

Treating an overactive bladder by enlarging it by keyhole surgery using a section of bowel

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 enlarging the bladder using keyhole surgery can be used in the NHS to treat people with an overactive bladder. 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 overactive bladder 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?

Although there is not much good evidence on how well the procedure works, it raises no major safety concerns, and open surgery for bladder enlargement is well established. This procedure can be offered routinely as a treatment option for people with an overactive bladder 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 specialists experienced in managing urinary incontinence and carrying out complex keyhole reconstructive surgery should decide who should have this procedure, and should carry it out.

NICE is asking surgeons to send information about everyone who has the procedure and what happens to them afterwards to the British Association of Urological Surgeons so that the safety of the procedure can be checked over time.

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

Treating an overactive bladder by enlarging it using a section of bowel by keyhole surgery

The medical name for this procedure is 'laparoscopic augmentation cystoplasty (including clam cystoplasty)'.

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

The aim of the procedure is to make the bladder larger and reduce pressure. Making the bladder larger is intended to reduce urgency and stop incontinence and reduce the need to empty the bladder as often.

This procedure is traditionally carried out using open surgery. The keyhole procedure is intended to involve less blood loss, a quicker recovery, less pain, a shorter stay in hospital and smaller scars.

It is carried out with the patient under general anaesthetic, through 4 or 5 cuts in the skin. The bladder is cut open and a piece of bowel is cut out and stitched over the opening. A catheter (a thin, hollow tube) is placed in the bladder, either through the abdomen or through the tube that carries urine from the bladder. This is removed 2–3 weeks later, once the bladder is healed and has no leaks. Some patients may need to insert a catheter when they want to pass urine after having the procedure. Patients may also need to do 'bladder washouts' using a catheter to reduce the risk of infection and bladder stones. They will also need to empty their bladder (either normally or using a catheter) at least every 4 hours to remain dry and avoid the bladder tearing.

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 surgeon thinks this procedure is a suitable treatment option for you, they should still make sure you understand the benefits and risks before asking you to agree to it.

NICE has decided that more information is needed about this procedure. Your surgeon 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?
- Will I need regular check ups in the long term?
- 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 8 studies on this procedure.

How well does the procedure work?

In a study of 17 patients, bladder control improved from an average of 14.9 points to 1.6 points on a bladder control scale when checked after 17 months. Patients' bladders could hold substantially more urine in 4 studies involving a total of 31 patients when they were checked between 4 weeks and 16 months later. The pressure in patients' bladders was also lower in 29 patients in 2 of the studies when they were checked after 13 or 16 months. In a study of 23 patients, 19 were checked after a year. They used a catheter to empty their bladder every 4–5 hours and none of them were incontinent in between emptying. (Before the procedure, 9 were incontinent.) In another study, within a month of the procedure, all 6 patients were 'generally dry' for 2–3 hours in between using a catheter.

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 aims of the procedure are symptom relief, rapid recovery and shorter hospital stay (compared with open surgery), reduced need for pain relief and improved appearance (less scarring).

Risks and possible problems

In the study of 23 patients, 1 had bladder stones when they were checked after 13 months. The stones had to be removed surgically. In the same study, 1 patient's bladder tore because they did not empty it every 4 hours using a catheter as recommended. The tear was repaired and a catheter inserted for 4 weeks. In the study of 17 patients, 1 had a collection of blood in the layer surrounding one of the muscles in the stomach, caused by one of the surgical instruments during the procedure. Another patient's bowel stopped working temporarily. One patient's bladder leaked through the stitches in the study of 6 patients – this got better without further 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 possible problems include bleeding, infection, infection of the blood, bowel damage, a leaking bowel or bladder, and metabolism problems.

More information about overactive bladder

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 overactive bladder, 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 'laparoscopic augmentation cystoplasty (including clam cystoplasty)'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG207

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2061). 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 978-1-4731-8100-7

N2061 1P Dec 09

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