

Understanding NICE guidance

Information for people who use NHS services

Treating lesions of the stomach wall using endoscopic submucosal dissection

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 dissection can be used in the NHS to treat people with lesions on the wall of the stomach. 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 stomach lesions 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 page 6.

What has NICE said?

Evidence shows that this procedure is able to completely remove small stomach wall lesions in most cases but there is not much good evidence about long-term survival after treatment of cancerous lesions. There are also concerns about the risks of stomach perforation and bleeding. If a doctor wants to use this procedure, they should make sure that extra steps are taken to explain the uncertainty about how well it works and how safe it is. They should also explain the uncertainty in relation to treating cancerous lesions, as well as the uncertainty surrounding risks of perforation, bleeding and possible need for subsequent open surgery. 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.

A team of healthcare professionals who specialise in upper gastrointestinal cancer should decide which patients should have this procedure, and it should only be carried out by surgeons with special training in the technique. The Joint Advisory Group on Gastrointestinal Endoscopy intends to prepare training standards on these procedures.

NICE has encouraged further research into this procedure.

This procedure may not be the only possible treatment for treating lesions on the wall of the stomach. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Treating lesions of the stomach wall using endoscopic submucosal dissection

The medical name for this procedure is 'Endoscopic submucosal dissection of gastric lesions'.

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

Abnormalities, or lesions, of the stomach wall can be cancerous, precancerous, or benign (harmless).

Current endoscopic treatment for small lesions is to remove them in pieces using a cutting wire loop (snare polypectomy) for protruding lesions or endoscopic mucosal resection (EMR) for 'flat' lesions. EMR usually removes lesions in several pieces.

The new procedure is called endoscopic submucosal dissection (ESD). It is carried out with the patient under sedation or general anaesthetic. A thin telescope (endoscope) is inserted through the mouth and gullet into the stomach to view the affected area. A solution is injected into the wall of the stomach to help lift the lesion. The lesion is removed in one piece with the intention of obtaining a clear margin around the lesion.

What does this mean for me?

If your doctor has offered you this procedure for treating stomach lesions, 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.

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 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 11 studies on this procedure.

How well does the procedure work?

In a study of 896 patients, non-ulcerated lesion removal rates, where the lesion was removed in 1 piece, were higher for lesions treated with ESD than with EMR (157 out of 169 compared with 343 out of 790).

Clear margin removal rates were also higher with ESD compared with EMR (157 out of 169 and 194 out of 790).

In a study of 900 cancerous lesions, removal rates for lesions with clear margins were higher for lesions treated with ESD compared with EMR (473 out of 572 compared with 195 out of 328).

In another study the lesion was removed in 1 piece in 44 out of 51 lesions, and 37 lesions also had clear margins.

Fewer lesions returned in patients who had ESD compared with those who had EMR: 0 out of 572 and 13 out of 328 lesions, respectively (timing of checks not known), and 10 out of 347 patients and 21 out of 478 patients when they were checked after nearly 7 years. In another study, lesions returned near the original site within 8 months in 5 out of 59 patients who had their lesions removed in several pieces using ESD.

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 key success factors are rates of removing the tumour in one piece and with clear margins, rate of the tumour returning, and survival.

Risks and possible problems

Perforation rates were higher in patients who had ESD compared with those who had EMR. In 2 studies, perforations occurred in 31 out of 815 patients and in 7 out of 431 patients, respectively.

A study of 655 patients reported that perforations were more frequent in patients who had the procedure compared with those who had EMR (11 out of 303 lesions and 5 out of 411 lesions, respectively).

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 bleeding was a possible problem, and thought that there could be a risk of perforation, leading to the tumour cells spreading.

More information about stomach lesions

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 stomach abnormalities, 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 gastric lesions'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG233

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2323). 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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ISBN 978-1-4731-8236-3

N2323 1P Oct 10

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