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Understanding NICE guidance

Information for people who use NHS services

Treating non-ampullary lesions in the duodenum using endoscopic mucosal removal or 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 different types of endoscopic removal can be used in the NHS to treat people with lesions in of the duodenum (the first section of the small intestine). 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 lesions in the duodenum 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 6.

What has NICE said?

There is not much good evidence about how well endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD) procedures work in non-ampullary duodenal lesions or how safe they are, and there are also concerns about the risks of perforation and bleeding. If a doctor wants to use either of these endoscopic techniques they should make sure that extra steps are taken to explain the uncertainty about how well the procedures work, as well as the uncertainty surrounding potential risks. They should also explain that the procedure might need to be changed to 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 these procedures, and they should only be carried out by surgeons with special training and expertise. The Joint Advisory Group on Gastrointestinal Endoscopy intends to prepare training standards on these procedures.

NICE has encouraged further research into these procedures.

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

Treating non-ampullary lesions in the duodenum using endoopic mucosal removal or endoscopic submucosal dissection

The medical name for these procedures is ‘Endoscopic mucosal resection and endoscopic submucosal dissection of non-ampullary duodenal lesions’.

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

Non-ampullary lesions of the duodenal wall are rare. These lesions may be cancerous, precancerous, or benign (harmless).

The aim of EMR and ESD is to remove the lesions without the need for abdominal surgery (open or keyhole). Both procedures are carried out with the patient under sedation or general anaesthetic. A thin telescope (endoscope) is inserted through the mouth, gullet and stomach into the duodenum to view the affected area. A solution is injected into the wall of the duodenum to help lift the lesion. In EMR the lesions are usually removed in several pieces, whereas in ESD the lesions are removed in one piece with the intention of obtaining a clear margin (complete resection).

What does this mean for me?

If your doctor has offered you one of these procedures for treating duodenal 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 6 studies on these procedures.

How well does the procedure work?

In 2 studies, lesions were completely removed in 23 out of 27 patients and in 18 out of 21 patients (8 of these in 1 piece) treated with EMR. In another study, 5 of the 6 lesions treated with EMR were removed in 1 piece, and all 9 lesions treated with ESD were removed in 1 piece.

In the study of 21 EMR-treated patients, the lesions had not returned within 13 months in all 8 of the patients who had their lesions removed in 1 piece. Of the 13 patients who had their lesions removed in several pieces, 5 of them were found to have a remaining non-cancerous tumour at an average of 10 months after surgery.

In 3 studies of 13 EMR-treated patients, 4 ESD-treated patients and 3 EMR-treated patients, there were no deaths or lesions returning at an average of between 18 and 52 months after the procedure.

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 were complete resection and recurrence rates, recovery period and mortality.

Risks and possible problems

Perforation was reported in 4 patients from a total of 18 patients who were treated with ESD.

One study looked at 92 patients treated with EMR in different parts of the gastrointestinal system (the stomach and intestine). Of these, 22 patients bled in total, with bleeding developing in 16 of them within 24

hours. Fourteen patients needed further treatment and 3 patients needed a blood transfusion.

Bleeding following the procedure was reported in 2 out of 9 ESD-treated patients and in 1 out of 5 EMR-treated patients in the study of 14 patients. In 2 other studies, 1 out of 23 patients and 1 out of 13 patients developed bleeding after 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 theoretical problems included delayed bleeding, perforation, bleeding and pain.

More information about duodenal 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 duodenal 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. Interventional procedures 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 mucosal resection and endoscopic submucosal dissection of non-ampullary duodenal lesions'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG232

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2321). 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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