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Intramural urethral bulking procedures for stress urinary incontinence in women

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG138

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0923 (full guidance)
- N0924 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on procedures for stress urinary incontinence in women that are given the general name of intramural urethral bulking procedures. It is not a complete description of what is involved in these procedures – the woman's healthcare team should describe in detail the one being considered.

NICE has looked at whether intramural urethral bulking procedures are safe enough and work well enough to be used routinely for the treatment of stress urinary incontinence in women.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of intramural urethral bulking procedures and how well they work
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the women and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

Stress urinary incontinence is the medical name for leaking urine when, for example, you exercise, cough, sneeze or laugh. It usually happens because the muscles and tissue in the pelvic floor, which support the opening of the bladder, have become damaged or weakened. Sometimes the ring of muscle that keeps the bladder closed is weak. Usually, the woman tries non-surgical treatments first (for example, pelvic floor exercises). If the condition does not improve, surgical procedures can be tried.

Intramural urethral bulking procedures aim to bulk up and strengthen the sides of the urethra so that the bladder closes with more force. The urethra is the tube that carries urine from the bladder to the outside of the body. There are different materials available to use to provide the extra bulk, and these are known as bulking agents. In the procedure, several millilitres of bulking agent are injected into the side of the urethra, just under the bladder. The woman usually has a local anaesthetic to numb the area before she has the injections. The doctor may use a special viewing tube called a cystoscope when carrying out the injections.

How well the procedure works

What the studies said

In one study, just over half the women who had a bulking procedure were free from incontinence 12 months later (34 out of 64 women or 53%; 53% means 53 out of 100). By comparison, nearly three quarters of women who had a standard operation to increase the support for the bladder opening had no incontinence after 12 months (39 out of 54 women, or 72%).

In another study that followed what happened in women after they'd had a bulking procedure, 38 out of 90 women (42%) had either no incontinence or an improvement when they were checked using standard tests 12 months later.

Another study that used silicone particles as the bulking agent found that 69 out of 102 women (68%) had no incontinence or a real improvement in their incontinence after 3 months. When the women were checked again around 18 months after the procedure, the number had fallen to 48% (40 out of 84 women).

Four studies compared different bulking agents and found that they appeared to work equally well.

What the experts said

The experts said that how well the procedure worked might depend on whether it was suitable for the woman, the type of bulking agent being used, and the method used to give the injections.

Risks and possible problems with the procedure

What the studies said

There were five studies that involved a total of 389 women. The most common problems following the procedure were urinary infection and what's known as urinary retention, which is when it becomes difficult to empty the bladder completely. In the studies, 1% to 12% of women had a urinary infection. And 0 to 11% of women had urinary retention.

Other problems that affected a small number of women were the development of an abscess at the place where the injections were given, the development of urinary urgency (which is where you have a sudden need to pass urine), and prolonged pain.

What the experts said

The experts said that it was possible that the bulking agent might move away from the site where it was injected. The woman might develop problems passing urine. Urine infections might happen, as might an allergic reaction to the bulking agent. Heavy bleeding (haemorrhage) might also be possible, though this is likely to be rare.

What has NICE decided?

NICE has considered the evidence on the safety of intramural urethral bulking procedures and how well they work in the short term. It has recommended that when doctors use these procedures for women with stress incontinence, they should be sure that:

- the woman understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

In particular, women should understand that the effects of the procedure wear off over time.

There should also be special arrangements for monitoring what happens when a woman has an intramural urethral bulking procedure. NICE is asking doctors to send information about every woman who has one of these procedures and what happens to them afterwards to one of two central stores of information held by the British Association of Urological Surgeons (www.baus.org.uk) and the British Society of Urogynaecologists. This information will help to show how well these procedures work in the long term.

Other comments from NICE

There are a number of different bulking agents and these may have different risks and benefits.

The effects of the bulking agent may wear off over time, but the procedure can be repeated.

What the decision means for you

Your doctor may have offered you an intramural urethral bulking procedure. NICE has considered this type of procedure because it is relatively new. NICE has decided that the procedures are safe enough and work well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of the bulking procedure before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above. In particular, you should understand that if the procedure is successful and helps with your incontinence, the effects are likely to wear off in the future.

NICE has also decided that more information is needed about how well intramural urethral bulking procedures work in the long term. So NICE has recommended that some details should be collected about every woman who has one of these procedures. These details will be held confidentially and will not include patients' names. The information will be used only to see how well the procedure works. If you decide to have an intramural urethral bulking procedure, you will be asked to agree to your details being entered into an electronic database for this purpose. A clinician looking after you will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, you will still be allowed to have the procedure.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on intramural urethral bulking procedures that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance on tension-free vaginal tape for stress incontinence (www.nice.org.uk/TA056), transobturator foramen procedures for stress urinary incontinence (www.nice.org.uk/IPG107publicinfo) and insertion of extraurethral (non-circumferential) retropubic adjustable compression devices (www.nice.org.uk/IPG133publicinfo). NICE is also producing guidance on insertion of biological slings for stress urinary incontinence (www.nice.org.uk/ip_264).

If you have access to the internet, you can find more information on urinary incontinence on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.



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