Issue date March 2010

Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Removing abnormal tissue from the lower bowel wall using an endoscope and an electrically heated knife

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 an endoscope and an electrically heated knife can be used in the NHS to treat people with abnormalities on the wall of the bowel. 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 abnormalities on the wall of the bowel 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.

Information about NICE HealthTech guidance 212

What has NICE said?

Although there is evidence to say that this procedure works, there are still uncertainties about its safety and how well it works in improving the survival of patients with colorectal (bowel) cancer. If a doctor wants to use this procedure, they should make sure that extra steps are taken to explain the uncertainty about the potential risks of the procedure, in particular the risks of bleeding and of puncturing the bowel. 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.

NICE has said that this procedure is difficult and should only be carried out by specially trained healthcare professionals. Patients suitable for the procedure should be identified by a colorectal (bowel) surgeon (and, if possible, an endoscopist) with experience in this technique.

NICE has encouraged further research into this procedure and may review the procedure if more evidence becomes available.

Removing abnormal tissue from the lower bowel wall using an endoscope and an electrically heated knife

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

The medical name for this procedure is ‘endoscopic submucosal dissection of lower gastrointestinal lesions’.

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

Abnormalities, or lesions, of the bowel wall can be cancerous or at high risk of becoming cancerous, or they can be harmless (benign). Treatment usually involves removing the lesion, together with a small area of tissue around the lesion. The medical name for this is ‘complete resection’. If there is no abnormal tissue found between the tumour and the edge of the tissue removed, it is called a ‘clear margin’.

This procedure is usually performed with the patient under sedation or general anaesthetic. A long camera called an endoscope or colonoscope is introduced through the anus to view the affected part of the bowel wall. The bowel wall is injected with fluid to lift and separate the lesion from the deeper layers of the bowel, and a special electrically heated knife is inserted to remove the visible lesion in one piece. The aim of the procedure is to help avoid the need for open surgery and to obtain the whole lesion as a single, good-quality sample for examining under the microscope.

What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that although the procedure works there are uncertainties about how safe it is. 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 9 studies and a review of 14 other studies on this procedure.

How well does the procedure work?

In a review of 14 studies including 1314 patients, 85% of bowel lesions were successfully removed in one piece, with a 'complete cure' (clear margins) in 75% (the length of follow-up was not stated). Two further studies of 42 and 35 patients reported complete removal of lesions in one piece with clear margins in 31 and 22 patients respectively.

In a study including 536 lesions, the procedure was more successful at removing lesions in one piece than either a 'simplified' version of the procedure using a cutting wire (snare) or a procedure called 'endoscopic mucosal resection' (a similar treatment that usually involves removing the lesion in several pieces). Success rates were 463 out of 468, 40 out of 44 and 20 out of 24 lesions respectively.

In 2 studies of 400 and 278 patients (405 and 292 lesions), 352 and 263 lesions respectively were removed in one piece. In the second study, 44 lesions were removed with clear margins. In this study, which followed patients for 36 months, 1 patient from the group whose lesions were not removed in 1 piece developed a further cancerous lesion in the bowel wall. The cancer was then successfully removed.

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 are completely removing the lesion in one piece, removing the whole lesion with clear margins, the cure rate and avoiding the need to remove sections of the bowel itself rather than just a part of the wall.

Risks and possible problems

Bowel puncture was reported in 9 patients in the study of 536 lesions. Seven of these patients were treated by the procedure and 2 were treated by a 'simplified' version of the procedure. None of the patients treated by 'endoscopic mucosal resection' in the same study had bowel puncture. In 2 studies of 405 and 186 patients, bowel puncture was reported in a total of 26 lesions. Of these, 25 were detected during the procedure, and 1 was detected 2 days later. Two of these punctures needed surgery to repair them.

In a study of 186 patients, 2 had rectal bleeding that required an emergency endoscopic procedure to stop the bleeding. Bleeding occurred on the day of the procedure in 1 patient and 10 days later in the other. A report of 1 patient treated by endoscopic dissection described a blockage in the intestine that developed 18 hours after the procedure (treated by fluids through a drip and easing pressure on the bowel using an endoscope).

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 disturbing the lesions could possibly cause a curable cancerous lesion to spread via a puncture and become incurable.

More information about bowel lesions

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 bowel lesions, visit our website at www.nice.org.uk/aboutguidance

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 lower gastrointestinal lesions'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG212

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2121). 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.

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

ISBN 978-1-4731-8115-1
N2121 1P Mar 10