N1020 (full guidance)
- N1021 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called percutaneous radiofrequency ablation for atrial fibrillation. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether percutaneous radiofrequency ablation is safe enough and works well enough for it to be used routinely for the treatment of atrial fibrillation.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of percutaneous radiofrequency ablation and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Atrial fibrillation is the name given to the irregular and rapid beating of the upper two chambers of the heart (the atria). It may be erratic, persistent or permanent. Some patients don't have any symptoms, but if present, symptoms can include palpitations, dizziness, breathlessness and tiredness. People with atrial fibrillation have an increased risk of stroke. Atrial fibrillation usually occurs in people who don't have any problems with the structure of the heart.

Treatments include medicine to control the heart rhythm and rate, electrical cardioversion (where an electrical current is used to reset the heart's rhythm) and medicine to stop blood clots from forming.

Surgery is another option. This involves making a number of cuts in both atria, and is usually done at the same time as open heart surgery to repair other problems. These cuts aim to isolate and stop the abnormal electrical impulses.

Other methods are also used to stop the abnormal electrical impulse, including use of heat (radiofrequency, microwave), cold (also known as cryotherapy) or ultrasound.

Percutaneous radiofrequency ablation is a new procedure that may be an option for patients whose symptoms haven't responded to medicine. It can also be used where patients can't have medicine because they are intolerant to it or because they have another condition that means they can't have it.

Outline of the procedure

Percutaneous radiofrequency ablation can be carried out without open heart surgery. Patients are usually given medicine to help them feel calm during the procedure (called sedatives). In this procedure, a catheter is inserted into a vein in the upper leg and moved up into the

heart, using X-ray to make sure it's in the right place. An attachment at the tip of the catheter produces heat that damages the nerves in the area where the abnormal electrical impulses are.

How well the procedure works

What the studies said

In a clinical trial of 70 patients, atrial fibrillation had returned within a year of the procedure in 4 out of 32 patients (13%) who'd had radiofrequency ablation, and in 22 out of 35 patients (63%) who'd had medicine. Fewer patients had to return to hospital in the radiofrequency ablation group: 3 out of 32 (9%) compared with 19 out of 35 (54%) patients who had medicine. Patients who'd had the procedure also reported improvements in their quality of life at 6 months.

A smaller trial measured the frequency of symptoms in 14 patients both before and after the procedure. Patients found that their symptoms decreased from an average of 42.8 attacks per month before the procedure to 0.9 attacks per month at 1 year after the procedure.

In a study of 1171 patients, 78% of patients who had undergone the procedure were estimated to be free of atrial fibrillation at 3 years, compared with 37% of patients treated with medicine. Patients who had undergone the procedure had a 54% reduction in risk of death compared with those having medicine.

A large survey reported that 6644 out of 8745 treated patients (76%) no longer had symptoms of atrial fibrillation after 12 months.

What the experts said

The experts said that there was not much long-term data.

Risks and possible problems with the procedure

What the studies said

In the survey of 8745 patients who'd had percutaneous radiofrequency ablation, 6% experienced complications (524 out of 8745 patients). The most significant problems were: four early deaths (0.1%); 20 strokes (0.3%); 47 transient ischaemic attacks (symptoms similar to stroke but only lasting less than 24 hours) (0.7%); 117 cases of pulmonary vein stenosis (a narrowing of the pulmonary vein) (1%); 107 episodes of cardiac tamponade (compression of the heart caused by the build up of fluid in the space between the heart muscle and the outer covering sac of the heart) (1%) and 37 cases of arteriovenous fistula (an abnormal connection between an artery and a vein) (0.4%).

In two studies of 1171 and 30 patients, problems specific to the procedure included: cardiac tamponade in less than 1% (4/589) of patients; stroke in 7% (1/14) and groin haematoma (a collection of blood caused by a break in the wall of a blood vessel) in 7% (1/14).

Two of the studies also reported that 2% and 4% of patients (12/589 and 340/8745, respectively) developed atypical atrial flutter (where the atrium contracts rapidly) for the first time after they'd had the procedure. In one study 2% of patients (that is, 15 out of 632) who had the procedure developed cardiac perforation (holes in the wall of the heart). In each case the sac around the heart needed to be drained; none of the patients died.

What the experts said

The experts said that stroke, cardiac tamponade, atrial fistula (abnormal connections going from the heart to blood vessels or organs) and pulmonary vein stenosis were potential problems that may develop with this procedure.

What has NICE decided?

NICE has considered the evidence on percutaneous radiofrequency ablation. It has recommended that when doctors use this procedure for people with atrial fibrillation, they should be sure that:

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

This procedure should only be performed in specialist units and with arrangements for cardiac surgical support in the event of complications.

This procedure should only be performed by cardiologists with extensive experience of other types of ablation procedures.

There should also be special arrangements for monitoring what happens when a person has percutaneous radiofrequency ablation. NICE is asking doctors to send information about every patient who has the operation and what happens to them afterwards to a central store of information at www.ccad.org.uk so that the safety of the procedure and how well it works can be checked over time.

What the decision means for you

Your doctor may have offered you percutaneous radiofrequency ablation. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of percutaneous radiofrequency ablation before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

NICE has also decided that more information is needed about percutaneous radiofrequency ablation. So NICE has recommended that some details should be collected about every patient who has this procedure in England and Wales. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to have percutaneous radiofrequency ablation, you will be asked to agree to your details being entered into an electronic database for this purpose. A clinician looking after you will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you will still be allowed to have the procedure.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on percutaneous radiofrequency ablation that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance on radiofrequency ablation (available from www.nice.org.uk/IPG121), microwave ablation (www.nice.org.uk/IPG122) and cryoablation for atrial fibrillation in association with other cardiac surgery (www.nice.org.uk/IPG123).

NICE is also developing Interventional Procedures guidance on high-intensity focused ultrasound for atrial fibrillation as an associated procedure with other cardiac surgery (www.nice.org.uk/ip_312) and a clinical guideline on atrial fibrillation.

If you have access to the internet, you can find more information on atrial fibrillation on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

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