

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
Health Technology Appraisal

Spinal Cord Stimulation for chronic neuropathic and ischaemic pain

PERSONAL STATEMENT

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I was introduced to spinal cord stimulation (SCS) in 1987, working as a Research Fellow at the Pain Research Institute, Walton Hospital in Liverpool. I became interested in it as an alternative method for neurostimulation, which appealed to me as a rational non-drug management of many chronic pain patients. By that time it had become clear to me that despite a good deal of enthusiasm for peripheral neuromodulation techniques, such as TENS and acupuncture, they are weak treatments at best, and that many patients I would see in my clinic were not benefiting from them. An introduction to spinal cord stimulation provided by colleagues at the Walton Centre was a positive experience. Since 1995 I have actively employed it as a therapeutic measure in the management for neuropathic pain, to be considered if pharmacotherapy fails. In mid-1990s, evidence based medicine in the management of chronic pain was in its infancy. For neuropathic pain, only some limited data were available from controlled studies on the efficacy of tricyclic antidepressants, and no studies had been completed regarding any of the host of antiepileptic drugs, antidepressants, opioids and topical treatments that we today consider as routine treatments. Around that time one would accept that, similarly to the choice of drugs, the evidence for or against SCS came from case series and expert panel recommendations rather than well-controlled trials.

Ever since I have applied SCS to chronic pain, I have repeatedly observed it to provide clinically meaningful pain relief to a large number of patients with various neuropathic conditions. However, I still have some uncertainties about SCS. One, already mentioned, is the paucity of published controlled studies. Many questions remain open, among them the real long-term effectiveness of this method. Another relates to indications and patient selection. Another, of some considerable interest to

me, is the real risk for serious complications, especially as they were not reported in a number of systematic reviews¹⁻⁵. I found it strange that an invasive procedure that involves working in the vicinity of the spinal cord can be so devoid of major neurological complications. While the reviews appear to list relatively benign and reversible problems, with electrode dislodgement and technical problems as the main problems, there is no data on any significant neurological sequelae in any of them¹⁻⁵. However, my search of the literature did yield early reports of major complications^{6,7} and discussion with more experienced colleagues revealed that they had acted as expert witnesses in a number of medico-legal cases in which a direct relationship between implantation of the stimulator and subsequent neurological damage was considered proven. I have in the last 3 years witnessed two cases of paraplegia from implantation of a permanent stimulator using a laminectomy. I am familiar with three cases of severe neuropathic pain evolving at the site of surgery (associated with one or several surgical revisions), and am currently with colleagues in the process of exploring our records of over 300 surgically implanted SCS patients to establish the percentage of significant complications in our case series.

As for efficacy, I remain convinced that the evidence from recent controlled trials^{2,8-10} reflects clinical reality. In well-selected cases, spinal cord stimulation provides the degree of pain relief that is crucial for patients who would otherwise do poorly. Some patients appear highly intolerant of drugs (while some are “nocebo” responders, and some simply cannot comply with a rigid drug regimen). Others simply have a neuropathic pain condition refractory to all well-established drug treatments. It seems that spinal cord stimulation can significantly reduce allodynia in neuropathic pain, one of the most troublesome clinical features of neuropathic pain. I observed that after having completed two clinical trials on the effect of certain drugs, those patients who had not responded, mostly did well with SCS (manuscript in preparation). I have also had some success in patients with patients with MS and central pain (the group that appears to have failed all clinical trials apart from cannabinoids) and am starting a small pilot study in July 2008 to further establish whether or not SCS is useful in this condition.

At the Walton Centre form Neurology and Neurosurgery where I work we primarily choose patients with neuropathic pain for SCS. We occasionally assess patients with pain associated with peripheral vascular disease, and very rarely are asked to see patients with critical limb ischaemia in an effort to try and salvage the

leg. We have not been asked to assess or treat patients with chronic angina (who are being treated at the local Cardiothoracic Centre). We have reached a local consensus in not attempting to manage patients with chronic axial mechanical low back pain (or any other nociceptive pain) using SCS.

I firmly believe in putting in a great deal of effort in the multidisciplinary assessment of the patient for their suitability for SCS, and that it must happen well in advance of a percutaneous trial I also firmly believe in the need for a trial; our own observations show that some 20% of patients who otherwise are considered entirely suitable fail the trial due to lack of efficacy, or more commonly, due to lack of evidence that SCS significantly improves their functionality and quality of life, or allows significant reduction in their drug intake. Some patients actually have to undergo a 4-week pain management programme (a cognitive-behavioural programme) to enable them to gain sufficient confidence and self-management skills to fully benefit from SCS; this is arranged before the trial in our patients.

I have in the last year established a practice whereby all patients are first assessed by the multidisciplinary team (pain physician, neurosurgeon, pain psychologist, neuromodulation physiotherapy and pain nurse), following which a percutaneous trial is carried out in those considered suitable for SCS. The trial is performed by myself (or a colleague Pain Consultant); the outcome is assessed by the pain nurse, specialist registrar, physiotherapist and neurosurgeon. We rely on evidence by the patient on reduction of pain (usually >50% or more, but a lesser percentage is accepted if there is good evidence of improvement in other areas), improvement of the patient's functionality and ability to reduce pain medication, and improvement in their general attitude toward pain and control over it. Other aspects, such as reported post stimulation effect are also considered. – I should add that at the moment two of our physiotherapists are developing outcome measures that involve objective targets (such as some endurance tests and pace of walking) for assessment of efficacy of trial SCS.

At the Walton Centre we do not internalise the percutaneous electrode. It is removed and in the positive case the patient will be referred to the Neurosurgeon for an implantation of the surgical SCS plate electrode. The procedure involving a laminotomy or a laminectomy is performed under GA. The stimulator is switched on after a few days, and the correct projection confirmed. After discharge, the patients are regularly assessed at a special Neuromodulation Clinic where any problems

associated with the stimulator are addressed. I am occasionally asked to diagnose and treat patients with complications, such as neuropathic pain at the operation site.

I very much welcome the decision taken by NICE to evaluate SCS for efficacy and safety in the management of neuropathic and ischaemic pain. Given the fact that it is adopted widely as a treatment modality in this country, it is most useful to have an authoritative opinion about its clinical usefulness and cost-effectiveness in certain conditions. I can see a potential difficulty for the panel in deciding how to assess - in a just yet critical fashion - the actual efficacy and effectiveness of SCS, based on the evidence from relatively few publications that are not of very high quality. Besides, the outcome measures that today might be considered applicable to pain procedures, were not routinely applied at the time the published studies were being conducted.^{11,12} It would seem to me that in the assessment of this technology, a special effort is needed to balance the weakness of existing published research data against the rather substantial clinical experience that comes from decades of clinical practice that should have, but never was, subjected to well designed decisive trials.

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