

Treating precancerous and cancerous changes in the oesophagus with endoscopic submucosal removal

*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 endoscopic submucosal removal can be used in the NHS to treat people with precancerous and cancerous changes in the 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.

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 precancerous or cancerous changes in the 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 8.

What has NICE said?

Oesophageal adenocarcinoma/Barrett's oesophagus

Currently there is not enough evidence to be certain about how well this procedure works for treating patients with oesophageal adenocarcinoma or Barrett's oesophagus with high-grade dysplasia. In addition, there are safety concerns about the risk of perforating the oesophagus.

For these reasons, NICE has said that this procedure should only be carried out as part of a research study in these patients.

Oesophageal squamous carcinoma/dysplasia

There is not much good evidence about how well this procedure works or how safe it is for treating patients with oesophageal squamous carcinoma or squamous dysplasia. Most of the evidence is from Japan, where oesophageal cancer occurs more commonly than in the UK. In addition, there are safety concerns about the risk of perforating the oesophagus. 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 upper gastrointestinal cancer should decide which patients should have this procedure. It is a difficult procedure and should only be carried out by healthcare professionals who have specific training in this procedure.

NICE has encouraged further research into this procedure.

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

Endoscopic submucosal removal of precancerous and cancerous cells of the oesophagus

The medical name for this procedure is ‘endoscopic submucosal dissection of oesophageal dysplasia and neoplasia’.

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

There are two types of oesophageal cancer: squamous cell carcinoma and adenocarcinoma. Both may be diagnosed at a precancerous stage (called dysplasia) or at a cancerous stage (neoplasia). An abnormality of the lining of the oesophagus called Barrett’s oesophagus can sometimes develop into adenocarcinoma. This is more likely if the cells are of a type called high-grade dysplasia.

Depending on the type and stage of the precancerous or cancerous cells, treatment options include surgical removal of all or part of the oesophagus, chemotherapy, radiotherapy, and procedures to destroy the cells using radiofrequency energy, or endoscopic treatment. Endoscopic treatment involves the use of a thin telescope with a camera attached (an endoscope) and special surgical instruments to

remove cells. The area of abnormal cells (called a lesion) can be cut out often in several pieces using a method called endoscopic mucosal resection (EMR) or using a wider cut to remove the lesion and a small area of healthy tissue in one piece by endoscopic submucosal dissection (ESD).

In ESD, the patient is sedated or given a general anaesthetic and an endoscope is inserted through the mouth and into the oesophagus to view the affected area. A solution is injected into the wall of the oesophagus, which raises the affected cells and makes them easier to see and remove. The abnormal part of the lining is then cut out and removed in one piece using special surgical instruments.

What does this mean for me?

Oesophageal adenocarcinoma/Barrett's oesophagus

Your doctor can only offer you this procedure as part of a research study if you have oesophageal adenocarcinoma or Barrett's oesophagus with high-grade dysplasia.

Oesophageal squamous carcinoma/dysplasia

If your doctor has offered you this procedure for oesophageal squamous carcinoma or squamous dysplasia, 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.

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.

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 10 studies on this procedure.

How well does the procedure work?

Two studies compared treatment using ESD and EMR techniques. In total, removal of the lesion in one piece was reported in 60 out of 63 patients (95%) who had ESD and 115 out of 186 patients (62%) who had EMR. Two studies of patients with precancerous or cancerous squamous lesions reported that 139 out of 165 lesions in total were completely removed in one piece while also leaving a border of normal cells around the lesion, called a clear margin.

In one of the studies that compared ESD and EMR, abnormal cells developed again in the same area in 1 patient out of 26 who had ESD and 11 out of 44 who had EMR.

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 successful treatment of cancer (complete removal of abnormal cells with a clear margin) and patient survival.

Risks and possible problems

Perforation of the oesophagus causing air to enter the chest cavity was reported in 5 out of 115 patients treated with ESD in two studies and during 4 out of 58 procedures in a study of 43 patients. Air in the chest cavity was also reported in 6 out of 102 cases in a further study. All were treated successfully.

Narrowing (stricture) of the oesophagus was reported in 9 out of 58 ESD procedures in the study of 43 patients. All were treated successfully by inflating a small balloon (dilatation) across the narrowed area. Blockage (stenosis) of the oesophagus needing dilatation was reported in 7 cases out of 102 ESD procedures checked at an average of 1 year and 9 months after the procedure in one study, and in 11 out of 65 patients checked about 3 years later in another.

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 pneumonia, uncontrollable bleeding and the need for emergency surgical removal of all or part of the oesophagus.

More information about cancer of the 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 cancer of the 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 'endoscopic submucosal dissection of oesophageal dysplasia and neoplasia'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG228

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2294). 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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