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Review

Recommendations for patient selection in spinal cord stimulation

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ABSTRACT

Studies have shown that spinal cord stimulation (SCS) can reduce chronic pain by at least 50% over prolonged periods, improve function and quality-of-life, reduce requirements for healthcare resources and enable return to work in appropriately selected patients. However, SCS does not provide pain relief in all patients and is an expensive, labor intensive and invasive procedure with complications and ongoing management that requires specialists with specific skills and judgment. Multidisciplinary selection of appropriate patients for SCS is essential to achieve maximal benefit from the procedure. The aim of the article is to provide a clinical practice guide to the likely effectiveness of SCS in treating various types of chronic pain, as supported by the literature. The article will summarize indications and contraindications for SCS, provide guidance on the selection and timing for referral, and highlight the benefits and complications associated with the procedure.

1. Introduction

Spinal cord stimulation (SCS) is a widely used technique that delivers electricity via implanted electrodes to treat chronic pain that is unresponsive to other treatments.[1,2] SCS is a sophisticated, reversible therapeutic technique to relieve pain and reduce medication use. Unlike surgical pain relief procedures, it does not ablate pain pathways or change anatomy.[3]

SCS has come a long way in the last 40 years, with more than 14,000 SCS implantations performed worldwide each year for a range of indications.[4] In 1965, Melzac and Wall announced the "gate theory", proposing that activating large, myelinated afferent nerve fibers would inhibit transmission in small, unmyelinated primary afferent nerves in the dorsal horn of the spinal cord.[5] In 1967, Shealy and colleagues were the first to test this theory, experimenting with surgically implanted electrodes to stimulate the dorsal columns for the treatment of chronic, intractable pain.[6] It became clear that SCS activates dorsal horn neurons and spinal roots as well as dorsal columns, thus the name SCS was coined. Current research suggests that SCS may actually inhibit transmission in the spinothalamic tract through activation of central inhibitory mechanisms that influence sympathetic afferent neurons and through the release of various inhibitory neurotransmitters.[7–9]

Today, the technique of SCS can be minimally invasive, with electrodes placed percutaneously under local anesthesia during a day surgery procedure.

This SCS clinical practice guide was developed by the Australasian Neurostimulation Working Group. The aim of the article is to provide information and guidance to clinicians on the appropriate referral of patients for SCS by indicating the likely effectiveness of SCS as supported by the literature. It is not intended as a review of the technique of neurostimulation; however, it will cover the benefits and complications associated with SCS as well as selection of patients and timing of referral.

2. Chronic pain

Chronic pain affects over 15% of the Australian population (about one in every six Australians).[10] Defined as pain persisting beyond a period of normal tissue healing, and/or experienced every day for 3 months or more, chronic pain can have a profound impact not only on the individual who is suffering pain, but also on their family and society in general.[10] Chronic pain may be ongoing or intermittent, and is always accompanied by physiological and psychological changes including sleep disturbance, frequent medication dependence, and emotional changes such as irritability,

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withdrawal and depression.[2] It has a substantial economic impact, much of which is borne by the individual, with an estimated total cost in 2007 of A$34.3 billion per annum ($10,847 per person).[10] The pathology of chronic pain may not always be well defined and therefore treatment outcomes may be unpredictable.

The aims of chronic pain management are to control pain to a tolerable level (it is rarely possible to eliminate pain), to enhance physical, psychological and social function, and to improve quality-of-life.[2]

Chronic pain has been typically categorized into nociceptive (pain arising from mechanical, chemical or thermal irritation via peripheral sensory nerves) and/or neuropathic (pain caused by a lesion or disease of the somatosensory nervous system), and their management approach differs.[11]

Neuropathic pain is caused by a primary lesion or dysfunction of the peripheral or central nervous systems. The pain is often described as burning, shooting or tingling and is often associated with allodynia. Pharmacotherapy of this type of pain is difficult as there is a lack of efficacy of conventional opioid analgesics.[12]

Nociceptive pain is due to tissue damage that results in somatic or visceral stimuli being sensed by peripheral nociceptors and transmitted by functional afferent sensory pathways. Nociceptive pain is often localized and described as aching, cramping or sharp. Unlike neuropathic pain, nociceptive pain is more responsive to conventional analgesics and has little evidence for effective relief with SCS.[12] Indeed, the question of whether SCS alleviates nociceptive pain, at least to some extent, is still controversial.

There are numerous internationally recognized guidelines for the pharmacological management of chronic pain, and treatment algorithms have been developed for managing neuropathic pain.[1,13–15] Few guidelines or algorithms include non-pharmacological management techniques. Interestingly, a recent American practice guideline makes recommendations for the use of techniques such as ablation, blocks, electrical nerve stimulation, epidural steroids, intrathecal drug therapies, physical or restorative therapy, psychological treatment and acupuncture, as well as pharmacological therapy.[16] SCS is one option for the management of selected patients with certain types of chronic (neuropathic) pain.

The British Pain Society's recommendations for best clinical practice provides a concise guide to the use of SCS in the management of pain, and was used as a basis for consensus within the Australasian Neurostimulation Working Group to produce this guide.[1]

All guidelines on chronic pain management stress the importance of multidisciplinary care for the patient and utilize several different approaches in a planned, long-term treatment program. Patients who do not obtain adequate pain relief and functional restoration from initial management should ideally be referred to multidisciplinary pain clinics (Fig. 1). These clinics provide overall assessments of the medical, psychological and social/environmental characteristics of patients, and develop multidisciplinary management plans that may include further investigations. They also identify goals, optimize medication and provide education/reassurance, physiotherapy, cognitive behavioral therapy or other psychological support, and provide interventions such as nerve blocks.[17] The Australian Pain Society has also developed minimum requirements for pain management services and multidisciplinary pain clinics (Table 1).

3. What is spinal cord stimulation?

3.1. Mechanism of pain relief in spinal cord stimulation

The theory behind pain mechanisms and transmission through the nervous system proposed by Melzack and Wall in 1967 has been significantly modified over the years, with increased understanding of the molecular changes that occur with neurotransmission.[5] The "gate control" theory proposed that activating large, myelinated afferent fibers of peripheral nerves which carry non-nociceptive, non-painful touch sensations inhibits transmission of nociceptive projections in small, unmyelinated primary afferent nerve fibers (A-δ and C) in the dorsal horn.[9] Therefore, strategically placed epidural electrodes would stimulate the dorsal columns to inhibit or modulate incoming nociceptive input through the smaller fibers.[9] However, this theory does not fully explain why all types of pain (particularly nociceptive) are not modulated uniformly, with SCS primarily affecting neuropathic and non-nociceptive pain.

It is known that the SCS device stimulates several structures: the dorsal column, lateral funicular and dorsal root fibers. It is believed that both anti- and orthodromic activation modulates pain through spinal and supraspinal circuits.[18] Stimulation of these fibers results in inhibition of pain transmission in the ascending nociceptive pathways and increased activity in descending anti-nociceptive pathways.

Advances in understanding of the mode-of-action since the "gate control" theory have moved towards direct modulation of neurotransmitters themselves. Animal studies suggest SCS promotes the release of an array of neurotransmitters including substance P, serotonin, noradrenalin, glycin and gamma-aminobutyric acid (GABA). Modulating the GABA-B receptor may be associated with a reduction of glutamate and other excitory amino acids being released, leading to pain modulation.[9] An additional putative mechanism includes modulation of the adenosine-A receptor which has been shown to potentiate SCS in both human and animal studies.[19] SCS may also abolish peripheral ischemic pain by rebalancing the oxygen supply through the alteration of sympathetic tone and possibly stimulating the release of vasodilatory neurotransmitters.[20]

3.2. Components of spinal cord stimulation

Spinal cord stimulator systems are designed to apply low voltage electrical pulses to afferent nerve fibers, usually within the dorsal column. Pulses are delivered via an epidural electrode that is implanted surgically or percutaneously, near the spinal cord. This electrode is connected to and powered by a neurostimulator device, which generates the electrical pulses and is surgically implanted under the skin. Stimulation of the spinal cord modifies patient experience of neuropathic pain; it can replace painful sensations with a paraesthesia (tingling sensation) that may be considered pleasurable. The electrode must be carefully positioned so that the paraesthesia overlaps the area where pain is experienced. The patient can turn the stimulator on or off and may vary the stimulation parameters within physician-set limits as required using a hand-held remote control.

Neurostimulators may be battery-powered (non-rechargeable or rechargeable) implanted pulse generators (IPG), or radio frequency devices that receive energy in the form of radio-wave pulses from an external source.[1,2]. Batteries used in IPG devices are now mainly rechargeable (used for patients with high-current use). Selection of the type of device used and the neurostimulator parameters applied are the responsibility of specialist SCS clinical teams, and depend on the type, intensity and location of pain.[1,2]

4. Historical use of spinal cord stimulation

SCS has been used in many thousands of patients worldwide, although few randomized clinical trials have been conducted over the full range of different indications. Trials have been performed in failed back surgery syndrome (FBSS) or leg pain despite