

# **Spinal Cord Stimulation for chronic neuropathic and ischaemic pain**

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Neurostimulation therapies have become increasingly popular as a substitute for surgical or pharmacological interventions. Of the many invasive neurostimulation methods available, spinal cord stimulation is most widely used and studied. It requires a relatively simple implantation and is generally perceived to be effective and safe in a number of chronic pain conditions. The main indication for spinal cord stimulation is chronic neuropathic and ischaemic pain, although case series have been published on its effect on mechanical low back and neck pain, interstitial cystitis, abdominal pain and cancer pain (Cameron et al 2004).

## **1. Neuropathic pain**

At least 5 different systematic reviews on the effectiveness of spinal cord stimulation in neuropathic pain have been conducted (Turner et al 2004; Cameron 2004, Taylor et al 2005, Taylor et al 2006, Cruccu et al 2007). The general conclusion from these reports is that there are few randomised controlled studies and the general quality of the many published case series is low. Recently guidelines have been proposed for future studies in the field (Coffey and Lozano 2006). Randomised controlled trials exists only for complex regional pain syndrome (CRPS) type I and radicular pain associated with failed back surgery syndrome (FBSS). There are case series on many other neuropathic conditions such as CRPS II, peripheral nerve injury, diabetic neuropathy, post-herpetic neuralgia, brachial plexopathy, amputation pain and partial spinal cord injury which are reported to respond to SCS, while deafferentation pain due to spinal cord injury or brachial plexus avulsion do not (Cruccu et al 2007).

Opinions are divided as to the weight of evidence in determining the clinical usefulness of SCS in this condition, with proponents pointing out to apparent long-term effectiveness (Cruccu et al 2007) and critics underlining the tendency of this treatment to lose its effect long-term (Turner et al 2007).

There only randomised controlled trial to date on SCS in the management of complex regional pain syndrome (Kemler et al 2002) consisted of 54 patients who were randomised to receive physiotherapy alone (N=18) versus physiotherapy or SCS (N=36). The results indicated that in the group receiving SCS pain levels were lower and quality of life higher than in the comparator group (Kemler et al 2000). Initial analysis also suggested that this method despite high initial costs become cost effective over time. This study has been criticised on the basis that all patients recruited into the study had previously failed physiotherapy (Turner et al 2007). The authors later reported that the difference between the two groups over a follow up of 3 years diminished and became non-significant. It is unclear if the long-term follow up was planned. At any rate, several patients were allowed to cross over from the physiotherapy-alone group into the SCS, while the analysis still followed the original intention-to-treat. It is therefore difficult to estimate the real long-term clinical and cost effectiveness of SCS in this indication.

Two prospective randomised controlled trials have been published in regard to chronic sciatica (failed back surgery syndrome, FBSS; North et al 2005; Kumar et al 2007). Both failed back surgery syndrome trials suggested superiority of SCS over the comparator treatment. In the first study (North et al 2005), 60 patients with FBSS were randomised to receive either SCS or a reoperation (usually laminectomy or foraminotomy) and could cross over to the alternative treatment after 6 months. A disinterested clinician assessed the outcome. The SCS reported more frequently than the reoperation group an average pain reduction of >50% but no greater improvement in daily activities. More patients in the reoperation group increased pain medication than in the SCS group. In addition, cross-over to reoperation happened less frequently than in the opposite direction (North et al 2005). The benefit was seen at an average of 3 years' follow-up. The critique against this study is that reoperation is not the mainstay of treatment of these patients who therefore represented a select group (Kumar et al 2007). In a recently published by Kumar et al (2007) 100 patients with

FBSS and predominantly leg pain, were randomised to receive either conventional medical management (CMM) or SCS. The primary endpoint, the proportion of patients achieving >50% leg pain relief at 6 months, favoured SCS (48%) over CMM (9%). Quality of life and patient satisfaction measures were higher and functional disability measures lower in patients receiving SCS. By contrast, there was no change in consumption of drugs between the two treatment groups. It is not clear what treatment prior to the trial patients in the CMM had received; it is noteworthy they improved very little. It has been pointed out that the duration of the study is too short to draw definite conclusions (Turner et al 2007). These two studies should be compared to case reports totalling 3307 patients with FBSS with a 62% responder rate. The overall evidence in regard to SCS in this latter condition is favourable and should be contrasted with the dubious effect of injection therapies which to date have not been shown to be effective, despite their wide-spread use.

Surprisingly, there seem to be no large-scale studies on diabetic neuropathy although a small case series suggested a good outcome which may be maintained (Tesfaye et al 1996 and Daousi et al 2006). Long-term follow up of all the above conditions are rare; in one of the longest follow-up series (median, 5.2 years) some 60% of seventy patients reported >50% at time of follow up, although most had needed at least one revision (Kay et al 2001).

### **Ischaemic pain**

Spinal cord stimulation has been shown to have anti-ischaemic effects although the precise mode of action remains unknown. A meta-analysis of 9 randomised controlled trials, comprising 444 patients, showed limb salvage to be significantly in patients receiving SCS than those on control treatment alone (risk difference -0.13, 95% CI -0.04 to -0.22). Not all studies reported pain separately. From those that did, results were variable, some studies showing a greater reduction in pain relief at 3 and 12 months in patients receiving SCS whereas other found no difference between groups (Ubbink et al 2004). Some studies also suggested that patients' use of analgesics was lower in those with SCS compared to control patients (Ubbink et al 2004)

Randomised and pseudo-randomised trials also suggest that SCS leads to fewer anginal pains, reduced use of short-acting nitrates and improvement in quality of life. From case series it is estimated that patients treated using this method show increase in exercise capacity on average of 60% and the effect is likely to last one year in 80% of patients. In a direct head-to-head comparison SCS provided as much symptomatic relief as did re-do coronary by pass surgery (Mannheimer et al 1999). In addition, at six months there were fewer deaths and strokes in the SCS group. A 5-year follow up showed no difference between the two groups in mortality. A cost effectiveness study suggests that SCS may be superior to redo surgery in refractory angina (Ekre et al 2002)

## Safety

SCS is generally well tolerated. Common adverse effects include technical mishaps (lead migration or breakage, battery failure and hardware malfunction), infections and unwanted stimulation. From literature, technical problems dominate but as technology has improved they are less frequent today than 10-20 years ago. Nevertheless, at least ¼ of the patients who have a permanent implant is likely to experience some form of discomfort that requires intervention. Cruccu et al (2007) conclude from their review that overall 43% of patients experience one or more complications.

Severe complications are reported rarely. However, anecdotal cases are circulated among pain clinicians and include major neurological complications. This author has witnessed 3 cases of severe neuropathic pain associated with repeat implantations and two cases of severe paraparesis that have developed as the result of implantation of a permanent spinal cord stimulator.

It is concluded that a thorough analysis of effectiveness, cost effectiveness and safety of spinal cord stimulation is timely.

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