National Institute for Health and Clinical Excellence

Using PENS for difficult-to-treat neuropathic pain

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how PENS (short for percutaneous electrical nerve stimulation) can be used in the NHS to treat people with refractory (difficult-to-treat) neuropathic pain. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures 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 document 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 neuropathic pain or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document 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?

This procedure can be offered routinely as a treatment option for people with difficult-to-treat neuropathic pain 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 specialist pain management team should decide which patients might benefit from the procedure and should carry it out.

NICE has encouraged further research into PENS for difficult-totreat neuropathic pain to provide more evidence about how well the treatment works in the long term and who will benefit most from it.

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

Treating refractory neuropathic pain using PENS

The medical name for this procedure is 'percutaneous electrical nerve stimulation for refractory neuropathic pain'. 'Percutaneous' means through the skin. 'Refractory' means that the pain has been resistant to other treatments.

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

Neuropathic pain is caused by damage or changes to nerves so they don't work properly. There are many underlying causes. Examples include painful diabetic neuropathy, post-herpetic (shingles) neuralgia and trigeminal neuralgia (which affects the face). People with neuropathic pain may experience altered pain sensation and areas of

numbness, and often describe the pain using words like shooting, stabbing, burning, tingling, or a sensation of pins and needles. The pain can have a significant impact on a person's quality of life.

Neuropathic pain is usually treated with medication such as painkillers, antidepressants, anticonvulsants or opioids, but these do not always work well and can cause side effects. PENS aims to mask neuropathic pain by electrically stimulating 1 or more nerves at the site of the pain and usually produces a tingling sensation. The procedure is similar to TENS (transcutaneous electrical nerve stimulation), but involves inserting a needle electrode under the skin rather than using an electrode pad on the skin. Once the needles are inserted they are connected to an electrical stimulator device. This may make muscles contract. The treatment usually takes between 15 and 60 minutes and can be repeated as often as necessary.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough in the short term for use in the NHS. If your doctor thinks PENS 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.

NICE has also decided that more information is needed about how well this procedure works in the long term. Your doctor 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.

NICE may look at this procedure again if more information becomes available.

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 3 studies on this procedure.

How well does the procedure work?

Two studies looked at how well PENS reduced pain. The first study involved 64 patients with pain from sciatica and compared PENS with TENS and with 'sham' PENS, in which the needles were inserted but no electrical current was applied. The second study involved 50 patients with diabetic neuropathic pain in the legs and compared PENS with sham PENS. In both studies patients rated pain on a scale from 0 (no pain) to 10 (worst pain). After 3 weeks of treatment, patients in the first study using PENS or TENS said their pain had reduced substantially (from a score of 7 to 4 for PENS and from 7 to 5 for TENS) but patients using sham PENS said there was no real difference. The second study also showed a substantial reduction in pain after treatment with PENS (from 6 to 3) but no real difference with sham PENS.

The study of 64 patients with sciatica also measured how physically active patients were on a scale from 0 (best) to 10 (worst). After 3 weeks of treatment, patients using PENS or TENS said their activity levels had improved substantially (from a score of 6 to 4 for PENS and from 6 to 5 for TENS) but patients using sham PENS said there was no real difference.

The study of 50 patients with diabetic neuropathy scored people according to how well they were mentally and physically on a scale of 0–100 (where 100 is best). The average 'normal' score is 50. Before treatment the average scores were 31 and 41. After treatment these scores increased to 37 and 44 with PENS and to 32 and 42 with sham PENS. The quality of life scores improved the most in the PENS group but were still below the normal score of 50.

After 3 weeks of PENS treatment, patients in the first study were able to halve the number of painkillers they took every day (50% reduction). There were reductions in the use of daily painkillers of 29% in the TENS group and 8% in the sham-PENS group.

The same study also asked patients to rate how well they slept on a scale from 0 (best sleep) to 10 (worst sleep). After 3 weeks of treatment, patients using PENS or TENS said their sleep had improved substantially (from a score of 6 to 3 for PENS and from 5 to 4 for TENS) but patients using sham PENS said there was no real difference. In this study, most patients (73%) rated PENS as the most 'desirable' treatment over TENS (21%) and sham PENS (6%).

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the main success factor was pain reduction leading to a better quality of life.

Risks and possible problems

No side effects were reported in 2 studies with a total of 81 patients.

As well as looking at these studies, NICE also asked expert advisers for their views. They said possible problems include making the pain worse, bruising and bleeding. In theory, other problems could include damage to blood vessels or nerves, collapsed lung, interaction with a cardiac pacemaker if used above the waistline, seizures if used near the head, possible effects if used in pregnancy, needles coming loose or falling out, unpleasant tingling sensations and collection of blood under the skin.

More information about pain

NHS Choices (<u>www.nhs.uk</u>) may be a good place to find out more.

For details of all NICE guidance on neuropathic pain, 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. Interventional procedures 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 document is about 'Percutaneous electrical nerve stimulation for refractory neuropathic pain'. This document and the full guidance aimed at healthcare professionals are available at quidance.nice.org.uk/IPG450

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on <u>Accessibility</u> at the bottom of the NICE homepage to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this document in their own information about this procedure.

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