

Understanding NICE guidance

Information for people who use NHS services

Keyhole surgery to remove the bladder

NICE 'interventional procedures 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 the bladder can be used in the NHS. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures 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 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 back page.

What has NICE said?

This procedure can be offered routinely as a treatment option for people with bladder cancer 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.

A team of clinicians who are experienced in the management of bladder cancer should decide which patients should have this procedure, and surgeons carrying out this procedure should have special training.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at the British Association of Urological Surgeons Cancer Registry & Sections Audit so that the safety of the procedure and/or how well it works can be checked over time.

Other comments from NICE

The published evidence was from patients with bladder cancer, but the procedure might also benefit other patients. Patients who may be suitable should be referred to units with experience in the procedure and in deciding who would most benefit from it. Most surgeons have stopped doing bladder reconstruction by keyhole surgery as part of this procedure.

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

Keyhole surgery to remove the bladder

The medical name for this procedure is 'laparoscopic cystectomy'. The procedure is not described in detail here – please talk to your doctor for a full description. Keyhole surgery to remove the bladder may be offered to patients who have bladder cancer as an alternative to conventional (open) surgery.

The procedure is carried out with the patient under general anaesthesia. It involves removing the bladder using special instruments that are inserted through small cuts in the wall of the abdomen. In some centres the surgeon may be assisted by a robot. The tubes that carry urine from the kidneys to the bladder (the ureters) may then be connected to a small piece of bowel that is used to form an artificial opening called a stoma (urostomy) with a collection bag worn outside the body, or a new bladder may be made using a section of bowel. These additional procedures may not use keyhole surgery. When the bladder is removed for cancer it may be necessary to remove the prostate gland in men. Women may also need the womb and/or ovaries removing depending on the spread of the cancer.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 13 studies on this procedure.

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 removing your bladder using keyhole surgery 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. 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?

How well does the procedure work?

In one study of 65 patients, 23 out of 30 patients who had the keyhole procedure and 28 out of 35 patients who had the open procedure had survived without the cancer returning 38 months and 46 months after surgery, respectively. A study of 84 patients reported that 70 had survived without the disease returning within 18 months. In another study of 42 patients, none of the 20 patients who had the keyhole procedure and 1 of the 21 patients who had the open procedure had died as a result of the disease within 20 months. In the studies of 65 patients and 42 patients, those who had the keyhole surgery needed less pain relief compared with those who had the open surgery.

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 main factors that determine success are the need for a blood transfusion, the time between surgery and discharge from hospital or returning to normal activity, the need for pain relief, tissue that is free from cancer cells close to where the bladder was removed, how many lymph nodes were removed, and 5-year survival without cancer. One adviser said the procedure hadn't been performed for long enough or in enough people to say how likely the cancer would be to return to the same area or to spread to other parts of the body.

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

Risks and possible problems

Four studies looked at how many of the keyhole procedures had to be changed to open surgery during the operation. Out of 220 people, 4 had to have their surgery changed. In four studies involving 213 people who had the keyhole procedure, 5 developed abnormal connections (fistula) in the body (for example, between the urinary tract and the bowel). In two studies of 50 people who had the procedure, 2 had injury to the rectum. Other problems included abscess in the abdomen (1 in 13 patients), abscess pus leaking through the skin (1 in 33), injury to an artery (1 in 84), urine leakage (1 in 83), urinary tract infection (8 out of 84) and bruising (3 out of 84). One patient was reported to have cancer at the site where one of the instruments had been inserted during the procedure 10 months after the surgery.

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. One adviser said that problems include difficulty controlling blood loss, bowel injury or obstruction, not removing all of the cancer and the cancer appearing at the site where the instruments were inserted during surgery. The advisers said that possible problems include abnormal connections (fistula) from the bowel, inflammation of the abdomen lining and long operating time. One adviser said that the keyhole technique may not be as thorough as open surgery, particularly when removing lymph nodes.

More information about bladder 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.

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 'laparoscopic cystectomy'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG287

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1797).

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 1-84629-905-5
N1797 1P Feb 09