NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Spinal cord stimulation for chronic pain

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost-effectiveness of spinal cord stimulation for chronic pain.

Background

Chronic pain is pain that persists for more than 3-6 months or beyond the normal course of 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. Withdrawal and depression are also common, which can cause family and social strain.

People of all ages may be affected. In general, pain prevalence increases with age, is higher among females 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.

There are two main types of pain: nociceptive and neuropathic. Nociceptive pain is caused by the irritation of specialized pain receptors in tissues like skin and joints and often indicates ongoing tissue damage. Neuropathic pain is initiated or caused by nervous system damage or dysfunction The pathophysiology is complex, multifactorial and is still poorly understood.

As the two types of pain are caused by different processes, they tend to respond to different treatment modalities. Neuropathic pain is very difficult to manage as affected individuals often present with complex natural history, unclear or diverse aetiologies and co-morbidities. The goal of pain management is to make pain tolerable and to improve functionality and quality of life. Existing treatments include pharmacological (e.g. tricyclic anti-depressants, anti-convulsants, local analgesics, nerve blocks), non-pharmacological (e.g. physiotherapy, transcutaneous electrical nerve stimulation, psychologically based rehabilitation, acupuncture) and surgical treatments (e.g. re-operation for failed back surgery syndrome, neuroablative techniques like sympathectomy). Some patients will continue to experience distressing and disabling symptoms despite a variety of treatments.

The technology

Spinal cord stimulation (SCS), also called dorsal column stimulation, is a form of neuromodulation that modulates neuropathic pain perception by stimulating the dorsal column of the spinal cord. The precise mechanism of pain

modulation is not fully understood but it is thought to involve direct and indirect inhibition of pain signal transmission. There is also a pronounced autonomic effect. SCS does not block noiciceptive pain.

Ever since its first use in 1967, SCS has been used in treating pain associated with a wide variety of conditions. A recently published consensus document prepared by the British Pain Society in consultation with the Society of British Neurological Surgeons identifies indications that have shown a good response and others that may respond, rarely respond or are unresponsive (see Appendix 1). The clinical and cost-effectiveness of SCS is likely to vary among the different indications. The safety and effectiveness in pregnant women and children have not been established.

In general, SCS is part of an overall treatment strategy and is used only after the more conservative treatments have failed. However, for indications well-supported by evidence, the British Pain Society suggests that SCS may be considered when simple first line therapies have failed. A thorough psychological assessment and trial stimulation is required prior to permanent implantation of the device. The implantation must be performed in an operating theatre with the requisite anaesthetic and post-anaesthetic care facilities. As a long-term therapy for a chronic condition, it also requires appropriate infrastructure and funding for ongoing surveillance and maintenance (e.g. replacing the pulse generator, revising the leads).

A typical spinal cord stimulator 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) electrode(s) near the spinal cord implanted either percutaneously under local anaesthetic or directly during open surgery under general anaesthesia, (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.

There are two types of spinal cord stimulators according to the method of pulse generation: implantable pulse generator (IPG) and radio-frequency (RF) receiver. First generation IPG has a non-rechargeable internal battery that requires surgical replacement once the battery is depleted. Second generation IPG has a rechargeable internal battery and therefore can be used for a longer period of time before surgical replacement is required. An implantable RF receiver detects RF signals from an external transmitter powered by a rechargeable battery. RF systems are smaller and are indicated for some patients like those with high current use, require multiple electrodes or who prefer them. Apart from the type of power source used, different spinal cord stimulation devices marketed in the UK also come in different numbers of electrodes and leads. The choice of spinal cord stimulator device depends on individual patient needs (e.g. pain patterns, power and coverage needs) and preference as well as the physician’s preference. The choice of different types of device is likely to involve different costs and complications risks.

A number of spinal cord stimulator devices have received European approval to market (CE mark) and are currently available in the UK. The CE marked indications are listed in Appendix 2. There is no information about how many devices are currently in use in the NHS.

Intervention(s)	Spinal cord stimulation • Spinal cord stimulators with implantable pulse generator systems (non-rechargeable and rechargeable) • Spinal cord stimulators with radio-frequency receiver systems
Population(s)	Adults with chronic neuropathic pain
Standard comparators	Current NHS treatment strategy without spinal cord stimulation
Outcomes	The outcome measures to be considered include: • pain • physical and functional abilities • health-related quality of life • 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 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 (i.e. non-rechargeable IPG, rechargeable IPG, RF systems) 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 are not considered in this appraisal. The Institute can only issue guidance according to the CE marked indications for the device.
Related NICE recommendations	Related Technology Appraisals: None Related Guidelines: None

Questions for consultation

- Which indication(s) for spinal cord stimulation should be included in the appraisal (e.g. failed back surgery syndrome, complex regional pain syndrome, or others)?

- Should the clinical and cost-effectiveness of the technology be appraised by the different types of spinal cord stimulators (IPG non-rechargeable, IPG rechargeable, or RF systems)?

- All the available devices carry the precaution statement that the safety and effectiveness in pregnant women and children has not been established. However, the recently published consensus document on SCS for the management of pain by the British Pain Society does not exclude children from being considered for SCS. Should pregnant women and children be excluded from this appraisal?

- The Institute is aware that the list of devices may not be comprehensive. To date we have identified the following companies marketing or about to market spinal cord stimulators in the UK: Medtronic Ltd, Advanced Neuromodulation Systems, UK Ltd and Advanced Bionics Corp (Algotec Ltd as UK distributor). Are there any further companies that we should be consulting with?

Appendix 1

Indications for spinal cord stimulation (SCS) as summarised in *Spinal cord stimulation for the management of pain: recommendations for best clinical practice – a consensus document prepared on behalf of the British Pain Society in consultation with the Society of British Neurological Surgeons,* p.10, Table 1. London: The British Pain Society, 2005. Available from: http://www.britishpainsociety.org/pdf/SCS_2005.pdf. [Accessed on: 31 August 2005]

INDICATIONS FOR SPINAL CORD STIMULATION

Good indications for SCS (likely to respond)

- neuropathic pain in leg or arm following lumbar or cervical spine surgery (FBSS/FNSS)
- complex regional pain syndrome
- neuropathic pain secondary to peripheral nerve damage
- pain associated with peripheral vascular disease
- refractory angina
- brachial plexopathy: traumatic (partial, not avulsion), post irradiation

Intermediate indications for SCS (may respond)

- amputation pain (stump pain responds better than phantom pain)
- axial pain following spinal surgery
- intercostal neuralgia e.g. post-thoracotomy or post-herpetic neuralgia
- pain associated with spinal cord damage
- (other peripheral neuropathic pain syndromes e.g. following trauma may respond)

Poor indications for SCS (rarely respond)

- central pain of non-spinal cord origin
- spinal cord injury with clinically complete loss of posterior column function
- perineal, anorectal pain

Unresponsive to SCS

- complete cord transection
- non-ischaemic nociceptive pain
- nerve root avulsion

Appendix 2: Spinal cord stimulators known to be available in the UK

	Name of product	Manufacturer	CE marked Indications
SCS devices with implantable pulse generator and non-rechargeable internal battery	Synergy	Medtronic, Ltd	As an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris.
	Versitrel,	Medtronic, Ltd	As an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris.
	Itrel 3	Medtronic, Ltd	As an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris.
	Genesis IPG (3608)	Advanced Neuromodulation Systems, UK Ltd.	The Genesis (IPG) Neuromodulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome, and intractable low back pain and leg pain.
	Genesis XP (3609)	Advanced Neuromodulation Systems, UK Ltd.	The Genesis (IPG) Neuromodulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome, and intractable low back pain and leg pain.
	Genesis XP Dual (3644)	Advanced Neuromodulation Systems, UK Ltd.	The Genesis (IPG) Neuromodulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome, and intractable low back pain and leg pain.
	Genesis G4	Advanced Neuromodulation Systems, UK Ltd.	The Genesis (IPG) Neuromodulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with any of the following: failed back surgery syndrome, and intractable low back pain and leg pain.

	Name of product	Manufacturer	CE marked Indications
SCS devices with implantable pulse generator and rechargeable internal battery	Restore Rechargeable Neurostimulation System	Medtronic, Ltd	As an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris.
	Precision Implantable Pulse Generator (IPG) Model no 1110	Advanced Bionics Corp (part of Boston Scientific Corporation, received CE Mark 13 September 2005 full launch in Europe expected in 2006; UK distributor Algotec Ltd)	The indication for use is the management of chronic intractable pain via spinal cord stimulation. The CE Mark included an expected battery life for its rechargeable battery implant of at least 5 years.
SCS devices with radio-frequency system	Renew (3408 and 3416)	Advanced Neuromodulation Systems, UK Ltd	The ANS Renew radio frequency spinal cord stimulation system is indicated for spinal cord stimulation in the treatment of chronic pain of trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.