NICE guidance

Functional electrical stimulation for drop foot of central neurological origin

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg278

1 Guidance

1.1 Current evidence on the safety and efficacy (in terms of improving gait) of functional electrical stimulation (FES) for drop foot of central neurological origin appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection for implantable FES for drop foot of central neurological origin should involve a multidisciplinary team specialising in rehabilitation.

1.3 Further publication on the efficacy of FES would be useful, specifically including patient-reported outcomes, such as quality of life and activities of daily living, and these outcomes should be examined in different ethnic and socioeconomic groups.

2 The procedure

2.1 Indications and current treatments

2.1.1 Drop foot can be caused by upper or lower motor neurone lesions. Functional electrical stimulation is used to treat the effects of upper motor neurone lesions that can result from conditions such as stroke, cerebral palsy, multiple sclerosis or spinal cord injury but may occur in other conditions. Symptoms and signs of upper motor neurone lesions include muscle weakness in a pyramidal distribution (an imbalance causing arm flexion and leg extension), hypertonicity, exaggerated reflexes, clonus and an extensor plantar response. Functional electrical stimulation is not normally suitable for patients with lower motor neurone lesions.

2.1.2 Treatment options include physiotherapy or an ankle-foot orthosis to align the lower leg and control the motion of the ankle and foot, providing stability and improving gait. Medical therapy includes oral administration of muscle relaxant drugs or botulinum toxin type A injections. Surgery (usually reserved for refractory cases) includes selective tendon release of muscles.

2.2 Outline of the procedure

2.2.1 Functional electrical stimulation aims to produce muscle contractions that mimic normal voluntary gait movement (lifting the foot and achieving correct placement on the ground) by applying electrical pulses to the common peroneal nerve through skin surface or implanted electrodes.

2.2.2 Various devices can be used for this procedure. Implanted FES electrodes are usually inserted into the epineurium of the peroneal nerve under general anaesthesia. The electrodes are either percutaneous (passed through the skin and connected to an external pulse generator) or fully implanted (operated by radiofrequency waves). In skin surface FES, electrodes placed over the nerve are connected by leads to a stimulator unit and controlled with a foot switch.

2.2.3 Patients may also use ankle-foot orthosis.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A meta-analysis (including three controlled studies) of 71 patients with stroke reported a mean increase of 0.18 metres/second (95% confidence interval [CI] 0.08 to 0.28) in gait speed in 36 patients treated by skin surface FES compared with 35 patients treated by conventional therapy (absolute numbers not given).

2.3.2 A case series including 111 patients with stroke treated by skin surface FES reported a mean increase in walking speed of 27% ($p < 0.01$) and a reduction in effort of 31% ($p < 0.01$), assessed with stimulation at 18 weeks. Corresponding improvements in speed and effort without stimulation were 14% ($p < 0.01$) and 19% ($p < 0.01$) respectively.

2.3.3 A randomised controlled trial (RCT) of 29 patients with stroke reported a 23% improvement in walking speed (during daily activity) in the 14 patients treated by implanted FES (assessed with stimulation), compared with 3% in the 15 patients who had conventional therapy (follow-up: 26 weeks; $p = 0.010$).

2.3.4 A second RCT of 29 patients with stroke, of whom 14 were treated by implanted FES over 12 weeks, reported subjective achievement of functional milestones (such as 'prepared dinner', 'walked outside') in 53 instances in the FES group and 11 instances in the conventional therapy group (assessed by bimonthly questionnaires; follow-up not stated).

2.3.5 The Specialist Advisers considered key efficacy outcomes to include improved gait, reduction in effort when walking, reduction in pain and discomfort, reduction in falls, return to work and other quality of life outcomes.

2.4 Safety

2.4.1 In an RCT of 29 patients with stroke, 14 of whom received implanted electrodes (percutaneous), there were four reports of skin erythema. In a case series of 17 patients who all received implanted electrodes (percutaneous), 14 cases of skin erythema were reported in 6 patients (1 of the 6 required electrode removal). A case series of 15 patients who received implanted electrodes (radiofrequency) reported wound infection in 2 patients. The second RCT of 29 stroke patients (14 of whom had implanted electrodes [radiofrequency]) reported one instance of device malfunction after 10 weeks.

2.4.2 The Specialist Advisers noted anecdotal adverse events included an increase in seizure incidence among patients with epilepsy, autonomic dysreflexia in patients with spinal cord injuries, problems with computed tomography (CT) or magnetic resonance imaging (MRI) scanning with implanted electrodes, increases in spasticity or spasms, infection when using implanted systems, and skin intolerance. They considered theoretical adverse events to include muscle fibrillation, problems caused by faulty equipment, or problems when treating pregnant women or patients who have a pacemaker.

2.5 Other comments

2.5.1 The Committee noted that most of the evidence related to patients with stroke; that there are a number of different FES devices; and that the technology is evolving.

2.5.2 The Committee noted that interpretation of the evidence was difficult because the evidence is based on studies that used different methods of applying the procedure (skin surface or implanted).

3 Further information

3.1 NICE has produced a clinical guideline on the diagnosis and management of stroke and transient ischaemic attacks and interventional procedures guidance on selective dorsal rhizotomy for spasticity in cerebral palsy.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It has been incorporated into the NICE pathway on stroke, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

9 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation