

Understanding NICE guidance

Information for people who use NHS services

Treating Barrett's oesophagus with a radiofrequency energy coil

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 a radiofrequency energy coil can be used in the NHS to treat people with Barrett's oesophagus. 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 Barrett's oesophagus 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 the back page.



What has NICE said?

Currently there is not enough evidence to be certain about how well this procedure works or how safe it is. For these reasons, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial).

NICE has said that any studies should record the grade of Barrett's oesophagus being treated and follow patients' progress for a long time after the procedure.

NICE may look at this procedure again if more information becomes available.

This procedure may not be the only possible treatment for Barrett's oesophagus. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Treating Barrett's oesophagus with a radiofrequency energy coil

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

Barrett's oesophagus is a condition in which the lining of the lower part of the gullet (oesophagus) becomes damaged by the long-term backward flow of the stomach's contents up into the oesophagus. Over time, the cells that line the lower part of the oesophagus change, and while the cells themselves are not cancerous, there is a small risk that they will become cancerous. These cells are called precancerous cells.

In the procedure that NICE looked at, the aim is to use heat energy to destroy the abnormal cells affected by Barrett's oesophagus and to promote the growth of healthy cells. The medical name for the procedure is 'radiofrequency ablation'. The word 'ablation' means removal or destruction.

The procedure is carried out while the patient is conscious but lightly sedated. The surgeon passes an endoscope (a thin flexible telescope with a light and a small TV camera) down into the patient's oesophagus. A small coil is guided into the area at the bottom of the oesophagus. The coil delivers a few seconds of heat energy and treats a thin layer of cells from around the inside of the oesophagus.

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.

What does this mean for me?

Your doctor should only offer you this procedure as part of a research study.

NICE has recommended that some details should be collected about every patient who has this procedure in the UK. 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 the procedure, you will be asked to agree to your details being entered into an electronic database for this purpose. A doctor looking after you will fully explain the purpose of collecting the data and what details will be held (all information will be held according to the Data Protection Act). You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you can still have the procedure.

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.

How well does the procedure work?

In a study of 102 patients whose progress was checked for 12 months afterwards, the procedure was successful in 67 patients with Barrett's oesophagus without precancerous changes.

In a second small study of seven patients whose progress was checked for 3 months afterwards, the procedure was successful in six patients.

The procedure has not been studied in patients who have Barrett's oesophagus with definite precancerous changes.

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. Two advisers said that the aim of the procedure is to completely remove the abnormal cells without narrowing or scarring the oesophagus. Four advisers said that there is no information available about how well this procedure works in the long term. The advisers said that the aims of the

procedure are to remove the abnormal cells without damaging the oesophagus, to prevent the remaining cells from becoming abnormal and reduce the chance of them becoming cancerous.

Risks and possible problems

In the study of 102 patients, eight patients felt nauseous and two had a fever after the procedure. There were reports of injury to the lining of the oesophagus, mild bleeding, scarring, problems with breathing and low blood pressure. Each of these problems was reported once. The problems with breathing and low blood pressure were thought to be linked to the sedation used. None of the problems lasted long.

In the second small study of seven patients, there were no problems reported in the 3 months after 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. The advisers said that potential problems include narrowing or scarring of the oesophagus, injury, pain, bleeding, and the risk of cancerous tissue being buried underneath the normal cells.

More information about Barrett's oesophagus

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice 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 'Circumferential epithelial radiofrequency ablation for Barrett's oesophagus'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG244

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1433).