

# **Understanding NICE guidance**

Information for people who use NHS services

# Treatment of early-stage oesophageal cancer with photodynamic therapy

NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

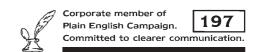
This leaflet is about when and how photodynamic therapy (often shortened to PDT) can be used to treat people with early-stage oesophageal cancer in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 oesophageal cancer 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.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. 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.

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### What has NICE said?

There are still uncertainties over how well the procedure works in reducing the size of tumours. If a doctor wants to use PDT for early-stage oesophageal cancer, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and 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 after the procedure.

Further information on the safety of PDT and how well it works will be helpful. NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) looking at PDT for early-stage oesophageal cancer. NICE may look at this procedure again if more information becomes available.

### Other comments from NICE

A number of different photosensitising agents are used, which may be different in terms of safety and how well they work.

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

# Photodynamic therapy

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

The oesophagus is the tube from your mouth down which food is swallowed to your stomach. A tumour in the oesophagus can make swallowing difficult and can cause weight loss, hoarseness, coughing and pain. Early-stage tumours are ones that are on the surface of the oesophagus and have not grown far into the wall of the oesophagus.

The aim of treatment is to cure the cancer. The options include surgery to remove the oesophagus, chemotherapy, and destruction of tumour tissue by radiation, laser therapy or PDT.

For PDT, the patient is sedated. A drug called a photosensitising agent is injected into the tumour. Special light is then shone at the tumour, usually using a low-power laser in an endoscope (a thin flexible tube that the patient swallows down into the oesophagus). The light causes the photosensitising agent to produce high-energy oxygen molecules that destroy tumour cells. The procedure can be done on an outpatient basis and the patient usually does not need to stay in hospital overnight.

### What does this mean for me?

If your doctor has offered you PDT for early-stage oesophageal cancer, he or she 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 that your doctor 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.

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.

# 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 seven studies on this procedure.

# How well does the procedure work?

In some studies PDT was used on its own but in others it was used with other forms of treatment. This can make it hard to work out how well the PDT worked.

In five of the studies that NICE looked at, between 37 and 100 out of every 100 patients (37–100%) had their tumours completely removed by PDT. For stage T1a tumours, 22 out of 33 (67%) were completely destroyed by PDT; 20 out of 22 (91%) squamous cell carcinomas were completely destroyed.

In one study, 72% of 56 patients survived for at least 5 years without the cancer returning after a single PDT session. In other studies, 38 patients survived to an average of 32 months without the cancer returning, and 13 out of 24 (54%) were still alive and showed no return of the cancer at check-up after an average of 21 months. In two other studies the average survival was 60.5 months in 18 patients and 60 months in 21 patients.

## Risks and possible problems

A common problem after PDT is that the skin becomes sensitive to sunlight. This happened in up to 13% of patients. Some patients (3–13%) had second-degree sunburn but it was not always clear whether this was caused by the PDT.

Another problem is that the oesophagus may get narrower after PDT. This happened to between 7% (3 out of 41) and 35% (43 out of 123) of patients.

In two studies, PDT caused a fistula (which is an abnormal opening between the windpipe (trachea) and oesophagus) in 8% of patients.

The expert advisers stated that, as well as the risks described above, PDT might cause nerve damage, chest pain, fever, nausea, damage to the oesophagus or lungs, effects on the heart, low blood pressure, bleeding, progression or recurrence of the cancer, and death.

# More information about oesophageal cancer

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. 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 and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG200

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1169).

### **National Institute for Health and Clinical Excellence**

MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

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