

Photodynamic therapy for high-grade dysplasia in Barrett's oesophagus

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

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**National Institute for
Clinical Excellence**

MidCity Place
71 High Holborn
London
WC1V 6NA

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called photodynamic therapy when it's used for high-grade dysplasia in Barrett's oesophagus. 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 photodynamic therapy is safe enough and works well enough for it to be used routinely for high-grade dysplasia in Barrett's oesophagus.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of photodynamic therapy for high-grade dysplasia in Barrett's oesophagus 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 photodynamic therapy for high-grade dysplasia in Barrett's oesophagus

Barrett's oesophagus is where the lining of the oesophagus (sometimes also known as the gullet) has changed from how it is normally. This is thought to happen after the person has had heartburn for many years. With heartburn (which is sometimes also called reflux), the stomach contents come back up into the oesophagus. And as the stomach contents contain acid and other digestive juices, it can damage the lining of the oesophagus.

In a small number of people, Barrett's oesophagus gradually develops into cancer. Before it gets to cancer, it goes through several precancer stages, which are called dysplasia. The stage just before cancer is called high-grade dysplasia. The time it takes for high-grade dysplasia to develop into cancer varies so it's not possible to predict how quickly this will happen.

The standard treatments for high-grade dysplasia include major surgery to remove the whole of the oesophagus. Other possible treatments, such as techniques called 'laser ablation' and 'endoscopic mucosal resection' aim to remove the abnormal lining so that a new normal lining will grow. Another one of the treatments that aims to do this is photodynamic therapy, which is the procedure that NICE has looked at.

Photodynamic therapy involves giving the patient something that makes them sensitive to light. Some hours after this, the second stage of the procedure gets under way. A special piece of medical equipment is put down into the oesophagus and is used to shine light onto the lining (this is usually done with a low-power laser). This activates the light-sensitive substance, starting off a chain of events that destroys the abnormal lining of the oesophagus.

How well it works

What the studies said

The four main studies that NICE found all showed that most patients went from having high-grade dysplasia to having Barrett's oesophagus without dysplasia after they'd had photodynamic therapy. In one study, under half of patients (42%) went back to normal after the procedure (that is, the Barrett's oesophagus went away). In another study, this happened in nearly all the patients who had the treatment (98%). Some of the patients who still had Barrett's oesophagus after the photodynamic therapy went on to have laser treatment to remove the last of the abnormal lining.

One study followed 65 patients for just under 5 years to see what happened to them after the procedure. Three people developed cancer.

Another study is comparing what happens in people who have photodynamic therapy with people who only take medicines to help. The early results from this study seem to show that after 2 years, double the proportion of people taking medicines have developed cancer compared with the people who had photodynamic therapy. But this study is still going on, so these results have to be treated with caution.

In general, NICE commented that the numbers of patients in the studies were small. Studies with larger numbers of patients tend to give more reliable results.

What the experts said

One of the experts said that some people who had photodynamic therapy would actually have cancer that hadn't been picked up when it was decided to try this treatment. In this case, the photodynamic therapy wouldn't help.

Risks and possible problems

What the studies said

In the studies, the most common problems with this procedure were:

- that the oesophagus became narrow afterwards (this happened in 11 out of

48 patients in one study, and in 34 out of 100 in another study)

- skin reactions to the light-sensitive substance, which happened in about a third of patients.

Although the skin reactions were sometimes mild, in one study, 7 out of 48 people needed medical treatment for it.

Other problems reported in the studies included damage to the oesophagus, a build up of fluid around the lungs (called pleural effusion), and an effect on the heartbeat. These affected 3 to 4 people out of 100 who had the procedure.

What the experts said

The experts agreed that narrowing of the oesophagus and skin reactions were likely to be the main problems. One expert was concerned that the lining may heal and cover an area of cancer that was missed the first time around, so the cancer may carry on growing without being detected.

Another expert said that a build up of fluid around the lungs and an effect on the heartbeat were possible problems.

What has NICE decided?

NICE has considered the evidence on photodynamic therapy. It has decided that, if a doctor wants to carry out photodynamic therapy for high-grade dysplasia in Barrett's oesophagus, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the long-term results. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

NICE had also said that the long-term results aren't clear, and that someone with Barrett's oesophagus who has photodynamic therapy may still go on to develop cancer at a later date.

NICE has encouraged doctors who carry out photodynamic therapy to talk to their patients about joining the clinical trials that are going on at the moment. NICE may look at the procedure again if new information becomes available.

What the decision means for you

Your doctor may have offered you photodynamic therapy for high-grade dysplasia in Barrett's oesophagus. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the long-term results of the procedure which you need to understand before you agree to it. Your doctor should discuss these with you.

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.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on photodynamic therapy for high-grade dysplasia in Barrett's oesophagus is on the NICE website (www.nice.org.uk/IPG082guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0683. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on heartburn or Barrett's oesophagus, a good starting point is NHS Direct (telephone 0845 4647) or NHS Direct Online (www.nhsdirect.nhs.uk).

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