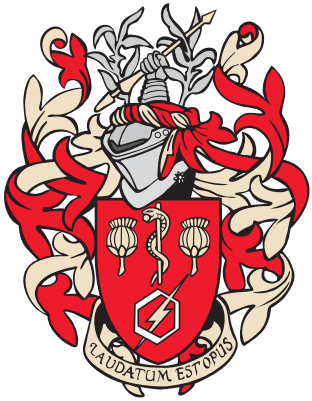

Spinal cord stimulation for the management of pain: recommendations for best clinical practice

A consensus document prepared on behalf of the Britsh Pain Society in consultation with the Society of British Neurological Surgeons

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Introduction

Spinal Cord Stimulation (SCS) is a theoretically principled treatment with a substantial and supportive evidence base which has been used for the treatment of pain since 1967. It is strategically aimed to reduce the unpleasant sensory experience of pain and the consequent modification of experience and behaviour. When SCS is used to treat patients with chronic pain it is important that the treatment is delivered within the context of a full understanding of the impact that pain has upon the patient and the extent to which pain interferes with their life and impacts on their psychological well-being. Treatment with SCS should therefore normally be delivered within facilities that can offer comprehensive assessments and a range of additional physical and psychological treatments.

These recommendations give guidance to practitioners delivering this treatment, to those who may wish to refer patients for spinal cord stimulation and to those who care for patients with stimulators in situ e.g. primary care staff. They provide a resource for organisations that fund this therapy.

These recommendations are accompanied by information for patients to help them and their carers understand the technique and to support treatment choices.

Methods

These recommendations have been produced by a consensus group of relevant healthcare professionals and patients' representatives. Opinion outside the consensus group has been incorporated by consultation with representatives of all groups for whom these recommendations have relevance. The recommendations make reference to the current body of evidence relating to spinal cord stimulation.

Competing interests

Members of the group have registered all competing interests and this information is available from The British Pain Society.

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1 Executive summary

1.1 Persisting pain is common. Whereas acute pain may only impact by interrupting current activity, episodic and persisting pain is likely to interfere with one or more aspects of a person's life and to affect their sense of identity.

1.2 Spinal cord stimulation (SCS) is an evidence-based therapy for the management of persisting pain.

1.3 Not all patients are suitable for treatment with SCS.

1.4 SCS is not currently available to all patients who may benefit.

1.5 A multidisciplinary pain management team is the most appropriate context in which to provide SCS.

1.6 Members of the team must include clinicians competent to deal with the complications of SCS.

1.7 SCS may be delivered in parallel with other therapies and should be used as part of an overall rehabilitation strategy.

1.8 Techniques of spinal cord stimulation vary. Clinical teams must have the requisite skills to offer the most appropriate technique according to an individual patient's needs.

1.9 Clinicians performing this intervention should insert sufficient electrode systems to maintain competence.

1.10 SCS must be performed in an operating theatre environment suitable for implant work with appropriate anaesthesia and post-anaesthesia care facilities.

1.11 The commonest organism to infect spinal cord stimulating systems is *staphylococcus aureus*. Where practicable, patients scheduled for SCS should be screened for methicillin-resistant *staphylococcus aureus* no longer than four weeks before the procedure. This will allow rational choice of antibiotic prophylaxis at the time of surgery.

1.12 SCS is a long-term treatment for a chronic condition and appropriate infrastructure for ongoing surveillance and support must be in place.

1.13 Patients should be fully informed of the benefits and burdens of SCS before implantation and should receive specific outcome and complication rates relating to the unit where the procedure is being performed.

1.14 Special considerations arise for patients with a spinal cord stimulator in situ who require an MRI scan. Experienced radiological advice must be sought in these circumstances.

1.15 Implanting centres should audit their SCS activity and networking between implanting centres should be encouraged.

2 Need for recommendations

2.1 Persisting pain occurs in up to half of the adult population at some time in their lives. One in ten of these would describe themselves as being severely disabled by pain. Most patients with chronic pain can be managed in primary care, but some patients will need specialised multidisciplinary assessment and management.

2.2 Patients who are referred to a pain clinic have frequently seen a number of other secondary care specialists, and have usually been extensively investigated.

2.3 Multidisciplinary pain clinics should offer a range of evidence-based interventions to patients with persisting pain. It is rarely possible to provide complete pain relief. Patients should also be offered advice on self-management and coping strategies, in tandem with pain-relieving interventions.

2.4 Persisting pain is difficult to treat and some patients will continue to experience intrusive and distressing symptoms following a variety of interventions.

2.5 Spinal cord stimulation (SCS) may be helpful in carefully selected patients. Some patients will not be helped by SCS.

2.6 SCS is not currently available to all patients who may benefit.

2.7 Some indications for SCS are well established and as the evidence base evolves other indications are emerging. As knowledge and expertise develops the techniques change and may be refined. Whilst there is a need to allow development, there is also a requirement for consistency in approach so that meaningful data can be collected.

2.8 The recommendations will

Guide **healthcare professionals** regarding

- whom to refer
- whom not to refer
- what to tell patients
- how to look after patients in the community who have had spinal cord stimulators implanted
- how to deal with complications that may occur in primary care

Promote **best clinical practice** for clinical teams involved in SCS services to

- select patients appropriately
- prepare them for the therapy
- deliver the therapy safely with minimal morbidity
- optimise outcomes
- provide appropriate continuing care

Allow **patients** to make an informed decision.

Inform **commissioners** of healthcare services.

Facilitate data collection, audit and research.

Create an environment in which advances in SCS are encouraged.

3 Scientific rationale

3.1 Sensory stimulation has been used in the management of pain since ancient times. The use of stimulation techniques in modern pain medicine dates from the publication of the Gate Theory of Melzack and Wall in 1965. This described how stimulation of neural pathways carrying innocuous (non-painful) information could influence the onward transmission of noxious information in the nervous system.

3.2 Although the introduction of SCS was inspired by the gate theory, its mechanism of action involves more than a direct inhibition of pain transmission in the dorsal horn of the spinal cord. If this were the principal mode of action then SCS would control nociceptive pain and this is not generally the case. Pain modulation by SCS also involves supra-spinal activity via the posterior columns of the spinal cord, probably recruiting endogenous inhibitory pathways. Our understanding of the neurotransmitter systems involved, e.g., GABA and adenosine, is increasing steadily. There is also a pronounced autonomic effect: the mechanisms of this are not fully understood.

3.3 Topographically appropriate posterior column function preservation seems to be necessary for SCS to be effective, but there is debate regarding which elements are necessary and to what degree.

4 Evidence

4.1 Randomised controlled trials (RCTs) of SCS have been undertaken for FBSS, CRPS (type I), refractory angina pectoris and chronic critical limb ischemia. Given the range of comparator therapies used and outcomes in these trials, it is not possible to directly compare their results. All RCTs appear to provide evidence of the benefit of SCS over comparative therapy. However, a recent systematic review of the benefits of SCS for the treatment of CRPS and FBSS emphasises the need for methodologically more rigorous studies to provide definitive data regarding improvement in pain and function in the short and long term (Turner et al 2004).

4.2 In addition, there are many case reports, retrospective and prospective case series, and observational comparative studies of SCS, particularly for FBSS and CRPS.

4.3 SCS is more effective for radicular (limb) pain following spinal surgery than for axial pain, although there is emerging evidence for the treatment of back pain using dual lead stimulation.

4.4 SCS produces analgesia in patients with ischaemic limbs. There is evidence from good quality trials that SCS may be limb salvaging in certain patients with critical limb ischaemia whose transcutaneous oxygen concentrations are in the midrange.

4.5 There is good quality evidence that SCS can be effective for patients with refractory angina pectoris. Treatment algorithms developed in the UK and by the European Society of Cardiology support the use of SCS for the minority of patients who need an analgesic intervention to facilitate a programme of goal-directed functional improvement.

4.6 Formal cost-effectiveness analysis has been undertaken regarding the use of SCS in the management of CRPS. This suggests that the initial acquisition costs can be offset by a reduction in post implantation healthcare care costs when SCS is compared to other therapies.

5 Context in which SCS is delivered

5.1 Pain interferes with physical function and may be associated with disturbance of psychological well-being. A patient being considered for SCS must be appropriately assessed with regard to physical, psychological and social functioning.

5.2 The most common approach to the treatment of pain is to attempt to modulate the unpleasant sensory experience by reducing the intensity, duration and frequency with which pain is felt. Medication, nerve blocks, physical therapies and SCS are all strategies used to achieve this outcome.

5.3 Psychological interventions – mainly cognitive-behavioural therapy – are largely focused at mitigating the interference in function that persistent pain induces. Such treatments may be offered in parallel with SCS.

5.4 Qualitative psychological testing does not predict outcome but psychological assessment is desirable to assess the patient's beliefs, expectations and understanding of the treatment in relation to their condition. It is also an important opportunity to discuss pain management strategies including activity pacing both before and after the procedure.

5.5 A multidisciplinary pain management team is the most appropriate context in which to provide SCS. Such a team should be able to deliver a range of therapies for pain.

5.6 The team will usually comprise several professionals. Members may include a consultant in pain medicine and one or more consultants from other relevant specialties e.g. neurosurgery, spinal surgery, cardiology or vascular surgery. Other members of the team might include psychologists, physiotherapists and nurses specialising in pain management. The team must have direct access to a spinal surgeon or neurosurgeon competent to deal with the complications of SCS.

5.7 The clinician performing the intervention must understand the multidisciplinary management of pain. They must have and maintain relevant surgical skills in carrying out insertion of SCS and managing complications. This will usually be a consultant in pain medicine or a neurosurgeon or spinal surgeon.

5.8 The "occasional implanter" is not acceptable. The competence of the implanter and the activity and competence of the team must be maintained. While an average of 10 electrode system insertions per year averaged over three years should deliver this requirement, it is recognised that there are circumstances in which a smaller number may be compatible with competence. An example would be an implanter who is an experienced and active pain physician or neurosurgeon working in the context of an active multi-disciplinary pain team. Where a new service is being established there should be evidence of progression towards the above. It is important to maintain networks of clinicians involved in neuromodulation therapy.

5.9 SCS is a long-term therapy for chronic disease and teams must have appropriate arrangements for ongoing care of patients including 24-hour availability for the investigation and management of potentially serious problems. Single handed practitioners must make appropriate arrangement for cover during absence.

6 Patient selection

6.1 Patients must have an up to date assessment in relation to the indication for SCS.

6.2 History and physical examination should be detailed, and include, in relevant cases, an assessment of posterior column function.

6.3 The indications for SCS are summarised in table 1.

TABLE 1

INDICATIONS FOR SPINAL CORD STIMULATION (ALSO SEE APPENDIX 2)

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

6.4 The use of SCS for other conditions such as visceral pain has been described. Its use in this and other emerging indications should be carefully audited.

6.5 Contraindications to the use of SCS are summarised in table 2.

TABLE 2

MEDICAL CONTRAINDICATIONS TO THE USE OF SCS

- uncontrolled bleeding disorder/ongoing anticoagulant therapy
- systemic or local sepsis
- presence of a demand pacemaker or implanted defibrillator
- immunosupression (this is a relative contraindication)

NB Cognitive impairment resulting in failure to understand the therapy is not a reason to exclude patients from SCS but these patients must have a cognisant carer and adequate social support.

6.6 There are specific considerations regarding surgical insertion of plate electrodes. These are summarised in table 3.

TABLE 3

SURGICAL INSERTION OF PLATE ELECTRODES: SPECIAL CONSIDERATIONS

- General contraindications to surgery should apply e.g. coagulopathy or sepsis.
- Plate electrode systems are larger than percutaneous systems; special note must be taken of the possibility of spinal canal stenosis if the electrodes are to be inserted beneath intact/residual laminae, to avoid the risk of cord compression. Pre-operative MRI of the target area of the spine should be considered (if not already performed).
- Extensive laminectomy (particularly in the cervical spine) has potential morbidity. The appropriateness of further laminectomy to insert electrodes must be considered carefully when patients have previously undergone extensive laminectomy in or adjacent to the target area.
- Open insertion of an electrode permits fixation of the electrode to the dura; if this option is taken sutures should pass through only the outer layer of dura to avoid the development of a CSF hygroma.
- Approximately 5 per cent of people undergoing a thoracic laminectomy may experience post-operative thoracic backache persisting for weeks or months. Patients should be warned of this possibility.

6.7 Many patients, e.g. those with pain following spinal surgery, will present a mixed neuropathic/nociceptive picture. Patients should be told that SCS will probably only help part of their pain. Teams offering SCS must be able to deliver appropriate additional therapies including pain management programmes.

6.8 Physical and psychological co-morbidity does not preclude treatment with SCS. Patients with concurrent physical or mental illness should be assessed in close conjunction with relevant clinical teams.

6.9 The management of children being considered for SCS should be in conjunction with a specialised multidisciplinary children's pain management team.

7 Timing

7.1 SCS may be delivered in parallel with other therapies e.g. medication and psychologically based therapies.

7.2 For indications strongly supported by evidence, i.e. CRPS, neuropathic pain following spinal surgery, peripheral vascular disease and refractory angina, SCS should be considered early in the patient's management when simple first line therapies have failed. SCS should not necessarily be considered a treatment of last resort.

7.3 For patients with refractory angina pectoris, the European Society of Cardiology recommends that:

- an interventional cardiologist with experience in managing patients with refractory angina should review the patient
- there should be documented evidence of reversible myocardial ischaemia
- SCS should be considered only if the patient continues to suffer from disabling angina despite cognitive behavioural intervention and the use of transcutaneous nerve stimulation (TENS)

8 Techniques of stimulation

8.1 Stimulation of the posterior columns is by means of an implanted electrode powered by a pulse generator. Electrodes may be inserted percutaneously via an epidural needle or plate electrodes may be surgically implanted via laminotomy. Electrodes may be bipolar or multipolar and multiple electrodes may be used. Pulse generation is achieved by either a fully implantable battery powered device (similar to a cardiac pacemaker) or a smaller implantable radiofrequency receiver powered by an external battery source. Radiofrequency systems are indicated for some patients e.g. those with a high current use including those with multiple electrodes and are preferred by some patients.

8.2 Clinical teams must have the requisite skills to offer the most appropriate technique according to an individual patient's needs.

8.3 Electrodes must be placed to elicit paraesthesiae that cover the region of reported pain.

8.4 It is recommended that percutaneous electrodes be placed under local anaesthetic with minimal sedation. This optimises electrode placement and reduces the risk of neural trauma.

8.5 Plate electrodes require open surgery (laminotomy or partial laminectomy) for placement. This is usually carried out under general anaesthetic. Such electrodes are less likely to be dislodged.

8.6 It is common practice to connect electrodes temporarily to an external stimulating device before proceeding to insertion of an implantable pulse generator (IPG) or radiofrequency receiver. This allows the patient to undergo a period of trial stimulation during which time pain relief, improvement in function and reduction in medication may be assessed. If the outcome of the trial is favourable, then the patient proceeds to IPG insertion.

8.7 The same team should carry out trial stimulation and definitive implantation.

8.8 Although a period of trial stimulation has considerable intuitive appeal, the predictive value of a period of trial stimulation is uncertain and it is well-accepted practice to insert electrodes without trial stimulation.

8.9 Following IPG insertion the patient may switch the device on and off with a magnet or hand held programmer and may vary voltage and frequency within physician determined limits.

8.10 IPG battery life is variable, but is usually between 2-8 years depending on the pattern of use and the output required. Radiofrequency systems use a power source external to the body. This is usually a 9V rechargeable battery.

8.11 Centres offering SCS to patients must ensure that their service is appropriately funded in order to support ongoing system maintenance, including the inevitable need for IPG replacement and the possible need for lead or system revision.

9 The procedure

9.1 Preoperative assessment and preparation

9.1.1 Preoperative preparation should be carried out prior to admission for the procedure.

9.1.2 Patients must be investigated appropriately for fitness to undergo surgery and anaesthesia or sedation.

9.1.3 The commonest organism to infect spinal cord stimulating systems is *staphylococcus aureus*. Where practicable, patients should be screened for the presence of methicillin-resistant *staphylococcus aureus* (MRSA) before implantation of a spinal cord stimulator. Swabs should be taken from the nose, groin and perineum not more than a month before the proposed implantation date: this may be done by the patient's primary care team. Patients who are carriers of MRSA should undergo eradication therapy for 48 hours before the procedure using nasal mupirocin or topical triclosan as appropriate.

9.1.4 The proposed position of the IPG or RF receiver transducer should be agreed preoperatively between the patient and operator.

9.1.5 There is little published evidence regarding the use of antibiotic prophylaxis for SCS. However, infection of spinal cord stimulating devices is a significant problem and the consequences of infection justify the use of antibiotic prophylaxis. Antibiotics should be given as a single intravenous dose 30 minutes before the procedure. Patients who are MRSA negative should be given a first or second generation cephalosporin: MRSA positive patients should receive vancomycin or teicoplanin with either gentamicin or a cephalosporin in accordance with local policy.

9.2 The theatre environment

9.2.1 Standard operating and post-anaesthesia care facilities must be available.

9.2.2 The operating theatre must be suitable for implant work (i.e. a clean theatre) and a full theatre team must be available.

9.2.3 X-ray screening will be needed for percutaneous lead placement.

9.2.4 A practitioner skilled in the programming and trialling of electrodes must be present for procedures performed under local anaesthesia. This individual must be familiar with the indication for which SCS is being used and should have experience of working with patients who have persisting pain.

9.3 Post-anaesthesia care and ward management

9.3.1 Programming of the implanted stimulator should not begin until the patient is fully conscious. It may be preferable that this happens when the patient has returned to the ward and the acute post-operative pain has settled.

9.3.2 Ward staff should be familiar with the aims and procedure of SCS, with the condition that it is used to manage and with the potential complications that may arise.

9.3.3 The postoperative observation regimen should take account of the potential complications e.g. spinal cord compression.

9.3.4 Ward staff should be able to seek advice from a member of the implant team at any time.

9.4 Discharge and ongoing care

9.4.1 Adequate arrangements for frequent surveillance and follow-up by the implant team must be made; the patient should be able to contact an appropriate professional if problems occur.

9.4.2 The primary care team must be given timely and appropriate advice in writing about all patients who are sent home under their care after SCS.

9.4.3 The patient will need continuing postoperative support from the implant team regarding appropriately paced physical rehabilitation, psychological support, medication adjustment and reprogramming of the SCS system.

9.4.4 In the event of complications related to the SCS or other pathology, there should be established relationships with other important disciplines e.g. spinal and neurosurgery, microbiology and neuroradiology.

9.4.5 SCS is a long- term treatment for a chronic condition. Most patients will need IPG replacement at some stage. Mechanisms should be in place to predict when this is likely to occur, so that stimulator function can be restored promptly.

9.4.6 If patients move beyond a reasonable travelling distance from the implanting centre, systems must be in place to transfer their care appropriately to other suitable services.

10 Special precautions

10.1 Unipolar diathermy should be avoided where possible in patients with a spinal cord stimulator in situ. If its use is unavoidable, the reference plate should be positioned so that the stimulator components are outside the electrical field of the diathermy.

10.2 Patients with a spinal cord stimulator in situ needing investigation with MRI may pose specific problems that should be discussed with an experienced neuroradiologist. Some combinations of spinal cord stimulator and MRI scanner are not compatible and could pose a danger of injury to the patient or damage to the spinal cord stimulator. Any proposed MRI examination whether of the spine or of other parts of the body must be discussed with an experienced neuroradiologist who will take responsibility for determining the compatibility or otherwise of the proposed spinal cord stimulator-MRI combination. For this the radiologist will require details of the spinal cord stimulator manufacturer, the type and serial number of the spinal cord stimulator and the date of manufacture. If there is any doubt about the compatibility, then alternative imaging (such as CT scan or myelography) should be performed.

10.3 Patients should be advised that airport (and other) security systems may be activated by the presence of the stimulator. The patient should carry information relating to their stimulator in situations where this may be relevant

10.4 Patients must inform their medical carers that they have a spinal cord stimulator in place.

10.5 Short wave diathermy, microwave diathermy and therapeutic ultrasound diathermy are hazardous in patients with a spinal cord stimulator.

10.6 There is no evidence to support the use of antibiotic prophylaxis for patients with a spinal cord stimulator undergoing incidental procedures that may generate bacteraemia.

11 Complications of SCS

11.1 Major complications of SCS are rare. SCS has been used in many thousands of patients worldwide; some clinical centres have reported follow up of greater than 10 years.

11.2 Common complications and rare, but serious, adverse effects must be discussed during the consent process; this must be documented. Patients should be told about the complication rates in the unit where the procedure is to be carried out.

11.3 Neurological damage relating to epidural electrode placement is a rare complication, and may occur with both percutaneous and plate electrodes. Damage may occur directly, or via unrecognised epidural haematoma or from infection. These latter complications are reversible if diagnosed and treated promptly, emphasising the importance of postoperative neurological observations. Vigilance and access to early imaging are essential (see 10.2).

11.4 Dural puncture may occur during percutaneous insertion of electrodes. This happens most frequently with the Tuohy needle, but may occur with the guide wire or the stimulating electrode.

11.5 Infection of implanted neurostimulators is a potentially serious problem and must never be ignored: in many cases the infection will not resolve unless the stimulating system is explanted. Infection of the entire system is rare but can result in epidural abscess formation with potentially disastrous neurological consequences. Explantation in this circumstance is mandatory. However, superficial low grade infections of the IPG/receiver pocket are more common and, although there is no published evidence, considerable anecdotal evidence does exist for the efficacy of conservative management in some cases and for the temporary explantation of just the IPG/receiver (preferably re-implanted in a fresh pocket) in others.

11.6 Patients should be aware that not only will surgery be necessary to replace a depleted IPG but that it may also be necessary to revise the electrodes or connections.

11.7 Electrode migration may occur immediately following the procedure, or at any time during the trial period (if used), or following IPG or receiver insertion. Cervical electrodes are more likely to be dislodged than those in the thoracic region. Migration is less likely with plate electrodes.

11.8 Other potential problems include ingress of fluid into the connectors or electrode, lead breakage and disconnection.

12 Patient information (also see patient information leaflet)

12.1 The risks and limitations of SCS should be discussed with patients and they should be given written information.

12.2 Patients must be aware of the evidence for efficacy of SCS for the indication for which it is being offered.

12.3 The patient should be given information relating to complications and outcomes specific to the unit where the therapy is taking place.

12.4 Detailed information regarding the procedure of SCS insertion including the operating theatre environment is necessary.

12.5 Infection of implanted devices is a significant problem. Infection is potentially serious and must not be ignored, however, such infections are usually low grade and do not cause serious morbidity. Although there is no published evidence to guide management it is common practice to manage superficial infections of the IPG conservatively but if this is unsuccessful or if there is infection of the electrodes the system will need to be explanted.

12.6 Patients should understand that SCS provides benefit only as part of a multidimensional approach to symptom management.

12.7 Patients should understand the need for ongoing care following SCS, including the likelihood of needing further surgery.

12.8 Patients must be given adequate time to consider the benefits and burdens of the technique prior to consenting to treatment.

12.9 Patient support groups are a valuable information resource for patients considering SCS.

12.10 Patients should not drive or operate dangerous machinery or equipment with their stimulator switched on in case an unexpected surge causes distraction or a motor effect.

13 Audit

13.1 There is currently no national database of patients treated with SCS.

13.2 Local audit of implanted patients is strongly recommended.

13.3 In addition to data relating to their implanting activity, centres should collect information on the patient demographic that they treat as well as information on diagnoses and outcomes.

13.4 Networking between implanting centres is strongly recommended.

Appendix 1

SPINAL CORD STIMULATION REVIEW OF LITERATURE

Search method

Randomised controlled trials and systematic reviews were identified from searches of MEDLINE (PubMed) and Cochrane Library based on search of 5th January 2004 and updated in January 2005.

Results

1. Randomised controlled trials

FBSS

North RB, Kidd DH, Lee MS. A prospective, randomized study of spinal cord stimulation versus reoperation for failed back surgery syndrome: initial results. *Stereotact Funct Neurosurg* 1994;62:267-72.

North RB, Kidd DH, Lee MS. Spinal cord stimulation versus operation for failed back surgery syndrome: a prospective, randomized controlled trial. *Acta Neurochir* Suppl 1995;64:106-8.

North RB, Kidd DH, Farrokhi F, Piantadosi SA Spinal cord stimulation versus repeated lumbo sacral spine surgery for chronic pain: a randomised, controlled trial. Neurosurgery 2005; 56: 98-107.

CRPS

Kemler MA, Barendse GA, van Kleef M, *et al*. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med* 2000;343:618-24.

Kemler MA, DeVet HCW, Barendse GAM *et al*. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two year follow-up of the randomized controlled trial. Ann Neurol 2004;55:13-18.

Refractory angina pectoris

De Jongste MJ, Staal MJ. Preliminary results of a randomized study on the clinical efficacy of spinal cord stimulation for refractory severe angina pectoris. *Acta Neurochir Suppl (Wien)*. 1993;58:161-4.

De Jongste MJ, Hautvast RW, Hillege HL, Lie KI. Efficacy of spinal cord stimulation as adjuvant therapy for intractable angina pectoris: a prospective, randomized clinical study. Working Group on Neurocardiology. *J Am Coll Cardiol* 1994;23:1592-7.

Ekre O, Eliasson T, Norrsell H, Wahrborg P, Mannheimer C; Electrical Stimulation versus Coronary Artery Bypass Surgery in Severe Angina Pectoris. Long-term effects of spinal cord stimulation and coronary artery bypass grafting on quality of life and survival in the ESBY study. *Eur Heart J*. 2002;23:1938-45.

Fiume D, Santini M, Cardinale M, Bubbico G, De Seta F, Gazzeri G. Permanent spinal cord stimulation in patients with coronary heart disease. Preliminary data *Acta Neurochir Wien* 1994;129:243-244.

Hautvast RW, DeJongste MJ, Staal MJ, van Gilst WH, Lie KI. Spinal cord stimulation in chronic intractable angina pectoris: a randomized, controlled efficacy study. *Am Heart J* 1998;136(6):1114-20.

Mannheimer C, Eliasson T, Augustinsson LE, Blomstrand C, Emanuelsson H, Larsson S, Norrsell H, Hjalmarsson A. Electrical stimulation versus coronary artery bypass surgery in severe angina pectoris: the ESBY study. *Circulation*. 1998;97:1157-63.

Norrsell H, Pilhall M, Eliasson T, Mannheimer C. Effects of spinal cord stimulation and coronary artery bypass grafting on myocardial ischemia and heart rate variability: further results from the ESBY study. *Cardiology.* 2000;94:12-8.

Santini. The spinal cord stimulation in ischemia: Preliminary data [La stimolazione spinale permanente nella cardiopatia ischemica: Dati preliminary] *Giornale Italiano di Cardiologia* 1993;23 Suppl 1:172.

Staal M, de Jongste M, Zijlstra G. Spinal cord stimulation for intractable angina pectoris Acta *Neurochir Wien* 1992;117:95.

Critical limb ischemia

Amann W, Berg P, Gersbach P, Gamain J, Raphael JH, Ubbink DT. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European peripheral vascular disease outcomes study (SCS-EPOS). *European Journal of Vascular & Endovascular Surgery* 2003;26:280-6.

Claeys LG, Horsch S. Transcutaneous oxygen pressure as predictive parameter for ulcer healing in endstage vascular patients treated with spinal cord stimulation *Int Angiol*. 1996;15:344-9.

Claeys LGV and Horsch S. Effects of spinal cord stimulation on Ischaemic inflammatory pain and wound healing in patients with peripheral arterial occulusive disease. *Pain Digest* 1997;7:200-3.

Claeys LGY, Horsch S. Epidural spinal cord stimulation following intravenous prostaglandin E1 therapy in patients with ischaemic pain (peripheral vascular disease Fontaine stage IV). Preliminary results of a controlled randomized study. *Pain Clinic* 1998;10:165-172.

Claeys LGY, Horsch S. Spinal cord stimulation (SCS) following intravenous prostaglandin E1 (PGE1) therapy in non-reconstructible peripheral vascular disease (PVD): Fontaine stage IV. *Pain Clinic* 1999;11:235-243.

Jivegard LE, Augustinsson LE, Holm J, Risberg B, Ortenwall P. Effects of spinal cord stimulation (SCS) in patients with inoperable severe lower limb ischaemia: a prospective randomised controlled study. *Eur J Vasc Endovasc Surg*. 1999;9:421-5.

Klomp, HM, Spincemaille, GHJJ, Steyerberg, EW, Habbema, JDF, van Urk, H, Spinal-cord stimulation in critical limb ischaemia: a randomised trial. *Lancet*, 1999; 353:1040-4.

Spincemaille GH, Klomp HM, Steyerberg EW, Habbema JDF. Pain and quality of life in patients with critical limb, ischaemia: Results of a randomized controlled multicentre study on the effect of spinal cord stimulation. European Journal of Pain 2000;4:173-184.

Spincemaille GH, Klomp HM, Steyerberg EW, van Urk H, Habbema JD, ESES study group. Technical data and complications of spinal cord stimulation: data from a randomized trial on critical limb ischemia. *Stereotactic & Functional Neurosurgery* 2000;74:63-72.

Suy R, Gybels J, Van Damme H, Martin D, van Maele R, Delaporte C. In: Horsch S, Claeys L: *Spinal Cord Stimulation: An innovative method in the treatment of PVD*. Darmstadt: Steinhoff, 1994.

Ubbink DT, Spincemaille GH, Prins MH, Reneman RS, Jacobs MJ. Microcirculatory investigations to determine the effect of spinal cord stimulation for critical leg ischemia: the Dutch multicenter randomized controlled trial. *J Vasc Surg*. 1999;30:236-44.

Diabetic neuropathy

Tesfaye S, Watt J, Benbow SJ, Pang KA, Miles J, MacFarlane IA. Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy. *Lancet*. 1996;348:1698-701.

2. Systematic reviews

FBSS & chronic low back pain

Mailis-Gagnon A, Furlan AD, Sandoval JA, Taylor R. Spinal cord stimulation for chronic pain (Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.

Taylor RS, Van Buyten JP, Buchser E. Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: a systematic review and analysis of prognostic factors. *Spine*. 2005;30:152-6

Turner JA, Loeser JD, Bell KG. Spinal cord stimulation for chronic low back pain: a systematic literature synthesis. *Neurosurgery* 1995;37:1088-96.

Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients for failed back surgery syndrome or complex pain syndrome: a systematic review of effectiveness and complications. *Pain* 2004;108:137-148.

Critical limb ischemia

Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia (Cochrane Review). In: *The Cochrane Library*, Issue 4, 2003. Chichester, UK: John Wiley & Sons, Ltd.

CRPS

Grabow TS *et al*. Spinal cord stimulation for complex regional pain syndrome:an evidence-based medicine review of the literature *Clin J Pain* 2003;19:371-383.

Taylor RS, Van Buyten PJ, Buchser E. A Systematic Review of the Clinical and Cost Effectiveness Literature and Assessment of Prognostic Factors. Eur J Pain [in press].

Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients for failed back surgery syndrome or complex pain syndrome: a systematic review of effectiveness and complications. *Pain* 2004 [in press].

Cost effectiveness of SCS [all indications]

Taylor RS, Taylor RJ, Van Buyten JP, Buchser E, North R, Bayliss S. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. J *Pain Symptom Manage.* 2004;27:370-8

3. Further reading

Simpson BA (ed). Electrical Stimulation and the Relief of Pain. *Pain Research and Clinical Management* Vol 15. Elsevier Science BV, Amsterdam 2003.

Appendix 2

SUMMARY OF RANDOMISED CONTROLLED TRIALS OF SCS

First author trial name (year)	Country	N*	Comparisons	Follow up**	Outcomes	Results+
REFRACTORY ANGINA PECTORIS Δ						
ESBY	Sweden	104	SCS vs coronary artery bypass surgery	6-months/ 4.8 years++	Antianginal drug intake Anginal attacks Exercise capacity Quality of life Mortality/Morbidity	= = – = =
DeJongste (1994)	Netherlands	17	SCS vs No SCS	8 weeks	Exercise capacity Physical activity Anginal attacks Anginal medication 24-hr ECG Ejection fraction,	+/= + + + = =
Hautvast (1998)	Netherlands	25	SCS vs No SCS	6 weeks	Antianginal drugs Anginal attacks 48-hr ECG Exercise capacity Quality of life	+ + +/= +/= =
Fiume (1994)	Italy	19	SCS vs No SCS	20 weeks++	Angina attacks Exercise capacity 24-hr ECG	+ = +

*: Number of patients randomised; **: Latest follow up reported with groups randomisation maintained; ++Mean follow up; Δ: angina pectoris unresponsive to drug therapy

Results:

+ Statistically significant (P≤0.05) improvements in outcome in SCS group compared to comparator at follow up;
– statistically significant (P≤0.05) decrement in outcome in SCS group compared to comparator group at follow up;
= no statistically significant (P>0.05) difference in outcome between SCS group compared to comparator group at follow up;

First author trial name (year)	Country	N*	Comparisons	Follow up**	Outcomes	Results+
FBSS						
North	USA	50	SCS vs reoperation	2.8-years++	Pain relief Analgesic use Activities of daily living Work status Complications	+ +
CRPS						
Kemler (2000 & 2004)	Netherlands	52	SCS+physical therapy vs physical alone	2-years	Pain score Functional capacity Quality of life Complications	+ = +/= –
PERIPHERAL NEUROPATHY						
Testaye (1996)	United Kingdom	10	SCS vs No SCS [stimulator implanted but not activated]	3-months	Pain score Exercise capacity Neurophysiological indices Metabolic control Complications	+ +/= = = –

*: Number of patients randomised; **: Latest follow up reported with groups randomisation maintained; ++Mean follow up; Δ: angina pectoris unresponsive to drug therapy;

Results:

+ Statistically significant (P≤0.05) improvements in outcome in SCS group compared to comparator at follow up;
– statistically significant (P≤0.05) decrement in outcome in SCS group compared to comparator group at follow up;
= no statistically significant (P>0.05) difference in outcome between SCS group compared to comparator group at follow up;

continued

First author trial name (year)	Country	N*	Comparisons	Follow up**	Outcomes	Results+
CRITICAL LIMB ISCHEMIA						
Suy (1994)°	Belgium	38	SCS vs conservative therapy	20 months++	Amputation Fontaine stage Ulcer healing Complications	= + + =
Claeys (1996)°	Germany	86	SCS+PGE 1 vs conservative treatment+ PGE I	1-year	Amputation ABPI Fontaine stage Ulcer healing TcpO2 Complications	= + + + + =
Jivegard (1995)	Sweden	51	SCS+oral analgesics vs oral analgesics	18-months	Amputation Pain relief ABPI Complications	+ +/= = =
Spincemaille (2000)°	Netherlands	37	SCS+ best medical care vs best medical care	2-years	Amputation Pain relief	= +
Klomp (1999) ESES	Netherlands	120	SCS+conventional medical care vs conventional medical alone	2-years++	Pain score TcpO2 Quality of life Amputation Mortality Analgesic use Complications	= – = = = +/= =
Amann 2003 ECS-EPOS°	Europe (multicentre)	112	SCS+ best medical care vs best medical care alone	18-months	Amputation Complications	+ –

*: Number of patients randomised; **: Latest follow up reported with groups randomisation maintained; ++Mean follow up; Δ: angina pectoris unresponsive to drug therapy; ° results taken from Cochrane view.

Results:

+ Statistically significant (P≤0.05) improvements in outcome in SCS group compared to comparator at follow up;
– statistically significant (P≤0.05) decrement in outcome in SCS group compared to comparator group at follow up;
= no statistically significant (P>0.05) difference in outcome between SCS group compared to comparator group at follow up;

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