NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

Final Scope

Remit/Appraisal objective

To appraise the clinical and cost effectiveness of spinal cord stimulation in the management of chronic pain of neuropathic or ischaemic origin.

Background

Chronic pain is pain that persists for more than 3-6 months or beyond the normal course of a disease or expected time of healing. The persistent pain becomes a significant disease in itself rather than being a symptom. Chronic pain is characterised by physiological and psychological changes for example sleep disturbances, irritability, medication-dependence and frequent absence from work. Emotional withdrawal and depression are also common, which can cause strain on family and social interactions.

People of all ages may be affected. In general, pain prevalence increases with age, is higher among women and among those with physically strenuous occupations. Estimates of the prevalence of chronic pain in the UK vary from under 10% to over 30% depending on the definition of chronic pain used in various studies.

Neuropathic pain is initiated or caused by nervous system damage or dysfunction. The pathophysiology is complex, multifactorial and still poorly understood. Neuropathic pain is very difficult to manage as affected individuals often present with complex natural history, unclear or diverse aetiologies and co-morbidities. Ischaemic pain is caused by a reduction in oxygen delivery to the tissues, usually caused by reduction in blood flow due to constriction of a vessel (vasospasm) or its obstruction by atheroma or embolus. Ischaemic pain is commonly felt in the legs or as angina but can occur anywhere in the body. .

The goal of treatment for chronic pain is to make pain tolerable and to improve functionality and quality of life. It may be possible to treat the cause but more usually the pain pathways may be modulated by pharmacological treatments (e.g. tricyclic anti-depressants, anti-convulsants, the application of local analgesics, anaesthetic or neurolytic agents , β blockers), non-pharmacological interventions (e.g. physiotherapy, acupuncture, transcutaneous electrical nerve stimulation) and psychologically based rehabilitation. A last resort is to create surgical lesions to the pain pathways.

Some patients will continue to experience distressing and disabling symptoms despite a variety of treatments.

The technology

Spinal cord stimulation (SCS), also known as dorsal column stimulation, modifies the perception of neuropathic and ischaemic pain by stimulating the dorsal column of the spinal cord. A typical SCS device has four components: (1) an electrical pulse generator or receiver device which is surgically implanted under the skin in the abdomen or in the buttock area, (2) implanted electrode(s) near the spinal cord (3) a lead that connects the electrode(s) to the pulse generator, and (4) a hand-held remote controller which the patient uses to turn the stimulator on or off and to adjust the level of stimulation, within limits as prescribed by the physician. The precise mechanism of pain modulation is not fully understood but it is thought to involve direct and indirect inhibition of pain signal transmission. It is also thought that for ischaemic pain that SCS gives an additional benefit of increasing microcirculatory blood flow.

There are two types of SCS according to the method of pulse generation: implantable pulse generator (IPG) and radio-frequency (RF) receiver. The choice of SCS device depends on individual patient needs (e.g. pain patterns, power and coverage needs) and preference as well as the physician's preference. A number of SCS devices from the following manufacturers have received European approval to market (CE Marking) and are currently available in the UK: Advanced Bionics (Precision), Advanced Neuromodulation Systems, UK Ltd (Eon, Genesis IPG (3608), Genesis XP (3609), Genesis XP Dual (3644), Genesis G4 and Renew (3408 and 3416)) and Medtronic Ltd (Synergy, Synergy Versitrel, Itrel 3 and Restore).

Intervention(s)	Spinal cord stimulator devices
Population(s)	Adults with chronic neuropathic or ischaemic pain who have had an inadequate response to non-surgical treatment.
Standard comparators	Best supportive care and/or surgical management, without spinal cord stimulators

Outcomes	The outcome measures to be considered include: • health-related quality of life • pain • physical and functional abilities • anxiety and depression • complications and adverse effects (e.g. procedural complications and technical failures)
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The costs relating to psychological assessment and trial stimulation required prior to permanent implantation of the device and ongoing surveillance and maintenance (e.g. replacing the pulse generator, revising the leads) should be included in the economic analysis. The costs associated with use of medication and healthcare services should be included in the economic analysis. The time horizon for the economic evaluation should be based on the time period over which costs and benefits can reasonably be expected to be experienced. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	If evidence allows, subgroups for which the technology may be particularly effective will be identified. If appropriate and if evidence allows, the clinical and cost-effectiveness of specific type of spinal cord stimulators for specific indications will be appraised. Neurostimulation that involves stimulation of other parts of the nervous system (e.g. peripheral nerves, deep brain) will not be considered in this appraisal. Pregnant women and children are not considered in this appraisal. The Institute can only issue guidance according to the indications in the CE marking documentation for the device.

Related NICE recommendations	**In progress:** Related Guidelines: The acute management of patients with chronic (longer than 6 weeks) non-specific low back pain Investigation, assessment and management of chest pain **Completed:** None