NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Treating men's stress urinary incontinence with adjustable fluid-filled balloons

NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how adjustable fluid-filled balloons can be used to treat men with stress urinary incontinence in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 men who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe stress urinary incontinence 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 the back page.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. 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.

Information about NICE interventional procedure guidance 224
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What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use this procedure, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks. 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 when a person has this procedure. NICE is asking doctors to send information about everyone who has the operation and what happens to them afterwards to a central store of information at the British Association of Urological Surgeons. This allows the safety of the procedure and how well it works to be checked over time.

This procedure should only be carried out in units that specialise in treating urinary problems in men and that can offer a range of treatments.

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

Adjustable fluid-filled balloons for stress urinary incontinence in men

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

Stress urinary incontinence is the involuntary leakage of urine during exercise, coughing, sneezing or laughing. The most common cause in men is following surgery for prostate cancer, in which normal continence may be affected.

Non-surgical treatments include pelvic floor exercises, electrical stimulation to improve control, or biofeedback (bladder retraining and physical treatments to improve bladder and pelvic floor coordination).

Several surgical procedures are also available, one of which is inserting adjustable fluid-filled balloons.

The procedure is carried out under a local anaesthetic. During the procedure, two balloons are inserted under the bladder neck, one each side of the urethra. This requires two small cuts to the scrotum. The balloons are filled with fluid via fine tubes which are left in place in case adjustments to the volume of fluid are needed later. The pressure from the balloons helps to support the neck of the bladder, keep the urethra closed and prevent accidental urine loss. Only a normal amount of effort is required to pass urine intentionally.

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 two studies on this procedure.

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 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.

NICE has also decided that more information is needed about this procedure. So it has recommended that some details should be collected about every patient who has this procedure in England and Wales. These details will be held confidentially in an electronic database and will not include patients' names. If you do not agree to your details being entered into the database, you can still have the procedure.

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.

How well does the procedure work?

Two studies looked at the number of incontinence pads needed each day before and after the procedure. In the first study of 117 patients, before the procedure the average number of pads needed each day was 6. Three months after the procedure, this fell to an average of 2 pads each day. Two years after the procedure, this fell further to an average of 1 pad each day. In the second study of 23 patients, before the procedure the average number of pads needed each day was 4.8. By 22 months after the procedure, this fell to an average of 1.8 pads each day.

Both studies looked at quality of life and reported significant improvements when patients were asked approximately 2 years after the procedure.

The study of 117 patients also looked at stress urinary incontinence symptoms, and found significant improvements in patients' symptoms scores when patients were asked at 3 months, 1 year and 2 years after the procedure.

The study of 23 patients also showed that continence when actively straining significantly improved when patients were asked after an average of 22 months.

The expert advisers said that there are uncertainties about how well the procedure works in both the short and long term.

Risks and possible problems

Complications such as damage to the urethra or bladder happened in 15 out of 117 patients in the larger study and 2 out of 23 patients in the smaller study. There was one report of damage to the rectum.

Some of the balloons became displaced from their original position in both studies. In the study of 117 patients, after an average of 13 months, 13 out of 231 balloons had become displaced. This caused damage to the urethra. In the study of 23 patients, after an average of 22 months, this had happened in 3 patients and the balloons were removed.

Another complication after the procedure was urge incontinence, which is a sudden uncontrollable need to empty the bladder. This happened in 2 out of 23 patients and was treated with medication.

The fluid from the balloons leaked in 24 out of 231 balloons in the larger study and in 1 out of 23 patients in the smaller study.

In the larger study of 117 patients, various problems meant that further procedures were required in 54 patients.

The expert advisers said that there are uncertainties about how safe the procedure is. They said that other possible complications included narrowing of the urethra, infection, bladder obstruction, problems emptying the bladder, and rupture of the balloon.

More information about urinary incontinence

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice 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. 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 and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG224

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1293).

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