

Treating Barrett's oesophagus with photodynamic therapy

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

This leaflet is about when and how photodynamic therapy (often abbreviated to PDT) 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).

This HealthTech 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 your doctor to help you reach a decision. Some sources of further information and support are on page 10.



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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. However, photosensitivity reactions (abnormal skin reactions to sunlight) often occur following treatment, and there is a risk of oesophageal stricture (narrowing of the oesophagus). 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.



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.

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.

Photodynamic therapy for Barrett's oesophagus

The procedure is not described in detail here – please talk to your doctor 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 (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 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 photodynamic therapy is to use a light-activated drug (called a photosensitising agent) with a laser 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 photosensitising agent is injected through a vein. Special light is then shone at the abnormal cells, usually using a low-power laser inserted into the oesophagus using an endoscope. The light causes the photosensitising agent to destroy the tumour cells. The procedure is usually done on an inpatient basis, needing an overnight stay in hospital. If the abnormal cells are widespread in the oesophagus, more than one treatment session may be needed. After the procedure, patients need to avoid bright light and direct sunlight for several weeks because it can cause photosensitivity reactions in exposed skin.



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 photodynamic therapy 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.



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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 7 studies on this procedure.

How well does the procedure work?

One study of patients with high-grade dysplasia found that 104 out of 138 (75%) patients treated with photodynamic therapy and a drug called omeprazole (used to treat acid reflux) had no high-grade dysplasia at 18-month review compared with 25 out of 70 (36%) patients who were treated with omeprazole alone. After 5 years, 48% of those who had photodynamic therapy and omeprazole and 4% who had omeprazole alone still had no high-grade dysplasia. In the same study, 21 out of 138 (15%) patients who had photodynamic therapy with omeprazole had developed cancer within 5 years of treatment compared with 20 out of 70 (29%) patients who had omeprazole alone.

A study of 72 patients with Barrett's oesophagus without dysplasia reported that 17 out of 34 patients treated with photodynamic therapy no longer had abnormal cells at 12-month review compared with 33 out of 34 patients who had an alternative treatment called argon plasma coagulation, in which an electric current is applied to a jet of argon gas directed at the affected cells.

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 aims of the procedure are to reverse cell abnormalities and prevent the development of cancer.

Risks and possible problems

In a study of 40 patients, in which 26 had photodynamic therapy, 1 patient died 3 days after photodynamic therapy (the cause of death was unknown).

In 5 studies involving a total of 376 patients who had the procedure, scarring causing narrowing of the oesophagus (called oesophageal stricture) was reported in 107 patients. Most were treated successfully to widen the oesophagus (by dilation), but 2 patients had perforation of the oesophagus during treatment. An operation to remove some or all of the oesophagus was needed for these patients.

The study of 208 patients, in which 138 were treated with photodynamic therapy, reported that 19% of these patients had difficulty swallowing. In the same study, 69% of patients who had photodynamic therapy had an abnormal skin reaction to sunlight (called a photosensitivity reaction). In 3 studies with a total of 176 patients who had photodynamic therapy, 84 patients had photosensitivity reactions.

In the study of 72 patients, 4 out of 17 who had photodynamic therapy and 7 out of 33 who had argon plasma coagulation treatment were



found to have abnormal cells buried underneath normal cells (which could conceal a return of the condition).

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 pain, inflammation, ulceration and severe low blood pressure. In theory, other problems could include liver failure in patients who already have cirrhosis of the liver, and damage to the skin and eyes caused by an abnormal reaction to sunlight.



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



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. This 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 'photodynamic therapy for Barrett's oesophagus'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG223

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2208). 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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