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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating faecal incontinence by stimulating the tibial 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 the tibial nerve near the ankle can be used in the NHS to treat people with faecal incontinence. 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 faecal 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 page 7.

What has NICE said?

Although there is evidence to say that this procedure appears safe, there are still uncertainties about how well it works because there is only evidence about how well it works in the short term, based on a small number of patients. If a doctor wants to use the procedure to treat faecal incontinence, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the 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 to the patient after the procedure.
The procedure should only be carried out in units that specialise in assessing and treating faecal incontinence that can offer a range of treatment options.

NICE has encouraged further research into how well this procedure works in the long term and may look at this procedure again if more information becomes available.

Other comments from NICE

This could be a simple and relatively non-invasive treatment for treating faecal incontinence and improving patients' quality of life, as long as further research shows it works.

The studies that NICE looked at involved patients with many different causes of faecal leakage, and not all patients found their incontinence symptoms to be severely disabling.

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

Treating faecal incontinence by stimulating the tibial nerve near the ankle

The medical name for this procedure is 'percutaneous tibial nerve stimulation for faecal incontinence'. It is often referred to as PTNS.

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

Faecal incontinence is when a person loses the ability to control their bowel movements, resulting in leakage of faeces. Faecal incontinence has many different causes. It can be distressing and can severely affect everyday life.

Initial treatment for faecal incontinence usually includes dietary management and medication to stop diarrhoea. This may be followed by pelvic floor muscle training and anal sphincter training. If these treatments fail, surgery may be needed.

In this new procedure, a fine needle is inserted into the tibial nerve just above the ankle and an electrode is placed on the foot. A mild electric current is passed through the needle to stimulate the tibial nerve. The exact mechanism of how the treatment works is not known. There is usually a tingling sensation in the ankle, foot or toes. The treatment usually consists of 12 outpatient sessions of 30 minutes each, about once a week, but it can be repeated if necessary.

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 although it appears safe there are uncertainties about how well it works. 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. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

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?
- 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 7 studies on this procedure.

How well does the procedure work?

In a study of 52 patients who had either PTNS or a sham (a 'dummy' or placebo) procedure, the 20 patients who had the sham treatment reported no improvement. Of the 32 who had PTNS, 17 reported 'good' results, 10 had 'fair' results and 5 had 'poor' results. Of the 27 patients who reported an improvement, symptoms had come back in 8 patients when their progress was checked at an average of 22 months after the procedure. Six patients had top-up treatments, but 2 refused further treatment.

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 aim of the procedure is sustained improvement in continence, measured as a reduction in weekly faecal incontinence episodes, and quality of life.

Risks and possible problems

A study of 22 patients reported that 2 patients had stomach ache that lasted for several hours, occurring 2–3 hours after the procedure. One patient reported leg numbness that lasted 2 hours. In a different study of 13 patients, 1 patient stopped treatment after 7 weeks because of swelling and pain in their leg. In a study of 30 patients, transient discomfort or throbbing pain at the insertion site, redness and inflammation where the needles were inserted, as well as temporary toe numbness, were all reported but the study did not report how many patients were affected.

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 complications include severe bruising and nerve injury.

More information about faecal incontinence

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 faecal incontinence, 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. HealthTech 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 tibial nerve stimulation for faecal incontinence'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG263

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2548). 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

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