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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating drop foot using electrical stimulation

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 electrical stimulation can be used in the NHS to treat people with drop foot caused by damage to the brain or spinal cord. 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 drop foot 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.

What has NICE said?

This procedure can be offered routinely as a treatment option for people with drop foot caused by damage to the brain or spinal cord, 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.

For the version of the procedure in which the electrodes are implanted, a healthcare team including rehabilitation specialists should be involved in deciding which patients should have the procedure.

Other comments from NICE

Most of the evidence was about patients with stroke.

There are a number of different electrical stimulation devices and the technology is continuing to improve.

It was difficult to draw conclusions from the evidence because the studies looked at two different ways of carrying out the procedure: either using electrodes on the surface of the skin or using electrodes implanted inside the skin.

Treating drop foot using electrical stimulation

The medical name for this procedure is 'functional electrical stimulation for drop foot of central neurological origin'.

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

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

Drop foot is the inability to lift the foot and toes properly when walking. It can result from conditions such as stroke, cerebral palsy, multiple sclerosis or spinal cord injury, but it may also occur in other conditions. Central neurological origin means that the drop foot is linked to damage or disease of the brain or spinal cord, rather than an injury to the nerves or leg.

Treatment options include physiotherapy or an ankle-foot splint to provide stability and improve gait. Medical therapy includes drugs to relax the muscles or botulinum toxin injections into the most affected muscles.

In this procedure, electrodes are used to deliver electrical pulses to stimulate the nerves to contract the affected muscles. The aim of the procedure is to improve walking ability. The electrodes can be placed on the surface of the skin or implanted under the skin.

Skin surface electrodes are placed over the nerve, on the surface of the skin. They are connected by leads to a portable stimulator.

Implanted electrodes are placed over the nerve, under the skin during an operation in which the patient has a general anaesthetic. They can be connected to a portable stimulator either by leads which go through the skin or they can be completely implanted under the skin and activated by radiofrequency waves.

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 happens if something goes wrong?

Summary of possible benefits and risks

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at seven studies on this procedure. Some studies looked at skin surface electrical stimulation and other studies looked at implantable electrical stimulation.

How well does the procedure work?

All the studies that NICE looked at were about patients with stroke.

One study looked at 71 patients, of whom 36 were treated with skin surface electrical stimulation. The patients who had the procedure were able to walk faster than the 35 patients who did not have the procedure.

In a study of 111 patients (who all had skin surface electrical stimulation) and a study of 29 patients (14 of whom had implanted electrical stimulation), the patients' average walking speed increased by 27% in the first study and 23% in the second study (both measured when the patient was using electrical stimulation). The study of 111 patients showed that they used 31% less effort in walking after the procedure.

In a second study of 29 patients, 14 had implantable electrical stimulation and 15 had no stimulation. More of the patients who had electrical stimulation were able to carry out tasks such as preparing dinner or walking outside.

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 the aims of the procedure are to improve walking speed and technique, reduce effort when walking, reduce pain and discomfort, reduce the number of falls, enable patients to return to work and generally improve the patient's quality of life.

Risks and possible problems

Two studies, involving a total of 31 patients who had implantable electrical stimulation, showed that 10 patients reported skin reddening after the procedure. In 1 patient the electrodes had to be removed.

A study of 15 patients showed that 2 patients had a wound infection after the electrodes were implanted.

A study of 29 patients (14 had implantable electrical stimulation) showed that after 10 weeks one of the devices stopped working in 1 patient.

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 an increased seizure risk in patients with epilepsy, autonomic dysreflexia in patients with spinal cord injuries, infections or problems with scans if electrodes have been implanted, increases in nerve spasms, skin or muscle problems, problems caused by faulty equipment, or problems if patients are pregnant or have a pacemaker.

More information about drop foot

Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information 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. 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 'Functional electrical stimulation for drop foot of central neurological origin'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG178

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1749).

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

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