Issue date May 2010

Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating Barrett's oesophagus with radiofrequency energy

Issue date May 2010

The advice on using endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia has been replaced by NICE interventional procedure guidance 496.

See www.nice.org.uk/guidance/IPG496 for more details.

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 radiofrequency energy 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.

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

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your doctor to help you reach a decision. Some sources of further information and support are on page 8.

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What has NICE said?

Barrett's oesophagus with high-grade dysplasia

There is evidence to say that this procedure is safe and works in patients with Barrett's oesophagus with high-grade dysplasia provided their progress is checked in the long term. This procedure can be offered routinely as a treatment option for these patients 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.

Barrett's oesophagus with low-grade or no dysplasia

There is not much good evidence about how well this procedure works or how safe it is in patients with Barrett's oesophagus with low-grade or no dysplasia, and it is unclear whether the benefits outweigh the risks of the procedure. If a doctor wants to use this procedure for these patients, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding 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 as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

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Additional information

A team of healthcare professionals who are experienced in the management of Barrett's oesophagus should decide which patients should have this procedure. It should only be carried out by healthcare professionals who specialise in endoscopy and have special training in this procedure.

NICE has encouraged further research into this procedure.

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.

Radiofrequency energy treatment for Barrett's oesophagus

The medical name for this procedure is 'epithelial radiofrequency ablation for Barrett's oesophagus'.

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 changes occur to the cells lining the lower part of the oesophagus (the tube from the mouth to the stomach down which food passes). It is caused by long-term backward flow of the stomach's contents up into the oesophagus (known as acid reflux or heartburn). Over time, the cells change, and although they are not cancerous, there is a small risk that they will become cancerous. The cells sometimes develop an abnormality called dysplasia (sometimes described as 'precancerous' cells), which has two types – low grade and high grade (sometimes shortened to LGD and HGD). Cells with high-grade dysplasia carry the highest risk of developing into cancer cells.

Patients with low grade dysplasia or no dysplasia are usually offered regular checks using an endoscope (a thin telescope for looking inside the body) and taking a small sample of cells (a biopsy) to look for signs

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of high-grade dysplasia or cancer. Patients with high-grade dysplasia are usually offered frequent checks using an endoscope and biopsy to look for early signs of cancerous changes and/or an operation to remove all or part of the oesophagus. Several other procedures, which are less invasive than surgery, have also been developed that aim to remove the abnormal cells.

The aim of this procedure is to use radiofrequency (heat) energy to destroy the abnormal cells and to promote the growth of healthy cells. The procedure is carried out while the patient is conscious but sedated. The doctor passes an endoscope down the patient's oesophagus. A small probe is then guided to the area of abnormal cells. The probe delivers a few seconds of radiofrequency energy at a time (in pulses) to destroy a thin layer of cells from around the inside of the oesophagus.

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What does this mean for me?

Barrett's oesophagus with high-grade dysplasia

NICE has said that this procedure is safe enough and works well enough in Barrett's oesophagus with high-grade dysplasia for use in the NHS as long as your progress is checked in the long term. If you have high-grade dysplasia and your doctor thinks radiofrequency energy treatment 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.

Barrett's oesophagus with low-grade or no dysplasia

However, if you have Barrett's oesophagus with low-grade or no dysplasia, your doctor 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 he or she should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. 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.

Additional information

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.

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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?

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 9 studies on this procedure.

How well does the procedure work?

In a study of 127 patients (approximately half with high-grade and half with low-grade dysplasia), 84 had radiofrequency treatment and 43 were given a 'sham' procedure, in which the patients had endoscopy without radiofrequency treatment. The study reported that at 12-month review, Barrett's oesophagus cells were completely destroyed in 65 patients who had radiofrequency treatment and in 1 patient who had the sham treatment. Of the patients who had high-grade dysplasia, fewer patients who had radiofrequency treatment (1 out of 42) had developed cancer at 12-month review compared with those who had sham treatment (4 out of 21).

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A study that reported results for 92 patients with high-grade dysplasia who had radiofrequency treatment found that 83 patients no longer had high-grade dysplasia, 74 had no dysplasia of either type and 50 had no Barrett's oesophagus cells at all approximately 1 year later.

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 success factors include the removal of Barrett's oesophagus cells, a lower rate of return of Barrett's oesophagus after treatment and a lower rate of cancer development.

Risks and possible problems

In 2 studies involving a total of 233 patients, scarring causing narrowing of the oesophagus (called oesophageal stricture) was reported in 13 patients.

In a study of 27 patients, abnormal cells were found to be buried underneath normal cells (which could conceal a return of the condition) when tissue samples were checked between 6 and 12 weeks after radiofrequency treatment. The patients were all given further radiofrequency treatment. Buried abnormal cells were also found in 1 out of 1475 tissue samples taken from 44 patients in another study.

In the study of 127 patients, 1 patient developed chest pain and another developed chest discomfort and nausea. Both patients needed an overnight stay in hospital.

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 possible problems include difficulty swallowing, bleeding, perforation of the oesophagus and pain.

More information about Barrett's oesophagus

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 Barrett's oesophagus, visit our website at www.nice.org.uk

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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 'epithelial radiofrequency ablation for Barrett's oesophagus'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG344

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2179). 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 booklet in their own information about this procedure.

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