Is Spinal Cord Stimulation Safe? A Review of Its Complications

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Key words
- Complications
- Electrode migration
- Infection
- Neuromodulation
- Spinal cord stimulation

Abbreviations and Acronyms
CSF: Cerebrospinal fluid
IPG: Implantable pulse generators
MRI: Magnetic resonance imaging
PE: Percutaneous electrodes
SCS: Spinal cord stimulation
SE: Surgical electrode
SEH: Spinal epidural hematoma

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OBJECTIVE: **We aim to evaluate the complications of spinal cord stimulation (SCS).**

METHODS: **This article is a nonsystematic review of literature about the safety of SCS. The complications of this technique are described, focusing the analysis in their prevention, diagnosis, and treatment.**

RESULTS: **Electrode migration is the most common complication of SCS and it is more frequent with percutaneous electrodes than with paddle-type ones. Lead migration may be solved by reprogramming the stimulator, but if it fails, surgical repositioning is mandatory. Several anchoring techniques are described in the text. Infection is a potentially reducible complication associated with the surgical procedure and the reported infection rates are comparable with those of several neuromodulation devices. Recommendations for the prevention of SCS device infections are listed in the article. Other complications were reviewed such as electrode fracture, extension wire or implantable pulse generator failures, cerebrospinal fluid leakage, pain over the stimulator, and spinal epidural hematoma, among others.**

CONCLUSION: **In spite of the existence of several complications, SCS may be seen as a safe technique. Furthermore, the incidence of life-threatening complications is low. The physician must be alert to recognize them during the follow-up. Complications may be avoided or at least diminished by performing a proper and strict aseptic surgical technique as well as carrying out an accurate patient selection before the implantation, according to the recommendations published in the literature.**

INTRODUCTION

Spinal cord stimulation (SCS) is a technique of electrical neuromodulation in which one or more electrodes are placed in the epidural space of the spine. It has been used since 1967, when Shealy et al. implanted the first electrode in the spinal cord, based on the gate theory, which had been published by Melzack and Wall in 1965 (63, 93). Although SCS evolved as a consequence of this theory, it does not explain the mechanism of action of SCS accurately. There are several studies that try to prove its mechanism of action and its exact electrical target; however, both of them remain still unknown. Probably, multiple mechanisms operate sequentially or simultaneously (50, 52, 76, 85). SCS was not a successful treatment at the beginning, probably because of technical problems, poor patient selection, and a high rate of complications. Several advances in these areas allowed SCS to become an effective tool to reduce pain. During the first era of SCS, leads were placed in the subarachnoid space through a laminectomy, but more recently, the electrodes have started being implanted in the epidural space to avoid some complications such as cerebrospinal fluid (CSF) leakage and arachnoiditis. Nowadays, there are two types of electrodes commercially available: cylindrically shaped percutaneous electrodes (PEs) and paddle-type surgical ones (SE) (26, 40, 44, 50, 52, 61, 69, 84, 85).

The hardware consists in electrodes, extension wires, the pulse generator and the programmer. Currently, fully implantable pulse generators (IPG) are used almost always, instead of radiofrequency systems or external pulse generator. The latter is generally used to stimulate the electrodes through a disposable lead during the trial, which is useful for selecting patients for permanent implantation, although some surgeons use implantation without trial. This trial stimulation may also have complications such as dural puncture during electrode placement, electrode migration, or infection. The battery duration depends on its usage, but it generally lasts between 4 and 5 years (4, 52, 67, 69, 79, 89, 103). Regarding the electrodes, both types of them present several differences. Placement of SE is more invasive than PE implantation, because they are located through a laminectomy. The number of contacts per lead varies on each type. To date, the PEs may have up to 16 contacts, whereas the SEs may reach up to 20, because a new model of SE has 5 columns of 4 contacts. Only the PEs are suitable for the stimulation trial; the SEs need a previous trial with PEs. The PEs have

higher battery usage and impedance because their cylindrical shape makes them less energy efficient. Electrode fixation is more difficult with the PEs; thus, the likelihood of migration is higher with this type of lead (8, 17, 40, 50, 52, 72, 84, 92, 96). It is important to make an accurate selection of the type of electrode for each patient. Although the incidence of SE failure is low, if it occurs, it acts as a risk factor for recurrent failure (1).

Failed back surgery syndrome is the most common indication for SCS, whereas complex regional pain syndrome is the second one. There are many other uses of SCS described in the literature, such as refractory angina, peripheral vascular disease, phantom limb pain, spinal lumbar stenosis, postthoracotomy pain syndrome, chronic head and neck pain, and chronic visceral abdominal pain, among others. Furthermore, new applications are being proposed and researched worldwide (3, 4, 19, 34, 44, 50, 52, 61, 67, 80, 104). Wolter et al. found that complications of cervical SCS were not significantly more frequent than in SCS for lower limb pain in their series of 23 patients (107).

The complication rate of SCS is high, ranging from 8%–75% in the literature. They may occur intraoperatively as well as in the early or late postoperative period (11, 15, 46, 51, 60, 62, 69, 73, 80, 99, 100, 103). This rate varies widely among different studies. Kumar et al. reported a mean complication rate of 31.9% in their series of patients, whereas Cameron and Turner et al., in their reviews of the literature, communicated a mean incidence of complications of 36% and 34%, respectively (11, 51, 100, 103). In 2005, Taylor et al. published a systematic review, which found that 43% of patients who had undergone SCS experienced one or more complications (99). Currently, this rate is thought to be about 35% (46). It must be taken in mind that although this rate is high, the number of life-threatening complications is low. Probably, in the past decade, the overall complication rate decreased because of advancements in technology and technique (15, 49, 51, 60 62, 85). On the other hand, reoperation for failed back surgery syndrome can also result in serious complications, which may lead to significant disability without producing pain relief. The same occurs with the chronic use of nonsteroidal anti-inflammatory drugs or opioids, which seems to have a higher risk of significant injury than long-term treatment with SCS. Intrathecal opioid delivery can have serious adverse side effects and catheter complications, which may require surgical revision (42, 60).

This article is a nonsystematic review of literature about the safety of SCS. The complications of SCS are listed in **Table 1**. Some complications of this technique, which are the most frequently seen in our department, are described below, focusing the analysis in their prevention, diagnosis, and treatment. Other complications, which are rarely or never seen in our department, are explained in **Table 2**. Hardware-related complications, including lead migration, are the most frequent ones, as occurs in other neuromodulation procedures like deep brain stimulation (11, 44, 49, 51, 87, 99). Regarding their prevention and management, the author's recommendations are given in **Table 3**. Also, some contraindications and precautions for the implanted patients are described in this table.

Electrode Migration

Electrode migration or displacement is the most common complication of SCS (6, 11, 15, 49, 51, 57, 62, 74). Cameron found that it occurred in 13.2% of 2753 patients included in that review (11). Kumar et al. reported an incidence of 11.3% in their series (51). Mekhail et al. published that 119 cases among 527 patients had lead migration (62). Turner et al. found that its incidence was 13.2% and it was the most frequent indication for surgical revision, other than battery change (103). On the other hand, Barolat and Sharan described an incidence of electrode migration of 1.5% among 509 patients in whom SEs had been implanted (6). It leads to an increased risk of infection with each surgical revision of the system (57). Electrode migration may likewise occur during trail stimulation. Unexpectedly, Osborne et al. found that anchoring the trial lead to the skin with a suture and tape resulted in significantly greater inferior migration when compared with anchoring the lead with tape only (79).

Electrode displacement is suspected when there is a change in the area of induced paresthesia, which is associated with a loss of pain control. The new stimulated territory may be outside of the area of the pain or they may be partially superimposed. Another way of presentation is as a change in voltage requirements for paresthesia perception. Lead migration and its direction can be accurately confirmed by radiography, which shows an undue and undesired location of the electrodes. Probably, very subtle displacements would be able to affect stimulation. Thus, in some cases, radiographs cannot detect a symptomatic lead migration, but it is not the typical situation. It is helpful to undertake an x-ray to document the final location of the electrode during the implantation procedure because it may be used as a reference to compare with ones that are made when migration is suspected (6, 37, 44, 51, 69, 101). It must be taken in mind that changes in the stimulated area associated with changes in posture can take place, but those modifications are due to an alteration in the distance of the lead from the spinal cord because of CSF displacement during movement, instead of being caused by migration of the lead. For example, it was found that the dorsal CSF layer at T11 was 2.0–6.0 mm in the supine position, but it was increased by approximately 2.2 mm in the prone position. Positional changes may result in overstimulation or understimulation and

Table 1. Complications of SCS (5, 11, 17, 33, 44, 50, 51, 62, 69, 82, 84, 95, 103)

Complication	Frequency
Electrode migration	+
Hardware malfunction	+
Cerebrospinal fluid leakage	+/–
Pain at the pulse generator site	+/–
Infection	+/–
Subcutaneous hematoma	+/–
Electrode fracture	+/–
Nerve root or spinal cord injury	–
Epidural hematoma	–
Allergic reaction	–
Skin erosion	–
Others	–

+, frequent; +/–, infrequent; –, very rare.

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