NHS
National Institute for
Health and Clinical Excellence

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Cryoablation for atrial fibrillation in association with other cardiac surgery

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

Information about NICE Interventional Procedure Guidance 123

Ordering information

You can download the following documents from www.nice.org.uk/IPG123

- 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:

- N0866 (full guidance)
- N0867 (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 the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

This information describes the guidance that NICE has issued on a procedure called cryoablation for atrial fibrillation that's usually done at the same time as other heart surgery. 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 cryoablation is safe enough and works well enough for it to be used routinely, at the same time as other heart surgery, for the treatment of atrial fibrillation.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of cryoablation for atrial fibrillation 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 9).

About cryoablation for atrial fibrillation

Atrial fibrilliation is the medical name for when abnormal electrical signals in the heart cause the upper two chambers of the heart (the atria) to beat too quickly and not in a regular pattern. The effect is that the heart doesn't work as efficiently as it should and pumps lower

levels of blood than normal around the body. The person may feel dizzy or breathless as a result. They may also be aware of their heart beating quickly (the medical name for this is palpitations). Having atrial fibrillation is also linked with a higher risk of having a stroke.

Cryoablation

Surgical treatment for atrial fibrillation aims to stop the abnormal electrical signals from being spread through the electrical system of the heart. In cryoablation, a probe that produces very cold temperatures is used to freeze tissue. This process makes scars through heart tissue in the atria. The scars may then interrupt the electrical signals and stop them from spreading and causing the problems. Scars may be formed on both the atria or on only the left-hand atrium. The surgeon may get to the tissue from inside the atrium or from the outside.

Cryoablation is usually carried out at the same time the person is having other heart surgery, and the NICE guidance described here has only looked at cryoablation when it is used in these circumstances. The most common type of surgery a person would be having is mitral valve surgery to replace or repair the mitral valve. The mitral valve is the valve that lets blood through from the left atrium to the left lower chamber of the heart (called the ventricle).

Other treatments

A person with atrial fibrillation may be offered medicines and/or electrical shock treatment (called cardioversion) to help to stop the atrial fibrillation. They may also be offered anticoagulant medicines to help to reduce the risk of a stroke happening.

The standard operation for atrial fibrillation, which is called the Cox maze procedure, involves making small cuts in the atria. There are also procedures that involve using heat from radiofrequency, microwave or ultrasound energy, to heat the tissue to produce scarring.

How well the procedure works

What the studies said

One trial compared patients who had mitral valve surgery and cryoablation with patients who had mitral valve surgery and the standard Cox maze procedure. The results were similar in the two groups: 94 out of 110 patients (85%) who had cryoablation had a normal heartbeat when they went home from hospital, and 95 out of 110 patients (86%) who had the standard procedure had a normal heartbeat at this time. After 3 years, 92% of the patients who'd had cryoablation were still alive, as were 98% of the patients who'd had the standard procedure.

Two studies compared patients who had cryoablation and heart valve surgery with patients who just had the heart valve surgery. In one study, all 36 patients (100%) who had cryoablation had a normal heartbeat straight after the surgery, compared with 5 out of 15 patients (33%) who just had the valve surgery. In the second study, the figures for this were 25 out of the 32 patients (78%) who'd had cryoablation compared with 4 out of the 18 patients (22%) who had not. In one of these studies, 26 out of 29 patients (90%) who'd had cryoablation still had a normal heartbeat 9 months later, compared with 4 out of 16 patients who'd not had cryoablation. The other study checked patients' heartbeats 6 months after surgery. It reported normal heartbeats for 28 out of 36 patients (78%) who'd had cryoablation and 3 out of 15 patients (20%) who hadn't.

What the experts said

The experts thought that the procedure was just a different way of doing the standard Cox maze operation.

Risks and possible problems with the procedure

What the studies said

Because patients in the studies usually had cryoablation at the same time as other heart surgery, it was difficult to be sure what problems in the studies happened specifically because of the cryoablation.

Three studies reported the numbers of patients who died while in hospital after the surgery. In one study, none of the 28 patients (0%) died while in hospital. In one of the other studies, 3 out of 95 patients died in hospital. In the other study, 1 out of 32 patients died in hospital. Both of these results are the same as 3%. Some patients needed a permanent pacemaker to control the heartbeat after the surgery. In the studies, the numbers who needed a pacemaker went from 1 out of 32 patients (3%) to 4 out of 28 patients (14%).

Other problems in the studies included:

- the need to have another operation
- a condition called cardiac tamponade where the heart becomes compressed
- inflammation in the space between the lungs (this is called mediastinitis)
- the need to have a device put in to open up the aorta (a major blood vessel taking blood away from the heart)
- the need for dialysis to filter the blood
- minor stroke (called transient ischaemic attack).

What the experts said

The experts said that the possible problems were damage to the oesophagus (the tube that carries food from the mouth to the stomach), heart block (which happens when the normal electrical signals that make the ventricles contract are partly or fully blocked), damage to important blood vessels around the heart and heart attack during the surgery.

What has NICE decided?

NICE has considered the evidence on cryoablation for atrial fibrillation. It has recommended that when doctors use it 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.

NICE has also recommended that a team of different types of healthcare professional should be involved in checking that a person is suitable for the procedure, and checking on them after they've had the surgery. Heart surgeons who carry out cryoablation should be specifically trained to use the equipment involved.

Other comments from NICE

Most of the patients in the studies NICE looked at were having mitral valve replacement and cryoablation. There was not much information about what happened in patients who were having other types of heart surgery at the same time as the cryoablation.

Cryoablation seems to work better in patients who have had atrial fibrillation for less than a year. Also, it might be difficult for surgeons always to know when they have produced enough scarring across the heart tissue.

What the decision means for you

Your doctor may have offered you cryoablation for atrial fibrillation. 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 cryoablation for atrial fibrillation before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

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 cryoablation for atrial fibrillation in association with other cardiac surgery. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance on radiofrequency ablation and microwave ablation for atrial fibrillation. The booklets describing these can be downloaded from www.nice.org.uk/IPG121publicinfo (radiofrequency ablation) and www.nice.org.uk/IPG122publicinfo (microwave ablation). NICE is also currently developing a guideline for the diagnosis and treatment of atrial fibrillation (see www.nice.org.uk/page.aspx?o=98520 for up-to-date information on this guideline).

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

You can also phone NHS Direct on 0845 46 47.

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