Case Report

Magnetic Resonance Imaging of the Lumbar Spine in a Patient with a Spinal Cord Stimulator

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Background: The use of magnetic resonance imaging (MRI) is continuously escalating for the evaluation of patients with persistent pain following lumbar spine surgery (LSS). Spinal cord stimulation (SCS) therapy is being clinically applied much more commonly for the management of chronic pain following LSS. There is an increased probability that these 2 incompatible modalities may be accidentally used in the same patient.

Objectives: The purpose of this case report is to: (1) summarize a case in which a patient with a thoracic spinal cord stimulator underwent a diagnostic lumbar MRI, (2) describe the 3 magnetic fields used to generate images and their interactions with SCS devices, and (3) summarize the present literature.

Study design: Case report.

Setting: University hospital.

Results: Aside from mild heat sensations in the generator/pocket site and very low intensity shocking sensations in the back while in the MRI scanner, the patient emerged from the study with no clinically detected adverse events. Subsequent activation of the SCS device would result in a brief intense shocking sensation. This persisted whenever the device was activated and required Implantable Pulse Generator (IPG) replacement. Electrical analysis revealed that some of the output circuitry switches, which regulate IPG stimulation and capacitor charge balancing, were damaged, most likely by MRI radiofrequency injected current.

Limitations: Single case of a patient with a thoracic SCS having a lumbar MRI study.

Conclusion: This case demonstrates the lack of compatibility of lumbar MRI and the Precision SCS system as well as one of the possible patient adverse events that can occur when patients are exposed to MRI outside of the approved device labeling.

Key words: Spinal cord stimulation devices, magnetic resonance imaging

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Magnetic resonance imaging (MRI) has become the non-invasive imaging modality of choice for the clinical evaluation of the central nervous system as well as musculoskeletal conditions and certain cardiovascular disorders (1). MRI is particularly useful in displaying soft tissue anatomic details even in the presence of extensive bony structure such as the spine. Superior anatomic imaging and non-invasiveness have made MRI the fastest growing radiologic test of the past decade (2). In addition, MRI with gadolinium is the imaging study of choice in patients with persistent pain after lumbar spine surgery (3).

Over the past 40 years, spinal cord stimulation

(SCS) has undergone a rapid increase in the scope of treatment applications as well as technological advancements. In particular, SCS has been well studied in failed back surgery syndrome (FBSS) and has been deemed safe, effective, and financially neutral when applied appropriately (4). SCS has proven to be more effective than comprehensive medical management or re-operation in the management of chronic lumbosacral radiculopathy following lumbar spine surgery (LSS) (5-7). Persistent pain following LSS is likely to continue to rise given the increasing trends of surgery over the past 3 decades (8-10). The resulting utilization of both MRI and SCS will escalate, thereby increasing the probability that an accidental lumbar MRI will be performed on a patient with an SCS implant. Presently, some SCS devices have limited MR conditional labeling to safely under go MRI of the head only using head transmit-receive coils with restricted exposure parameters (11). On the other hand, all SCS device manufacturers regard MRI of the lumbar spine contraindicated in patients with implanted SCS systems. This contraindication is due to a combination of real and potential risks of device failure and patient harm especially when imaging is performed in close proximity to the implant (12).

We present a case in which a patient with an implanted rechargeable SCS device for the management of FBSS underwent a lumbar MRI. We summarize the clinical outcome and review the literature.

Case Report

The patient is a 50-year-old man who presented to our pain management center for evaluation regarding SCS therapy. He was otherwise healthy but suffered a work related fall 3 years ago that resulted in right-sided C6 radiculopathy as well as right L5 radiculopathy. He was treated conservatively for one year with medications, physical therapy, and epidural steroid injections. Because of refractory pain, he underwent C5/6 anterior disc decompression and fusion as well as L4/5 discectomy and hemi-laminectomy later that same year. Two years later, the patient continued to have good remission of cervical radicular symptoms, but his low back and leg pain became progressively worse. Upon presenting to our clinic, he had tried multi-modal pharmacotherapy, including anti-epileptic medications, anti-depressants, anti-inflammatory agents, muscle relaxants, and opioid analgesics with modest benefit. An MRI was repeated 3 months prior to his initial presentation that showed patent foramina at L4/5 and L5/S1 on the right but with significant scarring of the L4 and L5 nerve roots. He complained of low back pain with sharp stabbing radiating leg pain associated with cold dysesthesias.

After favorable psychological evaluation, the patient had a temporary trial of SCS. He had marked reduction in both back and leg pain. Shortly thereafter, he had implantation of dual percutaneous 8 contact leads via the T12/L1 interspace and a rechargeable (Precision Boston Scientific, Valencia, CA) implantable pulse generator placed in the left buttock. After 6 months, the patient complained of progressive low back pain at the level of the belt line (right greater than left) with no significant change in the radiating leg pain component. Physical exam tests for sacroiliac joint provocation were negative, as were diagnostic blocks for facetogenic pain. Subsequent computed tomography of the lumbar spine was significant for moderate foraminal stenosis on the right greater than left at L4/5 and L5/S1 as well as severe disc degeneration at both of these levels. The patient then elected to have decompression as well as anterior and posterior fusion at both of these levels.

Six months following the surgery, the patient returned to his surgeon's office complaining of low back pain. The spine surgeon's physician-assistant evaluated the patient and ordered a lumbar MRI. The patient presented to the radiology suite during the weekend. The radiology technologist insisted that his device is MRI compatible, and after the patient turned the SCS device off, proceeded with the study (Figs. 1-2).

While in the MRI scanner, the patient reported a mild heating sensation at the IPG site. He also experienced mild shocking dysesthesias in the mid-back (up to 6 times lasting for 1 - 2 seconds) that he equated to the intensity and sensation of a 9-volt battery. Once returning home, he activated his stimulator and experienced immediately a brief but intense shock across the back to the abdomen. He immediately turned the device off. The next day, he activated the SCS device and had a similar experience. He deactivated the device and came into our clinic the next day. Upon device activation, he again had a similar brief and intense shock, but with the paresethesia coverage unchanged with the stimulator left on. Interrogation of the device revealed normal range impedances as well as no change in programming. Reprogramming failed to eliminate the shocks associated with device activation. Fluoroscopic evaluation of the leads demonstrated no migration.

Because the patient could no longer use his stimulator, he was scheduled for revision surgery. In the operating room, the IPG pocket site was accessed without electrocautery. The IPG was carefully removed

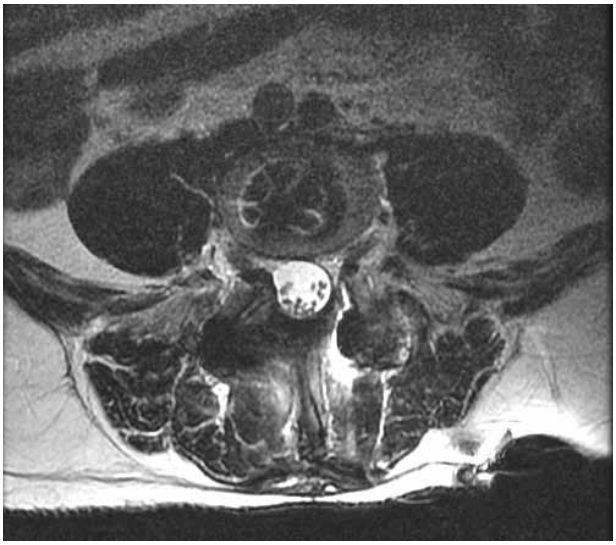

Fig. 1. *Axial T2 weighted image at the lumbar level of 4/5. The titanium coated implantable pulse generator appears as a non-enhancing black mass on the left subcutaneous tissue.*

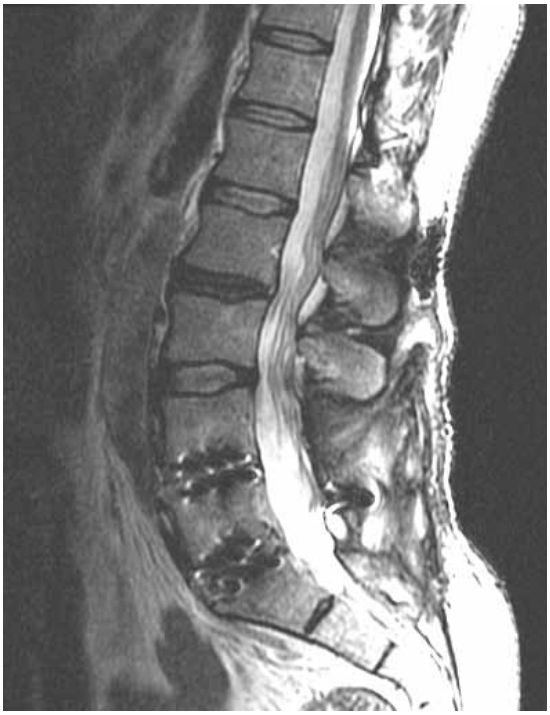

Fig. 2. *Mid-sagittal T2 weighted image demonstrating poorly enhancing tissue at the lumbar level of L1/2 in the subcutaneous tissues. This represents the fibrotic tissue reaction to the lead strain relief loops and anchors.*

and sent to Boston Scientific for analysis. The leads were directly linked to trial cables, and the patient reported no shocks and perfect paresthesia pain coverage. The IPG was replaced and again tested before closure with consistent paresthesia and no shocks. One year later, the patient has had good pain control with no device related complications. Analysis of the IPG after explant revealed that some of the output circuitry switches, which regulate IPG recovery and capacitor charge balancing, were damaged.

Discussion

The complications that arise from performing an MRI in a patient with an SCS device can be broadly categorized into injury to the patient and/or damage to the device. While adverse effects to patients are most concerning, both can result in morbidity. The complexity of establishing safety with this modality begins with an appreciation of the 3 magnetic fields utilized to generate an image, as each has specific interactions with an SCS system.

Magnetic Fields

First, the static magnetic field (measured in Tesla) is in the direction of the length of the patient. The static field exerts forces and torques on all metallic objects, with substantially stronger (between 10 to 10,000 fold) effects on ferromagnetic substances (13). Second, pulsed gradient fields (measured in Tesla/second; dB/dt, or as a slew rate in Tesla/meter/second) are time varying magnetic fluxes that can induce circulating currents in conductive structures. The induced circulating currents in the metallic case and internal circuitry of an SCS device (eddy currents) can yield local heating in the device pocket, and they can also induce a magnetic moment that interacts with the MRI static field to exert time-varying/vibratory force or torque on the device in the IPG pocket site (14). Lastly, the radiofrequency (RF) magnetic fields induce electric fields throughout the patient and give rise to currents and voltages in SCS system components and can then interact directly with patient tissue. The local RF power deposition, or specific absorption rate (SAR, measured in Watts/kilogram), is different in various tissues of the body, and it can concentrate particularly near longer conductive structures, such as leads, due to antenna effects (13). RF field interactions can be the most concerning with respect to SCS patients based on the potential for heating to occur at the distal ends of leads near the spinal

cord. However, each type of magnetic field carries risk for potential complications.

Static-field Effects in this Patient

The force/torque generated by the static magnetic has been raised as a concern for damage or displacement of the leads and/or the IPG. SCS electrodes are typically made of platinum and iridium with lead conductors and polyurethane insulators that lack ferromagnetic composition, making them unlikely to be affected by the static field (15). The leads in the case were not displaced when evaluated by x-ray imaging and the electrical integrity was intact as determined by impedance measurements. Furthermore, paresthesia pain coverage post-MRI was identical to pre-MRI and required no re-programming. With regards to the IPG, it was not displaced and the patient did not report a pulling or tugging sensation despite very close proximity of the magnetic fields.

The lack of reported static field effect also relates to the relatively small quantity of IPG ferromagnetic components. Specifically, the ferrite core is embedded within the header of the IPG. But perhaps more importantly, the anchor sutures and the pocket capsule that are in turn further compounded by the weight of the patient lying supine on the IPG secure it against motion. Taken altogether, static fields are unlikely to cause clinically relevant movement of the IPG.

Radiofrequency-Based Effects in this Patient

The strong applied RF field induces currents with elevated energy deposition near the contacts of the stimulating electrode, which can result in significant local tissue heating. Experiments in gel phantoms have demonstrated this effect for pacemaker leads and neurostimulator leads (16). The tip of the electrode typically has the highest current flux density and therefore has the greatest potential to generate enough conversion of electrical power into heat so as to damage the dura and underlying spinal cord. Serious neurological injury has been reported in a deep brain stimulator (DBS) patient, with attribution of the damage to RF-induced energy at the lead tip due to inappropriate use of the RF body coil to scan the patient's head--in direct violation of the device's MR conditional labeling (17). Fortunately, in our case, the patient did not experience any clinically detectable neurological injury despite exposure to the RF body coil for lumbar spine scanning. He did not report a sensation of heat in his mid back.

In addition to providing a potential for heating near the lead tip, the applied RF field can induce high voltages and currents in the leads that are injected retrograde to the IPG. In this case, the IPG appears to have been damaged post-MRI leading to shocks when the patient would first activate the device from an off to an on setting. Analysis of the IPG post-explant determined that some of the output circuitry switches, which regulate IPG recovery and capacitor charge balancing, were damaged and malfunctioning. These malfunctions could allow build-up of voltages on the output capacitors and discharge on initiation of stimulation that is consistent with the shock sensation that ultimately leads to the necessity for IPG replacement. The leads were left intact as its position and integrity were verified by appropriate stimulation coverage in the patient and as lead structures, being purely mechanical, are much more robust to voltages and currents than are the sensitive electronics in the IPG.

Gradient Field-Based Effects in this Patient

The pulsed gradient field in the MRI environment, as mentioned above, can generate voltage leading to stimulation-like currents, heat inducing currents, and magnetic moments in a conducting object. Eddy currents due to pulsed gradient magnetic fields on larger surfaces, such as the titanium IPG case, deposit energy and heat the case material directly (18). The gradient-induced eddy currents in the IPG probably contribute most of the mild heat felt by the patient in the IPG pocket site during the MRI process. The eddy currents in the IPG can concurrently cause small rapid torques, but like the static field force and torque effects, these gradient field-induced torques were not appreciated by the patient (19). On the other hand, the patient did begin to appreciate 6 incidences of mild shocks across his upper back some time into the MRI exam. There are likely 2 compounding effects of MRI scanning that contributed to electrical stimulation or shocks in this patient. The first is the direct induction of eddy currents in the lead/IPG system that can cause "unipolar" current flow from the contacts back to the IPG. The second is the fact that the RF energy discussed earlier damaged the output circuitry, hence making the IPG more vulnerable to gradient-induced currents. There is a reasonable temporal relationship to this charge build-up and discharge hypothesis as these shocking sensations did not occur until some time into the MRI exam, presumably after the IPG circuitry damage occurred, and would reoccur only after a period of time.

Table I. *Summary of Case Series and Studies of Patients with Spinal Cord Who Have then Received a Magnetic Resonance Imaging (MRI) Study*

Spinal Level of Leads	Type of MRI Study	Number of Patients	Reported Clinical Outcome
Cervical and Thoracic	Lumbar, thoracic, cervical spine	3	Two patients with changes in stimulating programs (22).
Thoracic	Functional MRI of the brain	3	No adverse events reported (23).
Cervical and thoracic	Cervical and thoracic spine	5	Painful stimulation in 2 patients with paddle style electrodes while in scanner (24).
Cervical	Cervical spine	1	No adverse events reported (25).
Cervical	Brain and spine	1	No adverse events reported (26).
Cervical and thoracic	Brain, all levels of spinal column	21	One patient with increased amplitude on one of the programs. One patient had an impedance elevation to greater than 4000 ohms. Two patients with low battery levels were found to have complete depletion after MRI (20).

Literature Review

The literature remains contentious regarding the safety of SCS devices and MRI without the use of a head transmit-receive coil, despite present contraindications set by device manufacturers, but reports so far suggest the possibility. There have been no serious adverse events reported thus far (Table I). However, one must keep in mind that serious neurological injury has been reported when patients with DBS devices undergo MRI. There are specific protocols for DBS devices but not any for SCS patients with the exception of brain MRI for certain devices. The primary basis for the uncertainty is in the RF-induced heating interaction and if a SAR threshold is appropriate for limiting patient exposure to RF-induced hazards. One study suggests a level of SAR of 0.9 watts/Kilogram (20). However, limiting SAR would not necessarily address the potential for high voltages or currents to damage the IPG (as happened in this case). There is also variability in the determination of SAR among MRI scanners and subsequent lead heating when using SAR to limit applied RF energy (21).

Conclusion

There is a demonstrated lack of compatibility of lumbar MRI scans and the rechargeable Precision SCS system. The circuitry of the IPG is susceptible to damage from the RF fields of the scanner. In conjunction, there remain no guidelines for safe performance of lumbar MRI scans in patients. The complexity remains in establishing safe parameters or conditions that can be translated into all MRI suites.

An MRI of the lumbar spine remains contraindicated in patients with Boston Scientific SCS neuromodulation systems as well as with all other presently available SCS systems. This case demonstrates a subset of the possible patient harms that can occur when patients are exposed to MRI outside of the approved device labeling, and other more serious consequences remain a concern until SCS device manufactures can provide MR conditional labeling for safer scanning of patients with their devices.

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