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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating cancer or pre-cancerous lesions of the oesophagus by keyhole surgery to remove all or part of the oesophagus

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 keyhole surgery to remove all or part of the oesophagus can be used in the NHS to treat people with cancer or pre-cancerous lesions of 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.

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 cancer or pre-cancerous lesions of 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?

This procedure can be offered routinely as a treatment option for people with cancer or pre-cancerous lesions of the oesophagus provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored and reviewed.

A team of healthcare professionals who are experienced in the management of oesophageal cancer should decide which patients should have this procedure. NICE has also said that this is a difficult procedure. It should only be carried out by surgeons with special expertise and specific training in keyhole surgery to remove the oesophagus, and they should initially carry out the procedure with another experienced surgeon.

Doctors should send information about everyone who has the procedure and what happens to them afterwards to a national database at www.ic.nhs.uk so that the safety of the procedure and/or how well it works can be checked over time.

Keyhole surgery to remove all or part of the oesophagus

The medical name for this procedure is 'minimally invasive oesophagectomy'. The procedure is not described in detail here – please talk to your specialist for a full description. Oesophagectomy is surgery to remove all or part of the oesophagus (the tube between the mouth and the stomach). It is used to treat cancer of the oesophagus and may also be a treatment option for pre-cancerous lesions in the oesophagus.

In traditional open oesophagectomy, the surgeon makes two large incisions − one in the chest and one in the abdomen. The surgeon cuts out part or all of the oesophagus and then makes a new tube out of part of the stomach or intestine, which is attached to the remains of the oesophagus in the chest or neck to form a new replacement oesophagus (the points at which attachments are made are called anastomoses).

In keyhole or minimally invasive oesophagectomy (MIO) the same procedure is performed through several small incisions made in the chest and abdomen. With the patient under a general anaesthetic, a viewing tube is inserted through a small cut in the chest, through which the surgeon removes all or part of the oesophagus using special instruments (this type of procedure is called thoracoscopy). The second part of the procedure can be done via small incisions in the abdomen in a similar way (called laparoscopy). Sometimes one part of the procedure is done using traditional open surgery. When a combination of minimally invasive surgery and open surgery is used, it is called hybrid minimally invasive oesophagectomy (HMIO). Keyhole oesophagectomy is a complex procedure and the operating time may be long.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks keyhole surgery to remove all or part of the oesophagus is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it. 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 35 studies on this procedure.

How well does the procedure work?

One study compared hospital information on 699 patients who had MIO or HMIO with information on 17,974 patients who had open oesophagectomy and found some evidence that the death rate within 1 year of the procedure was lower for patients who had a minimally invasive procedure.

Three studies gave recurrence rates of between 0% and 44% for patients who had HMIO and between 3% and 50% in patients who had the open procedure. A further study of 221 patients did not find a link between the type of procedure used and the rate of cancer recurrence.

A study comparing 27 patients who had HMIO with 29 who had the open procedure found that results for quality of life, determined using a questionnaire, were similar for both groups of patients before the operation. After surgery the scores for both groups decreased, but were worse in the open surgery group compared with the minimally invasive group 2 weeks after the operation. After 24 weeks, scores improved in both groups, but those who had the open procedure had comparatively worse results for physical ability and overall quality of life.

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 the success of the procedure could be measured by the speed of recovery compared with open surgery, cancer recurrence, survival, quality of life and the use of HMIO over open surgery.

Risks and possible problems

Several studies looked at the number of patients who died in hospital within 30 days of an oesophagectomy. In 6 studies (in total 475 patients who had MIO and 434 who had open surgery) the overall death rate was higher after open surgery (an average rate of 7%) compared with MIO (4%). In 8 studies, a combined total of 9 out of 272 (3%) patients who had MIO or HMIO and 15 out of 372 (4%) patients who had the open procedure died. In the study of hospital information, the death rate at 30 days was similar for both groups. Two studies that compared MIO, HMIO and open surgery reported death rates of 2% and 0% for MIO, 6% and 2% for HMIO, and 2% and 3% for open surgery.

In 21 studies, leakage at the join in the oesophagus (a serious complication called anastomotic leakage) occurred in up to 20% of patients who had MIO or HMIO (1371 patients in total) and in 2% to 29% of patients who had open surgery (1114 patients). Two further studies of 222 and 282 patients who had MIO reported that 12% and 13% of patients developed an anastomotic leak.

Damage to the windpipe (trachea) was reported in several studies. Perforation was reported in 2 studies in a combined total of 1 out of 43 patients treated by HMIO and in 9 out of 84 treated by open surgery. Tearing was reported in 4 out of 504 patients who had MIO in 2 further studies combined, and a minor perforation was reported in 2 out of 222 patients who had MIO in 1 study.

Damage to other nearby organs was reported in 5 studies as occurring in 0% to 8% of patients who had MIO or HMIO and in 0% to 15% of patients who had open surgery. Two studies reported injury to large arteries during minimally invasive procedures; 1 resulted in a change to open surgery and the other was successfully repaired during 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 possible problems include major bleeding in the chest, damage to vital structures, and injury to the windpipe and lungs, and necrosis of stomach tissue.

More information about cancer

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 and pre-cancerous lesions 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. HealthTech 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 'Minimally invasive oesophagectomy'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG272

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2667). 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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