

Treating an overactive bladder by stimulating a nerve near the ankle

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 stimulating a nerve near the ankle 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 syndrome 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 5.

What has NICE said?

The evidence shows that this procedure is effective in reducing symptoms in the short and medium term and that there are no major safety concerns, so it 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.

This procedure may not be the only possible treatment for an 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 stimulating a nerve near the ankle

The medical name for this procedure is 'Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome'.

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

The symptoms of an overactive bladder include the need to urinate often, and without much warning, and urge incontinence (sudden leakage of urine without warning). Overactive bladder is when the bladder muscle contracts before the bladder is full. In some cases, it is associated with neurological conditions such as multiple sclerosis or Parkinson's disease.

Current treatments include bladder training, pelvic floor muscle training and medication. Injections of botulinum toxin and stimulating a nerve in the lower spine may be used if these treatments don't work. Surgery, including bladder enlargement, may sometimes be an option.

In the percutaneous tibial nerve stimulation procedure, a fine needle is inserted near a nerve just above the ankle and an electrode is placed on the foot. A mild electric current is passed through the needle to relax the nerves that control bladder function in the lower back. There is usually a tingling sensation in the ankle, foot or toes. The treatment usually consists of 12 outpatient sessions of 30 minutes each, once a week.

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 it 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.

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 procedure?
- What happens if something goes wrong?

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 220 patients, 60 out of 110 patients treated with the procedure and 23 out of 110 patients treated with a 'dummy' procedure reported a reduction in bladder symptoms when they were checked after 13 weeks.

In another study, 35 out of 44 patients who had the procedure and 23 out of 42 patients who were treated with medication described themselves as being cured or improved after 12 weeks of treatment. Both groups reported a significant improvement in quality of life scores.

In a study of 90 patients who had the procedure, 58 asked for the treatment to be continued in the longer term to maintain the results. The same study reported that in 34 out of 60 patients the number of instances of urine leaking in a 24-hour period decreased by half or more.

In a study of 35 patients, 19 were free from symptoms immediately after treatment, but 8 were symptom free after 1 year. In another study in which patients were treated with the procedure over 12 sessions then with additional treatments for a further 9 months, 30 out of 32 patients when checked at 6 months, and 24 out of 25 patients when checked at 12 months, considered themselves to be cured or improved.

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 it is not clear how well the procedure works in the long term. Key success factors include a decrease in

frequency of urination and incontinence, reduction in the daily use of pads, and better quality of life and bladder capacity.

Risks and possible problems

In a study in which half the patients were treated with the procedure and half received medication, at least 1 side effect thought to be related to the treatment was reported in around 15% of the patients in each group (8 out of 49 and 7 out of 49, respectively). In the group that had the treatment, within 12 weeks of having the procedure there was 1 report each of generalised swelling, worse incontinence, headache, blood in the urine, inability to tolerate stimulation, leg cramps, foot or toe pain, and dizziness or fainting in response to the needle being inserted.

In the study in which 220 patients had the procedure, there were 5 instances of bleeding or discomfort where the needle was inserted, and 1 case each of ankle bruising or tingling in the leg.

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 minor bleeding, pain, and infection where the needle is inserted.

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 'percutaneous posterior tibial nerve stimulation for overactive bladder syndrome'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG235

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2327). 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.

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

Information about NICE HealthTech guidance 235

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