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Review Article

Spinal cord stimulation: a review of the safety literature and proposal for perioperative evaluation and management

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Abstract

BACKGROUND CONTEXT: There is currently no consensus on appropriate perioperative management of patients with spinal cord stimulator implants. Magnetic resonance imaging (MRI) is considered safe under strict labeling conditions. Electrocautery is generally not recommended in these patients but sometimes used despite known risks.

PURPOSE: The aim was to discuss the perioperative evaluation and management of patients with spinal cord stimulator implants.

STUDY DESIGN: A literature review, summary of device labeling, and editorial were performed, regarding the safety of spinal cord stimulator devices in the perioperative setting.

METHODS: A literature review was performed, and the labeling of each Food and Drug Administration (FDA)–approved spinal cord stimulation system was reviewed. The literature review was performed using PubMed and the FDA website (www.fda.gov).

RESULTS: Magnetic resonance imaging safety recommendations vary between the models. Certain systems allow for MRI of the brain to be performed, and only one system allows for MRI of the body to be performed, both under strict labeling conditions. Before an MRI is performed, it is imperative to ascertain that the system is intact, without any lead breaks or low impedances, as these can result in heating of the spinal cord stimulation (SCS) and injury to the patient.

Monopolar electrocautery is generally not recommended for patients with SCS; however, in some circumstances, it is used when deemed required by the surgeon. When cautery is necessary, bipolar electrocautery is recommended. Modern electrocautery units are to be used with caution as there remains a risk of thermal injury to the tissue in contact with the SCS. As with MRI, electrocautery usage in patients with SCS systems with suspected breaks or abnormal impedances is unsafe and may cause injury to the patient.

CONCLUSIONS: Spinal cord stimulation is increasingly used in patients with pain of spinal origin, particularly to manage postlaminectomy syndrome. Knowledge of the safety concerns of SCS and appropriate perioperative evaluation and management of the SCS system can reduce risks and improve surgical planning.

Keywords: Spinal cord stimulation; Neuromodulation; Electrocautery; Peri-operative evaluation and management; Neurostimulation; Spinal Cord Stimulator Safety

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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Introduction

Spinal cord stimulation (SCS) has been shown to be safe and effective in the management of chronic pain of spinal origin and complex regional pain syndrome [1–23]. Candidates are usually patients with limb pain with or without combined axial pain, manageable comorbidities, and a psychological profile that does not preclude surgical intervention or long-term management of hardware. Typical patients initially undergo an externalized lead trial of approximately 1 week. Patients who have successful trials often receive surgical implantation, either with percutaneous or surgical paddle lead placement.

Patients with implanted spinal cord stimulators who present with new spinal anatomic changes requiring surgical intervention present a unique challenge. There is currently no widely accepted strategy on how to properly evaluate and image patients who have SCS implants. Furthermore, perioperative management can be complicated by neurostimulation hardware, and questions have arisen with regard to the safety of these devices in the operating room. As neuromodulation has become more frequently used in the management of patients with chronic pain conditions, it has become increasingly common for spine surgeons to be challenged with patients who need a new operation and have an implanted neurostimulation device. In this article, we review the safety concerns related to SCS implants and how these can influence the evaluation and perioperative management of patients with spinal disease.

The safety concerns related to neurostimulation systems are not limited to the possibility of damaging the medical device. Although that is undesirable, expensive, and may require additional surgery, it can be managed. More importantly, the safety concern is related to direct injury to the patient, in particular the spinal cord. Reports of severe adverse effects related to imaging of patients with brain neurostimulators highlight the severity of these concerns [24].

Methods

An extensive literature review was performed, and the labeling of each currently Food and Drug Administration (FDA)–approved spinal cord stimulation system was reviewed. The literature review was performed using PubMed and the FDA website (www.fda.gov). The following terms were searched: ‘‘spinal cord stimulator,’’ ‘‘spinal cord stimulator complications,’’ ‘‘neuromodulation complications,’’ ‘‘neuromodulation and MRI,’’ ‘‘spinal cord stimulator and MRI,’’, and ‘‘spinal cord stimulator and electrocautery.’’ The results of the searches on PubMed and the FDA website returned several hundred articles, and the safety concerns related to these devices are discussed in the following section.

Results

There are three companies that currently market SCS devices in the United States. At the time of writing this article, these companies made available 16 pulse generators, 16 percutaneous SCS lead models, and 12 paddle lead models. There are multiple combinations of leads, pulse generators, and extension wires, which can result in many potential configurations of these systems.

Imaging studies

Magnetic resonance imaging (MRI) safety recommendations vary between the models. Of the three companies that market SCS systems in the United States, only one allows for the patient to undergo body MRI scans with the system implanted [25]. Certain systems allow for MRI of the brain to be performed [25–28].

A previous report of a patient death secondary to the heating of a deep brain stimulator during MRI has raised awareness of neurostimulator devices and their potential impact on patient care after implantation [24,29]. With spinal cord stimulators, there is a risk of thermal injury to the patient at any point along the course of the device because of induction of current by the magnetic fields during the MRI. At this time, there have been no published reports of this type of injury in patients with SCS. However, manufacturer recommendations for many SCS systems still preclude the use of MRI.

In some systems, an MRI of the brain has been possible under strict labeling conditions [27,28]. These conditions include: that the stimulator has been interrogated and has appropriate impedance levels; that the stimulator has been turned off (or into ‘‘MRI Mode’’); that the MRI is performed with a ‘‘transmit/receive’’ head coil; only a 1.5-T closed magnetic field with a maximum spatial gradient of 1900 Gauss/cm, a radiofrequency (RF) of 64 MHz, and a specific absorption rate$\leq$3.2 W/kg is allowed. Open-MRI devices have not been tested with these implants and are not considered safe. After the scan, the device must be interrogated and turned back on. During these scans, there is potential for heating or discomfort, and the patient must be advised to communicate with the technicians should this occur. The devices are also at risk for permanent malfunction after MRI, which would require surgical replacement [26].

In 2013, one manufacturer received FDA approval for an SCS system that could allow for an MRI of the entire body to be performed while implanted. This product requires the same interrogation of the system and the same technical limitations on the MRI scanner (except that specific absorption rate$\leq$2.0 for the body coil). Also, these MRI scans are limited to less than or equal to 30 minutes per the manufacturer recommendations and FDA approval.

Before an MRI is performed, it is imperative to ascertain that the system is intact, without any lead breaks or low impedances, as these can result in heating of the SCS and injury to the patient. It should also be noted that externalized